Witness Name: Dr John Pepper
Statement No. WITN7307001
Exhibits: None
Dated: 17/10/2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR JOHN PEPPER

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 December 2021

I, Dr John Pepper, will say as follows: -

Section 1: Introduction

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

1. My name is John Robert Pepper MB BChir, FRCS, M.Chir, FESC.

2. My date of birth is GRO-C 1948.

3. My qualifications are 1980 – 1982: Consultant cardiothoracic surgeon at London Chest and Southend Hospitals.

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.

4. 1982-1990: Consultant cardiothoracic surgeon at St. George's and St. Helier's, Carshalton Hospitals

5. 1990-2022: Consultant cardiothoracic surgeon at Royal Brompton and Harefield Hospitals.

6. 1999: Professor of Cardiothoracic Surgery at Royal Brompton and Harefield Hospitals and Imperial College, London.

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.

7. 2005 - 2010 I was a member of the blood transfusion committee at RB and HH hospitals. I did not have specific responsibilities but was the surgical voice on this committee.

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 vCJD, HIV, HBV and/or HCV in blood transfusions and blood products. Please provide details of your involvement and copies of any statements or reports which you provided.

8. I have never been involved in any way in relation to inquiries, investigations or any litigation with respect to vCJD, HIV, HBV or HCV in blood transfusions or blood products.

Section 2: London Chest Hospital, St George's Hospital and Royal Brompton and Harefield Hospitals ("the Hospitals")

General

5. **Please describe:**

    a. **Your role and responsibilities at each hospital and how these changed over time;**

    b. **Your specialism in cardiothoracic surgery;**

    c. **Your work at the Hospitals insofar as it involved treating patients with blood transfusions; and**

    d. **Your work insofar as it involved the care of patients who were infected with vCJD, HIV, Hepatitis C ("HCV"), Hepatitis B ("HCV"), viruses and/or other diseases patients may have been exposed to as a result of receiving a blood transfusion.**

9. a. My roles at all four hospitals was as a clinical cardiothoracic surgeon with full responsibility for patients under my care. At London Chest and St. George's I undertook both adult cardiac surgery and adult thoracic surgery. At Brompton and Harefield, I was primarily a cardiac surgeon except for undertaking a small number of lung and heart-lung transplants. In 1986 I began a heart transplant programme at St. George's Hospital.

10. b. In 1980 I undertook all forms of adult cardiac and thoracic surgery including a very small amount of oesophageal surgery. At St. George's I undertook adult cardiac surgery and at St. Helier, adult thoracic surgery. Since 1990 the only thoracic surgery undertaken was either lung transplantation or lung volume reduction surgery. Since 2010 I stopped being a primary operator but undertook research, teaching and some administration. My speciality in cardiac surgery has been the aortic valve.

11. c. The majority of operations have included blood transfusion except for coronary surgery where since 1996 the use of blood transfusion has been very restricted by agreed protocols.

12. d. I have not been involved in the care of patients infected with vCJD, HIV, HCV, Hepatitis B or C viruses.

6. We understand that you are on the advisory board of the European Journal of Cardio-thoracic Surgery. Please describe:

a. Your role and responsibilities as a member of the advisory board;

b. Particular matters in which you have advised on, which are relevant to the Inquiry's Terms of Reference; and

c. What role, if any, the advisory board had or has in terms of the development of the standard of care and blood transfusions.

13. I was on the Council of the European Association of Cardiothoracic Surgery as Education Secretary from 2007 to 2012 but have not been on the advisory board of the EJCTS.

7. Please:

a. Describe the roles, functions and responsibilities of the Surgical department ("the Department") within these Hospitals during the time you worked there. Please also explain how the Department worked with other departments within the Hospitals, such as critical care, emergency, obstetrics and/or other units in so far as it related to blood transfusion;

b. Outline the facilities and staffing arrangements for the care of patients who needed to undergo or were undergoing blood transfusions as part of surgery; and

c. Identify senior colleagues within the Department and their roles and responsibilities during the time that you have worked there, insofar as they were involved with the care of patients undergoing blood transfusions and/or patients infected with hepatitis and/or HIV in consequence of a blood transfusion.

14. a. Two of the hospitals where I have worked have been postgraduate specialist centres for the treatment of disease of the heart and lung. St. George's hospital is, of course a general teaching hospital. In each hospital there was a blood transfusion committee which met regularly with a representative from NHS Blood Transfusion on the Committee. It was only from 2007 at Brompton that I was on this Committee. In all cases there was a Consultant Haematologist, and the chair of the Committee was a consultant intensivist and anaesthetist, Dr. Cliff Morgan, now retired.

