Witness Name: Professor Roopen Arya
Statement No.: WITN7093001
Exhibits: WITN7093002 - WITN7093068
Dated:
24 May 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR ROOPEN ARYA, ON BEHALF OF KING'S COLLEGE HOSPITAL 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 Roopen Arya, 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 Roopen Arya. My work address is King's College Hospital, Denmark Hill, London SE5 9RS. My date of birth is GRO-C 1962. I hold the following professional qualifications: BMBCh (Oxon), MA, PhD, FRCP FRCPath. I am duly authorised to make this witness statement on behalf of King's College Hospital NHS Foundation Trust (the "**Trust**"). I make this witness statement in response to a request and email sent by Oliver Bogle, Inquiry Paralegal, Infected Blood Inquiry to the Trust's CEO on 17 December 2021 (the "**Request**"). I have liaised with the Trust's Director of Corporate Affairs and Trust Secretary on behalf

of the Trust's CEO. Kelly Nwankiti, the Trust's Lead Nurse for Patient Blood Management and Transfusion, has conducted a thorough review of documents and provided me with great assistance to enable me to submit the Trust's response to the Request to assist the Infected Blood Inquiry.

2. Please set out your current role at King's College Hospital NHS Foundation Trust and your responsibilities within that role.

2. I am currently employed at the Trust as a Consultant Haematologist, Clinical Director for Haematology. I am also Haematology Clinical Lead for Blood Sciences Laboratory, Director of the Trust's Thrombosis Centre, Chair of the Trust's Anticoagulation & Thrombosis Committee, Chair of the Trust's Haematology Clinical Governance Committee, Chair of Joint (Trust and Guy's and St Thomas' NHS Foundation Trust) Formulary Committee, and Chair of the Trust's Medication Safety Committee.

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

3. I was appointed by competitive interview to the Consultant, Clinical Director and Laboratory Lead roles and by invitation to the other roles.

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 qualified from Oxford University Medical School in 1986, did my SHO rotation at the Kent and Canterbury Hospital subsequently and joined the Trust in 1991 as Haematology SpR. I was MRC Clinical Training Fellow at the Trust from 1993 to 1996 and subsequently Clinical Lecturer until 1999 when I was appointed as Consultant Haematologist at the Trust, where I continue. I was Clinical Lead for Haematology for 13 years and since 2017 have been Clinical Director. I was reappointed to this role in August 2021.

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

5. NHS national policy and the Trust's local policy in relation to records retention means that much of the paperwork that may have been available with information sought would have been destroyed as it is over 20 years old. This has a direct impact on the ability to retrieve some of the requested information needed for this Request. All available paper records for transfusion, including minutes, training evidence, some guidance and policies that had been stored at off-site locations have been recalled but these only extend as far back as 2001. The Trust's Blood Transfusion Policy and Procedure (January 2002, Exhibit WITN7093002) (the "**2002 Policy**") states at page three that "[T]he Hospital Transfusion Committee at [the Trust] has been in existence since 2000 and reports to the Clinical Risk Management Committee".

6. The earliest minutes for the HTC that we can locate is dated 22 June 2001 (WITN7093003). These minutes reference a previous meeting and resignations from the committee, indicating that the HTC was in existence prior to this date. These minutes imply that there was an existing body prior to this that oversaw transfusion governance (this can be implied by the availability of transfusion guidance prior to the HTC commencement date) but the Trust is unable to locate any documentation stating when that prior body was established.

7. The first HTC chair according to the earliest minutes that we can locate from 22 June 2001 was David Scott-Coombes (WITN7093003), but we cannot locate any

documentation to confirm who was the chair at the formation of the HTC in 2000, or who established or chaired any prior body that discussed transfusion.

8. The Trust is unable to locate any documentation stating why the initial HTC was established. The introduction section (page 3) to the 2002 Policy (WITN7093002) does suggest that the HTC was established pursuant to Better Blood Transfusion (HSC 1998/224) (NHBT0083701_002).

9. The Trust is unable to locate any documentation stating what the initial aims of the HTC was when it was established. However, the HTC Terms of Reference from 2003 ("**2003 TOR**") (WITN7093005), does provide some assistance and is the first documented evidence of its aims that we can locate. The aim set out in the 2003 TOR was to "oversee and implement good transfusion practice through the Trust framework for clinical governance and clinical risk management structures." The terms of reference are then listed out in the 2003 TOR as:
    a. Ensures that the Trust complies with the HSC 2002/009 'Better Blood Transfusion – Appropriate use of Blood';
    b. Ensures that the Trust complies with the CNST standard for blood transfusion; 5.4.3 Reports to SHOT (Serious Hazards of Transfusion);
    c. Promotes best practice through local protocols based on national guidelines;
    d. Monitors, through audit, the use of blood components within the Trust;
    e. Audits blood transfusion practice against the Trust policy and national guidelines;
    f. Modifies and improves existing blood transfusion protocols and introduces appropriate changes to practice;
    g. Provides feedback to the Trust regarding audits, the use of blood and risk management by way of an annual report;
    h. Promotes the education and training of all clinical, laboratory and support staff involved in blood transfusion;
    i. Is a focus for local contingency planning for and management of, blood shortages;
    j. Reports regularly too and participates in, the Regional Transfusion Committee (and therefore the National Blood Transfusion Committee);

k. Consults with local patient representative groups, where appropriate; and

l. Provides feedback to individual Care Groups regarding Adverse Incidents and staff training.

