Witness Name: David Anthony Newsome
Statement No.: WITN3080002
Exhibits: N/A
Dated: 13 October 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DAVID ANTHONY NEWSOME

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

I, Dr David Anthony Newsome, will say as follows: -

Section 1: Introduction

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

1) My name is David Anthony Newsome. My date of birth is GRO-C 1942. My address is GRO-C Lancashire, GRO-C

2) My professional qualifications are MB ChB (St Andrews) 1967; MRCP (UK) 1971; FRCP (London) 1995.

3) I have been fully retired from medical practice since 2013 and am no longer on the Medical Register.

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

4) I was appointed as a Consultant in Haematology at the Blackburn District Health Authority in 1977. I was initially working at the Blackburn Royal Infirmary. In 2006 Blackburn Royal Infirmary closed and I moved to the Royal Blackburn Hospital (the Queens Park Hospital renamed) which was also part of the Blackburn District Health Authority. I finished in this post in 2008, and took up a Locum Consultant post in Burnley 3 days a week up until my retirement in 2013.

5) Prior to my appointment as a Consultant, I was a Senior Registrar in Haematology, working on a rotational basis through the blood transfusion service in Manchester, at the North Manchester General Hospital and the Manchester Royal Infirmary [1974-1977].

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.**

6) As to any additional appointments and committees: I was a member of the Haemophilia Directors Group following my appointment in 1977. Further, in approximately 2000, a hospital transfusion committee was established at the Blackburn Royal Infirmary. I was a member of this committee. I advised on what guidelines should be written and made available to junior staff within the hospital: on when blood and blood products were likely to be used; how much; under what circumstances. I am sure that the committee would have advised on or made known the risk of transmitting blood-borne viruses in transfusions. I cannot, due to the passage of time, speak to any specific guidance or any more specific involvement in the committee.

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

7) I have not provided evidence to any other inquiry or litigation concerning HIV, Hepatitis B or C, or CJD.

5. **The questions below focus, as appropriate, on your time as a consultant at, and director of, the haemophilia service in Blackburn. Some questions are also directed towards your earlier experiences as a senior registrar in haematology at the North Manchester General Hospital and the Manchester Royal Infirmary (on a rotational basis). If you have information concerning either Manchester hospital and/or your career as a registrar prior to becoming a senior registrar in 1974 which is not covered by those questions, but which is relevant to the questions posed in relation to Blackburn and/or to the broader issues being investigated by the Inquiry, please include that information in your response.**

Section 2: Employment prior to 1977

6. **Where did you work prior to becoming a senior registrar in 1974?**

8) Prior to 1974, I was employed as Lecturer in Medicine in the University of Leeds and initially had the honorary NHS grade of Registrar, although I was upgraded to Senior Registrar part way through my tenure. Before that, I was a Medical Registrar in Aberdeen. Despite what was said in the covering letter from the Inquiry I have never worked at the Royal Free Hospital.

7. **In relation to your role prior to 1974, please:**
    a. **describe your role and responsibilities and how they changed over time;**
    b. **describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis in consequence of blood or blood products;**
    c. **identify senior colleagues involved in the care of patients with bleeding disorders and/or patients infected with hepatitis in consequence of blood or blood products, and their roles and responsibilities during the time that you worked there.**

9) I worked in Leeds General Infirmary as a medical registrar in acute general medicine. I also had a teaching commitment and participated in the Department of Medicine's research. Neither my clinical work nor my research involved patients with haemophilia, other bleeding disorders or hepatitis due to blood or blood products. I was involved with the clinical care of general haematology patients, including patients with leukaemia, both as inpatients and outpatients, and it was this experience, plus my exposure to clinical haematology as a registrar in Aberdeen, that made me decide to become a haematologist. I did not have contact with senior colleagues specialising in haemophilia as the centre for that was in St James's Hospital.

8. **In relation to your work from 1974 to 1977 as a senior registrar at North Manchester General Hospital and the Manchester Royal Infirmary please:**
    a. **describe your role and responsibilities and how they changed over time;**
    b. **describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis in consequence of blood or blood products;**

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

10) To the best of my knowledge bleeding disorders were not treated at North Manchester General Hospital during my time as a Senior Registrar there. I was, predominantly, learning morphology under the guidance of Dr D Dawson, Consultant Haematologist. At Manchester Royal Infirmary (MRI) I was involved in general haematology (both laboratory and clinical) and had my first experience of treating haemophilia and similar bleeding disorders. The consultant in charge of the haemophilia centre at the time was Dr R Wensley. My main role was in administering treatment. I was not involved with patients infected with blood borne viruses and I had no involvement in the selection or purchase of therapeutic materials. My memory is that Factor VIII deficient patients were treated with cryoprecipitate made by the National Blood Transfusion Service (NBTS) at that time.

