Witness Name: Dr Janet Andrews
Statement No.: WITN5298001
Exhibits: WITN5298002-04
Dated: 17 March 2021

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF DR JANET ANDREWS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 18 January 2021

I, Janet Andrews, will say as follows: -

Section 1: Introduction

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

   Name: Janet Mary Andrews
   Address: GRO-C Edinburgh, GRO-C
   Date of birth: GRO-C 1951

   Professional qualifications:
   BSc Biochemistry - University of Birmingham 1972
   MB ChB - University of Birmingham 1975
   DCH – Royal College of Physicians 1979
   MRCGP – Royal College of General Practitioners 1980
   JCPTGP certificate - RCGP 1982

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.**

   Please refer to my CV for employment history [WITN5298002].

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.**

   Ordinary member - British Medical Association (1975 – 2013)

   Ordinary member - The British HIV Association (approx. 1997 – 2013)

   Associate member - Royal College of Physicians of Edinburgh (approx. 2000 – 2013)

   Ordinary member – European AIDS Clinical Society (approx. 2000 -2013)

   Ordinary member – Scottish HIV and AIDS Group (approx. 2000 – 2013)

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

   I gave a short statement to my then employer, Lothian Health Board, in connection with the Penrose Inquiry which was in answer to a specific question relating to a particular patient. I have not retained a copy of this.

5. **The questions below focus on your time as Clinical Assistant to Dr Ludlam at Royal Infirmary Edinburgh but if you have information relevant from the Infectious Diseases Unit at Western General Hospital where you subsequently worked, please also set that out.**

I took up the post of Staff Grade Doctor in the Regional Infectious Diseases Unit (RIDU) at the City Hospital Edinburgh on 1 January 1997. In 1998, RIDU moved to new premises at the Western General Hospital Edinburgh. In 2004 I was re-graded as an Associate Specialist, but my job description was unchanged, and I continued in this post until my retirement in April 2013.

In answer to this question, for the purposes of the Inquiry, I will limit my comments to matters relating to patients infected with HIV and Hepatitis C which made up the bulk of my workload. However, I would be happy to provide further information to the Inquiry if it is required

My main role initially, was to assist in the out-patient management of patients infected with HIV. The patients I saw were under the consultant care of either Dr R Brettle or Dr C Leen, both of whom are specialists in infectious diseases. All key management and therapeutic decisions were made after discussion at Multi-Disciplinary Team (MDT) meetings or after discussion with the individual consultant responsible for the patient's care. A small number of the patients I saw had contracted their infections from transfused blood products and were known to me from my time working at the Haemophilia Centre.

The development of drug treatments for HIV was advancing very rapidly in the 1990's and RIDU, being a regional specialist unit, was offered the opportunity to enter patients into drug trials run either commercially by pharmaceutical companies or non-commercially by institutions such as the UK Medical Research Council. Part of my role was to recruit patients into clinical trials which involved gaining the patient's informed consent. I had received training in GCP (Good Clinical Practice) which sets out international standards to which all clinical research should be conducted. Patients were given written and verbal information about the trials and

were then free to make their own minds up, it was also stressed that they could withdraw consent at any time. However, as participating in a trial often gave patients the opportunity to access a drug before it was licensed, many patients were eager to consent to participate in drug trials.

The management of patients infected with HCV, became an increasingly large part of my work over time. Many of the patients who attended RIDU, for treatment of HIV, were also infected with HCV. Managing HIV infection was the initial priority for two reasons, firstly HIV had a higher mortality and secondly, the response to treatment for HCV was, by then, known to be better if HIV was fully suppressed. In 2006 the Scottish Government launched a national programme called the Hepatitis C Action Plan which was designed to raise awareness of HCV. As a result of this programme, many individuals came forward for testing which resulted in a large increase in the referral rate of patients infected with HCV to RIDU and other specialist units in Scotland.

Significant advances in the treatment of HCV were made during my time in RIDU, but directly acting drugs with a high cure rate were not widely available until after I retired.