15. b. We had specific protocols for the assessment of bleeding and for the administration of blood or blood products both at Brompton and Harefield Hospitals. My only activity at Harefield was transplantation which always occurred outside of normal working hours.

16. c. I have identified the Chair of the Committee above. The Consultant Haematologist was Dr. John Burman retired for the last 15 years.

8. Please describe the practical steps that were taken when you decided that a patient required a blood transfusion. If this process changed over time, please set out relevant time periods and describe:

a. How blood was requested from the Hospitals' blood bank;

b. What the record keeping requirements were;

c. The consent process, including the information, if any, the patient was given before the transfusion; and

d. How, if at all, the consent process was documented.

17. It is not possible for me to answer this question with any accuracy as I have not been involved in acute care since 2010. However, I do know that the hospitals (RB and HH) continue to adhere to strict protocols and much energy is exercised in ensuring traceability of blood and blood products. This is subject to regular national scrutiny of which you will be well aware.

9. Did you have, on behalf of the Department, a relationship with the Regional Blood Transfusion Centre? If so, please describe that relationship.

18. I am unable to answer this question.

10. Did you have, on behalf of the Department, a relationship with the National Blood Transfusion Service ("NBTS")? If so, please describe that relationship.

19. I am unable to answer this question.

11. How many patients per week would receive a transfusion under the care of the Department? If you are able to give exact rather than approximate figures, please do so.

20. I am unable to answer this question.

12. Were you aware of any patients who subsequently developed HIV, HCV or HBV under the care of the Department? If so, how many patients were infected? If you are able to give exact rather than approximate figures, please do so.

21. I am unable to answer this question.

Research

13. We understand that you are currently the head of surgical research at the Royal Brompton and Harefield Hospitals. Please describe:

a. When you were made head of surgical research;

b. The role and responsibilities of this position; and

c. The research you have undertaken in this position in so far as it related to blood transfusion and/or matters covered by the Inquiry's Terms of Reference.

22. a. I was made head of surgical research in 2010. An additional person was appointed as head of all clinical research and development, Professor Tom Luescher, consultant cardiologist, in 2018.

23. b. I am responsible for the running of the Research Services Unit which exists to assist clinicians in obtaining the funding for studies, to assist in the running of such studies and to ensure that all ethical and governance rules are closely followed. I have been very ably assisted in this role by an Associate Director of Research. Since 2021 and the merger with Guy's Thomas' (GSTT) these positions have changed with control exercised by Dr. Andrew Menzes-Gow, Consultant Chest Physician at Royal Brompton.

24. c. I shall be retiring in March 2023.

14. We understand that you are currently the interim director of research for the Royal Brompton and Harefield Hospitals. Please describe:

a. **When you were made interim director;**

b. **The role and responsibilities of this position; and**

c. **The research you have undertaken in this position in so far as it related to blood transfusion and/or matters covered by the Inquiry's Terms of Reference.**

25. I am not the interim director.

15. Was any research undertaken within the Department regarding blood transfusion patients?

a. **If so, please explain what the research entailed, what the aims of the research were, whether patients were informed of their involvement in the research and whether consent was obtained;**

b. **What, if any, involvement did you have in this research?; and**

c. **Please provide details of any publications relating to the research.**

26. Many comprehensive audits have been undertaken regarding blood transfusion. These were masterminded by Dr. Andrea Kelleher, Consultant Anaesthetist, now retired. There have been no specific research projects during my tenure.

16. Please list all research studies that you were involved with in any other relevant positions of employment, insofar as relevant to the Inquiry's Terms of Reference, ensuring your answer addresses:

a. **What the research entailed, what the aims of the research were, whether patients were informed of their involvement in the research and whether consent was obtained;**

b. Your involvement in this research; and

c. Details of any publications relating to the research.

27. In an appendix I attach the research studies in which I have been centrally involved. These were controlled clinical trials run with the assistance of Research Services. Other publications are also attached, since 2000..

Section 3: Policies and practices regarding blood transfusions

Committees and Groups

17. Was there any Hospital Transfusion Committee at any of the Hospitals at which you have worked? If so:

a. Please provide a brief overview of the Committee, including when the Committee was created, its roles and responsibilities at the Hospitals, and its relationship with the Hospitals' Surgical Department; and

b. Please outline any significant policies or practices related to blood transfusion established by the Committee.

