Witness Name: Professor John Brennan
Statement No.: WITN7095002
Exhibits: WITN7095003 - WITN7095006
Dated: 17/6/22

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF PROFESSOR JOHN BRENNAN, ON BEHALF OF LIVERPOOL UNIVERSITY HOSPITALS NHS FOUNDATION TRUST

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

I, Professor John Brennan, will say as follows: -

Section 1: Introduction

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

1. My name is Professor John Brennan (DoB GRO-C 61, of GRO-C GRO-C). My professional qualifications are MD, FRCS and I am currently employed as the Interim Medical Director at Liverpool University Hospitals NHS Foundation Trust (the Trust").

2. Please set out your current role at Liverpool University Hospitals NHS Foundation Trust and your responsibilities within that role.

2. As Interim MD I am the senior doctor in LUHFT and as such sit on the Executive Team and Trust Board. In conjunction with the Chief Nurse my principal role is to ensure the delivery of safe and effective care to the Trust's patients.

3. Please explain how you came to be appointed to the role.

3. I was appointed into the Interim role in October 2021 by the Interim Chief Executive following major changes within the Exec Team in Aug/Sep 2021 which occurred following the publication of the Trust's CQC report in Aug 2021.

4. 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. I was appointed as a Consultant Vascular Surgeon to the Royal Liverpool Hospital in Aug 1997 and became Clinical Director for Vascular in 2006. I oversaw a process of Vascular reconfiguration in Merseyside, which resulted in the creation of the Liverpool Vascular & Endovascular Service (LiVES) in Sep 2012 and continued as CD until 2017. I was reappointed as CD for Cardiovascular Services in Apr 2019 and then following merger of the Trust's in Liverpool in Oct 2019 I was appointed as Divisional Medical Director for Surgery, commencing in post in Feb 2020. I continued in this role until appointed to the Interim MD role.

Section 2: Hospital Transfusion Committee history, structure & relationships

5. As part of the Inquiry process a thorough search has been undertaken into locating all documents that are relevant to the Inquiry. Unfortunately due to the passage of time, and the lack of electronic records held at the time, it has been an extremely difficult exercise to undertake. The Trust has therefore been unable to locate and provide documentation relating to a number of the questions raised by the Inquiry below.

6. As part of the Inquiry process the Trust has also obtained external legal advice from its solicitors; Hill Dickinsons. The advice received was to provide as much

documentation as possible, but concentrating on the improvements made by the Trust since this time and clarifying the process around the HTC as it operates now. As indicated above, due to the passage of time, the documentation has been difficult to locate and so the witness statement hopes to provide assurance on the Trusts processes now in place.

5. The Inquiry understands that the establishment of HTCs was being recommended as early as 1983, according to the proposal of Dr F. A. Ala [NHBT0016083_003]. Please provide details of the following:

- ***a. When the HTCs at the Hospitals were established;***
- ***b. Who established the HTCs and who the first Chair was;***
- ***c. Why the HTCs were established;***
- ***d. What the initial aims of the HTCs were when they were established;***
- ***e. Before the establishment of the HTCs, how the Hospital monitored transfusion practice.***

7. The Trust is aware from the Inquiry's letter to Sir David Dalton, dated 17 December 2021, that the establishment of Hospital Transfusion Committees (HTCs) was being recommended as early as 1983. Due to the passage of time the Trust does not hold any information regarding the details requested at question 5 (a-e) which relate to the establishment of HTCs.

6. Please explain the composition of the HTCs at the Hospitals including staff, positions and areas of specialty. Please explain if the composition has changed since the HTCs were established. You may wish to refer to [AHCH0000014], specifically the recommended membership.

8. The Trust currently has in place a Hospital Transfusion Committee and I have appended to my statement a copy of the Terms of Reference (WITN7095003) in place which includes the following membership:
    - Chair of Hospital Transfusion Committee (Chair)

- Consultant Haematologist with Responsibility for Transfusion (Deputy Chair)
- Transfusion Practitioners
- Liverpool Clinical Laboratories (LCL) Transfusion Services Lead
- Transfusion Laboratory Manager – Royal Liverpool/BGH Sites
- Transfusion Laboratory Manager – Aintree Site
- Haematology Laboratory Manager – Broadgreen Site
- Blood Sciences Quality Practitioner, Liverpool Clinical Laboratories
- Head of Clinical Education
- Director of Patient Safety
- Chief Nursing Information Officer
- Deputy Divisional Medical Directors (Governance & Quality) (x5)
- NHS Blood & Transplant Representative (Patient Blood Management Practitioner or Customer Services Manager)
- Divisional Director of Nursing (x5)
- Clinical Effectiveness and Audit Representative
- Governance and Risk Lead

7. The Inquiry understands that the roles, functions and responsibilities of HTCs were recommended to include:

a. ***Awareness of national guidelines for the 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 transfusion matters, such as availability of alternative treatments;***
g. ***Blood transfusion record keeping and documentation;***
h. ***Review and notification of post transfusion complications (including adverse reactions and transfusion associated infections);***

i. ***Assessment of transfusion practices in light of product usage; and***

j. ***Consent for blood transfusion.***

You may wish to refer to BCUH0000060 for assistance (See BCUH0000028 for a later, non-draft version of this document. Note this version is incomplete). What roles, functions and responsibilities did the HTCs carry out from the date established? Please also include any other functions not mentioned above.