10. As set out above, the earliest HTC minutes that we can locate imply that there was an existing body prior to this that oversaw transfusion governance (this can be implied by the availability of transfusion guidance prior to the HTC commencement date). The Trust is unable to locate any documentation of its purpose or structure to comment on how the Trust monitored transfusion practice prior to the establishment of the HTC.

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

11. The 2003 TOR (WITN7093005) sets the composition of the HTC membership as follows:

    a. A Chair – elected by members of the HTC from the 'users' (of blood components) with a term of service between 2-3 years;

    b. Representatives from: The National Blood Service, The Hospital Transfusion Team (this would have been the Consultant in Transfusion Medicine, Manager of the Blood Bank (Senior MLSO), and Blood Transfusion Nurse Specialist), Trust senior management, Trust Clinical Risk Management, Surgery, Critical Care, Women's Health, Liver, Renal, Pathology, Haematology, Accident and Emergency (Ad hoc), Theatres, Patient group (Ad hoc), and Primary Care Team (Ad hoc).

12. Between 2003 and 2012, there was no recorded change to the membership, but there were some minor changes to the terms of reference in 2007 (WITN7093006).

13. In 2013 the HTC terms of reference were updated (WITN7093007).

a. The main changes made to the membership to include: the pathology liaison manager; additional care groups including all existing care groups (and changed care group titles), perfusion, the Princess Royal University Hospital, and PCT/GP commissioning (by invitation).
b. The HTC was also listed as overseeing the Hospital Transfusion Team, this was made up of: Transfusion Practitioners, the Blood Transfusion Laboratory Manager, and Consultant in Transfusion Medicine.
c. The updated terms of reference included further HTC aims:
    i. consults with local patient representative groups, where appropriate;
    ii. reviews all blood component/product related adverse incidents for discussion, learning and progress, as well as escalation of any delays in completion of investigations; and
    iii. provides feedback to individual Divisions regarding Adverse Incidents, staff training, wastage, sample rejects and tag compliance.

14. In 2016 the HTC terms of reference were updated (WITN7093008) and included the following:
    a. A responsible organisation division: this was critical care theatres and diagnostics (the division that was responsible for the transfusion practitioner team);
    b. The chair was listed as a named user and there was a deputy chair listed as a named user;
    c. Membership was updated as follows: Representatives from the following divisions:
        i. Urgent care: Comprising of Acute and Emergency Medicine, Post - Acute and Planned medicine plus Outpatients, Women's Health, and Theatres and Diagnostics;
        ii. Networked Care: Comprising of Critical Care Radiology and MEP, the Variety Children's Hospital and Paediatric Board, Cardiovascular Sciences, Haematology and Precision Medicine, Liver and Renal, and Neurosciences;
        iii. Princess Royal University Hospital ("**PRUH**");

iv. Viapath-Transfusion and senior management;
v. External: NHS Blood and Transport; and
vi. Required by invite only: Dental, Planned Surgical Ophthalmology and Optometry, Therapy Rehabilitation and Allied Clinical Services, and Pharmacy.

d. The frequency of the meeting changed from every two months to quarterly; Quorum was also set to: a representative from the Transfusion Practitioner Team (A transfusion Practitioner), a representative from the Blood Transfusion Laboratory (The laboratory manager, a quality manager, or a biomedical scientist) and at least four representatives from different clinical areas;
e. The overall purpose of the committee was amended slightly to 'oversee and implement good transfusion practice and transfusion safety throughout the Trust'.
f. The Terms of Reference were revised to follow the domains of 'Better Blood Transfusion, Appropriate Use of Blood' (2002) HSC 2002/009 (NHBT0062177_001) and were to:
    i. Promote safe and appropriate blood transfusion practice through local protocols based on national guidelines;
    ii. Audit the practice of blood transfusion against the NHS Trust policy and national guidelines, focusing on critical points for patient safety and the appropriate use of blood;
    iii. Lead multi-professional audit of the use of blood within the NHS Trust, focusing on specialities where demand is high, including medical as well as surgical specialities, and the use of platelets, plasma, and other blood components as well as red cells;
    iv. Regularly review and take appropriate action on data on blood stock management, wastage and blood utilisation provided by the Blood Stocks Management Scheme (BSMS) and other sources;
    v. Be a focus for local contingency planning for and management of blood shortages;
    vi. Provide feedback on audit of transfusion practice and the use of blood to all NHS Trust staff involved in blood transfusion;

vii. Develop and implement a strategy for the education and training for all clinical, laboratory and support staff involved in blood transfusion;

viii. Promote patient education and information on blood transfusion including the risks of transfusion, blood avoidance strategies and the need to be correctly identified at all stages in the transfusion process;

ix. Modify and improve blood transfusion protocols and clinical practice based on new guidance and evidence;

x. Actively promote Patient Blood Management;

xi. Reviews all blood component/product related adverse incidents for discussion, learning and progress. Escalation of any delays in completion of investigations. Monitors reports to SHOT (Serious Hazards of Transfusion) and SABRE (Serious Adverse Blood Reactions and Events) via MHRA (Medicines and Healthcare products Regulatory Agency; and

xii. Review outcomes and action plans from regulatory inspections, including MHRA and UKAS, and escalate non conformances as required.