28. As I have already mentioned there was a Hospital Transfusion Committee as Brompton and Harefield Hospitals. I am quite sure that similar committees existed at St. George's, under the direction of the Consultant Haematologist, but I am not aware of the details. I cannot at this distance in time give any further details above what I have already provided in the previous sections These details could be obtained from the current director of the Cardiac Division, Dr. Vias Markides.

18. Please outline the extent to which any of those Committees were involved in the following matters:

a. Awareness of national guidelines for promotion of good transfusion practices;
b. Development of local hospital guidelines;
c. Transfusion policy induction procedure for new staff;
d. Review of nursing procedures for administration of blood products;
e. Promotion of new information regarding transfusion matters;
f. Ensuring patients are adequately informed of matters, such as availability or alternative treatments;
g. Blood transfusion record keeping and documentation;
h. Review and notification of post transfusion complications (included adverse reactions and transfusion associated infections);
i. Assessment of transfusion practices in light of product usage; and
j. Consent for blood transfusion.

Please ensure your answer includes any significant policies, guidelines, decisions relevant to blood transfusion practices or blood safety that were proposed, created, implemented and/or overseen by the groups.

29. When I was a member of the Transfusion Committee (2007 – 2012) at Royal Brompton and Harefield Hospitals all of the items a to j were actively dealt with and subjected to scrutiny both internally and externally. As it is 10 year since I served on this Committee it is not possible to give you the detailed answers you require.

19. Please identify any significant policies created by those groups / committees in which you were involved, insofar as relevant to the Inquiry's Terms of Reference. Please describe the reason for and impact of the policies, and the extent of your involvement.

30. Please refer to my comment to question 18 above.

Approach to transfusions

20. Please outline, during your career as a surgeon, the approach by the Hospitals in relation to blood transfusions. Were they considered to be an emergency procedure or a necessary component of surgery?

31. For most of my career as a cardiothoracic surgeon and since 1990 as primarily a cardiac surgeon, blood transfusion was considered as a necessary component of surgery. It was in 2004/5 that we abandoned the routine cross-matching of blood for elective, first time, straightforward, isolated coronary artery bypass surgery and this has continued, as far as I am aware, to the present. Over a period of about 4 years in which audits of blood usage were carefully undertaken we realised that blood products were rarely given after routine elective, first time, isolated coronary bypass surgery. The cost of a unit of blood was rising and comprised a significant part of the Department of Haematology's budget. This was the primary concern which drove us to avoid the unnecessary cross-matching of blood.

21. We note that you specialise in cardiothoracic surgery, namely diseases of the aortic valve and thoracic aorta, and aortic disease. To what extent is there a risk of significant bleeding in such surgeries, making a blood transfusion necessary?

32. In operations on the aorta and aortic valve, blood transfusion is usually required if one of the following conditions is present: an emergency procedure, eg. dissection, redo procedures, infective endocarditis, and operations involving replacement of the arch of the aorta. For the first time elective aortic valve replacement blood transfusion is seldom required. The recent introduction of minimal invasive valve surgery has made blood transfusion an uncommon event.

33. Minimal invasive valve surgery began slowly in the mid-1990's and became more popular in the UK by late 2000. The rationale was part of a larger drive to reduce the morbidity of heart surgery. The mortality of open heart surgery, which at its inception in 1960 was high, had fallen to less than 5% for most elective procedures. The focus was now to "soften the blow". The techniques for minimal invasive surgery require special training and to this day not all surgeons have adopted this. But in experienced hands minimal invasive valve surgery works well, the recovery time for the patient is quicker and there is less use of blood products. If a complication occurs it is more difficult to deal with than after traditional mid-line sternotomy (division of the breast bone). There have been no large randomised trials to compare minimal invasive versus traditional sternotomy operations, partly because such trials are very expensive and difficult to set up and partly because there are several different types of minimal invasive techniques.

22. We note that you are the clinical lead for acute aortic dissection in the North West Thames area. To what extent is there a risk of significant bleeding in such surgeries, making a blood transfusion necessary?

34. Acute aortic dissection is a serious emergency with a mortality, untreated of 1% per hour. Blood transfusion is always required because the ascending aorta has usually ruptured.

23. **Please outline at which level generally a patient's haemoglobin count would be considered low and thus require a blood transfusion. Please also explain how the level at which transfusion was deemed necessary may have changed over time. You may find the discussions within NHBT0004029_005 of use.**

35. I cannot add significantly to the discussions within your NHBT reference. As a rule, we do not transfuse unless the Hb is below 9g/dl, but this is a broad figure and there will be exceptions, for example patients with polycythaemia. This figure was reached after extensive systematic review of the literature and discussion at the Transfusion Committee.