9. To the best of your knowledge, what policies were formulated at (a) the hospital you worked at before 1974, (b) North Manchester General Hospital, and (c) Manchester Royal Infirmary regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked at each hospital? What if any involvement did you have in the formulation and application of these policies?

11) I do not recall any policies formulated at hospitals that I worked at prior to 1974 concerning the selection, purchase or use of blood products.

10. Who had responsibility at (a) the hospital you worked at before 1974, (b) North Manchester General Hospital, and (c) Manchester Royal Infirmary for the selection and purchase of blood products and what decisions were taken at each as to which products to purchase and use? In

addressing this issue please answer, 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 and how did those decisions change over time?**
b. **What were the reasons or considerations that led to the choice of one product over another?**
c. **Where were the products sourced and from whom were they purchased?**
d. **What role did commercial and/or financial considerations play?**
e. **What if any involvement did you have?**

12) I do not know who was responsible for the selection and purchase of blood products in the hospitals I worked in (as a member of the junior staff), and was not involved in the same.

11. **What blood products were used for treating patients with bleeding disorders at (a) the hospital you worked at before 1974, (b) North Manchester General Hospital, and (c) Manchester Royal Infirmary over what period of time and for which categories of patients? How were decisions taken at each hospital as to which products to use for individual patients? What involvement did you have in such decisions? What, if any, discussions took place with patients as to the choice of products?**

13) As I recall, cryoprecipitate was used for Factor VIII replacement and a Factor IX concentrate was used in MRI. At this time I do not think that there was any other option for discussion with the patients. However, it was a very long time ago and I cannot, therefore be certain. I do not know how decisions were taken at each hospital (as to use); I had no involvement in this.

12. **What was the relationship between (a) the hospital you worked at before 1974, (b) North Manchester General Hospital, and (c) Manchester Royal**

Infirmary and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions referred to above?

14) I have no knowledge of any relationship between any of the hospitals I worked in as a member of the junior staff and any pharmaceutical company. However, I would not have expected myself to have had this knowledge if there had been such a relationship.

13. **What alternative treatments to factor concentrates were available for people with bleeding disorders at (a) the hospital you worked at before 1974, (b) North Manchester General Hospital, and (c) Manchester Royal Infirmary? What were, in your view, the advantages and disadvantages of those alternative treatments? What use was made of them at the three hospitals referred to above?**

15) Tranexamic acid was available at this time and I can remember it being used in dental bleeding. Its close relative, epsilonamino caproic acid (EACA) also existed. I am not aware of vasopressin (DDAVP) being used although it did exist. These medications might have reduced the necessity for Factor VIII.

14. **What was the policy and approach at (a) the hospital you worked at before 1974, (b) North Manchester General Hospital, and (c) Manchester Royal Infirmary in relation to:**
    a. **the use of cryoprecipitate for the treatment of patients with bleeding disorders;**
    b. **home treatment;**
    c. **prophylactic treatment;**
    d. **the use of factor concentrates for children?**

16) Cryoprecipitate was, to the best of my knowledge, the mainstay of treatment in patients with haemophilia and Von Willebrand's Disease who were bleeding. I do not think that home treatment had been introduced at

this time. Cryoprecipitate could be used prophylactically preoperatively but I do not recall it being used for non-preoperative prophylaxis in severe haemophilia. I have no experience of treating children. I am not aware of any formal policy or approach in relation to these points.

15. To what extent, and why, were people with mild or moderate bleeding disorders treated with factor concentrates at each of the three hospitals referred to above?

17) I do not recall patients with only mild or moderate bleeding being treated with factor concentrates at the time I was working in MRI. These patients would, however, have needed some sort of prophylactic treatment peri operatively.

Section 3: Decisions and actions of the Blackburn haemophilia Centre ('the Centre') and your decisions and actions at the Centre

16. Please describe the facilities, organisation, roles, functions and responsibilities of the Centre during the time that you worked there.

18) Haemophilia had not been treated in Blackburn before I arrived. Blackburn was set up as an Associate Centre of the MRI. The idea was that patients living in Blackburn, Burnley and the easterly parts of Preston who suffered a bleed would have a shorter distance to travel to receive cryoprecipitate than if they had to go to Manchester and could, therefore, be treated sooner after, for example, a joint bleed.

19) Although I was primarily a clinician, I was based in the pathology laboratory. I had a clinic room staffed by three part time nurses who were trained in venepuncture and patients attended there, or, if out of hours, A&E. Cryoprecipitate would be administered by me, or occasionally an SHO working with me. We bought a -40 degree deep freezer to store the cryoprecipitate and it would be unfrozen as needed by the laboratory staff.

The cryoprecipitate came from the NBTS. Patients continued to be followed up at Manchester.

