Witness Name:	Dr Angela McKernan
Statement No.:	WITN3923008
Exhibits:	WITN3923009
Dated:	24 March 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ANGELA MCKERNAN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 8 December 2020.

I, Dr Angela McKernan, will say as follows: -

Section 1: Introduction

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

1.1 My name is Angela McKernan.
My Qualifications are MB, ChB; MD; FRCP; FRCPath
My date of birth is GRO-C 1958
My address is:
Department of Haematology
Royal Derby Hospital
Uttoxeter Road
DE22 3NE

2. **Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.**

2.1 I was Locum Consultant Haematologist with responsibility for the Haemophilia Centre at Royal Liverpool Hospital from 1st December 1994 to 28th February 1995. I was responsible for the diagnosis and treatment of people with hereditary bleeding disorders.

2.2 I took up my present position of Consultant Haematologist and Director of the Haemophilia Centre in Derby on 1st March 1995. Throughout this employment I have been responsible for the diagnosis and treatment of people with hereditary bleeding disorders. My job plan also includes thrombosis, anticoagulation, obstetric and paediatric haematology and general haematology. Until 10 years ago a large proportion of my work was in malignant haematology but this has gradually reduced over the past 10 years.

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

3.1 I became a member of the UK Haemophilia Centre Doctors Organization (UKHCDO) in October 1998. I was a member of the Dental Working Party of the UKHCDO between 2010 and 2013. I have been a member of the Musculoskeletal Working Party of the UKHCDO since 2012. I have been a member of the British Society for Haematology since early in my Consultant career but can't remember when I joined.

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, reports or documents that you provided.**

4.1 I have not 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.

5. The following questions are focused on your time as Locum Consultant Haematologist with responsibility for the Haemophilia Centre at Royal Liverpool Hospital and your role as a Consultant Haematologist and Director of the Haemophilia Centre in Derby.

5.1 This is not a question.

Section 2: Decisions and actions of the Royal Liverpool Hospital ("the Hospital") Haemophilia Centre in Derby ("the Centre")

6. Please describe the roles, functions and responsibilities of (a) the Hospital and (b) the Centre (insofar as relevant to the Inquiry's Terms of Reference) during the time that you worked there.

6.1 The Royal Liverpool Hospital was a large University teaching hospital. The Haemophilia Centre was a Comprehensive Care Centre. Derby haemophilia centre was a treatment centre, not a comprehensive care centre.

7. Please identify senior colleagues at (a) the Hospital and (b) the Centre involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products, and their roles and responsibilities during the time you worked there.

7.1 At the Hospital I was the only consultant dealing with people with hereditary bleeding disorders. There were several other consultants who would only be involved with these patients on-call. These were Professor John Cawley, Dr Patrick Chu, Dr Vanessa Martlew, Dr Jenny Duguid and Dr Richard Clarke.

7.2 At the Centre I was the only consultant dealing with people with hereditary bleeding disorders. There were a number of other consultants who would only be involved with these patients on-call. In 1995 these were Dr Deirdre Mitchell (deceased) and Dr Stewart Mayne (retired). In the 2000's these were Dr Cherry Chang, Dr Rowena Faulkner, and Dr Gama Sidra (all 3 moved on to other Trusts). Since 2010 Dr Adrian Smith, Dr Juana Addada, Dr Chris Millar, Dr Ian Amott – all still in post at Derby. Dr David Allotey and Dr Sangam Hebballi have moved to other Trusts. In the past 2 years we have appointed Dr Sarah Hartley, Dr Meghna Ruparelia, Dr Caroline Harvey and Dr Firas Al-Kaisi – all still in post.

8. Please describe your roles and responsibilities as Locum Consultant Haematologist at the Hospital and Consultant Haematologist and Director at the Centre and how, if applicable, this changed over time.

8.1 Throughout both these employments I have been responsible for the diagnosis and treatment of people with hereditary bleeding disorders. As a Consultant Haematologist and Director at the Centre in Derby my job plan also includes thrombosis, anticoagulation, obstetric and paediatric haematology and general haematology. Until 10 years ago a large proportion of my work was in malignant haematology but this has gradually reduced over the past 10 years.