24. Please outline the types of blood and blood products that were most commonly transfused to patients under your care and how this changed over time.

36. Back in 1980 blood transfusion was the standard practice supplemented by FFP and platelets in severe conditions. This practice has continued but what has changed is the introduction of glues and solvents to reduce the bleeding from raw surfaces and the availability of specific coagulation factors for rare problems such as Factor VIII deficiency. The results of the titre trials led by Professor Gavin Murphy have also been studied carefully.

25. During surgery, were preferred types of blood used for specific procedures? Please provide details of which procedures, if any, and how they were individually managed.

37. In recent years there has been much less whole blood transfusion, but reliance on blood products with packed cells often given after the acute event. In the case of acute dissection and trauma blood transfusion remains the mainstay. I have outlined procedures where blood products are likely to be required in question 21 above.

26. Was there a minimum number of units of blood transfused to patients pre-surgery, during or post-surgery? Did units of transfusions vary accordingly?

38. It is very unusual to give blood transfusions to cardiac patients before operation as fluid overload is often their main problem. We did not have a minimum number of units.

Policies and practices

27. To the best of your knowledge, was guidance provided to you and/or other medical professionals by the Hospital as regards transfusion

policies and practices during your employment? If so, please outline in as much detail as possible the policies in place which would prompt you to transfuse in the course of cardiothoracic surgery. If applicable, please ensure your answer addresses treatments throughout the 1970s and 1980s at any institution you worked at.

If possible, in your answer please refer to:

a. **how many units of blood would be used;**
b. **alternative treatments, including the option not to transfuse at all;**
a. **autologous transfusions within cardiothoracic surgery;**
c. **applicable haemoglobin threshold levels for transfusion;**
d. **adverse reactions or infection risk; and/or**
e. **resource and cost considerations.**

39. During the 1970s as a trainee there was minimal official guidance as regards blood transfusion and it was left to the consultant in charge of the patient. In the 1980s this began to change rapidly in my speciality of cardiothoracic surgery. Blood Transfusion committees formed were usually chaired by a clinician with representation from all acute branches of medicine and haematology. I think Brompton was ahead of its time as in the 1990's onward as we always had a senior person from NHSBT in attendance which was very valuable. We learned that there were a range of extremely rare complications which included bacterial infection. Prevention of the transmission of viral hepatitis was the main concern.

28. **In relation to alternative treatment to blood transfusions, during the period you worked at the Hospitals:**

a. **In your view, were the advantages and disadvantages of alternative treatments adequately explained to patients where possible?;**

b. Did the doctor/patient relationship have an effect on the way in which an agreement would be reached in selecting a treatment? If so, please explain that effect;

c. Did any aspect of this change over time?; and

d. Do you consider that alternatives could have been used in preference to blood transfusions so as to reduce the risk of infection? If not, why?

40. The issue of blood transfusion was always discussed with each patient at the time of obtaining written consent for operation. In the case of Jehovah Witnesses we developed a 60-page document. It was very unusual for a patient prior to 2010 to refuse a blood transfusion apart from on religious grounds. This was a Trust-generated document developed at the Royal Brompton and Harefield Hospitals. These two hospitals are, since April 2021, part of GSTT, Guys StThomas' Trust. I suspect most trusts have developed their own JW documents. You would need to contact a senior manager to obtain this.

41. As I have mentioned above we have had extensive experience in the use of glues and adhesives to reduce bleeding especially in complex redo procedures.

29. When comparing cardiothoracic treatment and transfusions of adults and children, were specific policies or guidelines implemented? If possible, please provide examples.

a. Please describe how retrograde autologous priming differs between adults and children if this technique was used by yourself or the Hospitals;

b. If changes were implemented, when did this occur?; and

c. Were policies regarding child transfusions national guidelines or, in your experience, did they vary?

42. I have not undertaken surgery on children so cannot comment on this section. In adult practice in the 1970's it was not unusual to extract a unit of blood during the early part of the operation in order to replace it with all its coagulation factors when the patient had been weaned off cardiopulmonary bypass. By the mid-1980's this practice had fallen out of favour because of concerns over sterility and the emergence of the glues and adhesives already mentioned.

43. I do not recall a particular case where this procedure caused infection but after a lot of argument it was stopped. There were no good publications at the time. This was clinical practice in a few specialist heart hospitals which fell out of favour for the reasons I have stated.

