

Witness Name: Janet Ann Shirley

Statement No.: WITN3901001

Exhibits: WITN3901002 – WITN3901018

Dated: 28<sup>th</sup> November 2019

## 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 September 2019.

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
2. My professional qualifications are: MB.BS. DCH, FRCPath., Dip. Hlth. Mgt.
3. I have held the following positions:
  - 3.1 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.

3.2 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.

3.3 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.

#### 3.4 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.

#### 3.5 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.

4. 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. I cannot recall whether this gave me full membership of the organisation.

5. Frimley Park Hospital was designated an Associate Haemophilia Centre about 1981-1982. 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 Comprehensive Care Centre where they were registered. As the consultant haematologist responsible for

their care at Frimley Park Hospital, I liaised with the relevant Haemophilia Comprehensive Care 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.

## **Section 2: Responses to criticism of witness W1303**

6. I first saw the husband of witness W1303 on 17<sup>th</sup> March 1983 in my outpatient clinic when he registered at Frimley Park Hospital Associate Haemophilia Centre upon moving into the area. He had previously lived in the GRO-B area and was registered at Oxford Haemophilia Centre. I wrote to Dr Rizza, Director of the Oxford Haemophilia Centre, for details of the patient's medical history [Exhibit WITN3901002].
  
7. Dr Rizza replied explaining that the patient was clinically mildly affected and his factor VIII level measured 1-3%. He had required treatment on only three occasions:
  - 7.1 In January 1968, when he had a dental extraction and was given NHS factor VIII concentrate;
  - 7.2 In September 1970, when he bled from an exfoliating tooth and was given NHS factor VIII concentrate; and
  - 7.3 In July 1971, when he had some dental extractions and was given cryoprecipitate.He was found to be HBs Ab positive in 1971 [Exhibit WITN3901003].
  
8. On 16<sup>th</sup> December 1984, the patient attended Frimley Park Accident and Emergency department complaining of pain in his right hip. He was treated with 10 units of cryoprecipitate following consultation with myself. He returned the following day with severe pain and stiffness in his right hip and numbness extending from his right ankle to just above the knee. A diagnosis of a right ileo-psoas muscle bleed with nerve root compression was made. This means that he had bled into the muscles at the back of his hip and the resulting swelling was pressing on the nerve supplying part of his leg, causing numbness. The combination of nerve and muscle damage and pain meant that he was unable to walk. In order to prevent further bleeding and damage 10 more units of cryoprecipitate were given by the medical team after consulting me. Unfortunately, this did not result in a therapeutic level of factor VIII. This was a serious bleed with the possibility of permanent disability if not treated adequately. I

therefore switched the patient to NHS factor VIII concentrates which resulted in a good therapeutic response. I arranged for him to have further NHS factor VIII concentrate over the following five days and he was discharged on 21<sup>st</sup> December 1984. I saw him in outpatients on 24<sup>th</sup> and 27<sup>th</sup> December 1984 when he was much improved. He still had an area of anaesthesia on his right leg but was now able to hobble using a crutch. I arranged for him to be given further NHS factor VIII concentrate on 22<sup>nd</sup>, 24<sup>th</sup> and 27<sup>th</sup> December 1984 prior to physiotherapy for weakness of his right quadriceps muscle caused by the bleed [Exhibits WITN3901004; WITN3901005; WITN3901006].

9. I saw the patient again on 15<sup>th</sup> January 1985 in my outpatient clinic. Full hip extension had returned and he was able to walk without crutches. Sensation in his right leg was improved but still abnormal and his right quadriceps muscle was still weak so he was to continue with physiotherapy. I referred him back to Dr Rizza at the Oxford Haemophilia Centre for further assessment in view of the severity of the bleed with no obvious precipitating factor [Exhibit WITN3901007].
10. I knew that the husband of witness W1303 was a clinically mildly affected haemophiliac who had been treated previously on only three occasions, the last one being in 1971. However, on this occasion he experienced a very severe muscle bleed with nerve compression which left untreated or undertreated could have led to severe permanent disability. It took until August 1985 for the function in his right leg to return to normal and he still had an area of diminished sensation [Exhibit WITN3901008]. As the therapeutic response to cryoprecipitate was inadequate it was necessary to treat him with NHS factor VIII concentrates.
11. The UK Haemophilia Directors' Organisation AIDS Advisory Document is dated 14<sup>th</sup> December 1984, which was a Friday. It was drawn up at a meeting of Haemophilia Reference Centre Directors. I was not involved in the production of the document nor was I aware of its contents at that time. In 1984, we had no FAX machines or computers so everything was distributed by post. Even if the document was posted on Friday 14<sup>th</sup> December 1984 it is very unlikely that I would have received it by Monday 17<sup>th</sup> December 1984 making allowances for the Christmas post.
12. Frimley Park Hospital received blood products from the National Blood Transfusion Service at Tooting in South London. The hospital accepted the factor VIII concentrates provided by the NBTS. Prior to the UK Haemophilia Centre Directors'