15. In October 2019 the HTC terms of reference (WITN7093010) changed to include:

a. The Hospital Transfusion Team ("**HTT**") Chair as the Deputy Chair;

b. Attendance for the PRUH to be more specific to request specifically the attendance of the PRUH Transfusion Team (this covers Transfusion Practitioners and the Laboratory manager);

c. The requirements for the Chair were amended to "Any consultant with interest in Transfusion. Cannot also chair HTT. Term is 2 Years with option of re-election for second term".

d. Reporting arrangements into higher committees were set out to escalate to the Patient Safety Committee and annual report, and Viapath annual management review.

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 HTC carry out from the date established? Please also include any other functions not mentioned above.

16. The HTC carried out all of the functions listed in your query:
    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.

17. In addition to this, the HTC carried out the following additional functions:
    a. Review of clinical incidents relating to transfusion both clinical and laboratory; and
    b. Review of financial aspects of transfusion including hospital/ divisional spend, wastage and projections going forward.

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 Hospital? Do you think this is a fair assessment of the HTC? Please explain your answer.

18. We cannot locate any documentation laying out the function of the HTC, how it existed, or how it was governed at the Trust as of 1996. This makes it difficult to state whether your queried statement was true at the time of its publication. However, within the earliest HTC terms of reference that we can locate (the 2003 TOR, WITN7093005), it was clear that there was a structure that showed that the HTC was expected to 'promote' good transfusion practice with the help of users from individual areas which allowed for representation across the hospital. The HTC reported directly to the Patient Safety Committee (formerly known as the Clinical Risk Management Group), which reported to the Medical Director and the Chief Executive. As representation was required from principal users in transfusion, most key areas would have been aware of the HTC. There is a risk that non-principal users or areas that did not attend or had little or no transfusion use will not have been aware of the existence and the function of the HTC.

19. As of 2003, the role of the HTC was well established and can be evidenced. The role of the HTCs in London was also well established through groups like the RTC

and various transfusion bodies which were attended by clinicians across the different hospitals. It was also well documented what was expected from HTCs within documents such as the Clinical Negligence Schemes for Trusts Risk Management Standards (Criterion 7) (2005). This set out the expectations of hospitals in relation to transfusion based on 'HSC 1998/224 Better Blood Transfusion NHSE (1998)' (NHBT0083701_002) and included the function and governance of HTCs. Within the Trust, there was attendance across different care groups but also across Risk Management which had oversight of risk across the Trust, making it more likely that most specialities would have been aware of the HTC.

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 Hospital? Do you think this is a fair assessment of the HTC ? Please explain your answer.

20. The HTC did serve as an interface between the laboratory and the clinical area as one of its many functions. There are many examples of how this interface was very successful in improving communication and interaction between the two but also on service delivery and associated patient outcome. Recognised issues relating to differing experience between the two bodies were evident, as the clinical area had limited laboratory experience and in the reverse, but this was often bridged with the use of clinicians to support the process of communication e.g. haematology consultants, registrars that would have laboratory insight with training, who were then responsible for discussing concerns with clinicians that were raised by the laboratory. These roles were also performed by transfusion practitioners. At times, there were also issues relating to the level of experience of those in such roles and the ability of the Trust to ensure that the roles were always filled.

21. When specific issues arose relating to specific clinical areas, efforts were made by the HTC members to facilitate communication directly with specialities to improve practice and service delivery. Sometimes there were difficulties in garnering clinician engagement for reasons including work pressures and disagreement between the HTC and parties that may have felt affected by proposed scopes. This still remains an issue today on a much smaller scale. Present day there is much more positive engagement and more people from clinical areas with an interest in transfusion who are willing to collaborate with the HTC to implement improvements.

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

22. The initial 2003 TOR (WITN7093005) stipulated that HTC meetings should occur bi-monthly (from the minutes we can locate this appears to have been every two months and, on some occasions, every three months). This is confirmed by the actual dates of the meetings, see WITN7093003 and WITN7093011 to WITN7093021 (HTC minutes 22 June 2001 to 22 June 2004). This continued until 2016, when the meeting frequency was changed to every quarter to be able to improve attendance and facilitate a longer meeting schedule. This is still the current frequency.

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 HTC was aware of this concern;***
- ***b. Any discussions the HTC 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.***

23. The HTC Clinical Risk Report, 2002 (WITN7093022) suggests that as at 2002 the HTC was aware of the need for training plans. The 2002 Risk Report documented low levels of training compliance across all staff groups.

