Witness Name: Dr Guy Lucas
Statement No.: WITN3485002
Exhibits: None
Dated:12 September 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR GUY LUCAS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 15 July 2020.

I, Dr Guy Lucas, will say as follows: -

Section 1: Introduction

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

My name, address and date of birth are:

Guy Stuart Lucas
GRO-C
GRO-C 1950

My professional qualifications are:

MD (Birmingham), FRCP, FRCPath

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. The Inquiry understands that you worked in Birmingham and Cardiff prior to taking up your post as a consultant haematologist in Manchester in 1989. Please ensure that your answer to this question sets out the periods that

you worked in Birmingham and Cardiff and the nature of your work there, as well as any other posts you have held.

My positions held and responsibilities were:

Consultant Haematologist, Manchester Royal Infirmary
(Oct 1989 - Sept 2010)
Acting Haemophilia Centre Director, MRI
(Jan 1992 – Sept 1994)

During the period Jan 1992- Sept 1994, I had day-to-day Consultant responsibility for most patients with bleeding or thrombotic disorders attending Manchester Royal Infirmary. For the remainder of the period, my only involvement with patients with bleeding or thrombotic disorders was on call at nights and weekends.

Previous appointments
Lecturer in Haematology
University of Wales College of Medicine
(June 1984 - Sept 1987, Oct 1988 - Sept 1989)

During this time, I worked for approximately four months as a Senior Registrar for Professor AL Bloom, who was responsible for patients with bleeding and thrombotic disorders attending the University Hospital of Wales, Cardiff. I was also on-call for such patients at night and weekends during most of my appointment, on a 1-in-5 basis.

MRC Training Fellow
Department of Haematology
University of Wales College of Medicine
(Oct 1987 - Sept 1988)

No responsibilities for patients with bleeding or thrombotic disorders during this appointment.

Research Registrar
Department of Haematology
Medical School, Birmingham University
(Aug 1982 - May 1984)

During this time, I worked for part of the time as a registrar on call for patients with bleeding and thrombotic disorders attending the Queen Elizabeth Hospital, Birmingham patients at night and weekends on a 1-in-4 basis

Registrar in Haematology
General Hospital, Birmingham

(June 1981 - July 1982)

No responsibilities for patients with bleeding or thrombotic disorders during this appointment.

SHO in General Medicine
East Birmingham Hospital, Birmingham
(Aug 1979 - May 1981)

No responsibilities for patients with bleeding or thrombotic disorders during this appointment.

House Physician
Dudley Road Hospital, Birmingham
(Feb 1979 - July 1979)

No responsibilities for patients with bleeding or thrombotic disorders during this appointment.

House Surgeon
Selly Oak Hospital, Birmingham
(Aug 1978 - Jan 1979)

No responsibilities for patients with bleeding or thrombotic disorders during this appointment.

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.

My relevant memberships (past and present) are: None
I attended meetings of the UK Haemophilia Centre Directors Organization as Acting Haemophilia Centre Director at Manchester Royal Infirmary between 1992 and 1994. I do not know if this constituted membership. I do not recall playing any other part in the organization.

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.

Save for investigation by the GMC that I refer to below, I have not provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. In particular, I do not recall litigation in the 1990s against Manchester Health Authority and the Department of Health by a patient with a bleeding disorder at the Manchester Royal Infirmary who was infected with HCV.

I was the subject of investigation by the General Medical Council in 2003 relating to a patient with Hepatitis C who had attended the Manchester Haemophilia Centre. At the conclusion of the GMC's investigation it determined that they did *"not need to take any further action on my registration, in respect of these allegations."*

Section 2: Decisions and actions of the haemophilia centres at which you worked prior to your appointment as a consultant haematologist at Manchester Royal Infirmary in 1989

This covers my responses to questions 5 to 19 of the Rule 9 request in the letter to me from the Infected Blood Inquiry dated 15 July 2020

Please answer the questions below in relation to each of the haemophilia centres, or hospitals providing treatment to people with bleeding disorders, at which you worked prior to being appointed a consultant haematologist in Manchester Royal Infirmary in 1989.

5. Please describe the roles, functions and responsibilities of each of the haemophilia centres at which you worked during the time that you worked there.

The Haemophilia Centre at the University Hospital of Wales had overall clinical responsibility for the diagnosis and treatment of all adult and paediatric patients with inherited and other bleeding disorders registered with the Centre. Virtually all patients came from south or mid-Wales.

6. Please identify senior colleagues at each of the centres and their roles and responsibilities during the time that you worked there.