For patients with established HCV related liver disease, treatment with the available drugs, Pegylated Interferon and Ribavirin, was offered in order to prevent further progression of their liver disease. In some cases, where the liver disease was mild, patients chose to defer treatment until more successful and less toxic therapy was available.

Over the period of my post at RIDU, my knowledge and experience in the management of patients with HIV and hepatitis C infections grew considerably so that I was able to work more independently. This was reflected in my regrading as an associate specialist in 2004.

Section 2: Decisions and actions of the Royal Infirmary Edinburgh ("the Centre")

6. **Please provide details of your role within the Centre, including the dates when you worked there, your responsibilities and, if you can remember, names of significant or senior staff members who were working there at the time. In particular please describe your involvement in the treatment of patients with bleeding disorders.**

I was employed as a temporary Clinical Assistant to Professor Ludlam to cover the maternity leave absence of Dr Rosemary Dennis commencing in October 1993. My contract was extended after Dr Dennis' return GRO-C until September 1996.

I would like to point out that the 3 years I worked at the Haemophilia Centre formed a very small part of my overall career. I left my post there 25 years ago and my recall for this period is incomplete.

My main responsibilities were the out-patient management of patients with bleeding disorders which included: regular periodic review and monitoring of their condition and treatment of any acute bleeds. An important part of the patients' ongoing review was the management of any infections such as HIV and HCV.
I also assessed and treated patients before they underwent dental treatment in the dental clinic attached to the Centre. In addition, I assisted in a weekly, general, haematology out-patient clinic.

For the final year of my employment, I did very little clinical work and instead I mainly worked on a service evaluation for Professor Ludlam, which involved collecting anonymised data from paper and electronic records. This work contributed to the publication 30(e).

The senior staff I can remember are Dr Rosie Jones, haematology registrar, Dr John Hanley, haematology registrar and Dr Angela Thomas, consultant paediatric haematologist.

7. **Please explain the hierarchy and dynamics at the Centre, identifying in particular who was responsible for (a) decisions as to the selection and**

purchase of blood products, (b) decisions as to use of blood products (including factor VIII and IX concentrates) for patients' treatment and (c) decisions as to what information to provide to patients about treatment, testing and/or diagnosis.

Professor Ludlam as Centre Director was in overall charge of the unit and, as a clinical assistant, I sought advice from him or one of the haematology registrars or senior registrars whenever necessary.

(a) Professor Ludlam was, I believe, responsible for the selection and purchase of blood products. I did not have any involvement in this.

(b) Part of my role, as I remember, was to assess patients who had sustained a bleed and prescribe appropriate treatment which sometimes included Factor VIII or IX concentrates. It is fair to say that, as I was a junior member of the team, my policy was to seek advice from Professor Ludlam or one of the haematology registrars for the treatment of all except very straight forward acute bleeding episodes. At no time would I have prescribed a blood product that the patient had not previously received without supervision from a senior colleague. I do not remember this ever happening.

(c) I am unable to recall any discussions about what specific information to provide to patients about treatment, testing or diagnosis. It has been my practice throughout my career to provide patients with up to date information about all aspects of their care, to give patients the opportunity to ask questions and to answer them to the best of my ability.

Section 3: Knowledge of, and response to, risk

General

8. **When you began work at the Centre, what did you know and understand about the risks of infection associated with blood and/or blood products?**

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

I came from a background in general practice and I had a general understanding that blood and blood products had the potential to transmit infections, including HIV and hepatitis. As a doctor I was aware of the risks of needle stick injuries which could lead to infections such as hepatitis B or HIV. Reading of medical journals such as The British Medical Journal and The Lancet and attending educational lectures and scientific meetings were my main source of information. I also read publications for general practitioners, but I cannot remember their titles.

My knowledge increased a great deal during my time at the Centre. Professor Ludlam taught me and also gave me copies of papers to read but I do not remember details about these papers. I also learnt about hepatitis C and liver disease from Dr Hayes when I attended the joint haemophilia and Hepatitis clinics in the Centre. I continued to read medical journals and I attended lectures and conferences.