30. **What policies were put in place when performing surgical transfusions in elderly patients, who were at a higher risk? Did they require a more restrictive approach to transfusions?**

44. Specific policies with regard to elderly patients and transfusion did not occur to my knowledge in cardiac surgery. The emergence of coronary stenting and more recently of transcutaneous valve implantation has led to almost no patients over the age of 90 being offered surgery and most 80 year olds choosing the non-surgical option.

31. **The enclosed document reports on a study conducted by Mallet et al (2000) titled 'Reducing red blood cell transfusion in elective surgical patients: the role of audit and practice guidelines', published in Anaesthesia [NHBT0086594_003]. The study found that 'haemoglobin was measured infrequently prior to transfusion' (p1). With respect to your experience at the Hospitals you worked at, please explain the process of measuring a patient's haemoglobin count, including the frequency with which it was monitored.**

45. In cardiothoracic surgery a full blood picture and electrolyte screen together with a coagulation are performed within a week of the operation and often 24 hours beforehand. Postoperatively the blood count is measured on POD 1 and 3 and usually 5 before the patient is discharged.

32. Please consider the enclosed guidelines for blood transfusion and the management of transfused patients produced in 1999 in collaboration with the Royal College of Surgeons of England [AHCH0000049]. Were any of these recommendations implemented during any institution at which you have worked, either before or after the publication of this document?

46. At Brompton and Harefield most of the 1999 guidelines were being followed in 1996.

33. In your experience at any of the institutions at which you have worked, did any particular blood products or transfusion methods carry a higher risk of viral infection?

47. No particular blood products or transfusion methods carried a higher risk of viral transmission.

34. What policies were in place pre-transfusion during surgery?

a. Were patients informed there would be a possibility of a transfusion?; and

b. What patient evaluations were in place at the hospitals you worked at?

48. In cardiac surgery, since its inception, the question of blood transfusion was invariably discussed with patients prior to operation. Consent is a process which for elective patients starts in the out-patient clinic and finishes when the

consent form is signed before the operation. One of the complications routinely discussed in the setting of open heart surgery, is the possibility of bleeding and the need for transfusion.

35. Please discuss the relationship between preoperative, intraoperative, and postoperative anaemia and the outcomes of cardiac surgical procedures.

a. To what extent did preoperative anaemia pose a significant risk to patients?; and

b. Can you elaborate on how transfusions differed between preoperative, intraoperative, and postoperative patients with anaemia, to those who did not have anaemia.

49. The literature on anaemia in patients listed for cardiac surgery is complex and unclear. In the centres where I have worked this has become more of a problem in recent years because of the spread of vegetarian and vegan diets. We have adopted a general policy of correcting anaemia before operation if the Hb level is less than 9g/dl in an elective patient. We have a system led by specific nurses to administer IV iron according to a strict protocol.

36. What were the different preoperative policies regarding transfusions given to severe anaemic or slight anaemics in cardiac surgery?

50. This is answered in question 35 above.

37. How common were blood transfusions managed on patients who were reoperated for cardiac surgery?

51. Blood transfusions were and are the norm for patients undergoing redo cardiac surgery. These are normally given in the form of blood products rather than full blood.

Red cell concentrates

38. What considerations were made by the Hospitals for the use of red blood cell concentrate transfusions? In particular:

a. In what circumstances would red blood cell concentrate transfusions be considered necessary, and if applicable, necessary over other blood components?;

b. Approximately how often this practice occurred;

c. The perceived benefits and/or risks of red blood cell transfusions known to the Hospitals and how this changed over time;

d. Any measures taken by the Hospitals to minimise the risk of infection, including post transfusion testing;

e. The process for obtaining informed consent and informing patients or their relatives of the risks associated with red blood cell concentrate transfusions; and

f. How many units of red cell concentrates would be administered in one sitting to one patient, and what factors would be taken into account in determining this amount?

52. It is difficult for me to answer these specific questions at a 12-year distance from acute medicine and surgery. We normally consider packed cell transfusions when the post-operative Hb on POD 2 is less than 9g/dl. It usually takes 24 hours after surgery for the total blood volume of the patient to approach normality due to the dilution effect of the prime (1.5 litres balanced salt solution) in the heart-lung pump. Open heart surgery is achieved by attaching the anaesthetised patient to a heart-lung machine for 1 to 4 hours

depending upon the complexity of the procedure. The machine consists of a pump to take over the function of the heart and an oxygenator to insert oxygen (O2) and remove carbon dioxide (CO2), the normal function of the lungs. The device involves plastic tubing connected to the heart of the patient. Obviously this tubing needs to be primed with fluid which is done with 1.5 litres of balanced salt solution.