Professor AL Bloom was the Haemophilia Centre Director at the University Hospital of Wales. I do not know his specific roles or responsibilities. There were no other senior (ie, Consultant) staff at the University Hospital of Wales.

7. Please describe: a. your role and responsibilities at each of the centres and how, if applicable, this changed over time; b. your work at each of the centres insofar as it involved the care of patients with bleeding disorders and/or

patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.

To the best of my recollection, I spent approximately four months as a junior doctor caring day-to-day for patients with bleeding disorders at the University of Wales during my time as Lecturer in Haematology (June 1984 - Sept 1987, Oct 1988 - Sept 1989). This would have included the assessment of patients during acute bleeding episodes and the prescribing of appropriate blood products for them, according to the usage at the Centre. Save for treating problems associated with their underlying blood disorder, I do not recall any direct clinical responsibility for these patients related to infection with HIV and/or hepatitis.

8. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated, at each of the centres at which you worked, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there?

I have no knowledge of how blood products (including factor concentrates) were selected or chosen during the time I worked at the University Hospital of Wales. As a junior doctor I would have used the blood products stocked by the Haemophilia Centre. I do not recall the specific blood products which were in use at the University Hospital of Wales between 1984 and 1989. I do not know what if any role commercial or financial considerations played in the choice or use of blood products. I had no involvement in the choice of type of blood product stocked by the Haemophilia Centre.

In addressing this question, please answer, to the extent that you are able to, the following questions:

a. How, and on what basis, were decisions made about the selection and purchase of blood products?

I do not know.

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

I do not know.

c. What particular products were used for treating patients, over what period of time and for which categories of patients?

I do not know.

d. What role did commercial and/or financial considerations play?

I do not know.

e. What if any involvement did you have?

None.

9. What was the relationship between the centre(s) and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the centre's decisions and actions?

I was not aware of any relationship between the centre and any pharmaceutical companies manufacturing/supplying blood products.

10. How were decisions taken as to which products to use for individual patients? What involvement did you have in such decisions?

Blood products available at the Haemophilia Centre were used based on their suitability for the patient.

11. What alternative treatments to factor concentrates were available for people with bleeding disorders?

I do not recall the specific alternatives to factor concentrates used at the University Hospital of Wales between 1984 and 1989.

12. What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the centre(s) make of them? 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?

Please see my response in 11 above.

13. What was the policy and approach at each centre as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and if so how?

I do not recall the policy for the use of cryoprecipitate at the University Hospital of Wales in 1984-1989.

14. What was the policy and approach at each centre in relation to home treatment? Did the policy and approach change over time and if so how?

I do not recall the policy for the use of home treatment at the University Hospital of Wales in 1984-1989.

15. What was the policy and approach at each centre in relation to prophylactic treatment? Did the policy and approach change over time and if so how?

I do not recall the policy for the use of prophylactic treatment at the University Hospital of Wales in 1984-1989.

16. What was the policy and approach at each centre in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?

I do not recall the policy for the use of factor concentrates for children at the University Hospital of Wales in 1984-1989, or whether it changed over that time.

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

I do not recall the policy for the treatment of patients with mild bleeding disorders at the University Hospital of Wales in 1984-1989.

18. What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at the centre(s) in consequence of the use of blood products?

I have no recollection of any evidence suggesting that any viruses or other infections other than HIV, HCV and HBV were transmitted to patients at the Haemophilia Centre at the University Hospital of Wales between 1984 and 1989. I have no recollection of any cases of variant Creutzfeld-Jacob disease in this population of patients.

19. The Inquiry is aware that you were working with Professor Bloom in Cardiff, at least in late 1984. Please provide an account (in as much detail as you are able to) of Professor Bloom's policies, decisions and actions, during the time that you worked there, as regards the use of factor concentrates, the risks of infection, the treatment of patients, the provision of information to patients and any other matter relevant to the Inquiry's Terms of Reference.

As I was a junior doctor I was not responsible for making policies. As this question relates matters that span a period of 5 years between 31 and 36 years ago this I have little recollection of these matters and so this questions may be better directed to the University Hospital of Wales Cardiff.

Section 3: Decisions and actions of the haemophilia centre at Manchester Royal Infirmary

This covers my responses to questions 20 to 27 of the Rule 9 request in the letter to me from the Infected Blood Inquiry dated 15 July 2020

20. Please describe the roles, functions and responsibilities of the Manchester Centre during the time that you worked there.

I have limited recollections now of what happened between 26 and 28 years ago. As this question relates to operational matters for which accurate rather than speculative evidence is required I believe that this question could be more accurately answered by the Manchester Royal Infirmary and/or the Manchester Haemophilia Centre.