9. The Terms of Reference at WITN7095003 outlines the roles, functions and responsibilities of the HTC. Due to the passage of time the Trust does not hold any information regarding the details roles, functions and responsibilities of the HTC when it was first established.

8. An Irish discussion document on Blood Safety and Self-Sufficiency: An agenda for the European Community from 1996 [DHSC0001926] notes 'The hospital transfusion committee can provide an ongoing assessment of the use of blood and blood products as well as introducing recommendations in order to promote the highest standards of patient care. The responsibilities of these hospital transfusion committees, where they exist are unclear and to whom they report'. Was this also the position at the Hospitals? Do you think this is a fair assessment of the HTCs? Please explain your answer.

10. The Trust is unable to provide evidence on previous reporting structures. However the Trust revised its operating model and governance structures from January 2022. The Trust's HTC will report to the Clinical Effectiveness Group chaired by myself as the interim Medical Director.

9. In a Penrose Inquiry Submission by NHS Scotland [STHB0000864, page 13], it is noted that 'Hospital transfusion committees were formed to create an interface between the laboratory as provider and the clinicians as users of blood and blood products. Their success was limited due mainly to the lack of clinician input. This problem, to a greater or lesser extent, remains today'. Was

this also the position at the Hospitals? Do you think this is a fair assessment of the HTCs? Please explain your answer.

11. The Trust is unable to comment on the success of previous HTCs; however it is fair to state that challenges with clinical input are experienced. The Trust is seeking a new Chair of the HTC and one of their responsibilities will be to galvanise clinician engagement.

10. The Inquiry understands that it was recommended by certain Regional Transfusion Centres that HTCs should meet quarterly. Please confirm how often the HTCs met and if this changed over time. You may wish to refer to [NHBT0016084_001].

12. The Trust is unable to provide evidence on how often previous HTCs have met. The Trust can confirm that the current HTC aims to meet monthly as stated in the Terms of Reference (WITN7095003).

11. The Inquiry understands that there was concern within the medical field about the level of education and training undertaken by those administering blood and blood products to patients. This was announced in the Better Blood Transfer Conference of 1998 [DHSC0004588_007], in which Mike Murphy (Blood Transfusion Consultant from the National Blood Service) stated 'The survey found that in general there was poor provision of training particularly for medical staff and for portering staff' . You may also wish to refer to [NHBT0010270_003] page 5. Please outline:

- ***a. If the HTCs were aware of this concern;***
- ***b. Any discussions the HTCs had as a result of the concerns;***
- ***c. Whether as a result of discussion, what, if any, training was implemented. If so, when it was and at what level the training was implemented. If it was not, why it was not?***
- ***d. The nature of the training, for example, if training was voluntary or compulsory, and whether this changed over time; and***
- ***e. A brief overview of what the training included.***

13. The Trust is unable to provide evidence of awareness of this issue, or the training arrangements in place at the time HTCs were first introduced. The Trust can confirm that following the recent Patient Safety Alert [CAS Alert - 103190] amendments are required to a unified training package for staff, including medical and portering staff. This will be completed by the end of March 2022.

12. Please explain the nature of the relationship between the HTCs and the various departments in the Hospital that administered blood transfusions. Has this changed over time? What oversight did the HTCs have over the decisions made by the different departments utilising transfusions? How did any such oversight operate? What was the aim of the HTCs' oversight? What were the challenges that arose in the relationship between the HTCs and the Hospital departments?

14. The Terms of Reference at WITN7095003 describe the attendance expected which includes senior medical and nursing representation from the clinical divisions.

13. Please describe the nature of the HTCs' relationship with the Regional Transfusion Committee (and the relevant prior bodies including the Regional Transfusion Centre). In particular, please explain:

- ***a. Who, if anyone, from the HTCs primarily interacted with the Regional Transfusion Centre, and subsequently the Regional Transfusion Committee;***
- ***b. The topics covered by the interactions;***
- ***c. How policy and guidance was cascaded from the Region to the Hospital Transfusion Committee;***
- ***d. What oversight the Region had over the Hospital Transfusion Committee;***
- ***e. Whether it was standard practice to have someone from the Regional Transfusion Centre sit on the HTCs;***
- ***f. The input, if any, that the Region provided to the HTCs in relation to updating and promoting transfusion practice; and***

g. How the relationship changed over time.

You may wish to refer to [BSHA0000061_029].

15. Due to the passage of time the Trust does not hold any information regarding the previous relationships between HTCs and the Regional Transfusion Committee. The Trust can confirm that it now actively engages with the Regional Transfusion Committee and I attach to my statement the agenda and supporting papers for the North West Regional Transfusion Committee in October 2021 (WITN7095004 to WITN7095006). WITN7095005 contains minutes from the Committee in May 2021 which confirms Trust representation at these meetings.