20) As time went on, more patients were transferred from cryoprecipitate to concentrates. This was done at Manchester and they would send the individual patient's concentrate to Blackburn for the patient to collect locally. Many of these patients then started treating themselves so I was personally injecting fewer and fewer. In 2006, Blackburn Royal Infirmary closed and we moved to the new Royal Blackburn Hospital. Here, there was no facility for treating patients in or near the laboratory but by then haemophilia patients rarely attended for treatment as they tended to treat themselves.

17. Please describe your role and responsibilities as consultant haematologist and director at the Centre.

21) My role was to assess bleeds and treat bleeding patients as appeared appropriate to arrest bleeding (usually into joints). I also liaised with the MRI centre as appropriate.

18. Please identify senior colleagues at the Centre involved in the care of patients with bleeding disorders there in the 1970s-1990s and their roles and responsibilities.

22) I had no senior colleagues. Apart from the laboratory staff, the nursing staff, whose main role was venepuncture of patients attending the laboratory for tests, I also had the help of an SHO from the general medical rotation who was with me for 3 months' haematology experience.

19. Approximately how many patients with bleeding disorders were under the care of the Centre when you became a consultant there in 1977 and over the years that followed? If you are able to give exact rather than approximate figures, please do so.

23) When I arrived in 1977, there were no patients. I do not have any exact figures but my guess is that we built up to a maximum of about 20.

20. When you took up your post at the Centre what policies were in operation regarding the selection, purchase and use of blood products (in particular factor concentrates)? How did those change over time?

24) When I took up my post there were no policies. We obtained cryoprecipitate from the NBTS. I cannot recall ever purchasing concentrate or FactorIX which I think we obtained from the Manchester Centre on the few occasions we used it ourselves. I cannot recall this position changing over time.

21. Who had responsibility at the Centre for the selection and purchase of blood products and what decisions were taken as to which products to purchase and use? In addressing this issue please answer the following questions:

- **a. How and on what basis were decisions made about the selection and purchase of blood products and how did those decisions change over time?**
- **b. What were the reasons or considerations that led to the choice of one product over another?**
- **c. Where were the products sourced and from whom were they purchased?**
- **d. What role did commercial and/or financial considerations play?**
- **e. What, if any, involvement did you have?**

25) I cannot remember ever purchasing concentrate commercially. I presume the responsibility was with the consultant in charge in Manchester, from whom we occasionally obtained the concentrate.

22. What was the relationship between the Centre and the pharmaceutical companies manufacturing/supplying blood products? What influence

did that relationship have on the decisions and actions referred to above?

26) I know of no relationship between the Blackburn Centre and any pharmaceutical company.

23. What viruses or infections, other than HIV, HBV and HCV, were transmitted to patients at the Centre in consequence of the use of blood products?

27) I do not know of any infections other than HIV, HBV or HCV transmitted by blood products administrated in Blackburn. In fact, I cannot recall a transmission of HBV.

Section 4: Knowledge of and response to risk, testing, diagnosis, and treatment

Knowledge of risk; general

24. When you became a senior registrar in haematology at the North Manchester General Hospital and the Manchester Royal Infirmary in 1974, 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?

28) It is very difficult to remember what I knew in 1974. I would have known that hepatitis B could be transmitted by blood and blood products. I believe that there was a suspicion that other forms of hepatitis might exist and which could be transmitted. Hepatitis C and HIV had not been discovered. The source of such knowledge would have been my general medical training.

25. How did your knowledge and understanding of the risks of infection develop during the time you worked at the North Manchester General Hospital, the Manchester Royal Infirmary and the Centre?

29) This is so long ago that I am unable to answer this question with any reasonable chance of accuracy.

26. At each stage of your career, what discussions, if any, did you have with your colleagues about how and why patients had been infected by the use of blood and/or blood products?

30) I can only think of informal discussions with colleagues, and having attended some formal meetings on this. I cannot remember with precision the content of any discussions.

27. At each stage of your career 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?

31) Throughout my career, I believed that products made by the NBTS and its successors were relatively safe but that concentrates, particularly of American origin were not. As time went on, I began to realise that NBTS products were not as safe as I had believed, particularly with respect to hepatitis C.

Knowledge of hepatitis

28. When you became a senior registrar in 1974, what was your knowledge and understanding of the risks of the transmission of hepatitis, including hepatitis B and non-A non-B hepatitis (hepatitis C), from blood and/or blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

32) I cannot be sure of my knowledge of transmission of hepatitis viruses in 1974 other than I knew that hepatitis B was transmissible by blood.

29. 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?

33) At the material time, I realised that hepatitis B could be a lethal infection.

Knowledge of HIV and AIDS

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

34) HIV, initially known as HTLV III, was not discovered until I was already a consultant in Blackburn. I realised early on that it could be transmitted by blood and blood products as there was a high incidence in haemophilic patients. My knowledge of AIDS increased as more became known about the disease.