21. Please identify senior colleagues at the Centre and their roles and responsibilities during the time that you worked there.

I was the Consultant working at the Centre between Jan 1992 and Sept 1994. Other senior members of staff included a Staff Grade Doctor (Dr M Bolton), an experienced Nursing Sister, and a Chief Medical Laboratory Scientific Officer (Dr A Cumming).

22. Please describe:

a. your role and responsibilities at the Centre and how, if applicable, this changed over time;

I was appointed acting Haemophilia Centre Director in January 1992 as an emergency measure following the departure of the previous Haemophilia Centre Director, Dr RT Wensley. I continued until a suitable replacement was appointed in September 1994.

b. your work at the Centre insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.

Day-to-day clinical problems would generally handled by the Staff Grade Doctor, although I would see patients which the Staff Grade Doctor was concerned about. I generally saw the majority of In-patients. There would have been weekly clinics where I reviewed patients. I chaired a regular Haemophilia Centre Meeting (probably weekly) attended by doctors, nurses, physiotherapists and laboratory scientists to review clinical cases. Some patients developed chronic liver disease and my recollection now is that where this progressed they would have been referred to hepatolgy.

There were joint HIV-Haemophilia Clinics at the Haemophilia Centre. I have no specific recollection beyond this and therefore would suggest that the MRI/Hemophilia Centre may be better placed to answer questions regarding the role of the Centre.

23. Approximately how many patients with bleeding disorders were under the care of the Centre when you took up your appointment there in 1989 and over the years that followed? (If you are able to give exact rather than approximate figures, please do so).

I do not recall. The Regional Haemophilia Centre at Manchester Royal Infirmary may be able to assist the Inquiry in answering this question, or the UK Regional Haemophilia Centres Directors Organisation.

24. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated, at the Centre regarding the selection, purchase

and use of blood products (in particular factor concentrates) during the time that you worked there?

I have no probative recollections relating to this question. The Regional Blood Transfusion Service may have supplied blood products. The Regional Haemophilia Centre at Manchester Royal Infirmary may be able to assist the Inquiry in answering this question.

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?

I refer the my answer to the stem of 24.

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

I do not recall.

c. What particular products were used for treating patients, over what period of time and for which categories of patients?

I do not recall.

d. What role did commercial and/or financial considerations play?

I do not know.

e. What if any involvement did you have?

My recollection is that my role was limited to clinical matters.

25. What was the relationship between the Centre and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Centre's decisions and actions?

The Regional Haemophilia Centre at Manchester Royal Infirmary may be able to assist the Inquiry in answering this question as I have no recollections of any relationship, decisions or actions.

26. How were decisions taken as to which products to use for individual patients? What involvement did you have in such decisions?

Although I have no specific recollections, decisions would have been based on what was thought to be the appropriate clinical practice at the time (1992-94)

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

I have no recollection of any.

Section 4: Knowledge of, and response to, risk

This covers my responses to questions 28 to 44 of the Rule 9 request in the letter to me from the Infected Blood Inquiry dated 15 July 2020

28. When you first began to work with patients with bleeding disorders, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

My background knowledge was derived from lectures, publications and medical textbooks. I endeavoured to keep up to date by attending lectures, and reading relevant publications and medical textbooks.

29. 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 do not recall the relative risks of infection from the use of commercially supplied and NHS blood products.

Hepatitis

30. When you first began work with patients with bleeding disorders, what was your knowledge and understanding of the risks of the transmission of hepatitis (including HBV and NANB hepatitis) from blood and blood products?

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

My knowledge was derived from lectures, publications and medical textbooks.

31. 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?

I do not recall the details of which liver function tests were used at the different centres I worked at between 1982 and 1994. The aim of undertaking liver function tests was to identify which patients had liver problems, if possible, to diagnose the causes and offer appropriate treatment.

32. What, if any, actions did you take, or were taken at any of the centres at which you worked at any relevant time, to reduce the risk to patients of being infected with hepatitis (of any kind)?

Due to the passage of time I have no specific recollection of what actions were taken at what times and so any response would be somewhat speculative. In relation to what products were used at what time and why I would suggest that the Regional Haemophilia Centre at Manchester Royal Infirmary may be able to assist the Inquiry in answering these questions.

33. 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?

My understanding was derived from and progressed by reading medical journals, attending lectures and conferences, meetings with colleagues and treating patients.