39. Were guidelines circulated to surgeons concerning the use of red cell concentrate? If so, did the usage pattern of red cell concentrate change as a result of these guidelines? If not, why were guidelines not provided?

53. Guidelines are given to surgeons and anaesthetists and intensivists regarding the use of red cell concentrates. These matters are under constant review both at the Transfusion Committee and the "Quality & Safety Committee" which meets 10 times per year.

Platelets

40. Please consider [NHBT0113679_002]. In particular, the concern that platelet concentrate "which is used to treat bleeding in patients", was being administered without full testing. Please outline:

a. Whether you used platelet concentrates to treat patients;

b. How often patients would require a transfusion of platelet concentrates;

c. Whether full testing was undergone before administering platelet concentrates;

d. How you or the Hospitals knew, or could have known, whether the platelet concentrates being administered to patients had undergone full testing;

e. **The perceived benefits and/or risks associated with platelet transfusions known to the Hospitals;**

f. **How many units of platelets would be administered in one sitting to one patient, and what factors would be taken into account in determining this number; and**

g. **Was there ever any difficulty in obtaining platelets?**

You may wish to consider [BSHA0000031] when answering questions regarding platelets.

54. a. We do use platelet concentrates

55. b. It was used mainly in redo procedures

56. c. Since 1990 in my experience some form of platelet testing is always used.

57. d. The testing is done both in the transfusion lab and in theatre from a dedicated blood trolley in theatre which contains all the necessary reagents. Near-patient testing has been a mantra in our hospitals.

58. e. We would usually give 1 unit of platelets only as we are aware that each unit involves 6 donors and so the chance of infection is increased. We have had excellent relationships with NHSBT and we have always been able to obtain platelet concentrates eventually.

Single Use Transfusions

41. **Please consider the enclosed document on the use of single unit transfusions of blood in the UK [DHSC0035471], which discusses concerns about unnecessary single unit transfusions of blood in the UK.**

a. **With reference to your experience at any of the institutions at which you have worked, please outline in what circumstances single-unit and two-unit transfusions were administered to patients. Please describe how, if at all, the position changed over time;**

b. **What did you understand to be the risks and benefits of single-unit transfusions or lower unit transfusions? How, if at all, did this understanding change over time?; and**

c. **Do you recall any instances or periods of time in which you or others raised concerns about unnecessary single unit blood transfusions? If so, please explain in as much detail as you are able to.**

59. I have no experience of single unit transfusions.

Autologous transfusions

42. **Please explain your knowledge and experience of autologous blood transfusion, including: the circumstances in which it was considered appropriate and any benefits or risks as compared to other methods of transfusion. You may be assisted by the enclosed document [NHBT0110350].**

a. **The circumstances in which autologous transfusions were considered necessary or beneficial;**

b. **Approximately how often this practice occurred;**

c. **The perceived benefits and/or risks of autologous transfusions; and**

d. The process for informing patients or their relatives of any risks associated with autologous transfusions.

60. I have already dealt with this above. It is a practice which died out in the 1980s.

43. To the best of your knowledge, if a patient had preoperative and intraoperative autologous blood donation, was the likelihood of allogeneic blood requirement in cardiac surgery reduced?

61. There was no likelihood.

Fresh Warm Blood

44. The Inquiry has received evidence that on rare occasions when a blood transfusion was needed urgently, fresh warm blood donated by hospital staff was administered to patients. To your knowledge, did this practice occur at any of the institutions at which you have worked? If so, please explain in as much detail as you are able to, ensuring your answer addresses:

a. The circumstances in which fresh warm blood transfusions were considered necessary;

b. Approximately how often this practice occurred;

c. The perceived benefits and risks of fresh warm blood transfusions (you may wish to refer to NHBT0000037_013);

d. Any measures taken to minimise the risk of infection, including assessing donor suitability and post transfusion testing; and

e. The process for obtaining informed consent and informing patients or their relatives of the risks associated with fresh warm blood transfusions.

You may also wish to refer to NHBT0072688.

62. The practice of fresh warm blood did occur during my training days in the late 1970's but had stopped by the time I became a consultant in 1980. It happened rarely perhaps 3-4 times in a year in extreme conditions when no surgical bleeding source could be found and the patient was deteriorating. It always occurred in the operating theatre when the chest was still open. I am uncertain whether this was ever discussed with the patient.

Other

45. During Parliamentary questions on 10 December 1985, Mr Hayhoe stated that 'supplies of whole blood are not imported since the United Kingdom is self sufficient in its needs for blood for transfusions; it is only certain blood products which are imported' [HSOC0018830]. To your knowledge, during your tenure at any of the institutions at which you have worked, were you aware of patients being given blood transfusions with red blood cells imported from the USA or any other country? If so, was there any concern about its use at the time?