14. Please describe the HTCs' working relationship with the National Blood Transfusion Service ("NBTS"), and the relevant prior bodies including the National Blood Authority. In particular please explain:

a. The input, if any, that the NBTS provided to the HTCs in relation to updating and promoting transfusion practice;
b. How the relationship changed over time; and
c. With particular regard to [NHBT0000649], was it standard practice to have a member of the National Blood Service as a member of the HTCs?

16. Due to the passage of time the Trust does not hold any information regarding the previous relationships between HTCs and the National Blood and Transfusion Service ("NBTS"). The Trust can confirm that a representative of the NBTS is noted as a core member of the current HTC within the Terms of Reference (WITN7095003).

15. Please describe the relationship between the HTCs and the Hospital Transfusion Laboratory ("HTL"), with particular regard to what effect this relationship had on the HTCs' work.

17. Due to the passage of time the Trust does not hold any information regarding the previous relationships between HTCs and the 'Hospital Transfusion Laboratory' ("HTL"). The Trust can confirm that a representative from the Liverpool Clinical Laboratories ("LCL") Transfusion Team attends the current HTC as noted within the Terms of Reference (WITN7095003).

16. What do you understand to be the main obstacles faced by the HTCs from the date established until the early 2000s? Did these obstacles change over time?

18. The Trust does not hold any information outlining the main obstacles faced by HTCs from the date established until the early 2000's.

Section 3: Policy and standard practice

17. Please outline the HTCs' knowledge as to the types of blood and blood products that were most commonly transfused to patients during the 1970s to the 2000s, the circumstances in which they were used, and how this may have changed over time.

19. Due to the passage of time the Trust does not hold any information regarding the details requested at question 17.

18. The Inquiry understands that many hospitals used a Maximum Blood Schedule or Blood Ordering Schedule in Elective Surgery. Was such a schedule used by the Hospital? If so, please explain:

- ***a. When these were introduced;***
- ***b. What the purpose of these schedules were and how they operated; and***
- ***c. Whether the type of blood component and/or the suggested unit amount for each surgical intervention changed over time; If so, please outline how and why.***

Additionally, please provide copies of all available schedules.

20. The Trust is unable to confirm when a Maximum Blood Schedule or Blood Ordering Schedule ("MSBOS") was introduced. The purpose of an MSBOS primarily was to have a uniform policy for reservation of red cells dependent upon elective surgical procedure to harmonise requesting between clinical teams. The ultimate aim was to conserve the blood stocks by minimising the amount of blood reserved for a patient's elective procedure. Due to the passage of time the Trust does not hold any documented schedules.

19. An audit of transfusion practice across the United Kingdom by the Royal College of Physicians in 1998 [NHBT0042247] noted six controversial areas of transfusion practice:

- ***a. The nature and frequency of patient observations***
- ***b. Who wrote local policies***
- ***c. The need for two signatures to confirm adequacy of the checking procedure***
- ***d. The use of wristbands for patient identification***
- ***e. The need for a doctor to be present during transfusion***
- ***f. The action to be taken in the event of a transfusion reaction.***

How did the HTCs at the Hospitals operate to standardise or enable the above practices? If the HTCs did not, why not?

21. The Trust notes reference to the audit of transfusion practice in 1998 but due to the passage of time the Trust does not hold any documented information going back to this time outlining how the HTC operated.

20. Did the HTCs provide any specific guidance to the departments within the Hospital and to clinicians administering blood transfusions in relation to the following medical situations:

- ***a. Obstetrics;***
- ***b. Trauma and emergency care;***
- ***c. Surgery;***
- ***d. Haematological malignancies;***

e. ***Thalassaemia; and***

f. ***Sickle Cell Anaemia.***

If so, please provide details of these policies and documentation if you are able.

22. The Trust is unable to provide any policies or documentation setting out specific guidance to the departments outlined within question 20. The Trust has never provided obstetric care, and with regards to the other medical situations outlined in (b) to (f) there was a close working relationship between the clinical area and laboratory.

21. Were the HTCs responsible for dealing with failure to comply with transfusion policies and practices? If so, how was this dealt with? If not, how did the Hospital deal with such failures?

23. The Trust notes that any incidents the laboratory was made aware of were reported to the Serious Hazards of Transfusion (SHOT) that commenced in 1996. The earliest report held by the Trust dates back to May 1998. These incidents were also discussed in the HTC. If there was a laboratory failure there was a review of current processes and changes applied if required.

22. A report by Dr Fiona Regan and Dr Clare Taylor on the Recent Advances of Blood Transfusion Medicine [NHBT0000668_001] concerning unnecessary transfusion states that, 'Implementing these plans requires effective teamwork and a clear understanding of the rationale for reducing unnecessary transfusion. However there are currently inadequate resources, in terms of funding, personnel and time, to facilitate this.' Please comment on this with regard to the situation in the Hospitals relating to unnecessary transfusion.

24. The Trust can confirm that structures and staffing are reviewed in line with the UK-Transfusion Laboratory Collaborative that publishes national guidance on laboratory skill and provision. There is no resource pressure on the laboratory aside from recruitment in a market with limited resource.

