Witness Name: Professor Jane EDDLESTON

Statement No. WITN7041001

Exhibits: WITN7041002-097

Dated: 20 May 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR JANE EDDLESTON, ON BEHALF OF MANCHESTER UNIVERSITY NHS FOUNDATION TRUST

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 17 December 2021.

I, Professor Jane Eddleston, will say as follows: -

Section 1: Introduction

1. This statement has been prepared collaboratively with the assistance of my colleagues in transfusion practice, clinical and laboratory haematology, biomedical science, and obstetrics and who have sat/are on the Hospital Transfusion Committee. It is true to the best of my knowledge, information and belief, based on the response to enquiries which have been made and the documents identified as relevant in the time available to respond to the request.

2. The Manchester University NHS Foundation Trust ('the Trust') was formed on 1 October 2017 by the merger of Central Manchester University Hospitals NHS Foundation Trust with the University Hospital of South Manchester NHS Foundation Trust and is constituted of ten hospitals across seven different sites (https://mft.nhs.uk/).

3. As set out in our letters to the Inquiry dated 10 October 2018 and 10 October 2019, the Trust has medical records stored in a secure off-site facility in accordance with legislative requirements.

4. In our off-site storage facility, our records show that we hold Hospital Transfusion Committee (HTC) minutes dating back to 1999. Information relating to a number of transfusions was only recorded from 2001.

5. Flooding in the Manchester Royal Infirmary in September 2008 destroyed a large number of records. In addition, a fire in the Blood Transfusion Laboratory at the Trafford General Hospital in 1993 resulted in all paper records on that site being destroyed.

6. As part of our search for records relating to this Rule 9 request the Trust has identified 13 boxes of records. A copy of the ledger for these boxes is exhibited as WITN7041002. Within these documents, HTC minutes have been identified from as far back as 2003.

7. Our appointed solicitors, Weightmans LLP, attended the Department of Laboratory Haematology on 19 and 20 January 2022 to conduct a review of these boxes and identified c2000 pages of records / documents which have been used to inform this response.

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

8. Professor Jane Margaret Eddleston.
Manchester Royal Infirmary, Oxford Rd, Manchester M13 9WL.
My date of birth is GRO-C 1957
MB ChB 1981 University of Dundee
FRCAnaes, FICM
My GMC number is 2553304.

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

9. I am the Joint Group Executive Medical Director. Within my role as Joint Group Executive Medical Director, I have the following responsibilities within my portfolio:
   - Research and Innovation
   - Clinical Oversight of Strategy
   - Clinical Oversight of Informatics
   - Provide Board oversight of hosted networks (Greater Manchester Critical Care and Major Trauma Operational Delivery Network, North West Genomic Alliance)
   - Shared responsibility for Quality and Safety with the other Joint Executive Medical Director
   - Provide Clinical Leadership and oversight to the work of our Associate Medical Directors and Medical Directors of the MFT hospitals.

10. I also hold roles outside MFT. These are: Chair of NHS England Adult Critical Care Clinical Reference Group; member of the Faculty Board for Intensive Care Medicine and interim Executive Medical Director (one of five) for GM Health and Social Care Partnership.

11. I also have maintained my clinical practice in Intensive Care Medicine as a Consultant within the Trust.

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

12. Competitive interview and following 24 years of extensive managerial experience in the Acute sector.

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.

13. My employment history is as follows:
    - Pre-Registration House Officer: August 1981-July 1982;
    - Anaesthesia Training: Senior House Officer Ninewells Hospital Dundee July 1982-1983, Aintree University Hospitals 1983-1984;
    - Registrar Training: Aintree University Hospitals and Royal Liverpool Hospital;
    - Rotation 1984-1987, Senior Registrar Training North West Deanery 1987-1991: University Hospital South Manchester, Manchester Royal Infirmary, Salford Hospitals, Royal Victoria Hospital Blackpool;
    - Full time Consultant in Anaesthesia Manchester Royal Infirmary with a special interest in Intensive Care. Appointed October, 1991;
    - Clinical Director Critical Care Directorate, Central Manchester Healthcare Trust 1994-2012;
    - Clinical Head of Division (Clinical and Scientific Services Division) Jan 2005-2013 Associate Medical Director CMFT August 2013-March 2017;
    - Deputy Medical Director April 2017-December 2017;
    - Medical Director CSS Managed Clinical Service from 1 January 2018 until 31st August 2018;
    - Deputy Group Medical Director MFT from 1 January 2018 until until 31st August 2018; and
    - Joint Group Executive Medical Director from 1 September 2018 until present day (ongoing).

Section 2: Hospital Transfusion Committee history, structure & relationships

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;

14. I have noted the document provided by the Inquiry [NHBT0016083_003], which is a proposal by Dr Ala dated 20 April 1983. I cannot say for certain when the HTC was established at the Trust since records are not held dating back that far, but if a proposal was put to the Trust in the 1980s then I am sure we would have taken steps to set up a HTC.

15. Document [WITN7041017] references a meeting of the HTC held on 11 December 1992.

16. I can say that our off-site ledger suggests that minutes exist from 1999, but we have so far been unable to locate these as part of this response. A selection of minutes from HTC meetings dating from 22 October 2003 to 2 December 2015 are attached as exhibits (WITN7041019-036 and WITN7041038-073). A selection of minutes from the Trafford Division HTC dating from 25 July 2011 to 27 November 2012 are also exhibited (WITN7041084-088).

b. Who established the HTCs and who the first Chair was;

17. I cannot be certain because records and the minutes are not held dating back to the first meetings, but the earlier and currently available minutes name Dr David Whittaker at the Oxford Road site as the Chair who was a Consultant Anaesthetist.

c. Why the HTCs were established;

18. I believe HTCs were established as a result of National Recommendations from the Blood Transfusion Service. I refer to the letter [NHBT0000649] which is a letter from Dr Angela Robinson the Medical Director of the Blood Service which refers to the need to *"...actively encourage appropriate use of blood and blood components. This objective is difficult to achieve if hospitals do not have active hospital transfusion committees*".

d. What the initial aims of the HTCs were when they were established;

19. I believe it was to support the production and implementation of safety recommendations and promote the better use of blood.

20. Document [NHBT0016083_003] lists other aims such as to review mortality and morbidity associated with blood transfusion, to review selected cases in order to assess the appropriateness of transfusion therapy, to discuss and evaluate overall criteria and policies for blood and blood component usage and to establish guidelines of blood ordering with the overall aim of improving availability of blood whilst reducing the cross-match burden imposed by the laboratory.

e. Before the establishment of the HTCs, how the Hospitals monitored transfusion practice.

21. Prior to HTC's, the Trust kept transfusion records which included ledgers (cross-match, compatibility, and blood issue record), traceability of blood transfusion, group and antibody tests and cross-matched worksheets (laboratory testing).

