

Witness Name: Dr Robert Ibbotson

Statement No.: WITN4678001

Exhibits: None

Dated: 9 March 2021

## INFECTED BLOOD INQUIRY

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### WRITTEN STATEMENT OF DR ROBERT IBBOTSON

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I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 17 November 2020

I, Robert Michael Ibbotson, will say as follows: -

#### Section 1: Introduction

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

Robert Michael Ibbotson,

GRO-C

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.*

Director of North Staffordshire Haemophilia Centre 1976-2004, Consultant Haematologist North Staffordshire Hospital 1975-2004, Senior Registrar in Haematology London Hospital 1971-1975. Providing laboratory and clinical management of patients with haematological malignancies and bleeding disorders and of late, thrombotic disorders.

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.*

Member and secretary to the West Midlands Regional Haemophilia Directors Committee 1975-2004.

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

Not involved in any investigation of blood infection or litigation.

## **Section 2: Decisions and actions of the Centre and your decisions and actions**

5. *In relation to your work at Stoke-on-Trent please:*

- a. *provide (to the extent that you are able to) an account of the Centre's history, its facilities and activities during this time;*

Established in 1975 to provide follow up and treatment of patients with bleeding disorders and later on thrombotic conditions. Then known as the North Staffordshire Haemophilia Centre.

- b. *describe your role and responsibilities and how they changed over time;*

To provide treatment and advice to patients with bleeding disorders, later on as management of complication of viral infection.

- c. *describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products;*

As referred in b. to manage and advise patient with bleeding and complications of treatment.

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

In my absence the cover was provided by Dr. P M Chipping.

6. *Approximately how many patients with bleeding disorders were under the care of the Centre when you first started working there and over the years that followed? Approximately what proportion have been adults and what proportion have been children? If you are able to give exact rather than approximate figures, please do so. You may find the information in CLBA0000940 of assistance in answering this question.*

Between 20-30 patients were registered. No children were treated by me as I had no paediatric training. My understanding was they were referred to Birmingham Children's Hospital.

7. *To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the Centre, regarding the selection, purchase and use of blood products (in particular factor concentrates)? 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?*

This was a regional decision which I was not directly involved with.

- b. *What were the reasons or considerations that led to the choice of one product over another?*

No knowledge

- c. *What role did commercial and/or financial considerations play?*

No knowledge

- d. *What if any involvement did you have in these decisions?*

None of significance.

8. *What products (NHS or commercial, and if commercial, which ones) were used during your time at the Centre for treating patients at the Centre, over what period of time and for which categories of patients?*

I believe we used B.P.L Cutler and Armour. I tried to give the British product to the all patients if it was available

9. *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? You may wish to consider the enclosed letters from a Cutter sales representative [BAYP0000009\_033, BAYP0000009\_047], referring to a meeting with you to discuss a particular product. To what extent did such meetings take place with representatives of pharmaceutical companies and over what period of time?*

I saw representatives of many pharmaceutical companies not just suppliers of blood products. I made it clear to all I saw that I did not have a budget and had no purchasing power. As far as the latter are concerned I made it transparent that North Staffs was a small user and thus felt it inappropriate for me to intervene in the procurement of blood products.

10. *The Inquiry understands that there was regional contracting in place for the purchase of commercial factor VIII in the West Midlands in the late 1970's. Is this correct? You may find the minutes of the West Midland Regional Health Authority Working Party on the Treatment of Haemophiliacs ("the Working Party") of assistance on this issue. [SHIN0000041, SHIN0000037, SHIN0000035, SHIN0000034, SHIN0000030, SHIN0000029, SHIN0000028, SHIN0000013].*

There was a subcommittee involved in purchasing blood products. I thought this made economic sense considering the financial climate of the NHS in the 70's and 80's.

11. *What part did you play in the award of that contract? What criteria were used? You may find [SHIN0000018\_002] and [SHIN0000012] of assistance.*

I was not involved

12. *How were decisions taken as to which products to use for individual patients? What involvement did you have in such decisions? To what extent, if at all, were patients offered a choice as to which products to use?*

Patients were offered the British product and if not available imported Factor V111. In the early days patients were declining cryoprecipitate.