Organisation AIDS Advisory Document on December 14<sup>th</sup> 1984, it was known that commercially produced factor VIII concentrates from the United States could transmit HIV infection. It was subsequently found that most patients who tested positive for HIV infection had received these products. It was therefore recommended that NHS factor VIII concentrates should be used. These products were not available in heat-treated form until 1985 [Exhibits WITN3901009; WITN3901010; WITN3901011].

13. The UK Haemophilia Centre Directors' AIDS Advisory Document of 14<sup>th</sup> December 1984 advises that moderate and severely affected haemophilia patients previously treated with factor VIII concentrates should in future be treated with heat-treated NHS factor VIII concentrates, if available, or heat-treated commercial factor VIII concentrates. Heat-treated NHS Factor VIII concentrates were not available and the advisory document states *'the evidence that heated US factor VIII is safer than unheated NHS is debatable and some Directors may wish to continue using unheated NHS material until all supplies are heated'* [Exhibit WITN3901012]. It also states *'If the bill for heated commercial concentrates is heavy at first it can be put to your Authority that increased supplies of heat-treated BPL material could be available later in the summer. Funding will need to be negotiated at local level although strong representations are being made to DHSS for central funding if needed.'* [Exhibit WITN3901012]. Commercial heat-treated factor VIII concentrates were not available at Frimley Park Hospital in December 1984.
14. The patient was treated by me to the best of my ability in the light of the knowledge available to me and according to best practice at the time.
15. The husband of witness W1303 was tested for HIV (known as HTLV III at the time) on 6<sup>th</sup> August 1985. This blood test was requested by Dr C. Cobb who was my senior house officer and who saw the patient in my clinic [Exhibit WITN3901008]. Dr Cobb wrote the clinic letter to the patient's GP [Exhibit WITN3901013]. Dr Cobb said the decision was taken not to tell the patient he was being tested for HIV. I cannot remember whether I discussed this with Dr Cobb but as the consultant in charge of the patient it is likely that this was my decision. On the blood request form, I have written the request for the HIV test although Dr Cobb filled in the rest of the form [Exhibit WITN3901014]. I informed Dr Rizza of the result [Exhibit WITN3901015].
16. At that time, all the haemophilia patients who had received blood products were being tested for HIV. I cannot recall what the usual practice was for consent for

testing for HIV but I was always careful to adhere to best practice. It is possible that we were advised to test first so as not to cause problems for those who were unaffected. I do remember that if an individual needed life insurance, for example, and they answered the question 'have you ever had an HIV test?' it could prove impossible to obtain life insurance, regardless of the result. We needed to find out who had been infected for future care but didn't want to put those who were not infected into a difficult situation.