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.

22. The HTCs are comprised of a chairperson who is a health care professional regularly involved in supporting transfusion for patients other than a consultant haematologist in charge of blood transfusion, i.e. from an unbiased speciality such as intensive care or obstetrics.

23. HTC aims to have representation from clinical divisions across the Trust, which can include clinicians and nursing, from this we have a designated distribution list which is used to circulate invites, agendas, notes and relevant papers.

24. An invite is then sent out through all clinical directors and lead nurses and education forums to invite anybody involved in the transfusion process to attend who feels that it will be beneficial for their speciality, so the HTC does canvas and recruit on a regular basis.

25. It is normal to have a haematologist join the meeting together with a NHS Blood Transfusion (NHSBT) - Blood Service - liaison person. Transfusion Practitioners will also sit in on the HTC meetings, as well as the hospital transfusion laboratory staff.

26. The quorum, therefore, for the HTC will include the chair or the deputy chair, a secretary post usually held by the Transfusion Practitioner, biomedical scientists, IT, clinical governance, and speciality representation from across the hospital divisions. The NHSBT Blood Service regional liaison officer would also be invited.

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.

27. I agree with the roles and functions listed above and, in addition to this, the HTCs perform audit review and feedback, dissemination of information through to various medical specialities and trend analyses of adverse incidents and provide a synopsis of these to relevant medical staff.

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.

28. I agree with the quote that "*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 standard of patient care*". The HTC monitors blood use and wastage and the promotion of patient care is the foundation of the committee.

29. In terms of governance, at our Trust the HTC reports to our own governance body through CSS Managed Clinical Services and we also have an internal risk register which is reviewed divisionally and through the Managed Clinical Services. So, in the case of our Trust, I do not believe it is unclear who the HTC reports to but I cannot speak for other Trusts.

30. I am aware that through the Northwest Regional Transfusion Group there are discussions about the HTCs.

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.

31. I am only able to comment on the structure at this Trust and can say that we have not faced any major obstruction in terms of recommendations from the HTC but have, historically, faced difficulty in recruiting clinical engagement.

32. Inevitably it can sometimes be a lengthy process to implement a recommendation as it needs to go through various bodies as part of the organisational structure at the Trust, but I do not believe that there is obstruction due to lack of clinical input.

33. I believe that over the past ten years the clinical engagement with the wider clinical teams has been very positive.

34. I cannot comment on the experience of other organisations.

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].

35. The aim initially was for the meetings to be quarterly, and this remains the case today, but like any NHS organisation the impact of Covid 19 meant that clinicians were taken out of such meetings so over the last couple of years we have seen an impact upon the regularity of these meetings which have more recently been held virtually.

36. The Trust has an Executive HTC as an oversight group, which was able to successfully maintain a number of meetings, there were 9 in 2019, 6 in 2020 and 7 in 2021. The 'new' MFT-Wide HTC commenced in September 2020, there were 3 meetings in 2021 (June, September and December)

37. The Terms of Reference for the HTCs do say quarterly, which is what we aim for at the Trust.

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;

38. Yes, there was an awareness of this concern.

b. Any discussions the HTCs had as a result of the concerns;

39. Yes, I believe that these concerns would have been discussed as this would fall within the remit of the HTC. Unfortunately, we have been unable to locate the minutes from that period.

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?

40. Two new Transfusion Practitioners were appointed. The role of the Transfusion Practitioner is to provide a link between the hospital transfusion laboratory and clinical services.

41. Training was devolved through those Transfusion Practitioners to local training and practice-based educators which was mandatory by way of three competency assessments developed from the NICE guidance, which is still in use today (right blood, right patient, and right time).

d. The nature of the training, for example, if training was voluntary or compulsory, and whether this changed over time; and

42. As above. The training was mandatory, as described in response to paragraph c above.

e. A brief overview of what the training included.

43. A session was run for all new clinical staff whether nurse, midwife, ODP or medic regarding transfusion induction training on arrival to the Trust as a new starter until 2018, when face to face induction ceased.

44. There continues to be additional training for nurses, midwives and paediatric nurses and medics on transfusion practice.

12. Please explain the nature of the relationship between the HTCs and the various departments in the Hospitals 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 Hospitals departments?

45. I think over time the relationship between the HTC and the various departments and hospital sites has become more structured and now the clinical teams look toward the transfusion team for additional advice and support.

46. In terms of oversight which the HTC has over the decisions made by different clinical specialties and departments, I do not think there is an oversight but rather an amalgamation of best practice and the development of guidelines and policies for those specialities, but the actual clinical decision lies with the medical staff; for example, the developments of guidelines on platelets, red cells and blood order schedules were/are all

a joint endeavour between the clinical teams and the transfusion team as part of the HTC.

47. In terms of challenges between the relationship of the HTC and the hospital departments, I do not think there were / are any which would not be faced by any other large organisation. I do not believe that there is any 'over negativity' or refusals to engage between the specialties and the HTC, but the Trust is a big organisation so it can take time to take on board everybody's thoughts and amalgamate ideas into a workable policy, guideline, process or work stream. This is not unique to the HTC.

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;

48. The HTC sent representation to the RTC's quarterly meeting which would be from the Transfusion Practitioner team, the Biomedical Scientist team or one of the consultant haematologists.

49. The HTC has regular contact with the regional NHSBT Blood Service liaison officer for advice, support and information and a consultant haematologist is in contact from a clinical perspective with their colleagues in the region as would be the case for the laboratory and clinical staff, if deemed necessary.

50. I, therefore, believe we have very good links available with the regional support network which has always been the case.

51. The earliest minutes currently available to me are from October 2003 [WITN7041019]. I have also seen the HTC Terms of Reference dated March 2003 [WITN7041018] These set out the members of the Committee and its objectives and scope. The Chairman at that time was Dr Whitaker (Consultant Anaesthetist) and the Secretary was Dr Hay (Consultant haematologist).

b. The topics covered by the interactions;

52. Anything that is topical. This might include for example risk management, new policies, new procedures, new manufacturing processes from NHSBT, new recommendations, or audit reports.

53. RTC meetings tend to be divided into the topics listed immediately above and then there is networking between the various attendees from the region with best clinical practice being shared and there is always a section on and around education.

c. How policy and guidance was cascaded from the Region to the Hospital Transfusion Committees;

54. These days this interface is through email, but prior to that it was done by fax or in a paper letter.

55. Guidance is cascaded through the regional chairs, transfusion practitioners, laboratory chief biomedical scientists (BMS) and hospital laboratory managers and if it is something high risk it goes through the Trust's risk management team.

d. What oversight the Region had over the Hospital Transfusion Committees;

56. The regional committees did not have oversight in the sense that they do not control how the HTC was run but rather they made suggestions and recommendations, but the HTC is / was not accountable to them.