9. Please describe your work at (a) the Hospital and (b) the Centre insofar as it involved the care and treatment of patients with bleeding disorders; the care and treatment of patients infected with hepatitis and/or HIV in consequence of infected blood or blood products; and the care and treatment of patients with blood or blood products other than for the treatment of bleeding disorders.

9.1 At both the Hospital and the Centre my work with the care and treatment of people with bleeding disorders includes regular reviews in outpatients, provision of clotting factor for home treatment and/or prophylaxis for severe haemophilia, an individualised management plan on how to treat bleeds and for perioperative management. I refer any patient with HIV and/or hepatitis to the relevant specialty for them to manage these conditions (Genitourinary Medicine and Hepatology respectively).

10. Approximately how many patients with bleeding disorders were under the care of (a) the Hospital when you worked there and (b) the Centre when you first started working there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so). What proportion were children and what proportion adults?

10.1 Liverpool: No children (they were treated at another hospital – Alder Hey). I can't remember how many adults there were.

10.2 Derby: There are currently 260 people with bleeding disorders registered with the National Haemophilia Database, 180 adults, 80 children. Most of these have mild bleeding disorders. There are 14 adults and 7 children with severe haemophilia.

11. What decisions and actions were taken, and what policies were formulated, by (a) the Hospital and (b) by you and by the Centre, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you were there? In addressing this question please answer, to the extent that you are able to, the following questions:

a. How, and on what basis, were decisions made about the selection and purchase of blood products?
b. What were the reasons or considerations that led to the choice of one product over another?
c. What particular products were used for treating patients, over what period of time and for which categories of patients?
d. From where were the factor concentrates used at the Centre sourced?
e. What role did commercial and/or financial considerations play?
f. What involvement did you have?

11.1 Liverpool: I was only at Liverpool as a Locum for a very short period (4 months) and don't remember making any decisions about the selection and purchase of blood products.

11.2 Derby:
a) All patients requiring factor 8 and factor 9 clotting factor were on plasma derived products when I started in 1995. I started changing people from plasma derived clotting factor 8 to recombinant factor 8 (Kogenate) by 1996.

This was because as a recombinant rather than plasma derived product it was considered safer from the infection point of view.

11.3 Existing patients already on clotting factor I changed to recombinant by age (younger first) as they were less exposed to plasma derived products. From 2005 after the national rollout of recombinant clotting factor some patients were changed to Advate and patients who were still on plasma derived clotting factor were changed to either of the recombinant products. I think part of the rationale for using 2 types of recombinant factor was to help manage supply problems. The national contract which I think started in 2013/14 meant we sometimes had to change product for some patients as we were asked to use a certain amount of different products per region.

11.4 b) Previously untreated patients with severe Haemophilia A were started on recombinant factor as it was safer than plasma derived factor. Derby is a small centre and I only had 1 newly diagnosed person with severe haemophilia A between 1995 and 2001. This patient was started on Kogenate in Jan 1996 subsequently changed to Recombinate – I don't know why (may be Kogenate supply problems). The next new severe haemophilia A person presented in Nov 2001 and was given Refacto as a 3rd generation product which had no human protein in the end product, which was perceived at that time to be an advantage.

11.5 c) From our historical treatment records which begin in 1978: Haemophilia A
1978 – 1982: Most treatment given was 'Cryo' which I assume was cryoprecipitate and Kryoglobulin. A small amount of Lister AHS was used.
1981: Factorate, Lister
1982: Factorate, Lister, Cutter and Hyland
1983 – 1984: Lister, Cutter
1985: Lister, Cutter, Alpha
1986: Alpha, Lister, 8Y/BPL
1987: Alpha, 8Y/BPL
1988: Alpha, 8Y, Replenate
1989 – 1993: Replenate/BPL
1992: a factor which had a batch number starting 'Aro' – I don't know the name.
1992 – 1993: Armour and Alpha
1993 – 1996: BPL, Armour and Alpha
1996 – 2005 : Kogenate, Recombinate, Refacto, BPL, Haemofil M, Fahndi
2005 to present: Kogenate, Refacto, Advate
Haemophilia B
'Factor IX'
1989: 9Y/BPL
Benefix
Alprolix
Type 2 von Willebrands:
Haemate P
Wilate

11.6 d) As far as I am aware these products were sourced from the manufacturers.

11.7 e) I can only comment on the period since 1995. I am not aware that commercial or financial consideration played any part.