24. The low levels of training compliance were reported to the clinical risk teams (who were representatives in the HTC) as part of the 2002 Risk Report. The 2002 Risk Report outlines the training for each staff group and the training priorities for 2003. There were discussions documented in planned objectives for 2002-2003 around plans to incorporate transfusion training into doctors' training and induction programs, senior medical staff training and nursing training. It was also discussed that transfusion training should become part of annual update programs for staff. There is documented evidence of the continued training efforts by the hospital transfusion team and reporting back to the HTC with training matrices demonstrating training being completed and compliance levels.

25. There was evidence that training was implemented. This included the production of transfusion training slides and acetate slides. Training records were held locally, but these have been destroyed in line with NHS document retention policy but from discussion with colleagues it appears that most training was directed to nursing and midwifery staff due to low levels of medical engagement. It is documented in the HTC minutes from 28 September 2001 (WITN7093011) that "[g]iven the constant change in junior doctors – it is felt that the training should be ward based – an ongoing project". Training became part of annual updates (2003) and was carried out by members of the hospital transfusion team (transfusion practitioners and the transfusion consultant). The HTC minutes from 10 September 2002 (WITN7093014) confirmed that short transfusion videos were

being shown at doctor inductions but this was considered as induction but not training.

26. Transfusion training was mandatory. There is a reference to mandatory transfusion training in the HTC minutes (see HTC minutes from 10 September 2002, WITN7093014) but this term does not appear to be used routinely within the minutes. It was documented that staff involved in ordering blood for patients were expected to have training (as set out in the 10 September 2002 HTC minutes, WITN7093014), it was documented in the 28 September 2001 minutes (WITN7093011) that the transfusion practitioners were keeping records of the numbers of staff trained and were reviewing the process that was were being used to facilitate training i.e. staff induction – there were also minutes around how training should be facilitated to improve compliance.

27. The majority of the initial training aids have not been retained but there are a few examples that include sampling and patient identification, blood collection, blood fridges, different blood components, administration, traceability and 'flying squad'.

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

28. The 10 June 2003 HTC minutes (WITN7093016) document that the HTC functioned as a development and training committee for transfusion. In the same minutes, it was also suggested that there was a clinical risk management function to its role with discussions being had with the committee and targeted members from relevant care groups.

29. It was documented in the 10 September 2002 HTC minutes (WITN7093014) that the HTC also functioned to give advice and had a joint responsibility with the care

groups over the cost of transfusion and overall blood component use. It does not appear clear how they provided advice outside of policy and guidance. There was feedback via the representatives to clinical areas about issues in transfusion relating to specific matters and the opportunities of such representatives to discuss and meet with the committee or relevant members e.g. transfusion nurses.

30. The function of the HTC became more established in 2001-2002 as SHOT reporting became part of the process and HTC representatives would also attend governance meetings to feed back on incidents and training related matters relevant to individual areas. Continued management of training and training compliance, providing feedback relating to new products and components and the creation and ratification of transfusion guidelines was also evident. It is clear from the minutes that the HTC were able to review why blood was being ordered, as it was frequently discussed in meetings but it was not always clear how this information was being collected. The HTC was involved in the process for the electronic patient record decision-making tree to support the ordering of blood components and discussed the implementation of telephone request forms and also the need for the 'approval' of transfusion through the transfusion consultant. There are mentions of fax requests and internal audits to measure compliance and thresholds being set for platelet use in 2004.

31. There was an intent to try and reduce the inappropriate use of blood components. This continued to be a theme until this day. The first Blood Transfusion policy came out of the HTC in 2001 based on the BCSH 1999 standards (WITN7093002). This also laid out guidance for appropriate blood transfusion. The Consultant haematologist is suggested to have been responsible for 'vetting' transfusion requests and the laboratory responsible for passing on the requests that needed to be vetted. It is noted on occasion that the HTC reached out to some care groups to discuss their ordering practice and there was repeatedly no response. It seems clear the HTC did not always have enough oversight to be able to control ordering practice and the lack of manpower in some circumstances meant that some aspects of the HTC role could not be fulfilled during out of hours which is reported as being raised as an issue in the minutes. Over time the HTC

control of the administering of blood components was discussed less within the minutes and rather the overall usage and wastage became a focus. There was still a responsibility to provide guidance which was disseminated amongst the HTC members for review prior to ratification, which gave the care groups the opportunity to comment on their own individual practice needs. The HTC continued to promote good transfusion practice but relied heavily on the members of the care groups going back to their clinical areas and implementing good practice. They did however, with the help of national comparative audit and audits of policy implementation, have opportunities to review poor practice that was raised during reports of findings.

13. Please describe the nature of the HTC's 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 HTC 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 HTC;***
- ***d. What oversight the Region had over the HTC;***
- ***e. Whether it was standard practice to have someone from the Regional Transfusion Centre sit on the HTC;***
- ***f. The input, if any, that the Region provided to the HTC in relation to updating and promoting transfusion practice; and***
- ***g. How the relationship changed over time.***

You may wish to refer to [BSHA0000061_029].

32. The 14 December 2001 HTC minutes (WITN7093012) state that the first South Thames Regional Transfusion Committee ("**RTC**") took place at St Thomas' Hospital on 22 November 2001 and was attended by Simon Cottam (the HTC chair) and Alex Mijovic (the consultant haematologist).