HIV and AIDS

34. How and when did you first become aware that there might be an association between AIDS and the use of blood products? What was the source of your knowledge? How did your knowledge and understanding of HIV (HTLV-III) and AIDS, and in particular of the risks of transmission from blood and blood products, develop over time?

I do not recall the specific date when I became aware of an association between AIDS and the use of blood products. I do recall meeting a young man in Cardiff who had haemophilia and was dying of HIV infection in about 1984-1985. I aimed to keep my knowledge of HIV (and previously HTLV-III and AIDS) current by reading medical journals, talking to informed colleagues, and attending lectures and conferences.

35. What, if any, actions did you take, or were taken at any of the centres at which you worked at any relevant time, to reduce the risk to your patients of being infected with HIV?

When products or techniques became available (with evidence suggesting their benefit), I endeavoured to use them. I do not recall dates or individual products relating to my practice in 1992-1994

36. To your knowledge, did Professor Bloom continue to use factor concentrates to treat patients, after becoming aware of the possible risks of

infection of HIV? What if any instruction, advice or information did he provide to you and to other staff working at the Cardiff haemophilia centre regarding HTLV-III/AIDS and treatment with factor concentrates?

Although I cannot recall specifics now due to the passage of time, I have no reason to believe that Professor Bloom was not following accepted practice at the time.

37. Did Professor Bloom revert to treatment with cryoprecipitate for some or all of his 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?

Due to the passage of time any recollections I have are non-specific and therefore may be speculative and inaccurate. This question may be better directed to the University Hospital of Wales.

38. Did you or your colleagues, at any of the centres at which you worked at any relevant time, take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps?

I have no specific recollections of particular patient cases but have no reason to believe that patients were not advised of risks in accordance with usual practice at the time based on available knowledge.

39. When did you begin to use heat treated factor products, at which centre(s) and for which categories of patients?

I do not recall.

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

I do not recall the background to the introduction of heat-treated products. In particular, I do not recall when they were first shown to be safer than other factor products and available for use.

41. Do you consider that your decisions and actions, and those of the centres at which you worked, 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 do not recall any specific incidents where my decisions or actions in response to known or suspected risks of infection were deemed to be inadequate or inappropriate by colleagues or by myself, based on the knowledge and best practice of the time.

42. Looking back now, what decisions or actions by you and/or by any of the centres at which you worked could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

Due to the passage of time and my lack of recollections I am unable to answer this question.

43. 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 do not sufficiently recall the actions, decisions, and policies of other clinicians and organisations more than 26 years ago to be able to answer this question.

44. Do you consider that greater efforts could and/or 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?

I am not in a position to speculate about what should have happened in 1980.

Section 5: Treatment of patients

Provision of information to patients

45. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients with a bleeding disorder, at each of the centres at which you have worked at any relevant time, about:

a. the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing?

Due to the passage of time and the historical nature of the question I cannot provide a specific answer, but advice would have been given dependent on the current knowledge and blood products available at the relevant time.

b. alternatives to treatment with factor concentrates?

Please see my response to 45a.

c. the risks of chronic and/or serious liver disease?

Please see my response to 45a.

HIV

46. When did you first discuss AIDS or HIV (HTLV-III) with any patient?

Although I have no recollection any specific discussions this was possibly sometime between 1984 and 1989.

47. Please describe how and when you learned that patients under your care/the care of the centre(s) at which you were working at the material time had been infected with HIV.

I assume that this would have been from the patient's medical history.

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

I do not know what arrangements were made in Cardiff. Although I cannot remember any specific case, to the best of my recollection during my time in Manchester, patients there were counselled before having an HIV test.

49. How and when and by whom were patients told that they had been, or might have been, infected with HIV?

I do not know what arrangements were made in Cardiff, or before my time as acting Hemophilia Centre Director. Whilst I do not now recall any specific patient details I recall that I gave a new diagnosis of HIV to a patient which was given at the Manchester Hemophilia Centre.

Were they told in person, by letter or by phone?

Please see my answer to the previous paragraph. I believe that this would have been in person.

Were they seen individually or in groups?

Please see my answer to the previous paragraphs under 49

What if any involvement did you have in this process?

Please see my answer to the previous paragraphs under 49

50. What information was given to them about the significance of a positive diagnosis?

I do not recall.

Were patients told to keep their infection a secret?

No

51. What was the policy 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?

I was not involved in this in Cardiff. I do not recall the policy for testing partners/family members of people known or suspected to have HIV in Manchester.

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

I do not recall specific policies.

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

I do not recall specific policies

Hepatitis B

54. Were patients infected with HBV at any of the centres at which you worked informed of their infection and if so, how? What information was provided to

patients infected with HBV about the infection, its significance, prognosis, treatment options and management? What if any involvement did you have in this process?