11.8 f) My involvement since 1995 was to move patients as soon as possible to recombinant factor.

12. What was the relationship between the (a) the Hospital and (b) the Centre/you and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the (a) the Hospital's and (b) the Centre's and your decisions and actions?

12.1 I am not aware of any relationship between the hospital or centre and the pharmaceutical companies.

13. If the responsibility for the selection and purchase of blood products lay with an organisation other than the (a) the Hospital and (b) the Centre, please specify which organisation and provide as much information as you can about its decision-making. You may wish to refer to your fax to Dr Hill enclosed at [HCDO0000013_226].

13.1 I remember that there were supply problems with Kogenate (Bayer). The fax to Dr Hill [HCDO0000013_226] shows that this could mean that some patients would have to change to another product.

14. How did you decide which products to use for particular patients? To what extent, if at all, were patients offered a choice, or given a say, as to what products would be used?

14.1 Newly diagnosed severe haemophilia A children were given Recombinant factor 8 to prevent them being exposed to human plasma. As a small centre dealing with a rare condition Derby had 2 children present with severe haemophilia A before the Recombinant rollout in 2004/5. The first in 1996 was started on Kogenate and subsequently changed to Recombinate. From memory I think that Kogenate was the only commercially available recombinant product in the UK at the time. I can't remember why this person was changed to Recombinate but it might have been due to supply problems with Kogenate. When Recombinate was phased out to be replaced by Advate this person was changed to Advate.

14.2 The second child was diagnosed in 2001 and was started on Refacto. Refacto was chosen as it was a so called third generation recombinant factor 8 which had no human protein in the final product. At the time this was thought to be an advantage. It was not available in 1996.

14.3 In 1996/7 I moved some existing patients – children, teenagers and young adults from plasma derived factor to recombinant factor: Kogenate. I can't remember the discussions I had with these patients but I would have given them the option of remaining on plasma derived factor whilst stressing the greater safety of recombinant factor. I moved this age group to recombinant as they had had less exposure to plasma derived factor.

15. What was the policy and approach at (a) the Hospital and (b) the Centre in relation to home treatment for patients with bleeding disorders? Did that policy and approach change over time and, if so, how?

15.1 All children and teenagers with severe haemophilia were on home treatment when I started at Derby. I continued that practise. I can't remember what the policy was in Liverpool.

16. What was the policy and approach at (a) the Hospital and (b) the Centre in relation to prophylactic treatment for patients with bleeding disorders? Did that policy and approach change over time and, if so, how?

16.1 I can't remember what the policy and the approach was at the hospital. My policy at the centre was for all severely affected children to be on prophylaxis. In later years I would encourage them to continue prophylaxis in to adulthood, and for adults who were on on-demand treatment to use prophylaxis.

17. What was the policy and approach at (a) the Hospital and (b) the Centre as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and, if so, how?

17.1 It has never been my policy to use cryoprecipitate for people with bleeding disorders.

18. To what extent, and why, were patients with mild or moderate bleeding disorders treated at (a) the Hospital and (b) the Centre with factor concentrates?

18.1 It has always been my policy to avoid the use of clotting factor wherever possible in people with mild and moderate bleeding disorders, using local

haemostatic measures, tranexamic acid, and in the case of haemophilia A and some platelet disorders, Desmopressin.

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

19.1 I am not aware of any other viruses or infections which have been transmitted to patients at Derby. I can't comment on Liverpool.

Section 3: Knowledge of, and response to, risk

General

20. **At the time you took up your position as Locum Consultant Haematologist at the Royal Liverpool Hospital in December 1994, 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 that knowledge and understanding develop over time?**

20.1 I understood that plasma derived clotting factor concentrate which was given to people with bleeding disorders in the 1970's and 1980's had resulted in many of them acquiring HIV, Hepatitis B and Hepatitis C. Professionally I learned about this when I was a Senior Registrar working with Dr Charles Hay at Royal Liverpool Hospital in 1994. I think I knew about this before that time but can't remember when I first heard about this.

21. **What was your understanding of the relative risks of infection from (i) the use of commercially supplied blood products, and (ii) the use of NHS blood products?**

21.1 I understood that in the 1970's and 1980's commercially supplied products could be a greater risk than NHS blood products because of the plasma source. NHS products were made from plasma freely donated in the UK. I understood that in America blood was donated for money which motivated people such as drug addicts to donate. In the late 1990's non-UK sourced plasma was thought to be safer from the vCJD perspective than UK plasma.