33. We do not hold any record of the RTC interaction other than as stated in the 14 December 2001 HTC minutes that "[t]he [RTC] was well attended and all profiles of transfusion were represented. [Alex Mijovic] and [Simon Cottam] will feed back as progress is made". This would have been fed back to the HTC by the chair and the consultant attendees.

34. It is not clear from our available records how the RTC initially fed into the HTC.

35. It is not clear from our available records what oversight the RTC had over the HTC.

36. We do not have records to comment on whether it was standard practice to have someone from the RTC sit on the HTCs. In our case, we had two HTC members who sat on the RTC. This meant that conversely, they were sitting as RTC members on our HTC. The HTC was not attended by other RTC members from outside the Trust.

37. There is no mention in our available records of how the relationship changed over time. There is occasional mention of attendance.

14. Please describe the HTC's 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 HTC 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 HTC?***

38. The Trust has a joint role provided by the consultant haematologist who worked with NHSBT.

39. The consultant continued to provide a joint role and was responsible for the clinical support for transfusion at this hospital whilst also working at NHSBT. In 2003 the terms of reference for the HTC was changed to suggest that NHSBT attendance was part of the membership. This was provided by the same consultant and then later by NHSBT customer relations officers on an ad hoc basis. The date of this transition is unknown from our available records.

40. It was standard practice for the joint transfusion and NHSBT consultant to attend the HTC. This role was designed to operate across both bodies and attendance at the HTC was expected and set out within the terms of reference since 2003.

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

41. The hospital transfusion laboratory representatives were core members of the HTC and were key in the oversight of the HTC into laboratory process and the relationship between the clinical area and the laboratory. They were essentially a sub-team of the HTC. The laboratory provided information relating to ordering practice and sampling issues and the overall use of components. It was able to advise on whether guidance around ordering was being adhered to. There was also a role of the HTC to oversee the transfusion service being provided by the laboratory and support the delivery and improvement of such a service. This included involvement in MHRA inspection, implementation of laboratory information and assisting with BMS empowerment to vet transfusions practice. The HTC was attended by the laboratory manager and their membership was documented in the terms of reference since 2003, with clear evidence of attendance prior to this.

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

42. Within the available HTC minutes (2001- present) in the early 2000s the main and recurring issues seemed to relate to:

    a. training and training compliance: not being able to train effectively as the Trust could not provide designated training slots that allowed staff to attend training or have time to attend training;
    b. a lack of clear chain of responsibility of the HTC members: there were clear initiatives and plans to implement change but when met with difficulties with compliance from the clinical areas, there was not much else that could be done;
    c. the rapid changing requirements in transfusion and the new guidance and policy that was being disseminated. Often tasks could not be completed before new ones were being raised and priorities would see projects abandoned in favour of more pressing issues;
    d. attendance of meetings: even though they were attended mostly by the same members, these were often senior nurses, risk management and people who were not well placed to influence change in the clinical areas;
    e. a lack of transfusion manpower to be able to roll out the desired changes and improvements; and
    f. a lack of consistency with compliance in the clinical area in relation to following recommendations relating to training, policy around transfusion practice and new guidelines.

Section 3: Policy and standard practice

17. Please outline the HTC's 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.

43. The types of blood components used are documented throughout the HTC minutes from 2001 (earliest minutes available) until present. There are also examples of audits (WITN7093022) and policy/guidelines that refer to the types of components available, including:

a. Red Cells
b. Autologous deposits
c. Platelets
d. Fresh frozen plasma
e. Cryoprecipitate
f. Octaplas
g. Albumin
h. Novo Seven
i. Anti-D

44. There is reference made to use in relation to component/product availability, audits of transfusion and specific mentions in relation to some clinical practice (all minutes between 2000-present). There are also discussions relating to the roll out of tracing of products.

45. In the 2002 Risk Report (WITN7093022), the Trust reported using 22,137 standard red cells, 7,467 units of fresh frozen plasma, 5,827 platelet units and 1,261 platelet units between 2001 and 2002. The 2002 Risk Report also reports the use of 16 units of autologous pre-deposits. These were mainly used in a surgical setting but were also used in obstetrics, medicine and child health.

46. The Trust cannot locate any clear documentation of usage prior to 2001.

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.

47. The precise introduction date of MSBOS (also called EBOS for a period at the Trust) is unknown. The earliest documentation we can locate referring to an 'MSBOS' is also the earliest minutes that we can locate (22 June 2001 HTC minutes, WITN7093003) where there is discussion surrounding an active MSBOS document. The 2002 Policy (WITN7093002) does reference an EBOS dated 2000. The earliest substantive EBOS guideline that we can still locate is from 2003 (WITN7093023).

48. The purpose of these schedules was to provide recommendations for the number of units that should be requested ahead of elective surgery. The guidance was recommended and did not supersede clinical judgement. The initial document was called the Elective Surgical Blood Order Schedule and is referenced in the 2002 Policy (WITN7093002) and the MBOS is also referred to in the 22 June 2001 HTC minutes (WITN7093003). It was eventually renamed the 'Maximum Blood Ordering Schedule' in 2010 (WITN7093024). The document guided clinicians on how many units could be ordered – however it appears that clinicians were able to order as required as noted in the reference in the 22 June 2001 HTC minutes that "Obstetrics and Gynaecology are essentially violating the MSBOS".