57. The HTC does feed back to the regional committees through a synopsis sent every quarter which I understand all hospitals in the region are asked to do. This covers key agenda items at the HTC and current practice and any significant changes.

e. Whether it was standard practice to have someone from the Regional Transfusion Centre sit on the HTCs;

58. Not from the Regional Transfusion Centre, but the liaison officer for the NHSBT Blood Service is invited to the HTC. This was in their capacity as liaison officer, and not in their capacity as part of the Regional Transfusion Committee or Centre.

f. The input, if any, that the Region provided to the HTCs in relation to updating and promoting transfusion practice; and

59. The NHSBT liaison officer would provide feedback and advice on current developments within the NHSBT Blood Service.

g. How the relationship changed over time.

You may wish to refer to [BSHA0000061_029].

60. From my understanding the relationship has always been a good one and the link with the liaison officers has also been exceptional for the HTC at our Trust. I believe that this has only got stronger over time.

61. As a Trust we have always participated in the Regional Transfusion Committee 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;

62. The various iterations of the NHSBT Blood Service have always, to my knowledge, had input into the HTC through a liaison officer.

b. How the relationship changed over time; and

63. In my understanding, the relationship has not changed and it remains the case that we invite a liaison officer from the NHSBT Blood Service to attend the HTC meetings.

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?

64. As far as I am aware the NHSBT Blood Service liaison officer was and is always invited to attend the HTC meetings as an interface between the Regional Transfusion Service, the Blood Service and the HTC.

65. I would define them as a guest rather than a member as they were and are invited to sit in on the meetings. The HTC can still proceed without their input and they are not part of the quorum of the HTC.

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.

66. It is a very close relationship and always has been.

67. A lot of the decisions made at the HTC are directly linked and driven forward by the HTL.

68. The chief biomedical scientist for transfusion sits in on the HTC meeting, as do the senior biomedical scientists. The meetings are open to junior members of staff for experience should they wish to attend.

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?

69. As with any large organisation with a finite amount of funding to be distributed between various competing interests, financial support can sometimes be an issue.

70. Given the size of the organisation, IT infrastructure can also sometimes pose difficulties although this is mitigated by updating our systems regularly. This goes hand in hand with funding and moreover the previous lack of availability of robust standardised IT systems for hospital blood transfusion, but I certainly believe that this is not just an issue confined to a local basis but on a national basis across the NHS.

71. I cannot think of an instance where there has been an obstacle for which we have not been able to find a workable solution that fits with service delivery, patient care and patient safety.

72. Take up of the meetings at the HTC has always been generally good depending on clinical availability, but that is not unique to HTC meetings. The issue with staff take up at committees and meetings can be variable for a number of reasons and applies across the organisation.

73. If there is representation of a particular clinical speciality that is required at the HTC, then members of the HTC team will target those to get their thoughts and comments. The HTC is committed to improving patient safety and service delivery by finding workable solutions to apply in the clinical environment.

74. The HTC does canvas for attendance very well and encourages all specialties to attend.

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.

75. Usage of types of blood and blood products has always been part of patient blood management and would have been discussed at the HTC meetings. For example, latterly topics such as appropriate usage, blood stocks management, stock rotation and blood availability, best practice and blood safety would all be issues covered.

76. Any changes instigated or driven by the NHSBT Blood Service or RTC would have also been the subject of discussion at the HTC.

77. I cannot comment specifically on any discussion about the types of blood or blood products used.

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;

78. The hospital does use a Maximum Surgical Blood Order Schedule, but I cannot say for certain when this was introduced. They are still used today. Exhibited to this statement is the Trust's Maximum Surgical Blood Order Schedule from 2010 (WITN7041003).

b. What the purpose of these schedules were and how they operated; and

79. The purpose is to ensure that patients undergoing treatment, such as surgical intervention, have the necessary blood components available should they be required. The Schedule indicates how many units of blood need ordering for specific surgical procedures, compiled in collaboration with surgical specialties. For example, total knee replacement (2 units) and revision total hip replacement (4 units).

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.

80. Yes, it has changed over time because surgical activity, processes and how patients are treated has changed over time. The changes over time in medicine and medical / surgical interventions has impacted upon the use of blood and blood components.

81. For example, for a coronary artery bypass graft in the 1980s/1990s the patient would have most likely been in hospital for two weeks and received multiple cross-matched units of blood, but these days cell salvage is used which is the reprocessing of the patient's own blood and components which is a much cleaner and safer process in terms of the surgery, reducing the inpatient time. Consequently, the usage of blood and blood products has reduced over time.

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?

82. The HTC developed a 'Transfusion Policy' (WITN7041004-008 (versions 2-6)) which includes the procedure for the collection and grouping of blood samples and the administration of blood / blood products. The Transfusion Policy was written by the Transfusion Practitioner and consultant haematologist. The original draft would have been written by Mary Marsden, Lead Transfusion Practitioner and Dr Elizabeth Love, Consultant Haematologist.

83. The need for two signatures and adequacy of checking is part of the NICE guidelines, 'Getting it Right First Time'.

84. The use of wristbands would have been part of the patient identification process which organisations including this Trust have. This would mirror the BBTS and SHOT recommendation and best practice shared in the region.

85. It was written into the policies that only a medic could prescribe a blood transfusion. This has now changed and includes non-medical prescribers.

86. We have guidance for all actions that should be taken in the event of a transfusion reaction which is written into the transfusion policy and we have separate policies to manage a transfusion reaction.

87. So, overall, the HTC was driven to standardise everything across the organisation in terms of transfusion practice.

88. The HTC is heavily involved in educating staff which covers a lot of the concerns written above.

20. Did the HTCs provide any specific guidance to the departments within the Hospitals 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.

89. The Trust Transfusion Policy covers all patients and the HTC also has input into other local policies and guidelines specific to other specialties, departments and teams, so in a sense the HTC has a specialist advisory role in these areas.

90. As mentioned above, the HTC would also be inviting members from these various divisions (listed above) to the meetings and if we had issues regarding a certain speciality, we would reach out to that speciality to attend the HTC meeting.

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 Hospitals deal with such failures?

91. Blood Transfusion Laboratories are legally required to investigate and report any serious adverse reactions (SAR) or serious adverse events (SAE) as soon as they are known. Both scenarios would be reported internally initially through our incident reporting system, investigated using our governance structures where any harm was categorised, learning from the event/reaction identified, internal changes to pathways/processes instituted, duty of candour fulfilled with the patient and family (if appropriate) and external actions completed. Adverse reactions and adverse events both constitute as incidents and are investigated through these Trust governance processes.