22. **What advisory and decision-making structures were in place, or were put in place at (a) the Hospital and (b) the Centre, to consider and assess the risks of infection associated with the use of blood and/or blood products.**

22.1 I can't comment on Liverpool as I was there for a few months only as a Locum. In Derby I decided to change the children, teenagers and young adults to recombinant factor as soon as I could.

Hepatitis

23. **What was your knowledge and understanding of the risks of the transmission of hepatitis, including HBV and NANB hepatitis (HCV), from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?**

23.1 I understood that plasma derived clotting factor concentrate was made by the pooling of plasma from thousands of donations. Before the introduction of heat treatment (which I think occurred in the mid 1980's) this meant that the vast majority of people who received these products acquired NANB (HCV) and a large proportion acquired HBV. I learned this when I was a Senior Registrar working with Dr Charles Hay at Royal Liverpool Hospital in 1994.

24. **What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?**

24.1 Whilst working with Dr Charles Hay as a Senior Registrar at Royal Liverpool hospital in 1994 I learned that HCV could cause chronic hepatitis which over many years could lead to cirrhosis of the liver and hepatocellular carcinoma. Hepatitis B could cause liver disease but it did not have a chronic course.

Section 4: Treatment of patients at the Hospital

Provision of information to patients

25. **What information did you provide or cause to be provided and/or what information was (to your knowledge) provided by others at the Centre, to patients with a bleeding disorder:**

a. **about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates), prior to such treatment commencing?**
b. **about alternatives to treatment with factor concentrates?**
c. **before they began home treatment/home therapy?**

Please detail whether and if so how the information provided to patients changed over time.

25.1 a) When I started in Derby in 1995 all the patients were already on plasma derived clotting factor, most of them for many years. I don't know what information they were given before starting treatment. I started newly diagnosed severe haemophilia patients on recombinant factor which has proven to be safe from the infection point of view, even so in the early days of recombinant I would counsel that the risk of infection would be very low but that we needed more experience to be sure. As far as I can remember any newly diagnosed patients were given written information as well as verbal discussion.

25.2 b) In mild bleeding disorders such as von Willebrands and platelet function disorders is my policy to use local haemostatic measures and tranexamic acid +/- desmopressin, and avoid the use of clotting factor concentrates wherever possible.

25.3 c) Before commencing home treatment patients/family are fully counselled and trained how to give the home treatment. They are supported by the KITE team (Kids in Their Environment) who can go out to the home environment. They receive written information about the clotting factor and also how to contact the centre in and out of hours.

Hepatitis C

26. When you took up your post at (a) Liverpool and (b) Derby, had all the patients who had received blood products in the relevant period been tested for Hepatitis C? If not, do you know why they had not been? How, when and by whom were such patients informed of their diagnosis of HCV? Were they told in person, by letter or by phone?

26.1 I can't remember what the case at Liverpool was. In Derby, as far as I am aware, all the patients who had received blood products in the relevant period had been tested for HCV before I was appointed. I don't know how they were told. There was 1 person with severe haemophilia who had been tested who was negative. As nearly everyone who was exposed to blood products in the relevant period acquired HCV this was unusual so I repeated the test which was then positive. At that time it was my usual practice to verbally consent the patient by telling them I would like to take blood for this reason and asking if that was OK. I told this person the result in person.

27. Please describe the process of testing patients for HCV. When a test for HCV became available, what if any steps were taken by (a) the Hospital and (b) the Centre and/or by you to ensure that all patients who had received blood products were traced and invited to be tested?

27.1 The test for HCV became available before I was appointed to Liverpool or Derby. As far as I was aware all patients had already been tested when I started in Derby. I don't know what steps were taken by my predecessor.

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

28.1 Patients with HCV were referred to the Hepatologists for management of their HCV. When referring a patient to the hepatologists I explained that HCV can be associated in a small proportion of people with liver problems and advised about keeping alcohol intake within recommended levels. Otherwise I left it to the hepatologists to discuss the prognosis, treatment options and management as this was their area of expertise.

29. How many patients (a) the Hospital and (b) the Centre were infected with HCV in consequence of infected blood/blood products?