23. Please consider 'Better Blood Transfusion' Health Service Circular 1998/999, issued on 11 December by Dr Graham Winyard, NHS Executive (NHBT0083701_002). Please outline:

- ***a. Any discussions the HTCs had about the Circular in relation to:***
  - ***i. Obstetrics; trauma and emergency care; surgery; haematological malignancies; thalassaemia; and sickle cell anaemia; and***
  - ***ii. Use of red blood cells, platelets and Fresh Frozen Plasma ("FFP")***
  - ***iii. Autologous transfusion***
  - ***iv. Single-unit transfusion***
  - ***v. Fresh-warm blood transfusion***
  - ***vi. Knowledge of risk of transfusion related infections***
- ***b. Any actions taken by the Hospital as a result of any of the discussions above or as a direct result of the circular.***

25. Due to the passage of time the Trust does not hold any information regarding the discussions HTCs had about the Circular as requested at question 23 (i-vi), nor the actions taken.

24. At a BTSAG meeting on 17 February 2004 [NHBT0060995], it was noted in a discussion about appropriate use of blood that 'Feedback from Hospital Transfusion Committee Chairs is that they have very limited ability to influence as Chief Executive Officers are not listening to their proposals.' To the best of your knowledge, were there occasions where HTC proposals were not being actioned? If so, please provide details.

26. To the best of my knowledge there were no occasions when HTC proposals were not being actioned.

Haemoglobin level

25. A Scottish Working Group on Blood and Blood Products in 1992 [SCGV0000004_007] noted that patients with a haemoglobin count of <10 g/d would require a blood transfusion. However, in the SHOT annual report 2005 [SHOT0000013] it states that, 'In general, the published data indicates that in adults, red cell transfusions will usually be required when the haemoglobin level is <6 g/dl, and will rarely be required when it is >10 g/dl. Comparative studies in adults with haemoglobin levels within the range of 6 - 10 g/dl have not shown red cell transfusions to improve outcome in surgical and intensive-care-unit (ICU) patients'. What did the HTCs understand to be the level at which a patient required transfusion and how did this change over time? Was guidance provided to clinicians at the time, and updated guidance once the HTCs became aware of any clinical change?

27. Due to the passage of time the Trust does not hold any information regarding the guidance provided or the clinical change.

26. The enclosed article 'Reducing red blood cell transfusion in elective surgical patients: the role of audit and practice guidelines' by Mallet et al published in Anaesthesia (2000) reports on a study that found that 'haemoglobin was measured infrequently prior to transfusion and the main 'trigger' for transfusion was an estimated blood loss of 500 ml' [NHBT0086594_003] (p1). The article adds that 'many clinicians continue routinely to transfuse to haemoglobin levels >10 g/dl despite little scientific evidence to support this practice' (p2).

Please address the following:

a. ***Did the HTCs hold any discussions about the frequency of monitoring haemoglobin levels? If so, please provide details and outcomes of any discussions.***
b. ***To the best of your knowledge, were the HTCs aware of excessive or unnecessary transfusion within the Hospitals? If so, please provide details, including any guidance provided to clinicians.***

28. Due to the passage of time the Trust does not hold any information regarding discussions held at the HTC or guidance provided.

27. Were the HTCs provided with guidance from the Department of Health, National or Regional Transfusion Committee concerning haemoglobin levels and transfusion? If so, what was this guidance?

29. The Trust cannot provide any information or guidance received from the Department of Health or National or Regional Transfusion Committee at this time.

Autologous transfusion

28. The Inquiry understands that autologous transfusion was considered suitable for some patients and that it avoided 'infections which may be transmitted by a blood transfusion', as per the guidelines for autologous transfusion, written by the British Society for Haematology and the British Blood Transfusion Society [BWCT0000088]. Please explain:

- ***a. What discussions the HTCs had about the use of autologous transfusions; and***
- ***b. Any considerations given to the perceived risks, benefits, suitability and cost implications of autologous transfusion.***

30. Due to the passage of time the Trust does not hold any information regarding the discussions HTCs had about the use of autologous transfusions, nor the perceived risks, benefits, suitability and cost implications.

29. In 'Guidelines for autologous transfusion. Pre-operative autologous donation', written by the British Committee for Standards in Haematology Blood Transfusion Task Force [BSHA0000017_021], the guidelines support predeposit autologous transfusion services within hospitals. In light of this, did the HTCs provide policy guidance to clinicians and hospital staff concerning autologous transfusions? If so, what was this guidance? If guidance was not provided, please explain why.

31. The Trust does not hold any information regarding the policy guidance provided to clinicians and hospital staff at this time.

30. Were the HTCs provided with guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of autologous transfusion? If so, what was this guidance?

32. The Trust is also unable to advise if the HTC was provided with guidance from the Department of Health, National or Regional Transfusion Committee.

Massive Transfusion

31. What is the HTCs understanding of massive transfusion, including number of units and type of blood components? In what circumstances would massive transfusion be provided to patients?