92. A SAR is defined as "*An unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity* (BSQR, 2005)".

93. A SAE is defined as "*Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity*. (BSQR, 2005)".

94. Incident reporting and investigation is an important part of Haemovigilance, which is the continuous monitoring and surveillance of the entire blood transfusion chain, from donation to final fate. External reporting, collection and analysis of Haemovigilance data nationally has a direct impact on guidelines, regulations and suggested best practice, and has been proven to continuously improve patient safety and blood transfusion practice across the United Kingdom (UK) (Bolton-Maggs, 2020).

95. All UK Hospital Blood Transfusion Laboratories are legally required to adhere to the Blood safety and quality regulations (BSQR) and the EU Blood safety directive. Hospital Blood Transfusion Laboratories are legally required to report any confirmed SAR or SAE as defined above to the Medicines and Healthcare products regulatory agency (MHRA) as soon as they are known. Reporting to Serious Hazards of Transfusion (SHOT) is considered voluntary but professionally mandated.

96. To support UK hemovigilance, collaboration and shared learning the MHRA and SHOT now use a joint online reporting system, known as Serious Adverse Blood Reactions and Events (SABRE)

97. Once reported MHRA will be responsible for deciding if the report qualifies as a SAR or SAE under BSQR definitions, while SHOT will be responsible for deciding if the report qualifies as reportable using SHOT definitions. Reports which are not required by either organisation can be excluded or withdrawn as appropriate (MHRA/SHOT, 2021).

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.

98. The Trust advocates that each transfusion episode is based on clinical presentation for that patient at that time and the ethos is to give the 'minimum components to get the maximum efficacy'. This is the pillar of good patient blood management.

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**

99. I am not aware of any particular discussion regarding the "Better Blood Transfusion" health service circular 1998/1999. Single unit transfusion is discussed on and off as is the use of red blood cells, platelets and FFP. This is all part of patient blood management and minimising unnecessary usage, which relates back to the above.

100. The issue of knowledge of risk of transfusion-related infections is discussed as part of the consenting process which is and has been a topic for discussion at the HTC. As new alerts come out, produced by NHSBT, and SHOT these are discussed at the HTC.

b. Any actions taken by the Hospitals as a result of any of the discussions above or as a direct result of the circular.

101. I am not aware of any actions taken specifically related to this circular from 1998.

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.

102. The question asks whether there are occasions where HTC proposals were not being actioned. It is ambiguous as to who the question relates to in terms of not actioning the proposals but on the assumption, this refers to the clinical teams then if a proposal is made, the HTC takes this forward in terms of education and writing changes into the policy. This relates to system changes and the SOPs. To my knowledge, the CEO would have no involvement with this. At our Trust, the HTC is taken very seriously.

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/dwould 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?

103. Blood transfusion is authorised to the individual patient and cannot be determined solely by haemoglobin levels. A transfusion is a bespoke treatment for that patient at that particular time. At this Trust, we have 'Indication Codes for Transfusion' (WITN7041009) i.e. R1 is red cells for acute blood loss and F1 is FFP for replacing a single unit of coagulation deficiencies etc. and these are based on national standards and a clinical indication on an ordering system for blood/blood products that gives the laboratory staff information on a patient. Our blood ordering system also has a free text box for additional information.

104. The Trust has red cell use guidelines (WITN7041010) which are reviewed on a regular basis and have evolved over time as practices have changed and new information has become available. This is the same with all policies and guidelines within the Trust.

105. Therefore, in answer to this question, the HTC did take the SHOT recommendations forward and provide guidelines.

106. The HTC can offer clinicians guidance and recommendations but sometimes the clinician will have to work outside of these if the patient circumstances dictate that and for achieving what is best for that patient.

107. Guidelines are therefore more flexible than policies.

108. I believe the national guidance on haemoglobin level is if the haemoglobin is less than 7 g/dl then consider transfusing a patient depending on how symptomatic they are; however, this is a guideline and does not mean that, for example, a patient that has a haemoglobin of less than 6 g/dl requires a transfusion and likewise a patient who has a haemoglobin of greater than 10 g/dl but is actively bleeding and in intensive care may require a transfusion.

109. Some patients with significant co-morbidities and who are acutely unwell require a higher base level haemoglobin and all of these things have to be taken into account.

110. The Trust, therefore, does work within this recommended guidance.

111. All of these guidelines and recommendations are reviewed and ratified by the HTC and have input from the specialities pertinent to them.

112. The Trust uses an algorithm to assist clinicians in deciding whether to transfuse a patient or not (WITN7041011).

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.

113. Yes, the HTCs do discuss monitoring of the haemoglobin levels, but this is a clinical decision made for the patient. The HTC does recommend that if a clinician is going to authorise a transfusion then they check the haemoglobin level.

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.

114. I do not believe the HTC was aware of excessive, unnecessary transfusion within this Trust. I cannot speak for other hospitals.

115. Any incidents where a patient had had an unnecessary or excessive transfusion would be reported through our risk management system and monitored/captured in that respect.

116. I think overall it is fair to say that there is a better and more restrictive use of blood now than there was for example 10 or 20 years ago and rather than giving blood as a prophylactic treatment, there is now a more cautious approach to it. This represents a change in practice over time, brought about by education and the availability of alternatives to transfusion.

117. Through clinical input, committees and laboratories there is now more vigilance about blood, but it still remains a bespoke treatment for a particular patient at a particular time.

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?

118. Yes, I believe guidance would have been provided, for example in the form of NICE guidance, and then cascaded through the hospital divisions and clinical services by the HTC, but I am unable to point to any specific examples.

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

119. Autologous transfusion is where a patient has their blood recycled and given back to them. I believe that the frequency of this used at the Trust was very low.

120. Historically, some (very few) patients would come in prior to elective surgery and have a unit of blood taken and then stored and given back to them during surgery. That process does not happen anymore at the Trust. From my memory, the process of autologous blood transfusion stopped in the early 1990s. The process of autologous transfusion has been replaced by cell salvage which is a closed system performed by the hospital perfusion team or an external provider.

121. Cell salvage is favoured over autologous transfusion because historically when patients would come in to give one or two units of blood prior to elective surgery, it would drop their haemoglobin which meant they were not optimised before their surgical procedure which, in turn, meant that they may require a transfusion that they would not have otherwise needed. Autologous transfusion also adds the additional risks associated with the storing of blood and potentially the wrong patient getting the wrong blood.

122. It is not best practice to keep autologous units of blood in a laboratory if this can be avoided as it creates an inherent risk factor.

b. Any considerations given to the perceived risks, benefits, suitability and cost implications of autologous transfusion.

123. I have set out above the perceived risks and benefits of autologous transfusion and why this was stopped.

124. Cell salvage is now used in place of autologous transfusion, but as far as I am aware there is no single standardised policy at national level for this, albeit there is a national cell salvage working group.