13. *What alternative treatments to factor concentrates were available in the 1970s and 1980s for people with bleeding disorders? What were, in your view, the advantages and disadvantages of those alternative treatments? What use was made of them at the Centre? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why not?*

Desmopressin was used if effective in mild haemophilia. Any acute bleeds were treated with BPL Factor V111 or if not imported Factor V111 was given as the infection risks were largely unknown. (Bar NonAnonB hepatitis) concentrates were used following the views of the Haemophilia Society.

14. *What was the policy and approach at the Centre as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?*

- a. *Did that policy and approach change over time and if so how?*

Cryoprecipitate was used universally until Factor V111 concentrate became more readily available. Its phasing out was welcomed by the patients requiring regular treatment.

- b. *How, if at all, was the policy and approach informed by discussions had with external parties?*

This policy I assumed had general support from colleagues.

15. *What was the policy and approach at the Centre in relation to home treatment? Did the policy and approach change over time and if so how?*

Patients were keen on home treatment especially as it was supported by the Haemophilia Society.

16. *What was the policy and approach at the Centre in relation to prophylactic treatment? Did the policy and approach change over time and if so how?*

It was left to the decision of the Haemophiliacs if they wanted to embark on prophylactic treatment. They worked out their usage.

17. *To what extent, and why, were people with mild or moderate bleeding disorders treated with factor concentrates?*

Very limited only treated with concentrate if there was a severe or life threatening bleed.

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

#### *General*

18. *When you began work as a Consultant Haematologist at the Centre what did you know and understand about the risks of infection (in particular, hepatitis) associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time? You may find the following documents of assistance in answering this question:*

- a. *The discussion as to the hepatitis risk arising from freeze dried factor VIII concentrates in the meeting minute of the Haemophilia Working Party of 22 November 1976 [SHIN0000043]*
- b. *The minutes of the UKHCDO meeting you attended on 20 - 21 November 1979 [CBLA0001028] and the report of the Hepatitis*

*Working Party [HCDO0000135\_\_023] presented by Dr Craske at that meeting.*

- c. The minutes of the Haemophilia Working Party minutes of 3 December 1979 [SHIN0000037].*

It was apparent to me that all blood and blood products had a hepatitis risk of non A and non B. The greater the number of donors the greater the risk. Over time is becoming apparent that my views were correct and I did not change them.

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

None to my knowledge

20. *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?*

I considered the use of commercial Factor V111 at higher risk than UK Factor V111 as the history of the donors was limited compared to UK donors. Hence my effort always to receive UK material.

21. *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?*

I assumed Hep A was not clinically severe. As for Hepatitis B is concerned I had no dealings with it as the patients at North Staffs. as none were positive. NonAnonB initially felt to be insignificant but history proved otherwise.

22. *What, if any, actions did you, or the Centres at which you worked, take to reduce the risk to patients of being infected with hepatitis (of any kind)?*

Patients were informed of the risk and it was suggested that an attempt made to reduce the use of concentrates.

#### *HIV and AIDS*

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

Initially there was no indication that blood products could cause the transmission of HIV. Over time it became clear that it was a serious developing problem. Unfortunately it was apparent that stopping the use of blood and blood products could not happen.

24. *How and when did you first become aware that there might be an association between AIDS and the use of blood products? You may find the minute of the Haemophilia Working Party meeting of 27 June 1983 [SHIN0000030] of assistance. You may also find the memorandum from UKHCDO in relation to trials of hepatitis reduced factor VIII [CBLA0001831] of assistance.*

During various meetings it became apparent that there was an association between blood products and HIV in approximately 1983.

25. *What, if any, actions were taken at the Centre to reduce the risk to patients of being infected with HIV? You may wish to refer to the regional treatment recommendations drawn up by the Haemophilia Working Party at the meetings on 17 December 1984 [SHIN0000026\_002], 15 February 1985 [SHIN0000025] (at which the UKHCDO recommendations were considered [HCDO0000270\_007]) and 29 July 1985 [SHIN0000023] (at which Professor Bloom's letter to the British Medical Journal was considered [PRSE0001917]).*



All patients were treated with heat treated blood products. Fortunately, at North Staffs. we were lucky in that regard, even though heat treated BPL Factor V111 was very limited and the demands of Birmingham Children's Hospital had to be met.

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

Yes. To my recollection all patients were switched to heat treated products as soon as available.