29.1 I can't comment about the hospital.

29.2 Derby: As far as I am aware 26 patients were infected with HCV in consequence of infected blood products.

Delay/public health/other information

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

30.1 I am only aware of 1 patient where there was a delay in informing him of the diagnosis. I can't explain the delay. This was the source of a complaint to the Inquiry which I have made a statement about [WITN3923001].

31. To what extent, if at all, did you or your colleagues at (a) the Hospital and (b) the Centre take into account the public health implications of HCV, when taking decisions as to what information or advice to provide to patients or what treatment to offer patients?

31.1 I can't comment on Liverpool. In Derby patients with HCV were referred to the Hepatologists for management of their HCV.

32. What information was provided to patients about the risks of other infections that could be transmitted through blood or blood products?

32.1 Patients were notified in 2001 and 2004 about the possible risk of vCJD from clotting factor. I sent the standard letter from BPL in 2001 [WITN1271005] and vCJD and plasma products – Information for Patients in 2004 [WITN3923009] to all relevant patients.

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

33.1 Patients with HCV were referred to the Hepatologists for management of their HCV. I don't know what the Hepatology team told patients about risks to others.

Consent

34. How often were blood samples taken from patients when attending (a) the Hospital and (b) the Centre for treatment of their bleeding disorder and for what purposes? What information was given to them about the purposes for

which blood samples were taken? Were patients asked to consent to the storage and use of those samples? Was their consent recorded and, if so, how and where?

34.1 It was my usual practise to take blood for virology at outpatient appointments which were routinely held every 6 months (HBV, HCV and HIV). Also FBC, LFT, renal function. I consented patients verbally by telling them I would like to take blood for this reason and asking if that was OK. I far as I am aware the samples weren't stored. For 1 patient on 1 occasion I arranged for an aliquot of plasma to be frozen in order to do further diagnostic tests if indicated. This was for a patient who had tested negative for HCV antibodies in 1991. In 1996 I arranged to repeat the test. If positive I intended to send the frozen sample for HCV viral load and genotype without having to take blood from the patient again. However, I don't think the sample was used as the positive result wasn't seen until the patient came back to clinic in which case I arranged for a fresh sample to be taken for repeat HCV Ab, plus PCR and viral load. I would have obtained consent from him as I did then – telling him what I was testing for and asking if it was OK. This is the same patient referred to in answer to Q26 and Q30 [WITN3923001].

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

35.1 It was my usual practise to inform and verbally consent patients and/or their parents before giving factor. In later years if giving factor for the first time I would obtain written consent which would then be filed in the hospital notes. I can't remember if I obtained written consent in my early years at Derby.

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

36.1 When testing for HIV and hepatitis I consented the patient verbally by telling them I would like to take blood for this reason and asking if that was OK. I didn't use a consent form. I can't remember if I documented it in the notes.

PUPS

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

37.1 Any previously untreated patients and/or their parents were counselled about their condition and if clotting factor was necessary a careful explanation would be given of why giving the factor was necessary, for example to treat a bleed or prevent bleeding at operation. In recent years I have obtained written consent which was filed in the hospital notes. I can't remember if I obtained written consent in my early years at derby. Haemophilia A and B patients were given recombinant products.

38. Did you use the term PUP or PUPS when speaking about or referring to any of your patients? If so, what did you mean by the use of the term?

38.1 A previously untreated patient is someone who has not been exposed to clotting factor previously. I have used the term.

Treatment of patients who had been infected with HIV or Hepatitis

39. How was the care and treatment of patients with HIV/AIDS managed at (a) the Hospital and (b) the Centre? In particular:

a. *What steps were taken to arrange for, or refer patients for, specialist care?*
b. *What treatment options were offered over the years to those infected with HIV?*
c. *What information was provided to patients/their parents about the risks and benefits of specific treatments and about side effects?*
d. *What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?*

39.1 I don't remember what arrangements were in place at Liverpool. At Derby patients with HIV were managed by the genitourinary GUM) team. They had been referred to GUM before I started at Derby. I had no involvement in the management of HIV.

40. How was the care and treatment of patients with HBV managed at (a) the Hospital and (b) the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years?
c. What information was provided to patients/their parents about the risks and benefits of specific treatments and about side effects?
d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HBV?