125. Cell salvage is arranged by the medical specialities if it is required. The Trust has a service provider which is available for multiple specialities who may require cell salvage.

126. The process of call salvage extracts the patients' blood into a reservoir and separates the red cells from the other components which are then decanted into an infusion bag and some additives added such as anticoagulant, then it is transfused back to the patient. Whilst the patient may only get 300ml of red cells back this is the equivalent 2-2 ½ units of whole blood. The process reduces the risk of the patient having to have a

transfusion and works for patients who decline blood and blood components.

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.

127. I am sure guidance would have been provided but I am not aware of any and on the whole I do not think the Trust performed many autologous transfusions.

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?

128. Yes, I believe so and any guidance that came through would have been discussed and then cascaded to the relevant individuals through the HTC. I am unable to point to any examples.

'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?

129. I believe the term 'massive transfusion' has changed over time. This would have previously been known as a 'massive bleed' or a 'major haemorrhage' which are terms sometimes used interchangeably. These

days the term is 'major haemorrhage'. There are, however, some subtle differences as a 'massive transfusion' is different from a 'major haemorrhage'. A massive transfusion is when a patient requires multiple components, whereas a major haemorrhage is where a patient is bleeding profusely. The Trust has a guideline for massive blood loss (WITN7041012).

130. It is a clinical decision when blood is given and as explained above, is subject to the needs of the patient. Some patients will require more blood than others whereas some patients who are bleeding profusely may not require any blood at all. It all comes down to how clinically compromised the patient is.

131. I do not think an arbitrary figure has ever been placed on what would be classed as a massive transfusion. It could be said that anything over 2 units would be classed as a massive transfusion.

132. In terms of circumstances when this would be required, it may be when a patient has a major haemorrhage i.e., when they are bleeding out, but as explained above, major haemorrhage and massive transfusion are two different things.

133. In the case of major haemorrhage, we are trying to replace blood that the patient is losing. Separately a massive transfusion could be a large volume transfusion where the patient has got a low haemoglobin but there has been no blood loss, i.e. secondary to a chronic or underlying condition.

134. There will be patients that require exchange transfusions which may be classed as a massive transfusion, for example patients with sickle cell disease.

135. These are decisions that the HTC would not get involved in as they are clinical decisions with a specific clinical pathway subject to a particular clinical speciality.

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?

136. If an incident is submitted regarding massive transfusion it is followed up by the Transfusion Practitioner Team. If there are learning outcomes from this then these would be shared with the wider clinical team.

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.

137. Yes, in the hospital 'Transfusion Policy' (WITN7041004-008) and we have our own guideline for major haemorrhage, a copy of which is exhibited as above.

34. 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?

138. I have no knowledge or recollection of this, but any guidance that was provided would have been discussed and cascaded down from the HTC to clinical staff in the specialties.

Fresh Frozen Plasma ("FFP")

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

139. The HTC would have discussed this and written it into the 'Transfusion Policy'.

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

140. I am unaware of any historical discussions.

141. Historically, whole blood would be given but now this is split down into components.

142. In patients with a major haemorrhage, we replace the red cells and replace their plasma and any other necessary components (e.g. platelets) until the patient is stabilised.

143. There is guidance to support the decision to give FFP in the Transfusion Policy, based on national best practice and guidance.

37. 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.

144. Yes, we do through the Transfusion Policy and any changes or recommendations are cascaded through the divisions to clinical staff and incorporated into any local policies or guidance.

38. 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?

145. I cannot say for certain but if recommendations were provided by the Department of Health or a Blood Service either regionally or nationally

then these would have been discussed by the HTC and cascaded through the organisation and acted on as appropriate.

Platelets

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

146. The HTC has written platelets guidelines (WITN7041013) which include rationale for whom, when, why and how much is required. This is based on national and local policies, guidance and best practice.

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

147. Perceived risks, benefits and cost implications of platelet transfusions are all discussed at the same time that the policies and guidelines are formulated, as mentioned above at question 39.

41. 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.

148. Yes, the Trust has formal platelet guidelines which have been ratified by the HTC as exhibited above.

42. 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?

149. Yes, when guidance and recommendations come through the HTC will act upon this and then cascade it through the organisation to the relevant clinical staff.

Single-unit transfusion

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

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

150. This is part of patient blood management and also part of minimising risk to the patient.

151. There is guidance on single unit transfusion, and when this is recommended. These transfusions are more common than they used to be.

152. A single unit transfusion is where a patient receives 1 unit of red cells and is monitored to see if they become asymptomatic, and if so, they can be managed conservatively and may not require another unit.

153. The ethos now is if a patient is symptomatic, find out why and try to get to the root cause and if a transfusion is required then treat with a single unit, then re-assess the efficacy of that single unit.

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

154. I have set out my response to this question at question 43 above.

45. 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.

155. I have set out my response to this question at question 43 above.

46. 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?

156. I am not aware of any instances where excessive single units of blood transfusions were given either for an individual or group of patients.

47. Single-unit transfusions are described in [DHSC0025270] as a 'waste of resources' (p3). 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.

157. I have considered the document [DHSC0025270] provided by the Inquiry, which is a review for the Department of Health on the use of single unit blood transfusions by Dr Williams, Director of Medical Care Research at the University of Sheffield Medical School from November 1991 which states on page 1 that "*The practice of single unit transfusion is generally considered to be undesirable on the grounds that in only relatively few instances can it be justified clinically…single unit transfusions then represent a waste of resources*". I would not agree with this as a general statement. We have to bear in mind that this document was written almost 30 years ago, and views have changed since then.

158. As far as I am aware there was never a discussion at the HTC about single unit transfusions being a 'waste of resources'.

159. I understand that practice has now changed in relation to single unit transfusion and is now covered by the NICE Guideline https://www.nice.org.uk/guidance/ng24/chapter/recommendations.

48. 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?

160. I am not aware of any specific guidance but any that was made available to us by the Department of Health, NHSBT or other relevant organisation would have been discussed and cascaded down to our clinical staff via the HTC.

49. 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.

161. I am not aware of any audits that were undertaken on single unit transfusions.

Red blood cell concentrates

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

162. I cannot say what discussions would have taken place because this concerns product availability from NHSBT. It would not have been a discussion for the HTC.

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

163. This again would be out with the remit of the HTC, so I am unable to comment on this.

52. 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.

164. Any guidance on this would be in the transfusion policies ratified by the HTC.

165. This is more to do with how the NHSBT Blood Service has changed their product over time rather than specific discussions of the HTC. For the reasons already described, any minutes from the relevant period are not available to me so I am unable to comment.

53. 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?

166. Any guidance about a change in product would be communicated to us by the NHSBT Blood Service and then discussed at the HTC before being cascaded to the committee members and wider clinical teams.