I do not recall involvement with a new diagnosis of Hepatitis B infection during my time in Cardiff or the adult Haemophilia Centre at Manchester.

NANB Hepatitis/Hepatitis C

55. Were patients infected with NANB hepatitis at any of the centres at which you worked 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?

I do not recall the practice in Cardiff. In Manchester, my belief is that, in the time before testing for Hepatitis C existed (before 1992-1993), most if not all patients with abnormal liver function tests were aware of these test results and also aware that we were uncertain of the significance.

56. When did the Manchester Centre begin testing patients for HCV? How, when and by whom were patients informed of their diagnosis of HCV? Were they told in person, by letter or by phone? What if any involvement did you have in this process?

Due to the passage of time I do not have specific recollection in relation to testing for Hepatitis C at the Manchester Adult Haemophilia Centre in 1992-1993 but this may have started in 1992. Generally I believe that the Staff Grade doctor would communicate the positive results to the patient, who would be counselled.

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

I refer to my answer to 56 above. I believe that these matters would be addressed in counselling with the patient.

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

The Manchester Hemophilia centre should be able to provide this information.

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

I have no specific recollection although generally I believe that during the period 1992-94 the risk of infecting others was not understood.

60. What actions or decisions were taken by the Manchester Centre to trace patients who may have been infected through the use of blood or blood products?

In 1992-1993, attempts were made to contact and test all patients known to the Manchester (Adult) Centre, which should be able to provide the information the Inquiry requires.

Consent

61. How often were blood samples taken from patients attending the centres at which you worked and for what purposes? What information was given to patients about the purposes for which blood samples were taken? Did the patients give express and informed consent to the storage and use of the samples? Was their consent recorded and if so how and where?

I do not recall the specific policy for taking blood samples. The "centres" may be able to provide this information.

62. Were patients under your care or under the care of your colleagues at any of the centres at which you worked 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?

I only have one recollection relevant to the question. Sometime in 1992- 1994 a patient with Haemophilia B who had had a serious motor cycle accident went to an emergency operating theatre before it became clear that he had a known bleeding disorder. He received Factor IX treatment I can no longer recall his name or specific clinical details.

63. Were patients 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?

During my time as acting Haemophilia Centre Director, my recollection is that HIV testing was done after consent had been obtained, following counselling given according to the standards relevant at the time based on the current knowledge. I do

not recall how patients were counselled for Hepatitis C testing in 1992-1994 bearing in mind the paucity of knowledge surrounding Hepatitis C at this time. I believe that all patients deemed at risk of Hepatitis C would have been informed that that they were being tested.

PUPS

64. Please detail all decisions and actions taken at any of the centres at which you worked and/or by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS).

I was not involved in treatment decisions about previously untreated patients in Cardiff. I do not recall making any treatment decisions in 1992-1994 about previously untreated patients in Manchester.

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

65. How was the care and treatment of patients with HIV/AIDS managed at each of the centres at which you have worked at any relevant time?

I do not recall the arrangements for the care and treatment of patients with HIV/AIDS in Cardiff in 1984-1989., my clinical involvement would have generally been limited to treatment of their bleeding disorders.

The Haemophilia Centre/Manchester Royal Infirmary will probably be able to answer more specifically but my understanding is that in the year or so before my appointment as acting Haemophilia Centre Director at Manchester Royal Infirmary, some patients with bleeding disorders and HIV infection had chosen to move their HIV care to the Monsall Regional AIDS Unit, North Manchester Hospital, and others had chosen to continue their HIV care through the Haemophilia Centre. Others had moved their Haemophilia Care to the Liverpool Haemophilia Centre. Some of the patients who

were being seen in Liverpool for care of their Haemophilia may have had HIV; I do not know how their HIV care was given. On appointment in 1992, I arranged for an HIV specialist from the Monsall Regional AIDS Unit to have a regular joint clinic with me at the Manchester Haemophilia Centre. From this time on, my memory is that patients requiring inpatient treatment of HIV were free to choose where to be admitted for their care, unless complex haematological management was required.

In particular:

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

Please see my response to the stem of 65.

b. What treatment options were offered over the years to those infected with HIV? (You may wish to consider [PMOS0000013], the enclosed minutes of a meeting in May 1993 with the North West Group of the Haemophilia Society at which you outlined the then current policy of the Manchester Centre in relation to treatment with AZT).