33. Until NW Regional guidance was provided, blood components in an emergency situation, whether tested or not for serologically compatibility, were issued by component type and quantity as requested by the clinician. Following the publication of the guidance, the provision of blood components in massive haemorrhage packs and the constituent parts of these packs was provided as part of the Hospital Transfusion policy and communications with relevant clinical areas, especially the Emergency Department.

32. What discussions did the HTCs have in relation to incidents requiring massive transfusion? What process was followed after such an incident to assess the need for massive transfusion?

34. Due to the passage of time the Trust does not hold any information regarding the discussions the HTC had in relation to incidents requiring massive transfusion.

33. Did the HTCs provide policy guidance to clinicians and hospital staff concerning massive transfusions? If so, what was this guidance? If guidance was not provided, please explain why.

35. The guidance for massive transfusions was described within the Trust's Hospital Transfusion Policy at the time. The policy would have been ratified by the HTC at the time, following the NW regional Transfusion Committee guidance.

34. Please consider 'Management of massive blood loss - a template guideline with commentary' produced by Dr Stainsby on August 1 2000, for circulation to members of the Transfusion Committee at Royal Liverpool Children's Hospital [AHCH0000012_003].Please outline:

- ***a. Any discussions the HTCs had about the guidelines in relation to:***
  - ***i. Use of red blood cells, platelets and Fresh Frozen Plasma ("FFP") in massive transfusions.***
  - ***ii. Obstetrics; trauma and emergency care; surgery; haematological malignancies; thalassaemia; and sickle cell anaemia; and***
  - ***iii. Knowledge of risk of transfusion related infections.***
- ***b. Any actions taken by the Hospitals as a result of any of the discussions above or as a direct result of the circular.***

36. Due to the passage of time the Trust does not hold any information regarding the discussions the HTC had in relation to the guidelines, nor any information regarding what action was taken.

35. Were the HTCs provided with guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of massive transfusion? If so, what was this guidance?

37. The Trust is unable to advise if the HTC was provided with guidance from the Department of Health, National or Regional Transfusion Committee.

Fresh Frozen Plasma

36. What discussions did the HTCs have about the use of FFP transfusions?

38. Due to the passage of time the Trust does not hold any information regarding the discussions the HTC had about the use of FFP transfusions.

37. Please outline any considerations given to the perceived risks, benefits and cost implications of FFP transfusions.

39. The Trust is also unable to provide any information regarding the perceived risks, benefits and cost implications of FFP transfusions.

38. Did the HTCs provide policy guidance to clinicians and hospital staff concerning the use of FFP transfusions? If so, what was this guidance? If guidance was not provided, please explain why.

40. Due to the passage of time the Trust is unable to provide any information regarding what guidance was provided.

39. Were the HTCs provided with guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of FFP transfusions? If so, what was this guidance?

41. The Trust is unable to advise if the HTC was provided with guidance from the Department of Health, National or Regional Transfusion Committee.

Platelets

40. What discussions did the HTCs have about the use of platelet transfusions?

42. Due to the passage of time the Trust does not hold any information regarding what discussions were had about the use of platelet transfusions.

41. Please outline any considerations given to the perceived risks, benefits and cost implications of platelet transfusions.

43. The Trust is also unable to provide any information regarding the perceived risks, benefits and cost implications of platelet transfusions.

42. Did the HTCs provide policy guidance to clinicians and hospital staff concerning the use of platelet transfusions? If so, what was this guidance? If guidance was not provided, please explain why.

44. Due to the passage of time the Trust is unable to provide any information regarding what guidance was provided.

43. Were the HTCs provided with guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of platelet transfusions? If so, what was this guidance?

45. The Trust is unable to advise if the HTC was provided with guidance from the Department of Health, National or Regional Transfusion Committee.

Single Unit Transfusion

Please consider the enclosed documents [DHSC0035471] and [DHSC0025270] on the use of single-unit transfusions of blood in the UK.

44. What discussions did the HTCs have about the use of single-unit transfusions?

46. Due to the passage of time the Trust is unable to provide any information about what discussions were had about the use of single-unit transfusions. However the Trust notes there was a major push from the HTC following the publication of NICE guidance NG24 and a policy revision.

45. Please outline any considerations given to the perceived risks, benefits and cost implications of single-unit transfusions.

47. The perceived risks and benefits were laid out in NICE guidance NG24 (2015) as well as other published works. Although there is a reduction in the number of reserved red cell units when a single unit policy is employed, as well as a commensurate reduction in stock holding to supply the new demand, there is also a reduction in red cell wastage. The primary focus of the single-unit transfusion policy was to reduce patient risk by eliminating unnecessary transfusions by reassessing their clinical requirement of further red cells units following each transfusion. Although there is a cost benefit to reducing volumes of blood held as stock and transfused within the Trust, the patient safety element of this guidance was the primary driver.

46. Did the HTCs provide policy guidance to clinicians and hospital staff concerning the use of single-unit transfusions? If so, what was this guidance? If guidance was not provided, please explain why.

48. Due to the passage of time the Trust is unable to provide any information regarding what guidance was provided.

47. Are you aware of any instances or periods of time in which the HTCs became aware of concerns about unnecessary or excessive single-unit blood transfusions? If so, please explain in as much detail as you are able to recall, including how and why unnecessary transfusions were provided?