*Response to risk*

27. *Did you or your colleagues at the Centre take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps?*  
Yes. All patients were informed of infection risks. They had been before commencing on Factor V111 concentrate.

28. *When did you begin to use heat treated factor products and for which categories of patients? From where did you obtain heat treated products? Did you experience difficulties in obtaining such products? You may wish to consider:*

- a. *The minutes of the Haemophilia Working Party dated 17 December 1984 [SHIN0000026\_002] and the letter from you to the working party following that meeting [SHIN0000026\_001].*

Patients were provided with heated blood products as soon as they became available. All blood products were provided by the Regional Blood Transfusion Centre in Birmingham.

29. *Your letter to Dr Ala at the Regional Blood Transfusion Service dated 26*

*February 1985 [BPLL0002375\_004<sup>1</sup>]). Please explain the context of this letter and specifically how you decided which patients would be given heat treated Factor VIII?*

As directed I was asked to inform Dr Ala of the list of patients to receive Factor V111. All patients at North Staffs. were suitable to be given heat treated products.

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

I believe that this question is out of my remit. As a General Haematologist, and not a blood transfusion expert or virologist, I cannot answer.

31. *Did you revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, how was it determined which patients would be offered a return to cryoprecipitate and which would not? If not, why not? You may wish to refer to the discussions at the meetings of the Working Party on Haemophilia on 19 May 1980 [SHIN0000036], 23 November 1981 [SHIN0000033], 28 June 1982 [SHIN0000032] 6 December 1982 [SHIN0000031] and 13 May 1985 [SHIN0000024].*

All patients were offered local treatment with cryoprecipitate. Those on home treatment preferred Factor V111 and by the time the full information of HIV was available supplies of heat treated Factor V111 were on stream.

32. *At the 14<sup>th</sup> meeting of Haemophilia Centre Directors on 17 October 1983, there was a discussion of whether to revert to the use of cryoprecipitate [PRSE0004440]. Dr Chisholm raised the problem of patients refusing to take commercial Factor VIII concentrate because of the AIDS scare, queried whether directors should revert to using cryoprecipitate for home therapy, and referred to problems in her region getting large amounts of commercial concentrates, whereas she could get unlimited amounts of cryoprecipitate. Other directors reported the same problem.*

- a. *Please set out what you recall of this discussion. What if any contribution did you make to it?*

I do not recall. I did not contribute

- b. *Did patients raise with you concerns about factor concentrates, because of the AIDS scare? If so, when and what was your response?*

They did when it became public knowledge. I agreed there was a risk and let them make their own decision after a discussion.

- c. *Did you (like Dr Chisholm and other unnamed directors) have regional problems in getting sufficient amounts of commercial concentrates? If so, please describe them.*

We had no problems in securing Factor V111.

- d. *Were you (like Dr Chisholm and other unnamed directors) able to get unlimited amounts of cryoprecipitate?*

Yes

- e. *The decision recorded in the minutes of the meeting was that patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive NHS or commercial concentrates. Did you agree or disagree with this decision?*

I agreed with the decision

33. *Do you consider that your decisions and actions, and the steps taken at the Centre 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.*

I reacted immediately there was an infection risk.

34. *Looking back now, what decisions or actions by you and/or by the Centre could and/or should have avoided, or brought to an end earlier, the use of infected blood products?*

Looking back I would not change any of my actions.

35. *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?*

I feel the Haemophilia Society must accept some responsibilities on their push for home and prophylactic therapy knowing the British Product could not meet the demand.

#### **Section 4: Treatment of patients at the Centre**

##### *Provision of information to patients*

36. *What information did you provide or cause to be provided to patients at the Centre about:*
- a. *the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing?*
  - b. *alternatives to factor concentrates?*

The patients knew my views on blood products.

Cryoprecipitate and Desmopressin could be used. But this would not be suitable for patients with severe haemophilia and those with moderate haemophilia if they had a severe bleed. But as far as I can recall there was no request from patients to change their treatment.