49. The 2003 MSBOS (WITN7093023) only covered the ordering of red cells. Over time the introduction of less invasive techniques resulted in a reduction in some of the stipulations for the preparation of blood (evident in MSBOS guideline 2010 (WITN7093024). The use of repeated audits of MSBOS use 'returns to stock' and wastage also helped to drive down the amount of recommended units requested between 2010 and the present.

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 HTC at the Hospital operate to standardise or enable the above practices? If the HTC did not, why not?

50. The 2002 Risk Report (WITN7093022) documents a section referring to the observation procedure not being followed. This is the earliest mention of such a process in the available documentation. In the 2002 Policy (WITN7093002) patient observations were listed as:
    a. Temperature, pulse and blood pressure prior to the start of transfusion and at completion;
    b. Temperature and pulse 15 minutes after the commencement of transfusion;
    c. Temperature and pulse hourly until the completion of transfusion.

51. The authors of the 2002 Policy (WITN7093002) are not listed but it states the HTC as responsible for its review. The 2006 version of the policy (WITN7093025) listed the authors as the transfusion practitioners and the consultant haematologist.

52. The 2002 Policy states that 'blood must be checked by two professionals'.

53. Section 6 of the 2002 Policy states that all patients having a blood transfusion must wear a name band that contains their surname, forename, date of birth, hospital number and gender.

54. Section 8.6 of the 2002 Policy states that "[p]atients must remain within the supervision of a trained nurse or doctor at all times during transfusion". It does therefore not appear that a doctor needed to be present during transfusion in circumstances where a trained nurse was present.

55. The 2002 Policy states at Section 10.1 that the following should be reported in line with the 'Trusts Adverse Incident Reporting Policy':
    a. Severe reactions;

b. Suspected cases of transfusion transmitted infection (report immediately to Blood Bank so that the regional blood service can be notified, to prevent others receiving components from the same donation);
c. Incorrect blood component transfused; and
d. Any 'near misses'. Section 10.2 also provides that adverse events will be reported to SHOT, by the Blood Transfusion Nurse Specialist, according to their guidelines. The 2002 Policy indicates that Appendix 3 lays out what the different types of reactions may be and how they need to be managed, but our retained records do not appear to include the Appendix 3. An equivalent Appendix can be seen in the 2006 version of this policy at Appendix 6 of WITN7093025.

20. Did the HTC 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.

56. Sections relating to obstetrics in transfusion can be found in the 2002 Policy.

57. Sections relating to massive blood loss can be found in Guidelines for the use of blood components (WITN7093026, "**2002 Guidelines**"); and Guidelines for the use of blood components (WITN7093027, "**2006 Guidelines**").

58. There are references to MSBOS (2001 HTC minutes) in relation to the number of units that should be ordered for different surgical procedures. The 8 April 2003

HTC minutes (WITN7093015) discussed cell salvage as an agenda item and discussed its level of use in the 2002 Risk Report.

59. The 2002 Guidelines outline the use of irradiated blood components and trigger events for platelet transfusion in haematological malignancies. It also has a section on blood components for bone marrow transplant patients. The use of ABO groups in BMT patients is added in the 2006 Guidelines.

60. The 2002 Guidelines discusses the 'mandatory indications' of O negative for patients who become transfusion-dependent and highlights thalassaemia patients in this group.

61. The 2002 Guidelines discusses the 'mandatory indications' of O negative for patients who become transfusion-dependent and highlights sickle cell patients in this group. It also discusses the use of sickle negative blood for such patient groups. This is expanded on in the 2006 Guidelines.

21. Was the HTC 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?

62. Failure to comply with transfusion policies and practices was not set out in the terms of reference. Compliance failures discussed within the HTC minutes were usually acted on by having discussions with the areas involved. This is documented in the HTC minutes (22 June 2001 (WITN7093003), 28 September 2001 (WITN7093011), 14 December 2001 (WITN7093012), and 10 June 2003 (WITN7093016)). Feedback would usually be given at the next meeting if the issue had been addressed.

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 Hospital relating to unnecessary transfusion.

63. The HTC set out guidance around appropriate transfusion incorporating the BSCH 1999 blood transfusion guidance to try and reduce unnecessary blood transfusion. This is present in the 2002 Guidelines ((WITN7093026), the 2002 Policy (WITN7093002), and the MSBOS (WITN7093023 and WITN7093024). There is also evidence of good patient blood management initiatives within the policies to reduce transfusion including cell salvage and setting transfusion thresholds. However, it is clear from the HTC minutes that there were issues with clinical engagement and training for staff members involved in transfusion decision-making and this led to over-ordering and a difficulty in implementing change at times. This issue continues through the HTC minutes and up until the present day.

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 HTC 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.***

In relation to the 'Better Blood Transfusion' Health Service Circular 1998/99 ("**HSC**"):

64. No discussions are documented in direct relation to the circular in any of these divisions (obstetrics; trauma and emergency care; surgery; haematological malignancies; thalassaemia; and sickle cell anaemia).