I no longer recall this meeting some 27 years ago, but PMOS0000013 purports to be minutes of that meeting referring to the then current policy of the Manchester Centre in relation to treatment with AZT

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

I no longer recall the details of the risks, benefits and side effects of specific HIV treatments given in 1992-1994.

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

Although I do not recall the specific policy in place in 1992-1994, patients with known HIV attending the Haemophilia Centre would have been offered regular follow up. The frequency of follow up would have related to the stage of their HIV infection.

66. How was the care and treatment of patients with HBV managed at each of the centres at which you have worked at any relevant time?

I do not recall the treatment policies in place for HBV in Cardiff in 1984-1989. In Manchester in 1992-1994, my general recollection is that patients positive for the Hepatitis B Surface Antigen and deteriorating liver function tests or clinical symptoms of liver disease were offered referral to a liver specialist. I do not recall the process for patients who were positive for the Hepatitis B Surface Antigen but were asymptomatic with normal liver function tests.

In particular:

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

As outlined above

b. What treatment options were offered over the years?

I do not recall the specific details. Interferon may have been under consideration in 1992-1994 but I do not know when it gained a product licence for this condition.

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

I did not initiate the prescription of Interferon for this clinical condition, and was not therefore involved in discussing the risks and benefits of this treatment.

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

My recollection is that any patients receiving specific treatment for HBV would have been monitored for this by their hepatologist.

67. How was the care and treatment of patients with NANB hepatitis managed at each of the centres at which you have worked at any relevant time?

I do not recall the policy in Cardiff in 1984-1989. My recollection for Manchester in 1992-1994 is that patients with Non-A Non-B Hepatitis (and subsequently Hepatitis C) infection is that that they would have their liver function tests carried out when they attended for routine clinical appointments. If there was a deterioration in liver function or clinical features of chronic liver disease developed, patients would be offered referral to a hepatologist.

In particular:

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

See above.

b. What treatment options were offered over the years?

I do not know whether patients with chronic NANB Hepatitis were offered Interferon by the hepatologist. In 1993, I approached the North West Regional Medical Officer to ask him to look at the issue of Interferon treatment for patients with bleeding disorders and chronic Hepatitis C infection and to produce a regional policy. I do not recall his response, but I ceased being acting Haemophilia Centre Director a few months later.

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

I do not recall being involved in the initiation of any specific treatments for NANB Hepatitis

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

I refer to my response to the stem of 67.

68. How was the care and treatment of patients with HCV managed at the Manchester Centre?

I refer to my response to the stem of 67.

In particular:

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

Again, my recollection is that patients with Hepatitis C infection and either symptoms or deteriorating liver function tests would be referred to a hepatologist for further evaluation.

b. What treatment options were offered over the years?

Treatment for Hepatitis C infection would have been under the care of the hepatologist

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

I refer to my response to 68b.

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

Monitoring and follow up would have been organised by the hepatologist. The patient would also have continued to be asked to attend for routine clinical (haematological) review which would usually have included routine liver function testing.

69. At the 24th meeting of UK Haemophilia Centre Directors on 18 September 1992 [HCDO0000248_013] , the results of a survey were reported by Professor Preston (item 8 b) of the minutes) and there was a discussion on the use of alpha interferon and testing for HCV. (The Inquiry understands that you became acting director of the Manchester Centre in 1992. You did not attend this particular meeting, but sent your apologies. However, the Inquiry assumes that, as acting director at the time, you would have received a copy of the minutes.)

a. The survey suggested that some centres were not discussing the results of HCV testing with their patients. What was the position in Manchester?

I do not recall the 24th meeting of the UKHCDO. Professor Preston may be able to answer question in relation to his findings. In relation to Manchester please see my response to 56.

b. Reference was made to the deaths of 341 patients and to the prevalence of chronic liver disease. Members of the UKHCDO working party were said to be particularly interested in the instance of hepatocellular carcinoma. What steps were taken at the Manchester Centre to assess and monitor patients in relation to chronic liver disease and/or hepatocellular carcinoma?

Patients with chronic liver disease would have been monitored as part of their regular follow up appointments and referred to a hepatologist if required. I do not recall the arrangements for monitoring for hepatocellular carcinoma.

What information was provided to patients about the risks of developing chronic liver disease and/or hepatocellular carcinoma?

I do not recall the specific information provided.

c. When did you begin to recommend treatment with alpha interferon for patients with HCV?

Please see my responses to 67 and 68 above.

Did you enter patients with HCV into trials with interferon, as recommended by Professor Preston?

I do not recall doing so but I have no recollection of the "trials" and have not been provided with details of these.

d. The minutes record a recommendation that patients should be tested annually for HCV. Was that recommendation followed in Manchester?