49. The Trust is not aware of any instances prior to the introduction of the steps outlined in NG24.

48. Single-unit transfusions are described in [DHSC0025270, page 3] as a 'waste of resources'. To the best of your knowledge, did the HTCs have specific views on the use of single-unit transfusion in relation to potential waste and did this change over time? Please explain your answer.

50. Due to the passage of time the Trust does not hold any information regarding the HTCs specific views on the use of single-unit transfusions.

49. Were the HTCs provided with guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of single-unit transfusions and/or two-unit transfusions? If so, what was this guidance?

51. The Trust is unable to advise if the HTC was provided with guidance from the Department of Health, National or Regional Transfusion Committee.

50. A report on the 'Audit of Medical Input in the Blood Transfusion Services' produced by Scottish National Blood Transfusion Service on 27 June 1990 [SBTS0000685_088] states that a 'special emphasis' was placed on the review of single-unit transfusions. Were audits conducted about the practice of single-unit transfusions by, or under the auspices of, the HTCs? If so, please describe the nature of them and any conclusions drawn. If possible, please provide copies of the audit reports.

52. Due to the passage of time the Trust does not hold any information regarding audits conducted about the practice of single-unit transfusions.

Red Cell concentrates

51. What discussions did the HTCs have about the use of red blood cell concentrate in transfusions, specifically in relation to the use of red cell concentrates in place of whole blood or other blood components?

53. Due to the passage of time the Trust does not hold any information regarding what discussions were had about the use of red blood cell concentrate in transfusions.

52. Please outline any considerations given to the perceived risks, benefits and cost implications of red blood cell concentrate transfusions.

54. The Trust is also unable to provide any information regarding the perceived risks, benefits and cost implications of red blood cell concentrate transfusions.

53. Did the HTCs provide policy guidance to clinicians and hospital staff concerning the use of red blood cell concentrate transfusions? If so, what was this guidance? If guidance was not provided, please explain why.

55. Due to the passage of time the Trust is unable to provide any information regarding what guidance was provided.

54. Were the HTCs provided with guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of red cell concentrates? If so, what was this guidance?

56. The Trust is unable to advise if the HTC was provided with guidance from the Department of Health, National or Regional Transfusion Committee.

55. To the best of your knowledge, were there any specialty uses of red cell concentrate, platelets and/or FFP that lead to an adverse reaction that required investigation? Please provide details. You may want to refer to [NHBT0090084] for assistance.

57. To the best of my knowledge the Trust does not hold any information regarding adverse reaction that required investigation.

56. In relation to red blood cell concentrates:

- ***a. Were attempts made to persuade clinicians to increase their usage of red blood cell concentrates in transfusions during the 1970s and 1980s?***
- ***b. To the best of your knowledge, did the Hospital come under pressure during the 1970s and 1980s to increase usage of red blood cell concentrates? If so, where did this pressure come from?***

c. ***According to [HSOC0020283], British clinicians had a "traditional preference" for the use of whole blood in comparison with other countries. Is this an accurate representation of the position? Were the HTCs aware of why whole blood transfusions were preferred over red blood cell concentrates during the 1970s and 1980s?***

58. Due to the passage of time the Trust does not hold any information regarding question 56(a-c).

Fresh Warm Blood

The Inquiry has received evidence that on some occasions when a blood transfusion was needed urgently, fresh warm blood donated by hospital staff or other local authorities administered to patients. Please address the following:

57. What discussions did the HTCs have about the use of fresh warm blood in transfusions?

59. Due to the passage of time the Trust does not hold any information regarding what discussions were had about the use of flesh warm blood in transfusions.

58. Please outline any considerations given to the perceived risks, benefits and cost implications of fresh warm blood transfusions.

60. The Trust is also unable to provide any information regarding the perceived risks, benefits and cost implications of fresh warm blood transfusions.

59. Did the HTCs provide policy guidance to clinicians and hospital staff concerning the use of fresh warm blood transfusions? If so, what was this guidance? If guidance was not provided, please explain why.

61. Due to the passage of time the Trust is unable to provide any information regarding what guidance was provided.

60. Were the HTCs provided with guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of fresh warm blood transfusions? If so, what was this guidance?

62. The Trust is unable to advise if the HTC was provided with guidance from the Department of Health, National or Regional Transfusion Committee.

Section 4: Knowledge of risk

61. Please outline any discussions held during the course of the HTCs meetings regarding the knowledge of risks of viral infection associated with blood transfusion. What were the sources of this knowledge and how did this knowledge and understanding develop over time?

63. The Trust is unable to provide any information relating to the discussions held during the course of the HTC meetings due to the passage of time. The Trust is unable to comment on what the sources of knowledge were or how this developed over time.

62. What, if any, enquiries and/or investigations did the HTCs carry out, or cause to be carried out, in respect of the risks of the transmission of viral infections through blood transfusion? If applicable, what information was obtained as a result?