54. 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.

167. All suspected adverse reactions (on average between 50 to 90 per year) are reported clinically.

168. These adverse reactions can range from a patient getting a slight temperature rise after a transfusion through to the patient getting a rash or pain at the site of the infusion to the more severe reactions. They are all investigated if they are reported. The investigation is therefore dependent on the clinical team reporting a reaction.

55. 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?

169. Not that I am aware of. Red cells have always been a limited resource and there are schedules (as described in response to question 18) of how much blood is required for different procedures and this has been reduced over the years. Back in the seventies and eighties quite a lot of blood was used as "whole blood".

170. In an attempt to get more plasma for fractionation and various blood components, the proportion of blood issued as 'red cell concentrate' was increased so more plasma and/or platelets could be taken so one unit of blood could be used for several components and purposes.

b. To the best of your knowledge, did the Hospitals come under pressure during the 1970s and 1980s to increase usage of red blood cell concentrates? If so, where did this pressure come from?

171. Not that I am aware of. I believe that the position was to the contrary.

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?

172. I am unable to answer this question which related to the wider medical community in the 1970s and 80s. Intuitively, using 'whole blood' would reduce the number of patients exposed to that donation. With blood component therapy, a single donation could go to several patients (red cells + plasma + platelet concentrate) even if the plasma was not sent for fractionation.

'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 was administered to patients. Please address the following:

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

173. This is not something that I have come across before. I, therefore, do not believe that any discussions took place at the HTC. This is not a practice that I am aware of having taken place at this Trust.

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

174. My response is as above at question 56.

58. 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.

175. My response is as above at question 56.

59. 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?

176. My response is as above at question 56.

Section 4: Knowledge of risk

60. 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?

177. The risk of viral infection from blood transfusion would have been the subject of discussion at HTC meetings.

178. The source of this knowledge would have come through the Blood Service and currently NHSBT and SHOT.

179. As soon as a new virus is identified to us it is discussed by the HTC and then cascaded to the wider clinical team with recommendations.

61. 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?

180. I am unable to point to any examples, but I repeat, as I said in response to question 60 above - that any advice and guidance from the Blood Service or SHOT would be actioned and our clinical staff made aware as soon as practically possible.

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

181. The proceeding of the HTC meetings as well as the education and cascading of information would work to minimise the risk of exposure to patients through the restrictive use of blood and also minimising the risk of patients by setting up donor panels for patients that are having regular transfusion which is done in collaboration between the NHSBT and the clinical teams.

63. 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.

182. If and when a new virus is identified, then the HTC will cascade the information to the clinical teams as was the case more recently with Hepatitis E where the HTC put all the guidance in place including the recommendations and safety checks for the clinical teams.

64. 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.

183. I can only speak as to the records I have seen. As soon as we are aware something is a concern that may adversely affect patient safety the HTC acts on it as soon as it possibly can and to the best of its ability.

65. 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?

184. I am not aware of any such discussions. It is not clear what is meant by 'transfusion methods'.

Section 5: Reporting and audits

66. Did the Hospitals 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?

185. If an inpatient has any symptoms following a blood transfusion, then they are asked to report this to a nurse or doctor whilst an inpatient who will then escalate this by reporting an adverse reaction. If the patient has been discharged, then they are asked that if they feel unwell they should contact the ward who will investigate this.

b. Did this procedure extend to a time after a patient had been discharged from Hospital?

186. Yes, the patients are given advice and provided with a discharge card containing a contact number should they suffer symptoms following

discharge from hospital. This applies not just to blood transfusion but all medical procedures.

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

187. No, no time limit is set.

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?

188. The clinician would contact the transfusion laboratory and the haematologist would be asked for support and advice.

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

189. Yes, there is a form to report any untoward incident to the blood bank/RTC so that a recall of blood components can take place if necessary.

190. Adverse reactions are reported for formal systematic review with Transfusion Practitioners in collaboration with the clinical haematologist and based on the SHOT criteria for reporting these. They are then, if necessary, reported to SHOT and if we suspect there is an implicated unit we report it to NHSBT so they can do a recall if appropriate.

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.

191. If a patient dies because of a blood transfusion: Reporting to MHRA is a legal obligation of a Hospital Blood Transfusion Laboratory. Reporting to Serious Hazards of Transfusion (SHOT) is considered voluntary but professionally mandated. To support UK hemovigilance, collaboration and shared learning the MHRA and SHOT now use a joint online reporting system, known as SABRE. MHRA will be responsible for deciding if the report qualifies as a SAR or SAE under BSQR definitions, while SHOT will be responsible for deciding if the report qualifies as reportable using SHOT definitions. Reports which are not required by either organisation can be excluded or withdrawn as appropriate (MHRA/SHOT, 2021).

192. In circumstances where a patient received a blood transfusion as part of their treatment and later dies, but not because of the blood transfusion, then it would not appear on the death certificate as far as I am aware. A decision about what appears on the death certificate is a clinical decision (sometimes decided by HM Coroner if the death is reported) for the doctor overseeing the patient at the time. There is no guidance that I am aware of which would cover what ought to be put on the death certificate if the patient has received a blood transfusion prior to death.

193. Given that transfusions are often required in critically ill patients, it is not uncommon for patients to die following a blood transfusion and in those circumstances, I would not expect the transfusion to appear on the death certificate unless it was clinically felt that this was a cause of, or participating factor in, the death.

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

194. If Transfusion transmitted infection was suspected, this would have been reported by the patient's clinician to the Consultant Haematologist

onsite at the Hospital, the Consultant Haematologist would then communicate this to the Consultant at The Blood Centre. The Consultant Haematologist would ask the Transfusion laboratory to supply a list of all blood components transfused.

68. 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?

195. SHOT raised awareness of reporting amongst clinical users. Risk management received the incident forms (pre-online systems) and they would input into reports for clinical governance meetings by medical specialties. SHOT reports would be discussed at the HTC.

69. 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?

196. The Hospital Transfusion Laboratory acted upon guidance received either directly from NHSBT, British Committee for Standards in Haematology (BCSH), Clinical Pathology Accreditation (CPA), SHOT, Regional Transfusion Committees and the Department of Health and others as required.

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

197. The Transfusion Practitioners produce a quarterly wastage report to the HTC (WITN7041014). Historically audits were presented to the HTC. These were either audits by the Hospital Transfusion Laboratory itself i.e. blood wastage or the Clinical area with the assistance of the Hospital

Transfusion Laboratory in supplying blood usage data by surgical procedure, e.g. Orthopaedics audit with relevance to knee replacement and total hip replacement.

71. 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?

198. Audits were either local, regional or national NHSBT Comparative audits. Some were instigated as joint audits with specialities, such as Orthopaedics or Obstetrics.