40.1 I don't remember what arrangements were in place at Liverpool. At Derby patients with HBV were managed by the hepatologists. As far as I am aware they had been referred to Hepatology before I started at Derby. I had no involvement in the management of HBV.

41. How was the care and treatment of patients diagnosed with HCV managed at (a) the Hospital and (b) the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years?
c. What information was provided to patients/their parents about the risks and benefits of specific treatments and about side effects?
d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HCV?

41.1 I don't remember what arrangements were in place at Liverpool. At Derby patients with HCV were managed by the hepatologists. As far as I am aware they had been referred to Hepatology before I started at Derby. I had no involvement in the management of HCV.

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

42.1 Children would be managed jointly by a paediatrician and a hepatologist. I had no involvement in the management of HIV or hepatitis in children.

43. What involvement did you, or patients at (a) the Hospital and (b) the Centre, have with clinical trials in relation to treatments for HIV and/or HCV? Please provide full details.

43.1 I have had no involvement in clinical trials in relation to treatments for HIV and/or HCV. As far as I am aware none of the Derby patients have.

44. What (if any) difficulties did (a) the Hospital and (b) you/the Centre encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or HCV?

44.1 I am not aware of any such difficulties, but stress that I was not involved in the management of HIV or HCV.

45. What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support? What kind of counselling, if any, was made available to patients at (a) the Hospital and (b) the Centre?

45.1 I can't remember the arrangements in Liverpool. Counselling and psychological support would have been provided by the Genitourinary (HIV) and Hepatology (hepatitis) departments.

Research

46. Please list the research studies that you were involved with during your time as consultant/director at the Centre insofar as relevant to the Inquiry's Terms of Reference, and please:

a. describe the purpose of the research;

b. **explain the steps that were taken to obtain approval for the research;**
c. **explain what your involvement was;**
d. **identify what other organisations or bodies were involved in the research;**
e. **state how the research was funded and from whom the funds came;**
f. **state the number of patients involved;**
g. **provide details of steps taken to inform patients of their involvement and to seek their (or their parents) informed consent; and**
h. **provide details of any publications relating to the research.**

46.1 I have not been involved in any research relevant to the inquiry's terms of reference.

47. **What do you understand to be the ethical principles that should guide research? Did you apply those principles to the research studies referred to above and if so, how? If not, why?**

47.1 Research must be based on a properly developed protocol which has been approved by a research ethics committee. The safety, dignity and wellbeing of the participants must take precedence over the developments of treatments and the furthering of knowledge. Consent must be obtained from any participants before involving them in a research project. Participants must be informed that they have the right to decline to take part in research and to withdraw from the project at any time. The project must be stopped if results indicate that the participants are at risk of significant harm, or where no benefit can be expected. Research must be conducted with honesty and integrity. I have not been involved in any research relevant to the inquiry's terms of reference.

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

48.1 I have not been involved in any research relevant to the inquiry's terms of reference.

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

49.1 I have not been involved in any research relevant to the inquiry's terms of reference.

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

50.1 Patients were registered with the National Haemophilia Database and details of their clotting factor usage were reported. For most of my time at Derby consent was not obtained but assumed. More recently we have been obtaining consent.

50.2 At the request of the NHD I sent patient data for the hepatitis C lookback exercise in 2010, and 2018 – 2020.

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

51.1 Guidance on the Dental Management of Patients with Haemophilia and Congenital Bleeding Disorders. British Dental Journal. In print MSS-2013-515

51.2 Working party members: Julia Anderson, Andrew Brewer, Desmond Creagh, Susan Hook, Jason Mainwaring, Angela McKernan, ThynnThynn Yee, Albert Yeung. On behalf of the UKHCDO Dental Working Party.

51.3 Guidelines for the management of acute joint bleeds and chronic synovitis in haemophilia. J. Hanley, A. McKernan, MD Creagh, S. Classey, P. McLaughlin, N Goddard, PJ Briggs, S. Frostick, P. Giangrande, J. Wilde, J. Thachil and P. Chowdary On behalf of the musculoskeletal working party of the UKHCDO.

51.4 McKernan A, Hay CRM. Early rapid decline in CD4 count reversed by splenectomy in HIV infection. Haemophilia. 1.1994.