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

35) I cannot remember exactly when (I became aware there might be an association between Aids and the use of blood products) but I believe it would have been shortly after the discovery of the virus.

Response to risk of hepatitis

32. Did you or any of the hospitals you worked at from 1974 onwards take steps to ensure that patients/their parents were informed and educated about the risks of hepatitis? If so, what steps?

36) I am unable to remember what we told patients so many years ago. I was not involved in discussions with parents as I was not involved with the treatment of children.

33. What liver function tests and/or other forms of monitoring were undertaken at the centres at which you worked and how did that change over time? What was the purpose of such testing and monitoring?

37) I followed up few patients only as my involvement, initially, was with the treatment of patients with acute bleeds. Those I did follow personally would probably have a liner profile comprising bilirubin, alkaline phosphatase, GGT, and proteins (total, albumin and globulin) checked at each visit. This would be to see if their liver was deteriorating or not.

34. What if any enquiries and/or investigations did you or the centres at which you worked carry out or cause to be carried out in respect of the risks of transmission of hepatitis? What information was obtained as a result?

38) I am unable to remember any research that we might have carried out on the risks of transmission of hepatitis. I do not think that we carried out any research on this transmission.

35. What if any actions were taken by you and/or at the centres at which you worked to reduce the risk to patients of being infected with hepatitis (of any kind)?

39) I believe that we only administered blood and blood products when we considered it to be clinically necessary; I tried to prioritise the use of NBTS products.

36. Please find enclosed a letter from J.K Smith, Chief Project Scientist, to Charles Rizza dated 6 July 1987 [BPLL0006159] which is copied to you

and others. What steps, if any, did you take upon receiving this letter about implicated batch '8Y 3403'?

40) It is too long ago for me to remember what action we took with respect to batch 8Y 3403. I suspect that I would have checked that it had not been received in our hospital. Had it been, I think that I would have remembered as I do remember being alerted to a unit of cryoprecipitate from a donor later shown to be HIV positive which had been sent to us. We were able to trace the patient who received it.

Response to risk of HIV and AIDS

37. What, if any, enquiries and/or investigations did you or the Centre carry out or cause to be carried out in respect of the risks of transmission of HIV or AIDS? What information was obtained as a result?

41) I am unable to remember any research carried out in Blackburn on the risks of transmission of HIV. I do not think that we carried out any research on this transmission.

38. What, if any, actions did you or the Centre take to reduce the risk to your patients of being infected with HIV?

42) I did not need to change my practice as I was not involved in starting patients on factor concentrates and we did not operate on patients with haemophilia, as distinct from patients with Von Willebrand's disease, who were treated with cryoprecipitate.

39. Did you or the Centre take steps to ensure that patients/their parents were informed and educated about the risks of HIV and AIDS? If so, what steps?

43) I am sure that I discussed HIV and AIDS with patients, as required. As previously stated, I did not treat children.

40. Did you or the Centre revert to treatment with cryoprecipitate for some or all of your patients? If so, how did you decide which patients would be offered a return to cryoprecipitate and which would not? If not, why not?

44) I do not remember changing patients back to cryoprecipitate from concentrate – which would have been started by, or in conjunction with the Manchester centre.

41. How and when did you become aware of the recommendations made at a meeting of UK Haemophilia Reference Centre Directors on 10 December 1984 [HCDO0000394_117], including the recommendation to use heat-treated concentrates, and were those recommendations then implemented at the Centre?

45) I am unable to remember the answer to this question. It is unlikely that I would have been at this meeting because it was a meeting of personnel more involved in the treatment of haemophilia. If heat treated concentrate had been used in Manchester, then consequently I would have used the same for any patients.

42. Did you or the Centre continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why?

46) I believe that I would not have been involved with patients already on treatment with concentrate as they were supervised in Manchester or elsewhere.

43. When did you first begin to use heat-treated concentrates for your patients at the Centre?

47) I am unable to remember when I first came into contact with patients on heat treated products.

Response to risk generally

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

48) I do not have the detailed knowledge to answer this question. I suspect that it would have been beneficial had it been practical to do so.

45. Do you consider that your decisions and actions and those of the hospitals you worked at in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

49) I do not think that we did anything unreasonable; in view of the state of knowledge at the time regarding haemophilia and its treatment.

46. What decisions or actions by you and/or by the hospitals you worked at could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

50) I really do not know what would have been the correct action at the time if it was not possible to introduce heat treated products promptly.

47. What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients with bleeding disorders? What, if anything, do you consider could or should have been done differently by these others?

51) I do not have the knowledge to answer this question.