##### *HIV*

37. *When did you first discuss AIDS or HIV (HTLV-III) with any of your patients?*  
As soon as problem with Factor V111 concentrate became available.
38. *Please describe how and when you learned that patients under the care of the*

*Centre had been infected with HIV. You may wish to refer to the regional policy on screening of haemophiliacs for HIV set out at the Haemophilia Working Party meeting on 29 July 1985 [SHIN0000023] and the further discussion on this issue at a later meeting in December 1985 [SHIN0000022].*

When Factor V111 concentrate was implicated in HIV I began to screen.

39. *What if any arrangements were made at the Centre for pre-test counselling and for post-test counselling?*

A full discussion was undertaken prior to screening and post screening in out patients.

40. *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 letter or byphone? Were they seen individually or in groups? What if any involvement did you have in this process?*

I told them in person.

41. *What information was given to them about the significance of a positive diagnosis? Were patients told to keep their infection a secret?*

Unfortunately, the dire prognosis was known to those who were positive from the publicity surrounding HIV. I left it to their discretion who they told.

42. *What was the policy at the Centre in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were the tests carried out?*

All partners were offered tests when necessary.

43. *What, if any, information or advice was provided by you or colleagues to partners or family members of people who were at risk of infection with HIV or were infected with HIV?*

They were informed that their immune mechanism was compromised and to be aware of infectious diseases. Also their bodily fluids were contaminated.

44. *How many patients at the Centre were infected with HIV? Of those infected, how many (a) had severe haemophilia A, (b) had moderate haemophilia A, (c) had mild haemophilia A, (d) had haemophilia B and (e) had von Willebrand's disease? How many were children?*

I cannot remember.

45. *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*

No work was undertaken as no serum was retained.

46. *Please refer to the letter from Dr Ala, the Medical and Scientific Director of the then West Midlands Regional Blood Transfusion Centre dated 29 November 1994 regarding a donor who tested positive for HIV and whose donations were issued to the Centre [NHBT0044846\_003]. The letter relates to the tracing and testing of possible recipients of infected donations. Please describe, generally:*

- a. *What steps would have been taken by you/the Centre, when Dr Ala, or others from the West Midlands Regional Blood Transfusion Centre notified you of donations likely to have been infected?*

All transfusion records were kept and would allow us to identify recipients.

- b. *What steps would have been taken to investigate the matter, and what was the standard process for tracing recipients of infected blood at the Centre?*

As far as I can recall there were two recipients of the blood who sadly both died on the table during heart surgery.

- c. *Whether you believe that the investigations which were carried out were*

*sufficient, if not why not?*

Yes they were sufficient.

- d. What difficulties, if any, were encountered by the Centre in tracing recipients of donations known to have been infected? If you were unable to trace recipients known to have been infected, what were the next steps, if any?*

As far as I can recall there were no issues in tracing cases.

- e. Whether recipients who were traced were tested by the Centre, and if so, whether their consent was sought for such testing. If not why not?*

Not relevant

- f. Whether counselling was offered to such patients by the Centre. If not why not?*

Not relevant

- 47. Please refer to your letter to Dr Ala, the then Director of the Regional Blood Transfusion Centre in Birmingham dated 30 October 1985, regarding screening haemophiliacs for HTLV-III who had received a certain batch [NHBT0046145\_006]. You state that "I have not written to Dr Craske at Manchester as I am concerned regarding confidentiality."*

- a. What process was in place regarding who was to be informed about screening results?*

Only the patient was informed.

- b. What were your specific concerns regarding confidentiality?*

It was of no concern of Dr Craske as to the name of the patient.

- c. Were your concerns resolved? What policy changes were made if any?*

The matter was not brought up again.

*Hepatitis B*

48. *Were patients infected with hepatitis B informed of their infection and if so, how? What information was provided to patients infected with hepatitis B about the infection, its significance, prognosis, treatment options and management? What if any involvement did you have in this process?*  
As far as I can recall no patients were infected with Hep B

49. *How many patients at the Centre were infected with hepatitis B?*  
As far as I can recall no patients were infected with Hep B

#### *NANB Hepatitis/Hepatitis C*

50. *Were patients infected with NANB hepatitis informed of their infection and if so, how and by whom? What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management? What if any involvement did you have in this process?*  
As far as I can recall no patient had clinical non A or non B Hepatitis

51. *When did you begin testing patients for hepatitis C? How, when and by whom were patients informed of their diagnosis of hepatitis C? Were they told in person, by letter or by phone? What if any involvement did you have in this process?*

As soon as this test became available for Hep C at the North Staffs. lab all patients were informed by me in person of their Hep C status. I cannot recall the date that testing began.