I do not recall whether patients were tested annually.

70. On 27 September 1993 you wrote the enclosed letter to Dr Horsley, the Chief Medical Officer at the North West Regional Health Authority [DHSC0002545_070]. What was your purpose in writing this letter?

I wished to make clear my feeling that there was a need for a national or at least regional policy for the management of Hepatitis C infection caused by the use of infected blood products.

What did you mean by your statement that "it is vital that the problem is actively managed"?

I wanted a decision to be made by the Regional Health Authority

Did you receive a response from Dr Horsley (if so, please provide a copy if you are able to)?

I do not recall receiving a response from Dr Horsley. I ceased being acting Haemophilia Centre Director the following year.

What "discrete sounding out of the Haemophilia Society" had you undertaken and to whom at the Society had you spoken about this issue?

I do not recall to whom I spoke. My intention was to pressurize the Regional Medical Officer to provide treatment of value for Hepatitis C for this group.

71. What arrangements were made for the care and treatment of children infected with HIV or hepatitis?

I do not recall the arrangements in Cardiff,. The Haemophilia Centre in Manchester was for adults.

How did those arrangements differ (if at all) from the arrangements made for adults?

Not applicable.

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

I do not recall any clinical trials of treatments for HIV or Hepatitis C at the Manchester Centre.

Please provide details.

Not applicable.

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

A counsellor was retained to provide support. I do not recall the counsellor's specific remit.

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

I do not recall any. Treatment for Hepatitis C would have been initiated by a hepatologist.

Records

75. What was the policy, at each of the centres at which you have worked at any relevant time, with regard to recording information on death certificates when a patient had been infected with HIV or hepatitis?

I do not recall specific policies with regard to recording information on death certificates when a patient had been infected with HIV or hepatitis in Cardiff (1984-1989) or Manchester (1992-1994).

76. At the 8th meeting of UK Regional Haemophilia Centre Directors on 10 February 1992 [HCDO0000443], which you attended, there was a discussion (at item 11) about the numbers of those infected with HIV who had died. You were recorded as welcoming the idea of an agreed policy of wording for death certificates and as stating that "the Coroner always wanted an inquest in the Manchester area".

Why did you want an agreed formula?

This would provide consistency and assist in gathering data for future analysis.

Was an agreed formula of wording for death certificates formulated and if so what was it? What did you mean by your statement that "the Coroner always wanted an inquest in the Manchester area"?

I do not recall whether an agreed formula of wording for death certificates was formulated. My perception at that time would have been that the coroner in Manchester wished to open an inquest on all deaths with diagnoses of HIV and any form of bleeding disorder.

77. What were the retention policies, as regards medical records, at each of the centres at which you have worked at any relevant time, during the time you were practising there?

I do not recall the details of retention policies for medical records either at Cardiff (1984-1989) or Manchester (1992-1994). The respective organisations may be able to provide this information.

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

No

79. 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 the centre? If so, why, what information and where is that information held now?

Only related to the GMC investigation that I previously referred to.

80. 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.

Please see my response to 79 above.

Research

81. Please list the research studies that are (or may be) relevant to the Inquiry's Terms of Reference in which you have been involved

None that I would consider is relevant to an Inquiry relating to the use of infected blood products.

and:

a. Describe the purpose of the research.

Please see my response to the stem of 81.

b. Explain the steps that were taken to obtain approval for the research.

Please see my response to the stem of 81.

c. Explain what your involvement was.

Please see my response to the stem of 81.

d. Identify what other organisations or bodies were involved in the research.

Please see my response to the stem of 81.

e. State how the research was funded and from whom the funds came.

Please see my response to the stem of 81.

f. State the number of patients involved.

Please see my response to the stem of 81.

g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent.

Please see my response to the stem of 81.

h. Provide details of any publications relating to the research.

Please see my response to the stem of 81.

82. Were patients involved in research studies without their express and informed consent?

Please see my response to the stem of 81.

If so, how and why did this occur?

Please see my response to the stem of 81.

83. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose without their express and informed consent?

My only recollection is that data was shared with the UKHCDO. I do not recall the form of consent obtained from the patients for this.

If so, what data was used and how and why did this occur?

Please see my response to the stem of 83.

84. Was patient data (anonymised, de-identified or otherwise) shared with third parties (such as UKHCDO) without their express and informed consent?

Please see my response to the stem of 83.

If so how, and why did this occur, and what information was provided to whom?

Please see my response to the stem of 83.

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

No relevant articles or studies published.