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

I regret that I cannot remember whether advisory and decision-making structures were in place to consider and assess risks of infection from blood.

Hepatitis

10. **When you began work at the Centre what was your knowledge and understanding of the risks of the transmission of hepatitis (including hepatitis B and hepatitis C) from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?**

When I began work at the Centre I had some basic knowledge about hepatitis C and I knew that the virus had been isolated a few years previously in 1989. I was aware that it could be transmitted through contact with infected blood and body fluids. I was also aware that historically, transfusion of blood and blood products, particularly those derived from pooled plasma donations carried the risk of transmitting infections including HCV. My knowledge increased significantly over time; again, I was taught by Professor Ludlam and Dr Hayes and I read medical journals and attended scientific seminars and lectures on the topic.

HIV and AIDS

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

I had some knowledge about HIV and AIDS from my time in general practice in Edinburgh. I was aware of the ways in which HIV could be acquired and of the precautions that should be adopted to prevent transmission. I remember attending a talk from Dr Judy Bury who came to my surgery in Brunton Place Edinburgh to speak about the management of patients with HIV in general practice. Her talk also covered the infection control measures that should be adopted in the surgery. I recall seeing patients with HIV in my GP surgery on a few occasions. Although the majority of patients in Edinburgh had acquired HIV either from intravenous drug use or from sex with an infected individual, I was also aware that some patients with haemophilia had been infected from transfused blood products.

My knowledge increased considerably over time from attending scientific meetings, reading journals and from discussions with Dr Brettle, consultant in Infectious Diseases, who came to the Centre to advise on the treatment of patients with HIV attending the Centre.

Section 4: Testing, treatment and care of patients at the Centre

12. What information was provided to patients at the Centre about the risks of infection (generally and/or specifically in relation to hepatitis and/or HIV) associated with the use of blood and blood products, and by whom?

I am unable to remember what information was provided to patients about the risks of infection associated with the use of blood products. As I recall, the patients I saw, had been diagnosed with a bleeding disorder many years previously (in childhood in most cases), and they were very well informed about all aspects of living with their condition. I do not know where they received this information from, but I do recall that information leaflets produced by the Haemophilia Society were usually available in the Haemophilia Centre.

13. What was the Centre's approach and in particular, the approach of Professor Ludlam to obtaining patient consent to treatment and to testing? What information was provided to patients and by whom? To what extent were decisions about treatment and testing taken by the doctors rather than the patients? Did this change or develop over time and if so how?

As I recall, verbal consent to treatment was implied by the patient's co-operation with being treated. The same was true of taking blood samples. I am aware that some testing of stored blood samples had taken place, but I do not know what information was provided to the patient or whether consent was gained. In the 1990's as far as I remember, it would have been usual practice for doctors to make recommendations about treatment and testing which might lead to a discussion between doctor and patient about the options. Over time this approach has tended to change with patients taking a bigger role in decisions about their treatment.

14. Was any training or advice or instruction provided to you at the Centre in relation to obtaining patient consent to treatment and to testing? If so, please describe the training, advice or instruction given.

I do not recall any specific training in relation to obtaining consent to treatment or testing during my time at the Centre. However, I had already been trained in the

correct approach to obtaining informed consent from patients being considered for clinical trials in a previous post I held in Liverpool in 1985.

15. **Were you ever told to withhold information from a patient or patients about risks, or treatment, or testing, or diagnosis, or their condition? If so, by whom and in what circumstances?**

I do not recall ever being told to withhold information of any kind from a patient.

16. **Was it customary to take blood samples from patients when they attended the Centre and for what purpose? What information was given to patients about the purposes for which blood samples were taken, and by whom?**

It was usual practice to take blood from patients when they attended the Centre for either routine follow-up or for the treatment of a bleed.