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



All patients at the Centre were tested for HCV.

53. *What information was provided to patients infected with hepatitis C about their infection, its significance, prognosis, treatment options and management?*

All information in my possession was discussed with the patient.

54. *How many patients at the Centre were infected with hepatitis C?*

I am sorry but I cannot recall.

#### *Delay/public health/other information*

55. *Were the results of testing for HIV and 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.*

As far as I can recall there would have been no delays in indicating results.

56. *To what extent, if at all, did you/your colleagues take into account the public health implications of HIV, AIDS, hepatitis B, NANB hepatitis and hepatitis C, when taking decisions as to what information or advice to provide to patients or what treatment to offer patients?*

We took into account general health and public health repercussions.

#### *Consent*

57. *How often were blood samples taken from patients attending the Centre and for what purposes? What information was given to patients about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of the samples? Was their consent recorded and if so how and where?*

All patients were tested for Hep C and HIV when testing became available. The patients were all aware of the significance of the tests. No record of consent

was recorded as the request for blood testing was written in front of the patient. No one was tested without being told.

58. *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?*

All patients gave consent verbally to me. Only one patient was treated without consent. He was unconscious having fallen down the stairs.

59. *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?*

No one was tested without consent. As I described in my answer to question 57, no record of consent was kept and I received no complaint.

#### *PUPS*

60. *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).*

Fortuitously when the problems of Hep C and HIV arose the centre received no new untreated patients.

#### *Research*

61. *Please list any research studies that you were involved with during your time at the Centre that could be relevant to the Inquiry's Terms of Reference and provide a brief summary of the purpose of the research and your involvement.*
- As far as I can recall there were none.

62. *The Inquiry understands that you may have contributed to or provided data for the following:*

a. *An article published in September 1995: "Mortality before and after HIV infection in the complete UK population of haemophiliacs" [HCDO0000264\_095]*

I have no knowledge of this.

b. *An article published in 1996: "The Importance of Age at Infection with HIV-1 in Determining Survival in the Complete UK Population of Haemophiliacs" [HCDO0000017\_064]*

I have no knowledge of this.

c. *An article published in November 1997: "Mortality from liver cancer and liver disease in haemophilic men and boys in UK given blood products contaminated with hepatitis C" [HCDO0000264\_150]*

I have no knowledge of this.

d. *An article published in 1998: "Immune status in HIV-1-infected men and boys with haemophilia in the United Kingdom" [HCDO0000017\_001]*

I have no knowledge of this

e. *An article published in 2001: "Treatment of haemophilia in the United Kingdom 1981-1996" [HSOC0023510]*

I have no knowledge of this.

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

As far as I can recall there I was not involved in research studies.

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

I have no memory of this.

65. *Was patient data (anonymised, de-identified or otherwise) shared with third parties without their express consent? If so how, and why did this occur, and what information was provided to whom?*

This could have occurred without my knowledge but I was not involved if it was.

*Treatment of patients who had been infected with HIV and/or Hepatitis*

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?*

The patients were managed locally but offered referral to Birmingham.

- b. *What treatment options were offered over the years to those infected with HIV?*

Initially single agent Zidovudine (AZT) and later, but not by me, triple agent therapy, as no patient had survived by then.

- c. *What information was provided to patients about the risks and benefits of specific treatments and about side effects?*

All the latest information was given to patient. No patient ever complained as could see me any time by phoning the centre

- d. *What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?*

T-Cell subsets were monitored through testing in the department of immunology.

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 over the years?*
- 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 ongoing monitoring was arranged in respect of patients who were infected with hepatitis B?*

No patients had Hepatitis B.

68. *How was the care and treatment of patients with NANB hepatitis 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 over the years?*
- 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 ongoing monitoring was arranged in respect of patients who were infected with NANB hepatitis?*

No patient had Non A Non B Hepatitis whilst I was at North Staffs.

69. *How was the care and treatment of patients with hepatitis C managed at the Centre? In particular:*

- a. What steps were taken to arrange for, or refer patients for, specialist care?*

All patients were offered referral to Queen Elizabeth Haemophiliac Unit.