48. Do you consider that greater efforts should have been made to inactivate viruses in blood or blood products prior to 1980? If so, who should have made or coordinated those efforts and what steps should have been taken and when? If not, why?

52) I do not have the knowledge to answer this question.

49. In relation to your work at any hospital prior to 1974:

a. **How often (typically) were blood samples taken from patients and for what purpose(s)? What information was given to patients about the purposes for which blood samples were being taken?**
b. **Were samples stored for prolonged periods and if so, why? Did the hospital obtain patients' informed consent for the storage and use of those samples? Was their consent recorded and if so, how and where?**
c. **Were patients under the care of that hospital tested for hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was the approach to obtaining consent for testing? Was their consent recorded and if so how and where?**

53) I do not know the answer to these questions.

50. In relation to your work at the North Manchester General Hospital:

a. **How often (typically) were blood samples taken from patients and for what purpose(s)? What information was given to patients about the purposes for which blood samples were being taken?**
b. **Were samples stored for prolonged periods and if so, why? Did the North Manchester General Hospital obtain patients' informed consent for the storage and use of those samples? Was their consent recorded and if so how and where?**
c. **Were patients under the care of the North Manchester General Hospital tested for hepatitis or for any other purpose without their express and informed consent? If so, how and why did this**

occur? What was the approach to obtaining consent for testing? Was their consent recorded and if so how and where?

54) To the best of my knowledge, haemophilic patients were not treated at North Manchester General Hospital at the time I worked there. If they were, then I was not involved in their care.

51. In relation to your work at the North Manchester General Hospital:

a. **How often (typically) were blood samples taken from patients and for what purpose(s)? What information was given to patients about the purposes for which blood samples were being taken?**
b. **Were samples stored for prolonged periods and if so, why? Did the North Manchester General Hospital obtain patients' informed consent for the storage and use of those samples? Was their consent recorded and if so how and where?**
c. **Were patients under the care of the North Manchester General Hospital tested for hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was the approach to obtaining consent for testing? Was their consent recorded and if so how and where?**

55) I am afraid that I do not know or recall the answer to these questions concerning patients' samples at MRI.

52. In relation to your work at the Manchester Royal Infirmary:

a. **How often (typically) were blood samples taken from patients and for what purpose(s)? What information was given to patients about the purposes for which blood samples were being taken?**
b. **Were samples stored for prolonged periods and if so, why? Did the North Manchester General Hospital obtain patients' informed consent for the storage and use of those samples? Was their consent recorded and if so how and where?**
c. **Were patients under the care of the North Manchester General Hospital tested for hepatitis or for any other purpose without their**

express and informed consent? If so, how and why did this occur? What was the approach to obtaining consent for testing? Was their consent recorded and if so how and where?

56) Blood samples were only taken from patients under my care as part of my clinical assessment. They were never taken for research purposes. The frequency of bloods taken would depend upon the frequency at which I was seeing them, and that would depend upon the clinical need. I am not aware of any samples being stored for prolonged periods. I am unaware of any patients being tested for HIV or hepatitis without consent. I would obtain consent in a face to face discussion. I did not require patients to sign a consent form but it was my policy to record in the notes that consent had been obtained.

PUPs

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

57) I cannot recall any new, untreated patients being referred to me to commence treatment. I do recall a few Von Willebrand patients being referred preoperatively. I treated them, as I believed appropriately, with cryoprecipitate, vasopressin or tranexamic acid.

Testing and communication of diagnosis

54. During your career what involvement did you have in arranging for patients to be tested for (a) HIV and (b) HCV?

58) As far as I remember, I only arranged for patients to be tested for HIV or HCV on clinical grounds. Patients newly diagnosed with HIV, most of whom had presented to my haematology clinic, were referred to our GUM consultant and treated in conjunction with a chest physician if they had presented with pneumocystis carinia pneumonia (PCP). Patients with HCV were referred to a gastroenterologist with an interest in liver disease. I believe that they may, at least in some cases, have been referred on to Manchester.

55. If you were involved in arranging for patients to be tested for HIV, please address the following questions:

a. How and when did you learn that patients under your care had been infected with HIV?

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

c. How and when and by whom were patients told that they had been, or might have been, infected with HIV? Were they told in person, by phone or in writing?

d. What information was provided to patients?

e. Were patients told to keep their diagnosis a secret?

f. Was testing offered to the family members or partners of people known or suspected to be infected with HIV?

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

59) I would be informed of a positive HIV test by our microbiologist who would have been informed by the virology laboratory in Preston. Pre-test counselling would have been done by me, often with the help of the Health Advisor from the GUM clinic. I would inform patients of their result in a face to face conversation usually in conjunction with the Health Advisor who would provide further information as appropriate, including sexual advice. I do not think that we told patients to keep the information a secret as it would be appropriate for sexual partners to be informed. Post-test counselling was part of this process. As already stated, most of these patients came to me symptomatic through the general haematology clinic. Haemophilic patients were usually diagnosed in Manchester.