64. The Trust is not aware of any enquiries and/or investigations that were carried out by the HTC.

63. What decisions and actions were taken by the HTCs to minimise or reduce exposure of your patients to viral infection from blood transfusions?

65. Due to the passage of time the Trust is unable to provide any information regarding the decisions and actions taken by the HTC.

64. Did the HTCs provide policy guidance to clinicians and hospital staff concerning the transmission of viral infections through blood transfusion? If so, what was this guidance? If guidance was not provided, please explain why.

66. Due to the passage of time the Trust is unable to provide any information regarding what guidance was provided.

65. Do you consider that the HTCs' decisions and actions, and the steps taken at the Hospitals, in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what could or should have been done differently.

67. As the Trust is unable to provide any information regarding the HTCs' decisions and actions, the Trust is unable to comment on the appropriate of the decisions made at the time.

66. Please outline any discussions by the HTCs concerning particular blood components or transfusion methods that carried a higher risk of viral infection. If applicable, what action was taken or guidance implemented as a result?

68. The Trust is also unable to provide any information regarding the discussions by the HTC.

Section 5: Reporting and audits

67. Did the Hospital have any procedures in place to ensure patients reported any adverse reactions or symptoms following a blood transfusion? If so, please explain:

a. What procedure did the Hospital have in place?

b. **Did this procedure extend to a time 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 Hospital to report any adverse reactions or symptoms to the Regional Transfusion Centre?**
f. **In the event of a patient's death after receiving a blood transfusion, what process was followed? Specifically, please address the position in relation to the registration of the death and/or any consideration of what was recorded on the death certificate.**

69. The Trust is unable to provide evidence of the processes that were in place to ensure patients reported any adverse reactions or symptoms following a blood transfusion. The Trust can confirm that should a patient experience an adverse reaction from a blood component today, an incident is submitted to the Trust's risk management system (Datix) and reported to the MHRA and SHOT. The incident is reviewed by the Trust from a clinical perspective.

68. Please explain whether and how the HTCs reported suspected transfusion-transmitted infections to their supplying blood centre prior to SHOT being established.

70. Due to the passage of time the Trust is unable to provide evidence on whether and how the HTCs reported suspected transfusion-transmitted infections to their supplying blood centre prior to SHOT being established.

69. What impact did the launch of SHOT have on the process of reporting? How did the HTCs ensure that (a) all reportable events were reported to the HTCs and (b) all reportable events were reported to SHOT?

71. The Trust holds records of reporting to SHOT since May 1998, and all incidents that the Transfusion Team are aware of have been reported to SHOT since that date. All incidents are also discussed at the HTC meeting. Current practice within the Trust is for clinical and laboratory staff to report all transfusion incidents and reactions on the Trust local incident reporting system (Datix), and these are reviewed by the Transfusion Team and investigated further and escalated as indicated.

70. In light of the Recommendations on the Hospital's and Clinician's Role in the Optimal Use of Blood and Blood Products, by the European Health Committee [NHBT0001504], did the process of reporting adverse reactions change over time?

72. The Trust is unable to provide evidence on whether the process of reporting adverse reactions has changed over time; however the Trust's current process is outlined above.

71. How was transfusion practice, blood usage and blood wastage audited by the HTCs? Did this change over time?

73. The Trust is unable to provide evidence on how transfusion practices, blood usage and blood wastage was audited by the HTC and whether this changed over time. The Trust can confirm that in relation to existing practice, blood usage and wastage is reported to the HTC. Wastage is also reported to the Blood Stocks Management Team.

72. Under what circumstances were external and internal audits conducted? How often were internal and external audits conducted by the HTCs from the date the HTCs were established?

74. The Trust is unable to advise of the circumstances under which external and internal audits were conducted, and the frequency they were carried out.

73. Did the HTCs record any information regarding the volume or number of transfusions that occurred in the Hospitals on an annual or cumulative basis? If so, please explain what information this consisted of and how it was recorded.

75. Due to the passage of time the Trust is unable to provide information on previous mechanisms for reporting information regarding volume or number of transfusions. The Trust can confirm that both Telepath and Winpath are now used to record units of blood given to patients.

74. If the HTCs did record any information on the volume or number of transfusions as described in your answer to question 72 above, was this information ever reported or disseminated to any other institution or body? If so, please explain the reporting process involved.

76. The Trust is unable to advise regarding the number of transfusions.

75. Were audits specifically conducted in relation to the use of:

- ***a. FFP;***
- ***b. red blood cell concentrate;***
- ***c. platelets;***
- ***d. massive transfusions; and/or***
- ***e. autologous transfusion.***

If audits were not conducted, why not? [NHBT0090084] may be of assistance.

77. Due to the passage of time the Trust does not hold any information regarding question 75 (a-e).

76. Did the HTCs ever have to take corrective action as a result of an audit relating to blood transfusion practice? If so, what was the process for corrective action and what was the result? Please provide details.

78. The Trust is unable to provide any evidence relating to corrective action taken as a result of an audit.

Section 6: Treatment of patients

Provision of information to patients

77. What discussions, if any, did the HTCs have about providing patients at the Hospitals with information about the risks of infection as a consequence of treatment with blood?