From memory, blood was routinely tested for full blood count, clotting factor levels, clotting factor inhibitors, clotting function tests, urea and electrolytes and liver function tests. This list may be incomplete due to my incomplete recall. Blood samples were also sent to the virology laboratory, but I cannot remember which tests were done routinely. If patients were known to be infected with HIV or HCV then other tests would have been done. It was my practice to explain to patients if I was doing a test that hadn't previously been done and to explain the reasoning for doing it. For example: Hepatitis C PCR is a test for the presence of hepatitis C virus which, if positive, would suggest active infection with hepatitis C.

As I recall, patients were not given specific information about routine tests but either the attending doctor or nurse would have answered any questions asked by the patient.

17. **Were patients informed if their blood was going to be tested for HIV, HBV and/or HCV and, if so, by whom? Did the approach to informing patients change over time?**

I cannot remember whether or not patients were informed about testing for HIV, HBV or HCV.

As far as I recall, by 1993, when I started working at the Centre, all the patients had already been tested for antibodies to HIV, HCV and HBV. I do not recall a case of a new diagnosis of these infections during my time at the Centre.

18. **What information would routinely be given to patients about liver function tests and the results of such tests?**

As far as I recall, routine liver function test results would only be discussed if the results were significantly abnormal. In which case it would be usual practice to explain the results and advise whether additional investigations were necessary, but I cannot remember a consultation where this happened.

19. **What was the practice at the Centre about informing patients of test results (whether positive or negative or inconclusive) for HIV, HBV and/or HCV? Were patients informed of the test results promptly or were there delays in test results being communicated to them? How, as a matter of usual practice, were they advised of their test results (e.g. by letter, or by telephone, or in person at a routine appointment or at a specific appointment) and by whom? What, if any, involvement did you have in informing patients of test results?**

I was not involved in informing patients of results of HIV tests. It is possible that I told a patient about HCV infection in a routine clinic appointment but I do not remember a specific incidence of this happening.

20. **In a letter dated 16 December 1993, you stated "I took the opportunity to discuss hepatitis C with W2232. Our investigations have demonstrated that he is hepatitis C antibody positive, but his liver function tests are normal. Our policy is to invite patients who have hepatitis C to a joint liver clinic run with Dr Peter Hayes, Consultant Hepatologist," [WITN2232025]. Without making reference to the specific patient or any information which might identify the patient, please answer the following:**

a. **What "investigations" were you referring to? Would the patient have been informed he was being tested for hepatitis C before the tests were undertaken?**

b. **What does "I took the opportunity to discuss hepatitis C." mean? Had the patient been told his test results prior to this routine appointment, or was this the first conversation in which he was told about his infection? If the latter, did you say in terms that the patient had hepatitis C or would you have discussed it in more technical language? What did you do to make sure that the patient had understood the diagnosis that you were conveying to him?**

c. **How many patients were referred to the joint liver clinic, and how many attended the referral?**

I do not remember the consultation with this patient. My responses to the following questions are therefore based on the information in the letter [WITN2232025].

(a) The investigations referred to in the letter would have been the hepatitis C antibody test. I do not know if the patient had been informed before the test was undertaken as it would almost certainly have been done before I took up my post.

(b) This phrase: "I took the opportunity to discuss hepatitis C" means that I talked to the patient about HCV. As I do not remember this consultation I do not know if he had been given the result previously. I outline below my general approach to patients found to be HCV antibody positive.

I would first establish whether the patient was aware of the HCV antibody result and if not tell him that his test was positive. I would then explain that the result indicated infection with the hepatitis C virus at some time in the past, but that another test, HCV PCR, was necessary to determine if the infection was still present. I would also explain that HCV had been identified in 1989, and that it was now thought to be the organism responsible for what was formerly called nonA

nonB hepatitis (NANBH) (Many haemophilia patients were aware of NANBH and that it could be acquired from transfused blood products.) As HCV could be passed on by contact with blood and body fluids, I would counsel the patient about measures to prevent transmission to others, such as the need to use condoms to prevent sexual transmission and also the precautions that should be taken to protect household members such as avoiding sharing toothbrushes or razors. (This patient was HIV positive and would have been aware of these precautions.)