56. How many patients at the Centre were infected with HIV? Of those infected:

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

f. How many were children?

60) I am afraid that I do not have these figures. I am aware that one had Von Willebrand's disease as she was a very special case. None would have been children.

57. Was work undertaken at the Centre to establish the time period during which patients seroconverted? If so please describe what work was done and what if any conclusions were reached.

61) No work was done to establish a time frame for seroconversion.

58. When did the Centre begin testing patients for HCV?

62) I cannot remember the answer to this question. Routine testing was done at the MRI.

59. How and when were patients told of their diagnosis of HCV? Was it your practice to inform patients in person, by phone or in writing?

63) I cannot recall telling a patient that they had HCV. I would have told anybody found to be positive personally as I did with HIV.

60. Were patients informed at routine or specifically arranged appointments?

61. Do you consider that patients were promptly informed of their diagnoses or were there delays in informing people of their infections?

62. What information was provided to patients infected with HCV about the infection, its significance, prognosis, treatment options and management? What information was provided to patients about the risks of infecting others?

64) As above I cannot recall any haemophilic patient newly diagnosed with HCV under my care.

63. How many patients at the Centre were infected with HCV?

65) I do not have these figures.

64. When a test for HCV became available, what, if any, steps were taken by the Centre and/or by you to ensure that all patients who had received blood products were traced and invited to be tested?

66) This was not done in Blackburn. I believe that such testing was carried out in Manchester.

65. Please explain your views about routine screening of patients' partners and children. Did such screening take place at the Centre? If so, when?

67) I believe that testing patients' partners would be reasonable. I do not know the degree of risk to their children so it would be inappropriate for me to comment. I cannot recall doing any screening. I can recall one patient who asked if we would check his wife annually, which we did, and she was repeatedly negative.

66. How was the care and treatment of patients with HIV/AIDS managed at the Centre? In particular:

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

68) I can only remember one patient, who had Von Willebrand's disease, and who we diagnosed with AIDS when she was admitted, previously unknown to be HIV positive, with PCP pneumonia. She was treated in conjunction with a chest physician and initially given anti-HIV agents in Blackburn but was later transferred to care in Manchester and found also to have HCV. To the best of my knowledge she is still alive. HIV and HCV treatment options were discussed with her by the appropriate specialists.

67. How was the care and treatment of patients with hepatitis B managed at the Centre? In particular:

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

69) I do not recall treating patients with hepatitis B in Blackburn. I was not involved in HBV treatment in my junior posts.

68. How was the care and treatment of hepatitis C managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered to those infected with hepatitis C?

c. *What information was provided to patients about the risks and benefits of specific treatments and about side effects?*
d. *What follow-up and/or on-going monitoring was arranged for patients who were infected with hepatitis C?*

70) The same applies to HCV. Any hepatitis treatment in Blackburn would have been under the care of a gastroenterologist with an interest in liver disease; I believe that nearly all, or possibly all these patients were treated in Manchester.

HCV and/or HIV treatment

69. Please describe the counselling and/or psychological support and/or social work available to patients at the Centre following diagnosis and/or treatment.

71) Counselling and psychological support was provided via the Health Advisor. There was no social worker support specifically for haemophilic patients.

70. Did the Centre have a dedicated counsellor or social worker to provide support? If so, how was this funded?

72) There was no dedicated counsellor or social worker.

71. What, if any, difficulties did you and/or the Centre encounter in obtaining sufficient finding for the treatment of people who had been infected with HIV and/or hepatitis?

73) I am not aware of funding problems for these patients.

72. What, if any, involvement did you and/or colleagues at the Centre have with any clinical trials in relation to treatments for HIV and HCV? Please provide details.

74) I had no involvement in clinical trials. I am unaware of clinical colleagues with whom I was working having any involvement.

73. Please see the enclosed correspondence between Dr Shwe, Peter Flanagan and yourself dated 21 June 1996 [NHBT0074896] about the HCV look back. Page 1 states that, as at 21 June 1996, 'the only hospital with low returns is Blackburn Royal Infirmary, Haematologist is Dr Newsome'. Please explain the circumstances of the HCV look back at the Centre.

75) I have only the vaguest memory of the HCV look back. Until I read about it within the Inquiry's questions, I had completely forgotten about it, and suspect that at that time I was involved with very few haemophilic patients.

Research

74. Please list all research studies that you were involved with during your career.

76) I was not involved in any research in relation to haemophilia or other bleeding disorders. As a House Surgeon, I was the co-author of a paper concerning the somatotropic representation of the vesicomotor pathway in the spinal cord of man, in conjunction with Mr E.R. Hitchcock, Consultant Neurosurgeon in Edinburgh. As a Lecturer in Medicine in Leeds, I conducted some animal experiments seeing if anticoagulation reduced metastasisation of carcinoma cells in mice. As a senior registrar in NMGH, I was the co-author of a paper on Vitamin B12 and folate assays. I think that was all my research.