17. I next saw the patient in my outpatient clinic on 1<sup>st</sup> October 1985. I told him that the blood test taken in August for HIV was positive and that a repeat test was required, which he consented to [Exhibit WITN3901016]. I informed the patient of his HIV result when it was available, between 18<sup>th</sup> and 30<sup>th</sup> October 1985 [Exhibit WITN3901016]. I was not aware that he was trying for a baby but I saw him again in my outpatient clinic on 22<sup>nd</sup> November 1985 when I gave him the Haemophilia Society booklet on safer sex and the DHSS guidelines on the prevention of the spread of infection of HIV (known as HTLV III at the time). I also gave him the name and telephone number of the counsellor for HIV patients [Exhibit WITN3901017].
18. I do not know what the survey is that witness W1303 refers to. I did not enter the patient into a survey as far as I am aware and this is not documented in the patient's clinical records. I informed Dr Rizza of the batch numbers of the factor VIII concentrates that the patient had received and the results of the blood tests carried out at Frimley Park Hospital [Exhibit WITN3901015].
19. Dr Rizza informed me in his letter of 28<sup>th</sup> March 1983 that the patient had tested positive for the hepatitis B antibody in 1971 [Exhibit WITN3901003]. I would have assumed that the patient had been informed of this result by Dr. Rizza. Blood tests for hepatitis B antigen were carried out at Frimley Park Hospital on 5<sup>th</sup> March 1985, 28<sup>th</sup> June 1989 and 12<sup>th</sup> July 1989 and were negative. Blood tests for hepatitis B antibody carried out on 28<sup>th</sup> June and 12<sup>th</sup> July 1989 were positive with an anti-HBs titre of >100miu/ml, showing that the patient was immune to hepatitis B following a past infection and was not a carrier of hepatitis B [Exhibit WITN3901018].
20. I requested access to the medical records of the husband of witness W1303 from the time that I was appointed consultant haematologist at Frimley Park Hospital in February 1980 until I left to take up another post in May 1997. I received records from 17<sup>th</sup> March 1983 when the patient moved into the area until 12<sup>th</sup> December 1990

when he moved out of the area. I had access to the clinical records, correspondence, the blood products transfused and laboratory results. I do not know what medical records have been disclosed to witness W1303 and therefore cannot say whether I have accessed any additional medical records.

21. I asked for a copy of the UK Haemophilia Centre Directors' Aids Advisory Document, 14<sup>th</sup> December 1984, which I received. I also requested access to any advice or protocols for the treatment of haemophilia patients prior to December 14<sup>th</sup> 1984 but none have been provided.

22. In addition, I have carried out a literature search to find out the current practice during the time period in question.

### **Section 3: Other Issues**

23. There are no further issues I wish to address in my statement.

### **Statement of Truth**

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

Signed GRO-C \_\_\_\_\_

Dated 28<sup>th</sup> November 2019



**Table of exhibits:**

<b>Date</b>	<b>Notes/ Description</b>	<b>Exhibit number</b>
17.03.1983	Letter from Dr .Shirley to Dr Rizza	WITN3901002
28.03.1983	Letter from Dr Rizza to Dr Shirley	WITN3901003
24.12.1984	Letter from Dr Shirley to Dr <span style="border: 1px dashed black; padding: 0 2px;">GRO-B</span>	WITN3901004
17.12.1984 - 15.02.1985	Clinical notes entries	WITN3901005
16.12.1984 - 27.12.1984	Blood transfusion records	WITN3901006
15.01.1985	Letter to Dr Rizza from Dr Shirley	WITN3901007
06.08.1985	Clinical notes entry	WITN3901008
1985	AIDS and haemophilia: morbidity and mortality in a well defined population. P. Jones et al. Br.Med.J (Clin Res Ed) 1985.291 :695	WITN3901009
2008	The best of times, the worst of times: a story of haemophilia. Christine A. Lee. Clin. Med., October 1, 2008, vol3 no 5, 453-458	WITN3901010
1985	HTLV-II, haemophilia and blood transfusions. AL Bloom, CD Forbes, CR Rizza. Br. Med. J, 22 June 1985, volume 290, 1901	WITN3901011
14.12.1984	UK Haemophilia Centre Directors' Organisation AIDS Advisory Document	WITN3901012
06.08.1985	Letter from Dr C. Cobb to Dr <span style="border: 1px dashed black; padding: 0 2px;">GRO-B</span>	WITN3901013
06.08.1985	Blood request form and result for HIV test	WITN3901014
28.08.1985	Letter from Dr Shirley to Dr Rizza	WITN3901015
01.10.1985; 18.10.1985; 30.10.1985	Clinical notes entries	WITN3901016
22.11.1985	Clinical notes entry	WITN3901017
05.03.1985; 28.06.1989; 12.07.1989	Blood test results for hepatitis B	WITN3901018