I would further explain that HCV infected the cells in the liver and it could cause inflammation (hepatitis) resulting in raised liver function tests and that over time, usually many years, this could progress to scarring of the liver which is called cirrhosis. I would also outline the investigations that were recommended to assess the condition of the patient's liver. It was always my practice to use non-technical language and to give the patient the opportunity to ask questions.

(c) As far as I can remember, all patients attending the Haemophilia Centre, who were HCV positive, were invited to attend the joint liver clinic. I do not know how many were referred or how many attended.

21. **What was the practice at the Centre as regards testing and/or providing information to the partners and/or family members of people known or suspected to be infected with HIV, HBV or HCV?**

As far as I remember family members were advised to be tested but I do not remember if this was done at the Centre or elsewhere. I do not remember whether any written information was provided to them.

22. **Was any form of counselling or psychological support made available to patients infected with HIV, HBV and/or HCV or to their families? If so, please detail what support was available, and when this became available to patients.**

A clinical psychologist, Dr Alison Richardson, had been seeing patients for support in the Centre before I started working there, I do not know when she started doing this.

23. **Was any form of social work support made available at the Centre to patients infected with HIV, HBV and/or HCV or to their families? If so, please detail what support was available.**

I remember that there was a social worker in the Royal Infirmary who saw patients from the Haemophilia Centre. I believe her name was Geraldine.

24. **What information or advice was provided to patients diagnosed with HIV, HBV and/or HCV regarding the management of their infection including risks of infecting others? How did this change or develop over time?**

Patients were advised about the precautions they should take to prevent transmitting HIV, HBV or HCV to others. The precautions included using condoms and clearing up spillages of blood themselves whenever possible. Family members of patients infected with HBV were advised to be vaccinated against Hepatitis B. Patients with HBV and HCV infections were managed from the joint hepatitis clinic. As far as I can remember, the management of HIV was supervised by Dr Brettle and Dr Ludlam. I do not know if patients were given information about the risks of transmission or management of their conditions, but these topics would have been discussed in clinic appointments.

25. **You may wish to refer to the following letters when answering the below; letter from yourself to Dr J Cowan dated 15 March 1994 [WITN2315015], and letter from yourself to Dr B. V. Keunssberg dated 6 October 1995 [WITN2167012]:**

    a. **How was the care and treatment of patients diagnosed with HIV, HBV and/or HCV managed at the Centre?**

b. **What treatment options were offered over the years to those diagnosed with HIV, HBV and/or HCV?**

c. **Was it common for patients to refuse treatment?**

d. **What follow-up and/or ongoing monitoring was arranged?**

e. **To what extent were patients at the Centre referred for specialist care elsewhere? You may wish to refer to your letter from your time at the Regional Infectious Diseases Unit, to Dr Rosemary Dennis dated 15 May 1997 [PRSE0003447, p. 51-52]**

f. **How did any of this change or develop over time?**

As far as I remember, I was not involved in the care of any patients with HBV, so my answers will refer only to HIV and HCV infections.

(a) Patients infected with HIV and HCV were managed in clinics run in the Haemophilia Centre by Dr Ludlam, Dr Hayes, haematology registrars, Dr Dennis and myself. As far as I remember Dr Brettle did not usually see patients personally. Instead, meetings were held in the Centre, attended by Dr Brettle and the Haemophilia Centre staff, where the management of the patients with HIV was discussed. The recommendations made by Dr Brettle would then be discussed with patients at their subsequent clinic appointments. At this time, as I was a junior member of staff, I would have taken advice from more senior members of staff about treatment decisions.
Patients attended both for routine follow up appointments and also emergency appointments if needed.

(b) During my employment at the Haemophilia Centre from 1993 to 1996, treatment for both HIV and HCV infections was in its infancy.
There were only a few drugs available to treat HIV and most of the medical management was directed at preventing or treating the other infections which patients were susceptible to, because of their impaired immunity, due to HIV. I

remember some patients attended the Centre weekly to receive a drug called pentamidine which was administered via a nebuliser. This was given to prevent a type of pneumonia called PCP.