199. Currently as an example, MFT carry out an internal biannual bedside audit of the administration and documentation process from a nursing point of view (WITN7041092). I cannot comment on audit schedules from early HTC's for the reasons explained.

72. 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.

200. This was done as part of the SLA agreement with the NHSBT.

201. Audits consist of components *ordered and transfused* and *ordered and not used.*

73. 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.

202. A report is produced on the NHSBT Blood Stock Management System, the information for which is submitted from the Hospital Laboratory Transfusion Team.

74. 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.

203. I believe that audits and data collection were conducted in relation to FFP, red blood cell concentrates, platelets, and massive transfusions. I am not aware of any audits in relation to autologous transfusions because these were very infrequent, and I do not believe national comparative ever asked for audits in relation to this.

75. 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.

204. By the very nature of an audit there tends to always be findings with a preventive or corrective action put in place.

Section 6: Treatment of patients

Provision of information to patients

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

205. As information packs and leaflets have been developed and made available to us by the Blood Service, we have used those leaflets and cascaded them to the clinical staff in paper format, but also more recently in the form of electronic links which can be sent to a patient email or mobile phone.

206. As the leaflets and information provided by the Blood Service are standardised and formulated in a very patient-friendly and attractive way, we have tended to use these rather than develop our own local information leaflets. An example of these leaflets is attached (WITN7041015).

207. The HTC has worked closely with NHSBT and clinicians to review the risk to patients with emerging infections e.g. Hepatitis E in particular required action in 2015 as it emerged that immunosuppressed patients were at risk of chronic Hepatitis E infection and required Hepatitis E negative blood products.

208. The HTC worked with NHSBT to ensure these products were available to 'at risk' patients (as designed by the expert Advisory Committee on the Safety of Blood, Tissues and Organs [SaBTO]) and with clinicians to ensure that they were aware of at risk groups and could consent and counsel these patients appropriately. All blood products are now Hepatitis E negative and have been since 2017.

209. Guidance from SaBTO and NHSBT is routinely discussed at the HTC meetings to ensure that guidance is being met and that this information is passed to the appropriate clinical teams.

77. 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?

Consent

210. The HTC would make sure that the clinical teams had access to the advice and information provided by the NHSBT Blood Service and then it would be up to the clinicians to provide this information to their patients.

211. Consent is included in the transfusion prescription form which the Trust uses (WITN7041016).

212. The Trust will shortly be moving to the fully electronic system of which consent is a large part and will include consent for blood transfusion.

78. 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?

213. I cannot say whether this was discussed as part of an HTC meeting, but I am aware that the consent process of blood transfusions was variable and much less robust in the 1990s than it is currently.

79. 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.

214. The Trust Transfusion Policy advises clinicians that it is good clinical practice to discuss blood transfusion with patients and discuss the benefits, risks and alternatives to transfusions. The discussions should be documented in the notes and the blood prescription has a question to ask if consent has been obtained. The blood prescription form was being updated in 2019 to include a consent form for patients with clear advice on the discussions the clinicians should have prior to transfusion. This has not been introduced into clinical practice as of yet but has been built into the electronic patient record which is going live on 8 September 2022.

215. Patients will have to provide written consent (with considerations for capacity, children under 16 etc. as per the Trust consent policy) prior to a transfusion, or after the event if given in an emergency.

216. Patients who have regular transfusions (such as haematology patients) will have their consent reviewed annually.

Section 7: vCJD

80. 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].

217. Variant CJD emerged in the mid-1990s as the human version of spongiform encephalopathy in cows. It was recognised early that it had many features that distinguished it from classical (human sporadic or hereditary) Jacob Creutzfeldt disease, not least deposits of prion protein outside the central nervous system, notably in lymphoid tissue. This raised what was then a theoretical possibility that the condition could be transmitted by blood or blood transfusion. In 1997, the first blood donor to

develop vCJD was reported and there were further cases in 1999 and 2000.

218. Until December 2003, when the first case of vCJD in a recipient of blood donation was reported, there was no evidence of haematogenous spread. Thus, between 1997 and 2004, haematogenous spread remained a theoretical possibility only. A second possible case of spread by blood donation was reported in July 2004. Not all recipients of an implicated blood donation or its components went on to develop vCJD. Those that did develop vCJD from blood donation had all received a unit of red cells. No recipients of blood components or fractionated plasma products had developed vCJD.

219. I am unable to answer the extent to which the HTCs were involved in assessing and managing the risk of vCJD, since I do not have minutes from that time period available to me.

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

220. I refer to my answer to question 80.

82. 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].

221. I refer to my answer to question 80.

83. 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

222. I refer to my answer to question 80.

223. I have reviewed documents [BART0002418], [NHBT0001123_002], [HCDO0000643] and cannot add any more than what is already stated in these documents.

Section 8: Look back

84. 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.

224. There was a national transfusion lookback for hepatitis C back in 1995 where attempts were made to trace recipients of blood from donors who had tested HCV positive after October 1991 when HCV testing was introduced but who had donated blood prior to that date. Patients so identified were asked to be tested for HCV by their GP and referred on to a hepatologist if positive.

85. 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?

225. I am unable to say what actions or decisions were taken by the HTCs to trace those infected with HCV as part of the national lookback since I do not have documents or accounts from those involved from that time period available to me.

86. What were the major obstacles that the Hospitals faced when attempting to undertake the HCV lookback?

226. I refer to my answer to question 85. I can speculate that the availability of medical records might be an issue.

Section 9: Other

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

227. Personally and as an organisation I wish to pay tribute to those infected and affected and who are trying to understand the events of the past. We will do our best to support the Inquiry in any way we can.

88. 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.

Statement of Truth

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

Signed GRO-C

Dated 20 May 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
Undated	Ledger of records	WITN7041002
May 2010	Maximum Surgical Blood Order Schedule Adults 2010, CMUH NHS	WITN7041003
May 2001	Blood transfusion policy, CMUH NHS (version 2)	WITN7041004
August 2002	Blood transfusion policy, CMUH NHS (version 3)	WITN7041005
October 2005	Blood transfusion policy, CMUH NHS (version 4)	WITN7041006
November 2006	Blood transfusion policy, CMUH NHS (version 5)	WITN7041007
May 2008	Blood transfusion policy, CMUH NHS (version 6)	WITN7041008
2004	Adult indication Codes for Transfusion, CMUH NHS	WITN7041009
February 2007	Adult red cell use guidelines, CMUH NHS	WITN7041010