63. During my career I am not aware in any of the hospitals where I have worked, of blood from the USA or any other country being used in a transfusion.

<u>Section 4: Knowledge of risk</u>

General

46. During your training at medical school, what was your understanding of the risks of blood-borne infections from blood transfusions? Please outline this in relation to your experience at each of the Hospitals.

64. As a medical student in the 1960's this was mentioned. It came to the forefront when I decided on a surgical career and attended courses for the

primary and Final FRCS. As a consultant it has become more prominent over the last 40 years of my career.

47. When you began working as a surgeon, what did you know and understand about the risks of infection associated with blood transfusions? What were the sources of your knowledge? How did your knowledge and understanding develop over time? Please include details of both past and present hospitals you have been employed with.

65. I have answered this in 46 above. There was very little in surgical textbooks but I learned about it from looking after patients on the ward and speaking to blood transfusion technicians at all times of day and night!

48. What were you taught during your training about when a transfusion should be given? Please apply this to your postgraduate training in cardiothoracic surgery and training once qualified.

66. Specific guidelines about blood transfusion did not occur during my training. But as I have already mentioned I gained an understanding from working on ICU and frequent communications with technicians in the transfusion laboratory.

Hepatitis

49. What was your knowledge and understanding of the risks and transmission of hepatitis, including HBV and HCV from blood transfusion? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

67. My first housejob (F1) was on a vascular service where renal transplants were also undertaken. I also looked after renal A/V shunts in the forearm. I had very close contact with an excellent renal unit and two of my friends developed hepatitis while working on that unit. I escaped but learned a great deal about hepatitis at that time. Subsequently Hep C came and was lethal Now we have

effective vaccines and it is mandatory before entering theatre for any reason to have an adequate HepB vaccination history.

HIV and AIDS

50. When you began work as a surgeon, what was your knowledge and understanding of HIV and AIDS and in particular of the risks of transmission through blood transfusions? How did that knowledge and understanding develop over time?

68. Until 1984 I had almost no knowledge of HIV and AIDS. I was at St.George's at the time and an excellent course was constructed which provided vital information. Since then I have tried to keep up with the literature relying on the New England Journal of Medicine.

Other

51. If you were responsible for making decisions and actions on behalf of the surgical department or any other departments in response to any known or suspected risks of infection, please explain what decisions and actions were involved. If applicable, do you consider that those decisions were adequate and appropriate? If so, why? If not, please explain what you believe could or should have been done differently.

69. I have not been in such a position.

<u>Section 5: Treatment of patients</u>

Provision of information to patients

52. Were you involved in discussions with patients regarding risks of infection by blood transfusion? If so, what information did you provide or cause to be provided to patients under your care about those risks prior to treatment commencing?

70. I have not been involved with patients regarding risks of infection, because this was usually handled by the anaesthetist, who was the person who would be administering the blood. We have had 6 monthly information days and the question of transfusion risk has arisen at that time. We had the haematologist available to give in depth answers.

53. Prior to treatment being started, what, if anything, were patients being told about the likely risks and/or side effects of transfusion? In surgeries that posed a higher risk of bleeding, such as cardiothoracic surgery, were the risks of infections from transfusion clearly considered and communicated?

71. It is only in the last 10 years that the risks of transfusion have been discussed routinely with patients prior to operation. This has been prompted partly by the patients and partly by the availability of easy to understand summaries by our Trust.

54. To what effect did restrictive patient blood management ('PBM') impact transfusions given to patients? Did you apply more restrictive PBM policies in order to reduce risk?

72. We have applied PBM in our transfusion policy but the impact has not been significant. We do continue to apply PBM but in cardiac patients we do not want to be more restrictive. We apply PBM cautiously because we do not want to allow the haemoglobin (Hb) level to fall too low. As you know Haemoglobin is a complex molecule inside red blood cells which is able to carry oxygen and deliver it to the tissues of the body. Our patients are often ill with heart failure before operation so as a general rule, we do not want the Hb level to fall below 90g/dL (normal range 120 to 140g/dL).

55. If the nature of provision of information changed over time during your employment as a surgeon. Please explain what changes occurred, and the reasons for any such change/s.

73. I have dealt with this in question 53 above.

56. How, if at all, did a patient's infectious status (including HIV, HBV and HCV) affect their treatment and care, if at all, as regards blood transfusion in surgery?