79. The Trust is unable to provide evidence on what discussions the HTCs had about providing patients with information about the risks of infection in consequence of treatment with blood. The Trust can confirm that an information leaflet is given to patients now, which outlines the risk of infection.

78. Did the HTCs take steps to ensure that patients were informed and educated about the risks of viral infection as a result of being transfused? If so, what steps did the HTCs take?

80. The Trust is unable to provide evidence on what steps were taken by HTCs to ensure patients were informed and educated about the risks of viral infection as a result of being transfused. Patients are now informed of the risks of transfusion and provided with the information leaflet referred to above.

Consent

79. An audit of transfusion practice across the United Kingdom by the Royal College of Physicians in 1998 [NHBT0042247] indicated that none of the participating 47 hospitals required informed consent for blood transfusions. In light of this, were the HTCs aware if patients under the care of the Hospitals were treated with blood transfusions without their express or informed consent? If so, how and why did this occur?

81. Due to the passage of time the Trust cannot advise if the HTCs were aware if patients were treated with blood transfusions without their express or informed consent.

80. Did the HTCs issue guidance to clinicians and hospital staff on informed consent for blood transfusions? If so, please explain when this guidance was introduced, what this guidance was and whether this changed over time.

82. The Trust is unable to provide evidence on what guidance was issued to clinicians and hospital staff on informed consent for blood transfusions at the time. Currently at the Trust one consent form is completed with the patient for every 'episode' of transfusion. Consent is then sought verbally and discussion at the bedside for every time blood is transfused during that episode.

Section 7: vCJD

81. When and in what circumstances did the HTCs become aware of the risks of transmission of vCJD associated with the use of blood transfusions? Please outline any discussions held by the HTCs and explain how the HTCs' knowledge developed over time. You may be assisted by [BART0000554] and [DHSC0041442_171].

83. Due to the passage of time the Trust does not hold any information regarding when the Trust became aware of the risks of vCJD transmission, and what discussions were held.

82. Please outline the extent to which the HTCs were involved in assessing and managing the risk of vCJD transmission by blood transfusion.

84. The Trust is unable to comment on the extent to which the HTC was involved in assessing and managing the risk of vCJD transmission.

83. Please confirm if policies, guidance, standards, or protocols were formulated at the HTCs at the Hospitals with regard to the transfusion of vCJD.

If so, please describe what these were. You may be assisted by [NHBT0001719].

85. The Trust is also unable to provide any information regarding what policies, guidance, standards or protocols were formulated at the HTC.

84. Did the HTCs have involvement in decisions as to what information should or would be provided to patients about vCJD? If so, please answer the following:

- ***a. What steps were taken/put in place by the HTCs for informing patients about the risks of or possible exposure to vCJD before transfusion?***
- ***b. What steps were taken/put in place by the HTCs for informing patients about the risks of or possible exposure to vCJD after transfusion (for example emergency situations)?***

You may be assisted by BART0002418, NHBT0001123_002, HCDO0000643.

86. Due to the passage of time the Trust is unable to advise on what involvement the HTC had in decision making. However in 2004 patients were informed of the risk of vCJD, and asked if they wished to know if they had been recipients of British plasma products. A look back exercise was undertaken, a help line was set up and extra clinic sessions were held for patients to have full discussions about this.

Section 8: Look back

85. Were the HTCs ever involved in establishing the policy or procedure to be followed in any lookback exercise relating to blood transfusions? If so, please set out or provide a copy of the relevant policy or procedure.

87. The Trust is unable to provide any information as to the HTC's involvement in any lookback exercise relating to blood transfusions, except that outlined below in response to questions 86 and 87.

86. What actions or decisions were taken by the HTCs at the Hospitals as part of the HCV 'look back' programme that commenced in 1995 to trace those infected with HCV through the use of blood transfusions?

88. The Trust is also unable to advise on all the actions or decisions that were taken by the HTC at the time to trace those infected with HCV. However, the Trust did review all those patients registered with the centre who had received treatment in the past, and cross referenced it with those who had been tested after 1991. If any patient hadn't been seen, the Trust attempted to contact them and invite them in for review and referral to Hepatology if appropriate.

87. What were the major obstacles that the Hospital faced when attempting to undertake the HCV lookback?

89. The major obstacle faced by the Trust was contacting those patients that were 'lost to follow up', especially those who had moved house, or who were choosing to not respond to letters sent.

Section 9: Other

88. Please provide any further comment that you wish to provide about matters of relevance to the Inquiry's Terms of Reference.

90. The Trust does not wish to provide any further comments to the Inquiry's Terms of Reference.

89. 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.

91. There are no other documents, except those exhibited to this statement, which the Trust holds relevant to the Inquiry.

Statement of Truth

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

Signed GRO-C

Dated 17/6/22

Table of exhibits:

Date	Notes/ Description	Exhibit number
Undated	HTC Terms of Reference	WITN7095003
22/10/2021	North West RTC Meeting, agenda	WITN7095004
07/05/2021	North West RTC, unconfirmed minutes	WITN7095005
October 2021	North West RTC Objectives 2021-2022	WITN7095006