Undated	To transfuse or not, a guide for adult patients (flowchart)	WITN7041011
December 2006	Guidelines for massive blood loss in the adult patient, CMUH NHS	WITN7041012
June 2007	Guidelines for the clinical use of platelets in adults, CMUH NHS	WITN7041013
Undated	Blood product usage and wastage units (2020-21)	WITN7041014
June 2009	Indication codes for transfusion: An Audit Tool, NHSBT	WITN7041015
Undated	Adult blood/blood components prescription sheet, CMUH NHS	WITN7041016
15/12/1992	E Love, 'Transfusion Incidents Manchester Royal Infirmary' letter	WITN7041017
March 2003	CMHT (& MCUHT) HTC Terms of Reference	WITN7041018
22/10/2003	CMHT (& MCUHT) HTC Minutes	WITN7041019
21/01/2004	CMHT (& MCUHT) HTC Minutes	WITN7041020
12/05/2004	CMHT (& MCUHT) HTC Minutes	WITN7041021
29/09/2004	CMHT (& MCUHT) HTC Minutes	WITN7041022
24/11/2004	CMHT (& MCUHT) HTC Minutes	WITN7041023
18/01/2005	CMHT (& MCUHT) HTC Minutes	WITN7041024
08/06/2005	CMHT (& MCUHT) HTC Minutes	WITN7041025
28/09/2005	CMHT (& MCUHT) HTC Minutes	WITN7041026

07/12/2005	CMHT (& MCUHT) HTC Minutes	WITN7041027
26/04/2006	CMHT (& MCUHT) HTC Minutes	WITN7041028
19/07/2006	CMHT (& MCUHT) HTC Minutes	WITN7041029
30/08/2006	CMHT (& MCUHT) HTC Minutes	WITN7041030
25/10/2006	CMHT (& MCUHT) HTC Minutes	WITN7041031
24/01/2007	CMMC HTC Minutes	WITN7041032
18/04/2007	CMMC HTC Minutes	WITN7041033
25/07/2007	CMMC HTC Minutes	WITN7041034
24/10/2007	CMMC HTC Minutes	WITN7041035
23/01/2008	CMMC HTC Minutes	WITN7041036
February 2008	CMMC HTC Terms of Reference	WITN7041037
23/04/2008	CMMC HTC Minutes	WITN7041038
23/07/2008	CMMC HTC Minutes	WITN7041039
22/10/2008	CMMC HTC Minutes	WITN7041040
28/01/2009	CMUH HTC Minutes	WITN7041041
29/04/2009	CMUH HTC Minutes	WITN7041042
05/08/2009	CMUH HTC Minutes	WITN7041043
23/02/2010	CMUH HTC Minutes	WITN7041044
05/05/2010	CMUH HTC Minutes	WITN7041045
16/09/2010	CMUH HTC Minutes	WITN7041046

01/12/2010	CMUH HTC Minutes	WITN7041047
09/03/2011	CMUH HTC Minutes	WITN7041048
08/06/2011	CMUH HTC Minutes	WITN7041049
27/07/2011	CMUH HTC Minutes	WITN7041050
28/09/2011	CMUH HTC Minutes	WITN7041051
14/12/2011	CMUH HTC Minutes	WITN7041052
08/02/2012	CMUH HTC Minutes	WITN7041053
20/06/2012	CMUH HTC Minutes	WITN7041054
05/09/2012	CMUH HTC Minutes	WITN7041055
06/03/2013	CMUH HTC Minutes	WITN7041056
12/06/2013	CMUH HTC Minutes	WITN7041057
27/11/2013	CMUH HTC Minutes	WITN7041058
05/02/2014	CMUH HTC Minutes	WITN7041059
04/06/2014	CMUH HTC Minutes	WITN7041060
03/09/2014	CMUH HTC Minutes	WITN7041061
03/12/2014	CMUH HTC Minutes	WITN7041062
04/03/2015	CMUH HTC Minutes	WITN7041063
03/06/2015	CMUH HTC Minutes	WITN7041064
16/09/2015	CMUH HTC Minutes	WITN7041065
02/12/2015	CMUH HTC Minutes	WITN7041066

04/10/2004	Hospital Blood Transfusion Committee - Children's Division Minutes	WITN7041067
01/08/2005	Hospital Blood Transfusion Committee - Children's Division Minutes	WITN7041068
06/02/2006	Hospital Blood Transfusion Committee - Children's Division Minutes	WITN7041069
05/06/3006	Hospital Blood Transfusion Committee - Children's Division Minutes	WITN7041070
02/10/2006	Hospital Blood Transfusion Committee - Children's Division Minutes	WITN7041071
04/12/2006	Hospital Blood Transfusion Committee - Children's Division Minutes	WITN7041072
03/08/2007	Hospital Blood Transfusion Committee - Children's Division Minutes	WITN7041073
25/02/2004	Hospital Transfusion Committee Steering Group Minutes	WITN7041074
12/08/2004	Hospital Transfusion Committee Steering Group Minutes	WITN7041075
28/10/2004	Hospital Transfusion Committee Steering Group Minutes	WITN7041076
13/01/2005	Hospital Transfusion Committee Steering Group Minutes	WITN7041077
23/03/2005	Hospital Transfusion Committee Steering Group Minutes	WITN7041078

28/09/2005	Hospital Transfusion Committee Steering Group Minutes	WITN7041079
21/12/2005	Hospital Transfusion Committee Steering Group Minutes	WITN7041080
15/03/2006	Hospital Transfusion Committee Steering Group Minutes	WITN7041081
05/07/2006	Hospital Transfusion Committee Steering Group Minutes	WITN7041082
15/02/2010	Trafford Healthcare NHS Trust, Blood Transfusion Policy	WITN7041083
25/07/2011	Trafford Healthcare NHS Trust, HTC Minutes	WITN7041084
31/10/2011	Trafford Healthcare NHS Trust, HTC Minutes	WITN7041085
05/03/2012	CMUH, Trafford Division HTC Minutes	WITN7041086
04/09/2012	CMUH, Trafford Division HTC Minutes	WITN7041087
27/11/2012	CMUH, Trafford Division HTC Minutes	WITN7041088
2003	CMHT (& MCUHT) A Retrospective Audit, Orthopaedic Blood Use and the MSBOS	WITN7041089
March 2003	National Comparative Audit of Blood Transfusion, Report on Transfusion Practice in Manchester Royal Infirmary	WITN7041090
December 2009	CMUH, Audit of the Appropriate Use of Transfusion Indications	WITN7041091
July 2011	Bedside Transfusion Audit, CMUH NHS	WITN7041092

2014	National Comparative Audit of Blood Transfusion, Audit of Patient Information & Consent, CMUH	WITN7041093
2014	NW RTC Presentation 'Audit of Patient Information & Consent'	WITN7041094
March 2011	CMUH Draft Blood Transfusion Dashboard	WITN7041095
December 2011	CMUH Draft Blood Transfusion Dashboard	WITN7041096
April 2013 - September 2014	Quarterly Survey of Blood Use Forms	WITN7041097