51.5 Wilde JT, McKernan A, Hay CRM. Treatment of HIV infected haemophiliacs with Didanosine. Haemophilia. 2.1995.

Records

52. What was (a) the Hospital and (b) the Centre's policy or practice as regards recording information on death certificates when a patient had been infected with HIV or hepatitis?

52.1 I don't know what the policy was or if there was a policy for recording information on death certificates.

53. What were the retention policies of the Centre in relation to medical records during the time you were director?

53.1 The retention policies of the centre would have been those of the Trust. I have been informed by the Trust Health records department that the Trust policy is in line with NHS policy.

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

54.1 I have not maintained any separate files.

55. Did you keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere other than (a) the Hospital and (b) the Centre? If so, why, what information and where is that information held now?

55.1 I have not kept any records or information anywhere other than the Centre or Hospital.

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

56.1 I don't hold any records or information about any patients other than at the Centre.

Section 5: Blood services

57. Please outline the interactions and dealings you had with the blood services, whether on a regional or national level, in your capacity as director of the Centre.

57.1 I have not had any interactions or dealings with the blood services in my capacity as director of the Centre.

58. What if any involvement did you have with any decisions or actions taken by any blood service (regional or national) in response to the risks arising from blood and blood products?

58.1 I have not had any involvement with any decisions or actions taken by any blood service in response to the risks arising from blood or blood products.

Section 6: UKHCDO

59. Please describe your involvement with UKHCDO (including any of its working parties, committees or groups) and the dates of your involvement.

59.1 I became a member of the UK Haemophilia Centre Doctors Organization (UKHCDO) in October 1998. I was a member of the Dental Working Party of the UKHCDO between 2010 and 2013. I have been a member of the Musculoskeletal Working Party of the UKHCDO since 2011.

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

a. the purpose, functions and responsibilities of UKHCDO, as you understood them;
b. the structure, composition and role of its various committees or working groups;
c. the relationships between UKHCDO and pharmaceutical companies;
d. how decisions were taken by UKHCDO;
e. how information or advice was disseminated by UKHCDO and to whom;
f. any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to: the manufacture, importation,

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

60.1 a. My understanding is that the UKHCDO is an organisation of doctors who manage patients with bleeding disorders with the aim of improving haemophilia care, research into bleeding disorders, their treatment, epidemiology and complications and to facilitate healthcare planning. The UKHCDO has established a national data-base (the National Haemophilia Database) which produces annual reports. The data-base and secretariat are based at Manchester Royal Infirmary.

60.2 b. Specific clinical and research areas are dealt with by relevant Working Parties. These produce published clinical guidelines, conduct research and data collection. The Data Management Working Party oversees and directs the National Haemophilia Database. An Annual General Meeting of all the membership is held in November of each year.

60.3 c. I am not aware of any relationships between the UKHCDO and pharmaceutical companies.

60.4 d. I don't know how the UKHCDO makes it decisions.

60.5 e. Information and advice is disseminated to the membership by its website, email, the annual general meeting and the annual report.

60.6 f. I was a member of the Dental Working Party of the UKHCDO between 2010 and 2013. I have been a member of the Musculoskeletal Working Party of the UKHCDO since 2011. I have been involved in 2 publications:

60.7 Guidance on the Dental Management of Patients with Haemophilia and Congenital Bleeding Disorders. British Dental Journal. In print MSS-2013-515 Working party members: Julia Anderson, Andrew Brewer, Desmond Creagh, Susan Hook, Jason Mainwaring, Angela McKernan, ThynnThynn Yee, Albert

Yeung. On behalf of the United Kingdom Haemophilia Centre Doctors' Organisation Dental working party:

60.8 Guidelines for the management of acute joint bleeds and chronic synovitis in haemophilia. J. Hanley, A. McKernan, MD Creagh, S. Classey, P. McLaughlin, N Goddard, PJ Briggs, S. Frostick, P. Giangrande, J. Wilde, J. Thachil and P. Chowdary On behalf of the musculoskeletal working party of the UKHCDO.

Section 7: Pharmaceutical companies/medical research/clinical trials

61. Have you ever:

a. **provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products?**
b. **received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products?**
c. **sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?**
d. **received any financial incentives from pharmaceutical companies to use certain blood products?**
e. **received any non-financial incentives from pharmaceutical companies to use certain blood products?**
f. **received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?**
g. **undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products?**
h. **provided a pharmaceutical company with results from medical research studies that you have undertaken?**

If your answer to any of the above questions is Yes, please provide details.