As I recall, some patients were prescribed the available anti-retroviral drugs zidovudine (AZT), didanosine or zalcitabine. Some patients were enrolled in clinical trials which are detailed later in this statement. Other drugs may have been available, but I cannot remember clearly. As previously mentioned, decisions about prescribing these agents were made by Dr Ludlam and Dr Brettle.

There was only one treatment licensed for HCV infection at that time: a drug called interferon (IFN) which was administered by injection, three times a week, usually for a period of six months. This treatment was available and was offered to patients who had active hepatitis C. The decision to offer treatment with IFN was made by Dr Ludlam and Dr Hayes.

(c) I do not remember how many patients declined treatment, but I do not think it was more than a few.
Interferon can cause severe, unpleasant and wide-ranging side effects and a few patients declined to take it whilst others stopped it prematurely because of the side effects. Others, as in the case of the patient referred to the letter (WITN2167012), declined because they did not want to have injections 3 times a week.
I would like to point out that, the clinic letter referred to from myself, is a record of the patient's attendance in the liver clinic. I accept that the letter does not make this clear. It is most likely that Dr Hayes and Dr Ludlam were also present although I do not recall the appointment.

(d) It was usual policy to routinely see patients with bleeding disorders once, twice or three times a year or more depending on the severity of their condition. Patients with hepatitis C who were taking IFN were seen weekly at the start of their treatment and then monthly. Blood was taken for various tests including full blood count, liver function tests and HCV PCR. There may have been other tests, but I cannot remember what the usual practice was at that time.

At routine appointments, blood tests were done as has been described already. Liver ultrasound scans and endoscopies were repeated but I cannot remember exactly how frequently.

(e) I have described already that Dr Hayes and Dr Ludlam organised a joint liver clinic so that patients with HCV could receive specialist care.
Patients infected with HIV were managed at The Royal Infirmary by Dr Ludlam with advice from Dr Brettle, during my time at the Centre. When patients required admission for treatment for HIV, as I recall, they were usually admitted to RIE but some were occasionally admitted to RIDU. However, in late 1996, new drugs known as HAART (highly active antiretroviral therapy) became available to treat HIV and at this time, some if not all, patients were referred to RIDU for management of HIV. I am aware that some patients did not want to be referred to other units because of perceived stigma or because of unwillingness to associate with the other patients in other units such as RIDU.

(f) Patients were referred to specialist units for management of HIV as more effective drugs (Highly Active Antiretroviral Therapy – HAART) became available and therapy became more complex.

26. Do you recall patients diagnosed as HIV, HBV and/or HCV positive being treated differently to others? If so in what respects? What if any measures were implemented to address any risks of cross-infection?

I do not remember patients with HIV, HBV or HCV being treated any differently from other patients. All specimens including blood samples, from all of the patients, irrespective of their diagnoses, were treated as though they could potentially be infectious. From memory, they were double bagged and had a "high-risk" sticker attached. It was standard policy to wear gloves when taking blood or other samples and to dispose of all equipment e.g., needles, immediately after use, into a safe disposal unit.

27. To your knowledge, were clinical staff made aware of patients' infected status in relation to HIV, HBV and/or HCV?

The patients attending the Centre were well known to the staff and therefore their infected status would also have been known. New members of staff would become aware as they became familiar with the patients. All staff were very aware of the need to respect patient confidentiality at all times.

28. Please describe what you can recall about the impact of the infection(s), and/or of treatment for the infection(s), and/or of the stigma associated with the infection(s), upon the Centre's patients and upon their families over the years.

I remember that having these infections was very difficult for the patients. Stigma surrounding HIV was considerable at that time, and patients were understandably very concerned about confidentiality. I recall one patient, who worked within the hospital, being given a pseudonym, in order to protect his confidentiality. Patients were unwilling to visit their GP's and preferred to have all their medical care provided by the Centre. Some patients became very seriously ill with HIV and subsequently died, which not only had a devastating effect on their families but also on other patients and the Centre staff.