74. I have not been involved in operations on such patients.

Adverse reactions

57. Did any of the Hospitals have any procedures in place to ensure patients reported any adverse reactions or symptoms? How, if at all, did this change over time? Please explain:

a. What procedure did the institutions at which you worked have in place?;

b. Did this procedure extend to after a patient had been discharged from hospital?;

c. Were patients asked to report any adverse reactions or symptoms within a certain timeframe?;

d. If clinicians were informed and/or became aware of a patient having suffered any adverse reactions or symptoms, who were they required to report this to?;

e. Was there any mechanism for the Hospitals to report any adverse reactions or symptoms to the Regional Transfusion Centre?; and

f. In the event of a patient's death after receiving a blood transfusion, what process was followed? Specifically, in relation

to the registration of the death and/or any consideration of what was recorded on the death certificate.

75. All the hospitals in which I have worked had procedures in place to ensure that adverse reactions were recorded. Today this would be reported as a SI.

76. a. Full report to be sent to the Medical Director.

77. b. I do not think so.

78. c. Patients were asked to report in hospital but not from home.

79. d. To the medical director.

80. e. I am not aware of the mechanisms prior to 1990 but that does not mean that they were not in place. At RB/HH the regional Transfusion Centre was always informed.

81. f. I have not seen a death after receiving a blood transfusion so I cannot comment.

58. Did the institutions at which you worked have a process of informing patients that they had been, or might have received infected blood through a transfusion? If so, how were patients and/or their relatives informed? What, if any, involvement did you have in this process?

82. I am ignorant of this process but am sure that patients were informed and visited by the Consultant Haematologist.

59. At any of the institutions at which you have worked, were you involved in any efforts made to trace potentially infected donors or recipients of infected blood transfusions? If so, please explain these processes, the findings, and the impact they had on blood transfusion standards and practice.

83. I have not been involved in any tracing of potentially infected donors.

Consent

60. Were blood samples taken from patients at the Hospitals and if so, for what purposes? Was this information shared with patients? Was patient consent recorded and if so, how and where?

84. Many samples were taken from patients at the hospitals where I have worked. No written consent was obtained but they were asked so verbal consent did occur. Occasionally a patient refused to give a blood sample and so it did not occur at that time but a subsequent conversation to persuade a change of mind did take place.

61. Are you aware if patients at the Hospitals were treated with blood transfusions without their express or informed consent? If so, how and why did this occur?

85. I am not aware that elective blood transfusions were given without consent. Of course, the situation is quite different for unconscious patients in extremis. However, we have strict protocols for the delivery of blood products.

Other

62. Were any audits or surveillance programmes regarding the use of blood transfusions in surgery conducted? If so, please explain these processes and the impact they had on blood transfusion standards and practice.

86. From 1996 to 2000 several audits of blood usage took place and this led to patient protocols for assessment of bleeding and for the use of blood products in our trust. There have been modifications since, but now no patient receives a blood product transfusion without it being given according to protocol.

63. And were any audits carried out to assess the use of blood by other departments?

87. This question has already been answered with respect to surgery and it occurred in ICU as well. There were no other relevant departments.

Section 6: vCJD

64. When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood transfusions? Please explain how your knowledge developed over time.

88. I became aware of this by attending Grand Rounds in the 1990's in St. George's Hospital and later from many meetings at Brompton.

65. Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so, what steps were taken/put in place in the Surgical Department at the institutions at which you worked for informing patients about the risks of or possible exposure to vCJD?

89. I have not been involved in decisions regarding transfer of information to patients.

66. What measures were put in place in relation to the care and treatment of patients in light of the risk associated with vCJD transmission by blood transfusion?

90. This is well documented and there are procedures but I cannot recall the details.

67. What measures were put in place from a public health perspective at the institutions at which you worked in relation to the care and treatment of

patients in light of the risk associated with vCJD transmission by blood transfusion?

91. There was a large publicity campaign within the two hospitals. It was part of the induction programme for junior staff.

68. Please outline the extent to which any of those committees were involved in assessing and managing the risk of vCJD transmission by blood transfusion.

92. The transfusion committee was closely involved in compiling hospital guidelines and disseminating information to all staff in both hospitals.

Section 7: Other Issues

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

93. I have not had any complaints made about me.

70. 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.

94. I have no other details relevant to this inquiry.

71. In addition to any documents exhibited in support of your statement, the Inquiry would be grateful to receive copies of any potentially relevant documents you possess relating to the issues addressed in this letter.

95. I have appended the research papers mentioned above.

Statement of Truth

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

Signed GRO-C

Dated 17th October 2022