65. The HTC lists the HSC as the basis for guideline implementation in transfusion. Within the 2002 Guidelines (WITN7093026) and 2006 Guidelines (WITN7093027) there is discussion around the use of packed red cells, FFP, platelets, cryoprecipitate and Octaplas. This includes thresholds, volumes of use, rates of administration and special requirements. There are discussions within the minutes around the guideline development and roll out.

66. In relation to HSC the HTC lists the 'Exploration of autologous blood transfusion, especially peri-operative cell salvage' as one of its actions within the 2002 Policy (WITN7093002).

67. We cannot locate any reference to HTC discussions about the HSC in relation to single unit transfusion.

68. We cannot locate any reference to HTC discussions about the HSC in relation to fresh warm blood transfusion.

69. There is documentation in relation to cytomegalovirus transmission and advice on how this can be avoided in the guidelines for the use of blood components 2002 and 2006. There is other documented discussion in relation to transfusion transmitted infections.

70. The 2002 Policy comments on the actions required by Trusts (as highlighted in the HSC) and it appears that as a direct result of the HSC the following was commenced:
    a. The development of the Hospital Transfusion Committee in 2000;
    b. Participation in SHOT reporting since May 2000;
    c. The writing of a blood transfusion policy that was completed and circulated in 2002; and
    d. The development of an MSBOS/EBOS document in 2000 (as

referenced in the 2002 Policy).

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.

71. The HTC implemented triggers for transfusion. There is discussion within HTC minutes from 2001-2006 suggesting that even though triggers went into policies they were not followed through.

72. In the HTC minutes, HTC members laid out the requirements for training of staff, including medical, porter, nursing and midwifery. Throughout the minutes, there are references to continuing issues with the continuity of support being offered from the hospital to raise compliance. Training is reported to have been cancelled and transfusion was removed from local and trust inductions repeatedly.

73. The EPR decision tree was supposed to support the appropriate ordering of blood components electronically. Despite the implementation of EPR, the decision tree for transfusion was never followed through.

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 HTC 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 once the HTC became aware of any clinical change?

74. In the 2002 Guidelines (WITN7093026), the trigger threshold for transfusion is set at 7.0G/dl without additional risk factors and 8.0g/dl for patients over 65 with heart, lung disease or a higher haemoglobin if the patient is severely symptomatic. It then states 'aim to increase the haemoglobin by 2g/dl. Unless the patient continues to lose blood, this should be achieved by transfusing 2-3 units of packed red cells'. The 2006 Guidelines (WITN7093027) have the same triggers for transfusion and advise transfusion of 2-3 units of blood but finish with 'Occasionally symptoms of anaemia may be alleviated by giving 1 unit of red cells'.

75. The 8 February 2002 HTC minutes (WITN7093013) note: "There was a discussion about red cell transfusion triggers. Several members thought that in a fit surgical patient, the trigger should be specified as 7g/dl of haemoglobin. AM cautioned against reducing the triggers too far. GW and AM will redraft the guidelines and present at the next meeting". It is not clear how this was resolved but the next guideline that was published stated a trigger of 7.0g/dl. The introduction of single unit transfusion was also included in further publications of the guidelines.

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 HTC 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, was the HTC aware of excessive or unnecessary transfusion within the Hospital? If so, please provide details, including any guidance provided to clinicians.***

76. We cannot locate any records of discussions about the frequency of monitoring haemoglobin levels.

77. There are documented discussions within the HTC minutes relating to over-transfusion in surgery and 'poor use' in obstetrics. MSBOS guidance was audited to be able to reduce inappropriate use as was the 2006 Guidelines (WITN7093026) and 2006 Guidelines (WITN7093027).

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

78. There is reference to the BSCH Guidelines in the 2002 Policy (WITN7093002), suggesting that the HTC had received the BSCH Guidelines on 'The Administration of Blood and Blood Components and the Management of Transfused Patients'. There is no further reference to documents used to guide haemoglobin levels.

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

79. The 2002 Risk Report (WITN7093022) refers to the use of autologous deposits for that year as units for elective procedures, 8 patients had a total of 16 units collected.

80. The 2006 Policy (WITN7093025) has a reference to autologous blood stating: 'Autologous (patient's own) blood transfusion only available if clinically indicated via Tooting NHSBT'.

81. We cannot locate any records of discussions on the perceived risks, benefits, suitability and cost implications of autologous transfusion.

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 HTC 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.

82. The 2002 Policy (WITN7093002) makes reference to whole blood stating that it is "[u]sed exceedingly rarely nowadays… However if autologous blood (patient's own) has been deposited prior to surgical intervention, it is used as whole blood". In the 2006 update to the same policy (WITN7093025) this is expanded on, stating that autologous blood can be made available via Tooting (National Blood Service Branch).

83. There is also documentation showing the existence of 'SOP/BT4-34 – Issue of Autologous Blood' but we do not hold a record of this SOP, so are unable to

comment on the content.