61.1 a - h) No, to all. I have received sponsorship from pharmaceutical companies to attend educational meetings. This has never affected my choice of blood product.

62. What regulations or requirements or guidelines were in place during your employment concerning declaratory procedures for involvement with a

pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take to comply with them?

62.1 The Hospital Trust I work for requires that sponsorship to attend educational meetings be declared when applying for study leave. As far as I am aware I declared sponsorship for attending all educational meetings. The UKHCDO also requires its member to declare any interests in pharmaceutical companies which as far as I am aware I also complied with.

63. **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?**

63.1 I haven't received any funding for research from pharmaceutical companies.

Section 8: vCJD

64. **When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products?**

64.1 I can't remember when I first heard about vCJD and blood products however I was present at the UKHCDO AGM in 1/10/1998 when vCJD was mentioned. [BART0000947].

65. **How and by whom were decisions taken as to the information that should be provided to patients about vCJD and as to any steps which should be taken in relation to patients and their care and treatment?**

65.1 I followed the advice of the UKHCDO and BPL.

66. **What was the process at the Centre for informing patients about possible exposure to vCJD? You may wish to refer back to the letter enclosed at [WITN1271005].**

66.1 In 2001 I sent out the standard letter to all relevant patients that had been sent to me at [WITN1271005]. In 2004 I sent out the letters and information to all relevant patients which were sent to me by the UKHCDO [WITN 3923002].

67. How and when were patients first told of possible exposure to vCJD? What subsequent notifications were provided to patients?

67.1 As far as I can remember the 2001 letter [WITN1271005] was the earliest. There was also a mass mailing in 2004 [WITN3923009].

68. What information was provided to patients about the risks of vCJD?

68.1 I sent the information for patients to all relevant patients in 2004 [WITN3923009].

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

69.1 As well as the written information which was sent to them, I discussed this at clinic visits.

70. What measures were put in place, from a public health perspective, in relation to the care and treatment of patients?

70.1 A list of the relevant patients was sent to the Trust Infection Control team and the Microbiology lead clinician. An alert that each patient is 'at risk of vCJD for public health purposes' was put in the case notes, and I included this information in clinic letters.

Section 9: Involvement with the financial support schemes

71. What involvement did you have with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation and the Skipton Fund) which were set up to provide financial support to people who had been infected?

71.1 I have had no involvement with these organisations.

72. To what extent did (a) the Hospital and (b) the Centre and its staff (including you) inform patients about the different trusts or funds?

72.1 I can't comment on Liverpool. In 2011 when the review of support for individuals infected with hepatitis and/or HIV I wrote to all the relevant patients to make sure they had applied to the fund.

73. Did (a) the Hospital and (b) the Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

73.1 There wasn't guidance but it was my personal policy to make people aware of the funds and to encourage them to apply.

74. What kind of information did (a) the Hospital and (b) the Centre (whether through you or otherwise) provide to the trusts and funds about or on behalf of patients who were seeking assistance from the trusts and funds?

74.1 The results of HCV tests. Any evidence of liver disease or cirrhosis (e.g. blood tests such as liver function tests, scan results, liver biopsy results, cause of death on death certificates).

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

75.1 I didn't act as a gateway I simply provided the necessary information to the Fund.

76. Was (a) the Hospital and (b) the Centre or any staff (including you) involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.

76.1 No.

77. **Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of the Hospital's and Centre's patients in relation to the trusts or funds, do you consider that the trusts and funds were well run? Do you consider that they achieved their purposes? Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?**

77.1 I can't comment on whether the Trusts and Funds were well run or whether they achieved their purpose. I am not aware of any difficulties or shortcomings in the way in which they operated.

Section 10: Other issues

78. **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.**

78.1 Only the patient complaint to the inquiry responded to last year. [WITN3923001].

79. **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.**

79.1 I am not aware of any other matters that might 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 24/3/21

Table of exhibits:

Date	Notes/ Description	Exhibit number
2020	Delay in giving positive HCV result	WITN3923001
2001	Letter re vCJD sent to patient	WITN1271005
1998	Minutes of UKHCDO AGM October 1998	BART0000947
2004	vCJD patient information	WITN3923009