75. 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?

77) I believe that patients involved in research studies should be made fully aware of the fact that they are part of that research, its aims and any dangers or benefits to them that might result from it. They should give their consent after full information has been divulged to them and they should be able to withdraw from any study at any time should they wish to do so. Their data should be anonymised. I believe that these principles were applied in the research that I was involved in although none of it related to haemophilia.

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

78) No.

77. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose with patient consent? If so, what data was used and how and why did this occur?

79) No.

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

80) Not as far as I am aware.

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

81) None.

Records

80. What was the Centre's policy and practice for recording on death certificates when a patient had been infected with HIV and/or hepatitis?

82) I cannot recall any death certification of any haemophilia patient I had treated in Blackburn. I would have expected that HIV or hepatitis would have been given as either the primary cause of death or a contributory cause as appropriate.

81. What were the retention policies of the Centre in regards to medical records?

83) I did not have dedicated records for haemophilia. I used a section in the hospital notes to record attendances. The hospital notes for these patients were booked out to the laboratory. If a patient was also being seen in the Haematology Clinic, I used that section for haemophilia as well. I believe that the hospital policy was to keep these notes indefinitely although sections could be archived if the notes became huge.

82. To the best of your recollection, did you maintain separate files for some or all patients? If so, why? Where were those files located and where are those files now?

84) I do not recall doing so.

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

85) No.

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

86) No.

Section 5: vCJD

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

87) I cannot remember when I first became aware of vCJD. I think that it would have been when it became known that it was caused by the same prion as that which caused bovine spongiform encephalitis, probably in the early 1990s. I cannot remember how my knowledge developed or when we first became worried about transmission by blood or blood products.

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

88) I cannot remember the answer to this question.

87. Please describe the process at the Centre for informing patients about possible exposure to vCJD.

88. Was the possibility of transmission of vCJD via blood products communicated to (i) colleagues, and (ii) infected and affected individuals / their interest groups sufficiently promptly? If not, why not?

89. Were estimations about the incidence of vCJD infection by blood and/or blood products accurate? If not, why not? Did this change over time?

90. Were 'look back' exercises designed to trace patients infected by implicated batches conducted competently and sufficiently promptly? If not, why not?

89) I do not remember being involved with this in Blackburn. By this time I was seeing very few haemophilia patients and I do not remember any involvement.

91. Please find enclosed a letter from you to Dr Hewitt enclosing look back forms, dated 14 September 2004 [NHBT0059112_027]. Did this relate to vCJD or another form of look back? To the best of your recollection, please explain the circumstances of this letter and how many patients had died by 2004?

90) I have read the letter referred to. I am afraid that I have absolutely no memory of it: what it was about or how many patients it referred to.

Section 6: Other blood products

92. The questions above have focused on the care and treatment of patients with bleeding disorders. Provide details of what role, if any, you played in overseeing, managing or administering, (i) blood transfusions, and (ii) blood products other than those used to treat bleeding disorders, during your career.

91) As a consultant haematologist I had overall responsibility for the Transfusion Laboratory in Blackburn. Later in my career a Transfusion Committee was formed. I was a member, but not the chairman of this committee. Later in my career, we appointed a Transfusion Practitioner, who was a trained biomedical scientist to supervise and check on transfusions throughout the Trust. Between us, throughout my career, we tried to educate medical and nursing staff on the correct use of blood and blood products. This was done by informal discussions and at clinical

meetings. Towards the end of my career it became part of the annual mandatory training for all staff.

92) The patients I spoke to directly were usually general haematology patients many of whom were transfusion dependant. I would try to explain the aim of the transfusions and the risks, including the risk of blood borne virus transmission. I would be in frequent contact with these patients. I believed that the consultant in charge of the patient had the ultimate responsibility but that the clinician who decided to give the transfusion also bore responsibility for his or her decision. I saw prescribing blood or blood products to be the same as prescribing any other medicinal product.

Section 7: UKHCDO

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

94. 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 relationship between UKHCDO and pharmaceutical companies.

d. How decisions were taken by UKHCDO.

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

f. Any policies, guidance, actions or decision of UKHCDO in which you were involved

93) I was a member of the UKHDO and attended some of its meetings, but was never a member of its working parties, committees or groups. I was not an active member of the organisation and considered it to be advisory as far as clinical activity was concerned. I would not like to comment on

the various committees or groups of which I have had no input and therefore little or no knowledge. In particular, I have no knowledge of its relationship with the pharmaceutical companies. I do not know how decisions were taken. I cannot remember how information reached me and I would have regarded its advice to be precisely that.