Section 6: UKHCDO

1.This covers my responses to questions 86 to 87 of the Rule 9 request in the letter to me from the Infected Blood Inquiry dated 15 July 2020

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

I attended at least one meeting of the UK Regional Haemophilia Centre Directors Committee while acting Haemophilia Centre Director at Manchester in 1992. I do not recall whether I attended any other meetings of the UKHCDO. I was not a member of any other committees, working parties or groups.

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

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

My general understanding is that the United Kingdom Haemophilia Centre Doctors' Organisation was and still is an association of medical practitioners who work within the Haemophilia Centres of England, Scotland, Northern Ireland or Wales; and have an interest in the care of people with Haemophilia or other inherited bleeding disorders.

b. How decisions were taken by UKHCDO.

I do not recall the details.

c. How information or advice was disseminated by UKHCDO and to whom.

Minutes were taken of meetings and circulated to those members who had been invited to attend. Save for this, I do not recall the policy for disseminating information .or advice between 1992 and 1994.

d. Any policies, guidance, actions or decisions of UKHCDO in which you were involved.

I do not recall.

Section 7: Pharmaceutical companies/medical research/clinical trials

1.This covers my responses to questions 88 to 97 of the Rule 9 request in the letter to me from the Infected Blood Inquiry dated 15 July 2020

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

I do not recall doing so.

89. 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.

I do not recall doing so.

90. 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 and of any financial or other remuneration you received.

I do not recall doing so.

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

No.

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

None relating to the use of Infected Blood Products.

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

No.

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

I do not recall whether specific regulations or requirements or guidelines were in place at the time (1992-1994) concerning declaratory procedures for involvement with a pharmaceutical company.

95. Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.

Not relating to the use of Infected Blood Products.

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

Not relating to the use of Infected Blood Products.

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

I did not receive any funding from pharmaceutical companies for medical research related to the use of infected blood products.

Section 8: vCJD

This covers my responses to questions 98 to 99 of the Rule 9 request in the letter to me from the Infected Blood Inquiry dated 15 July 2020

98. 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?

2003, from a statement by John Reid, the then Health Secretary. (The exact year and other details provided by a search of the British Medical Journal.)

99. Did you have any involvement in decisions as to the information to provide to patients about vCJD?

No.

If so please answer the following questions:

a. What steps were taken to put in place a process at the Manchester Centre for informing patients about possible exposure to vCJD?

Not applicable.

b. What steps were taken to tell patients of possible exposure to vCJD?

Not applicable.

c. What steps were taken to provide information to patients about the risks of vCJD?

Not applicable.

d. 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?

Not applicable.

Section 9: The Financial support schemes

This covers my responses to questions 100 to 106 of the Rule 9 request in the letter to me from the Infected Blood Inquiry dated 15 July 2020

100. 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, EIBSS) which were set up to provide financial support to people who had been infected?

I do not recall any direct personal involvement with the different trusts or funds which had been set up to provide financial support to people who had been infected.

101. To what extent, during your time at the Manchester Centre, did staff (including you) inform patients about the different trusts or funds?

My recollection is that providing information to patients was the responsibility of our Counsellor.

102. Did the Manchester Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

I do not recall a specific policy or guidelines for staff members in relation to referring patients to the trusts and funds for support.

103. What kind of information did the Manchester Centre provide to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?

I do not recall what information the Manchester Centre provided to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds.

104. Did the Manchester Centre, or any of their staff, act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.

I do not recall whether the Manchester Centre, or any of its staff, acted as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds.

105. Was the Manchester Centre or any of its staff involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.

I do not recall whether the Manchester Centre or any of its staff were involved in determining applications made by patients for assistance from the trusts or funds.

106. 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?

I do not recall and so cannot provide an opinion.

Do you consider that they achieved their purposes?

I do not recall and so cannot provide an opinion.

Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

I do not recall and so cannot provide an opinion.

Section 10: Other Issues

1.This covers my responses to questions 107 to 108 of the Rule 9 request in the letter to me from the Infected Blood Inquiry dated 15 July 2020

107. 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.

See my response to Question 4.

In 2019, I received a request from the Infected Blood Inquiry to respond to criticisms made by the widow of a (deceased) patient with haemophilia. I sent my response to the Infected Blood Inquiry in June 2019.

I do not recall any other complaints about me relevant to the Inquiry's Terms of Reference.

108. Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.

I am not aware of any other matters relevant to the Infected Blood Inquiry.

Statement of Truth

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

Signed GRO-C

Dated 12 September 2020

Table of exhibits:

DateNotes/ DescriptionExhibit number