Section 5: Research

29. Please list all research studies that you were involved with during your time at the Centre insofar as relevant to the Inquiry's Terms of Reference, and provide a brief summary of the purpose of the research and your involvement.

I have listed below the research studies that I can remember being part of during my time at the Haemophilia Centre.

(i) Delta Trial. I was involved in the follow up of patients in the Delta trial. This study, run by the Medical Research Council (MRC), was a randomised controlled

trial comparing different drug regimes for HIV infected individuals. My role was to see patients in clinic, to review them and organise any investigations, usually blood tests, required by the study protocol. I also had to fill in the trial clinical report forms (CRF) which were kept in folders, separate from the medical notes. A monitor from the MRC visited the Centre regularly to check these forms and also to check that the study was being carried out correctly according to the trial protocol.

(ii) Trial of a novel recombinant Factor IX product. I was involved in the follow up of one patient in a pharmaceutical company trial of a new treatment for patients with haemophilia B. I saw the patient for review and completed the CRFs as in the Delta trial and a monitor from the company visited regularly to check the forms.

(iii) Service review of Haemophilia Care in Scotland. I was involved in data collection for this study, organised by Dr Ludlam, which involved reviewing patients' clinical case records and electronic records of coagulation factor concentrate usage.

30. The Inquiry understands you coordinated, contributed, or provided data to the following:

a. An article published in 1995: "Treatment of hepatitis C infection in haemophiliacs: the Edinburgh experience." Please provide a copy of this should you have one.

b. An article published in 1996: "Investigation of chronic hepatitis C infection in individuals with haemophilia: assessment of invasive and non-invasive methods" [RLIT0000366]

c. An article published in 1996: "Delta: a randomised double-blind controlled trial comparing combinations of zidovudine plus didanosine or zalcitabine with zidovudine alone in HIV infected individuals" [HSOC0019358]

d. **An article published in 1996: "Interferon for chronic hepatitis C infection in haemophiliacs: influence of virus load, genotype and live pathology on response" [OXUH0001656_006]**

e. **An article published in 2000: "Haemophilia Care in Scotland 1980-1994, Demographic Characteristics, Hospital Admissions and Causes of Death." Please provide a copy of this should you have one.**

Please set out what involvement you had in them.

(a) **Treatment of HCV infection in haemophiliacs: the Edinburgh experience**

I was involved in the follow up of patients who were receiving treatment for HCV infection as part of their clinical care. Interferon was licensed for the treatment for HCV and it was the only treatment available at that time. Anonymised data from these individuals was published in this paper. Dr Hanley did the analyses and wrote the text. A copy of this article is attached as an exhibit [WITN5298003].

(b) **Investigation of HCV infection in individuals with haemophilia: assessment of invasive and non-invasive methods.**

I assisted in the assessment of patients attending the Haemophilia Centre who were HCV antibody positive. One of my roles was to ensure that all patients with a positive antibody test had been offered investigations to assess their HCV infection and stage of liver disease. This was done as part of routine follow-up and was not research. The anonymised results of these investigations were subsequently presented in this paper, by Dr Hanley, to disseminate the understanding of HCV infection in patients with haemophilia.

(c) Delta: a randomised double blind controlled trial comparing combinations of zidovudine plus didanosine or zalcitabine with zidovudine alone in HIV infected individuals.

I was in involved in the follow-up of patients who were enrolled in this study. I have described my involvement in question 29 (i).

(d) Interferon for chronic HCV infection in haemophiliacs.

I was involved in the follow-up of patients who received interferon treatment for HCV infection. This was not research but part of standard care. The anonymised results of from these patients were presented in this paper by Dr Hanley.

(e) Haemophilia Care in Scotland 1980-1994.

This article is a report of some of the aspects of the service review which I assisted with in 1995-1996. I have described my involvement in my answer 29(iii) above. A copy of this article is attached as an exhibit [WITN5298004].