Section 8: pharmaceutical companies/medical research/clinical trials

95. Have you ever provided advice or consultancy services to any pharmaceutical companies involved in the manufacture and/or sale of blood products? If so, please list the names of the companies and give details (including dates) of the advisory or consultancy services that you provided?

94) I have never provided any advice or consultancy to any company, pharmaceutical or other.

96. Have you ever 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? If so, please provide details.

95) I have never received any payment from any company of any sort.

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

96) I have never sat on any advisory panel, board or committee of any pharmaceutical company.

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

97) I have never received any incentives from any pharmaceutical company.

99. Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood products from a pharmaceutical company? If so, please provide details.

98) I have never received any funding from any pharmaceutical company to prescribe, supply, administer, buy or sell any blood products.

100. What regulations or requirements or guidelines were in place at the time you worked at the Centre concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations or requirements or guidelines and what steps did you take to comply with them?

99) I am not aware of any specific regulations, requirements or guidelines concerning declaratory procedures. I did, however, make an annual declaration of financial interests outside my contract of service. I believe that this was a national requirement.

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

100) I have never provided a pharmaceutical company with any medical results from any studies.

102. 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?

101) Not applicable.

103. Please see the enclosed internal memo from Cutter Laboratories, dated 2 October 1985 [BAYP0000024_149]. On page 4 of that document it refers to a visit by representatives of Cutter to you to 'encourage the use of Gamimune.' Please set out your account of that visit and whether it led you to purchase Cutter's products.

102) I am unable to remember a meeting with representatives of Cutter Laboratories in 1984. Whist "Gamimune" is familiar to me, I do not recollect it being purchased although I cannot be certain.

Section 9: the financial support schemes

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

103) I cannot remember having any involvement with the Trusts mentioned. I am sure that I had no involvement into the development of criteria for eligibility. I have a vague memory that I may have recommended a patient who had Von Willebrand's disease and had been infected with both HIV and HCV to make contact.

105. Did the Centre have policies or guidance in place for its staff to inform or refer patients to different trusts and/or funds for support. If so, what were those policies or guidance?

104) I am unaware of any such policies.

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

105) Whilst I cannot remember providing any specific information to a Trust, I think that I would have given, only with the patient's consent, any clinical information which would have helped their application.

107. What kind of support or assistance was provided by the Centre (whether through you or otherwise) to patients making applications for financial assistance?

106) I believe my answer here is as per 105.

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

107) I find this question difficult to answer. I cannot remember any incidents that make me feel that they were badly run.

109. Please see enclosed letter from Dr Love to you, dated 14 May 1992, [NHBT0092304] which refers to the possible eligibility of one of your patients under the HIV and blood transfusion / tissue transfer payment scheme. To the best of your recollection, what steps, if any, did you take upon receiving this letter? Please explain your experiences of the scheme referred to in this letter.

108) This is the patient I referred to when answering Question 104. I have only a vague memory of her involvement with a trust fund.

Section 10: Other issues

110. What, in your experience, has been the impact of the infection of patients with HIV and/or hepatitis through blood products:

a. **upon patients at the Centre (without identifying any individual patient);**
b. **upon the ways in which decisions about treatment and care were taken, and treatment and care were provided, at the Centre?**

109) I think that the effect on patients infected with viruses via transfusions has been devastating both physically and mentally. Physically they may have experienced years of ill health exacerbated by the side effects of life prolonging drug treatment and many have, of course, died. Mentally it has been horrible and I was particularly struck by a statement made by a patient in a submission to the Inquiry that HCV infection had resulted in her being treated like a leper. In addition, such infections have had serious effects on patients' careers and current employment. Relatives of the deceased have, very reasonably, felt robbed of years of happiness.

111. Did the infection of patients with HIV and/or hepatitis through blood products:

a. **change or influence your professional practice and approach and if so how?**
b. **change or influence the way in which haemophilia care at the Centre was provided and if so how?**

110) It brought home to me the dangers of prescribing blood and blood products. It also made me emphasise in teaching to junior staff that blood products could be dangerous.

112. Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, the General Medical Council, or any other body or organisation that has a responsibility to investigate complaints.

111) The only complaint about my handling of a patient was made in a submission to the Inquiry by a patient with Von Willebrand's disease who I had treated perioperatively with cryoprecipitate when she needed a Caesarian section on account of pre-eclampsia. She contracted HCV. I

prepared a Witness Statement relating to her treatment just over a year ago.

113. 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.

112) I cannot think of any more to say other than that I sincerely hope that the Inquiry will be able to come up with recommendations that will prevent a further therapeutic tragedy occurring.

Statement of Truth

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

Signed GRO-C

Dated 13 October 2020