*b. What treatment options were offered over the years?*

Interferon and Ribavirin

*c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?*

A full discussion took place with the patient regarding side effects

*d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis C?*

Liver function tests and Hepatitis C antibodies were followed up.

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

I was not involved with paediatric care I believe such patients were referred to Birmingham Children's Hospital.

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

As far as I can recall there was no involvement in such clinical trials.

72. *What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?*

As far as I can now recall no one ever requested the support suggested in this question. It was a long time ago before these services developed. The patients were happy to have discussions with me.

73. *Did the centres at which you worked receive funding from the Department of*

*Health and Social Security or from any other source to help with the counselling of patients infected with HIV?*

None to my knowledge.

74. *What (if any) difficulties did you encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or hepatitis C?*

None to my knowledge.

#### *Records*

75. *What was the policy at the Centre as regards recording information on death certificates when a patient had been infected with HIV or hepatitis C?*

As far as I can recall there was no policy

76. *What were the retention policies of the Centre in relation to medical records during the time you were practising there?*

As far as I know all medical records would be kept.

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

Yes in my office at North Staffs. Hospital Centre. I have no idea where these files would be now. I retired in 2004 and the hospital building that I worked in was demolished 10 years ago.

78. *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 at the hospital where you worked? If so, why, what information and where is that information held now?*

No

79. *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*

No

### **Section 5: Self-sufficiency**

80. *In December 1974 the Department of Health announced additional funding with the primary aim of making the NHS self-sufficient in Factor VIII blood products within two to three years. If you are able to respond, from your own knowledge, to the questions in this section please do so; if you are not, please say so.*

a. *When did you become aware of this announcement?*

I cannot recall

b. *What did you understand the term "self-sufficiency" to mean? In particular, did you understand it to mean self-sufficiency in providing Factor VIII blood products prophylactically, or solely in response to bleeding incidents?*

c. *I understood that self-sufficiency implied all Factor V111 would be sourced from UK plasma.*

d. *Did your understanding of what "self-sufficiency" meant change at any time? If so, when and why?*

No

e. *What was your understanding of how others defined "self-sufficiency"?*

I do not recall this term ever being discussed

f. *What if any role did you play, at any time, in any arrangements or initiatives designed to help achieve self-sufficiency?*

None.

81. *How were estimates made of how much Factor VIII blood product would be*



*required for use in England and Wales? In particular:*

- a. What was the role of the director of the Centre in making such estimates, and how did this change over time?*

I informed the local supplier of Factor V111 i.e. the BTS in Birmingham of our requirements based on the previous year's usage.

- b. What was the role of UKHCDO and how did this change over time?*

I am sorry but I do not know. I attended some meetings but was not involved in the organisation.

- c. What assumptions would underpin the estimates (including assumptions as to how the blood products would be used)?*

I refer to my answer to question 81a but would also take into account an increasing demand for the product and any increase in patient numbers.

- d. How would the estimate be made (e.g. by whom were they made, when and through what process)?*

I refer to my previous answers to this question. Myself and the chief MLSO at the blood bank would estimate the requirement for the product.

- e. How were the estimates shared with other interested parties?*

The estimates would be shared with the Director of the Birmingham Transfusion Centre and Chair of the local Haemophilia Directors Committee.

- f. How did any of these processes change over time?*

As far as I can now recall this did not change over time.

82. *How were annual figures derived for how much Factor VIII blood product had been used over the course of a year?*

- a. *What was the role of the director of the Centre in providing such figures, and how did this change over time?*

Records of usage were kept in the Blood Bank at North Staffs. Central Pathology Lab. Then I would provide the figures to our supplier at BTS.

- b. *What was the role of UKHCDO and how did this change over time?*

I am sorry but I do not know

- c. *How would the calculations be made (e.g. by whom were they made, when, through what process and using what data)?*

I refer to my answer to 82 a. I am sorry but I do not know anything further in relation to this.

- d. *How were those figures broken down geographically (e.g. by country, region or any other unit)?*

I do not know.

- e. *How were the figures shared with other interested parties?*

The estimates would be shared with the Director of the Birmingham Transfusion Centre and Chair of the local Haemophilia Directors Committee

- f. *How did any of these processes change over time?*

As far as I can now recall this did not change over time.