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

Patients were not involved in research studies without consent. There were very clear guidelines governing the conduct of research and I believe these were followed. It was mandatory to gain informed consent before patients could be enrolled in drug trials of any kind. This policy was universal and monitored by regulators from the trial investigators. Studies which consisted of audit or service review did not require patient consent as long as data was anonymised. This was the case in the studies mentioned in 30(b), 30(d) and 30(e).

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

Anonymised data from patients was reported in the publications 30(b), (d) & (e). Consent was not obtained because, service review and audit were not regarded as research and hence consent was not required.

Section 6: UKHCDO

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

I was not involved with UKHCDO working parties, committees or groups. I am afraid that I am unable to remember very much at all about the organisation. I am aware that Dr Ludlam was a member of the organisation and that they made recommendations about many aspects of care of patients with haemophilia. I also recall filling in forms for this organisation but I do not remember what information was requested.

Section 7: Pharmaceutical companies/medical research/clinical trials

34. Please describe the nature of your involvement with any pharmaceutical company involved in the manufacture and/or sale of blood products. Examples of such involvement may include:

a. **Providing advisory or consultancy services**

b. **Occupying a position on any advisory panel, board, committee or similar body**

c. **Receiving funding to prescribe, supply, administer, recommend, buy or sell a particular product**

d. **Undertaking medical research for or on a company's behalf**

e. **Providing results from medical research studies to a company**

If you were involved in any of the arrangements described above, please provide details of your involvement and any incentives, financial or otherwise, you received.

(a) I did not provide advisory or consultancy services.
(b) I did not occupy a position on any advisory panel, board, committee or similar body

(c) I did not receive funding to prescribe, supply, administer, recommend, buy or sell a particular product.

(d) I did not undertake medical research for a or on a company's behalf. I was, as previously mentioned in my answer to question 27(ii), involved in the follow-up of a patient in this study run by a pharmaceutical company. I did not receive any remuneration of any kind for this work.

(e) The pharmaceutical company mentioned in my response 34(d), received the follow -up data I collected, as required by the study protocol.

35. **At the Centre, what if any requirements and/or guidelines were in place concerning declaratory procedures for involvement with a pharmaceutical company? Did you follow these requirements and/or guidelines?**

I do not remember any requirements or guidelines being in place at the Centre concerning declaratory procedures for involvement with a pharmaceutical company. However, as I had no direct involvement with a pharmaceutical company, this is not something I would expect to have known about.

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

I did not receive funding from pharmaceutical companies for medical research.

Section 8: The financial support schemes

37. Please describe as fully as you can any involvement you have had in relation to any of the trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund, EIBSS) which were set up to provide financial assistance to people who had been infected. Relevant involvement may include:

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

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

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

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

(a) I did not occupy a formal position with any of the trust funds.

(b) I did not provide any advice to any of the trusts or funds.

(c) I do not remember if I informed or referred patients to any of the trusts, but I do not believe I did so.

(d) From memory, I did, on occasion, complete forms, I think for the Skipton Fund and/or the Macfarlane Trust.

Section 9: Later employment

38. Please outline your role at the Regional Infectious Diseases Unit. In your answer, please also identify any issues or aspects of your work that are relevant to the Terms of Reference.

I do not have anything to add to my statement on this subject in section 1, question 5.

Section 10: Other Issues

39. 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.

I have not had to answer any complaint made about me to my employer, the GMC or any other organisation having a responsibility to investigate complaints.

40. 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.

I am unaware of any other matters that I believe are relevant to the Inquiry.

Statement of Truth

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

Signed GRO-C

Dated 17.03.2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
	Curriculum Vitae	WITN5298002
1995	J.P Hanley, et al. Treatment of hepatitis C infection in haemophiliacs: the Edinburgh experience, Haemophilia (1995), 1, (Suppl. 4), 36-38	WITN5298003
2000	C.A. Ludlam, et al. Haemophilia care in central Scotland 1980-94. I. Demographic characteristics, hospital admissions and causes of death, Haemophilia (2000), 6, 494-503	WITN5298004