83. *Were there significant differences between the estimates that were made and actual use? If so, why?*

As far as I can recall there may have been some differences and this would have been related to unforeseen events such as a patient being involved in an accident and requiring blood products as part of their treatment.

84. *To what extent, if at all, did England and Wales (in your view) achieve self-*

*sufficiency of Factor VIII blood products? Why (if this is your view) was self-sufficiency not achieved? Do you consider that more could have been done to achieve self-sufficiency and if so what?*

I do not know if self-sufficiency was achieved and if not why not. I am not in a position to comment regarding the Blood Transfusion Service.

85. *Do you consider that there was a failure by haemophilia clinicians to provide timely and accurate estimates of future demand for Factor VIII blood products and/or a failure by haemophilia clinicians to identify the foreseeable increase in use of such products once they became available?*

No

86. *If self-sufficiency had been achieved in Factor VIII products, what, in your view, would have been the effect on the numbers of patients infected with (i) HBV, (ii) HCV, and (iii) HIV. Please comment on when self-sufficiency would have needed to be achieved (in your view) in order for any material difference to have been made in respect of each of these viruses.*

I think the number of HIV cases would have been less, but it would not have had the same effect on HCV or Hep B.

87. *To the best of your knowledge, did England and Wales achieve self-sufficiency in respect of Factor IX blood products?*

Yes, I think so as there were less sufferers of Factor V111 deficiency.

88. *If self-sufficiency in respect of Factor IX blood products was achieved, did you nonetheless use commercially produced products in preference to domestically produced products? If so, why?*

I only used NHS Factor IX

## Section 6: UKHCDO

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

I only attended the meetings.

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

- a. *The purpose, functions and responsibilities of UKHCDO, as you understood them.*

I think that this was to disseminate its ongoing views on management and investigation of bleeding disorders and to allow exchange of views and opinion.

- b. *The structure, composition and role of its various committees or working groups.*

I cannot now recall.

- c. *The relationships between UKHCDO and pharmaceutical companies.*

I was not involved with this

- d. *How decisions were taken by UKHCDO.*

I do not know.

- e. *How information or advice was disseminated by UKHCDO and to whom.*

It was within the meeting to those who attended and by the minutes of meetings to those who did not (as far as I can recall).

- f. *Any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to: the importation, purchase and selection of blood products; the manufacture of blood products; self-sufficiency; alternative treatments to factor products for patients with bleeding disorders; 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 for the testing and storage of their blood, for treatment and for research; heat treatment; other measures to reduce risk; vCJD exposure; and treatments for HIV and hepatitis C.*

I was not involved in this.

## **Section 7: Pharmaceutical companies/medical research/clinical trials**

91. *Have you ever:*

a. *provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products?*

No

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?*

No

c. *sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?*

No

d. *received any financial incentives from pharmaceutical companies to use certain blood products?*

No

e. *received any non-financial incentives from pharmaceutical companies to use certain blood products?*

No

f. *received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?*

No

*g. undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products?*

No

*h. provided a pharmaceutical company with results from medical research studies that you have undertaken?*

No

### **Section 8: vCJD**

92. *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? How did your knowledge develop over time?*

It was put to me that the vCJD could be transmitted by blood products when such information was generally available. I had no prior knowledge and my knowledge did not develop over time.

93. *Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so please answer the following questions:*

*a. What processes were put in place at the Centre for informing patients about possible exposure to vCJD?*

None that I can recall

*b. What information was provided to patients about possible exposure to vCJD and the risks of vCJD?*

None that I can recall

*c. What steps were taken to arrange for counselling, support and/or advice to be offered to patients who were being informed that they might have been exposed to vCJD?*

None that I can recall. At that time around the 1990s (I think) anyone

who ate beef could be infected.

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

None that I can recall

### **Section 9: The financial support schemes**

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

None.

96. *What, if any, involvement did you have with applications made by your patients to the various trusts and funds? Did you provide medical opinions or information in support of applications?*

None.

97. *Based on your own dealings with any of 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?*

I had no dealings

## **Section 10: Other issues**

98. *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.*

There were none that I know of.

99. *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.*

There are not that I can recall.

## **Statement of Truth**

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

Signed GRO-C

Dated 9 March 2021\_\_\_\_\_