84. The Trust cannot locate any further reference to policy guidance provided by the HTC on this.

30. Was the HTC 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?

85. The HTC archived a copy of the Health Service Circular 2002, Better Blood Transfusion document (NHBT0062177_001). This advised trusts to '[r]eview and explore the use of effective alternatives to donor blood and the appropriate use of autologous blood transfusion'.

Massive Transfusion

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

86. In Section 8 of the 2002 Guidelines (WITN7093026) massive blood loss is defined as 'loss of one blood volume within 24 hours, or loss of 50% of the blood volume within 3 hours'.

87. The 2002 Guidelines recommends the issue of blood in massive blood loss as follows:

> Stage 1: 6 units of red cells
>
> Stage 2: 6 Units of red cells; FFP 15ml/kg*
>
> Stage 3: 6 units of red cells; one dose of platelets if platelet count is <80,000 FFP 15ml/kg if PT or APTT ratio> 1.5; cryoprecipitate 1-1.5 packs/ 10kg if Fibrinogen <1.0g/l

88. The 2006 Guidelines (WITN7093027) was updated to include a further example of massive blood loss, stating: 'Red Cell transfusion should be considered if there is

acute blood loss of more than 20% of the patient's total blood volume and there are signs of an impending shock'.

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

89. Incidents related to massive haemorrhage were brought to the HTC, discussed, and then taken back to the clinical areas that were caring for the patients at the time of the incident. Most of the incidents were related to not following the correct process for ordering blood.

33. Did the HTC 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.

90. Guidance for Massive blood loss was within 2002 Guidelines and 2006 Guidelines. The first standalone policy was produced in 2010 (WITN7093047) with reference to its development in the 2009 HTC minutes.

34. Was the HTC 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?

91. We cannot locate any documentation relating to the provision to the HTC of guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of massive transfusion.

Fresh Frozen Plasma

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

92. The 8 February 2002 HTC minutes (WITN7093013) discuss the introduction of methylene blue treated plasma for the children born after 1 January 1996 but comments on the fact that the Trust was using Octaplas.

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

93. At page four of the 2002 Guidelines (WITN7093026) there is reference to the use of Solvent/Detergent treated plasma as being treated to potentially remove contaminating pathogens. There is also mention of the pathogen inactivating agent methylene blue treatment of plasma, to be used in children born after 1996.

94. The 8 February 2002 HTC minutes (WITN7093013) refer to the use of Octaplas being cheaper than methylene blue treated FFP. The Trust was using Octaplas at the time.

95. The 22 June 2004 HTC Minutes (WITN7093021) indicate that in 2004 the HTC updated the thawing guidance for FFP, noting that: "Plasma that has been thawed can now be used for up to 24 hours, so long as it has been stored in an appropriate fridge at 4°C and is not used for factor 8 activity. This is an increase from 4 hours at present."

96. There are no further considerations mentioned in our available documentation relating to the perceived risks, benefits and cost implications of FFP between 2001-2004.

37. Did the HTC 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.

97. Within the 2002 Guidelines (WITN7093026) there is a section on FFP. This includes what it should be used for, dosing and contraindications.

38. Was the HTC 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?

98. We cannot locate any documentation relating to the provision to the HTC of guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of FFP transfusions.

Platelets

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

99. There are no standing agenda items relating to platelets but there are discussions relating to the audit of their appropriate use in 2002 minutes and the 2002 Risk Report (WITN7093022).

100. The 8 February 2002 HTC minutes (WITN7093013) reference a discussion relating to providing a standing order of platelets. It was decided that the blood bank would stock two units of platelets group O, high-titre agglutinin negative, for immediate use in cardiac surgery.

101. Platelet transfusion would have also been discussed in meetings where it is recorded in the minutes that transfusion policies are being reviewed or updated.

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

102. There are no further considerations mentioned relating to the perceived risks, benefits and cost implications of platelets between 2001 and 2004.

41. Did the HTC 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.

103. Within the 2002 Guidelines (WITN7093026) there is a section on Platelet transfusion. This includes what it should be used for, dosing and contraindications and complications. A platelet policy was implemented in 2016 (WITN7093048).

42. Was the HTC 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?

104. We cannot locate any documentation relating to the provision to the HTC of guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of platelet transfusions.

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 HTC have about the use of single-unit transfusions?

105. Between 2001 and 2004 there was no discussion of single unit blood transfusion documented within the HTC minutes, however in the 2006 Guidelines (WITN7093027), it states 'Occasionally symptoms of anaemia may be alleviated by giving 1 unit of red cells'. This guideline was produced by the HTT and ratified by the HTC.

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

106. There is no evidence of considerations given to the perceived risks, benefits and cost implications of single unit transfusions between 2001 and 2004.

45. Did the HTC 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.

107. There is no evidence that policy guidance was provided to clinicians and the hospital staff concerning the use of single unit transfusions. Within the 2002 Guidelines (WITN7093026) issued in 2002, the HTC was still documenting the use of two units for transfusion. It is unclear why such guidance was not provided.

46. Are you aware of any instances or periods of time in which the HTC 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?

108. There are no documented instances or periods of time showing that the HTC had become aware of excessive single unit blood transfusion. There are references to inappropriate use of both red cells and platelets within the minutes, which was usually associated with a failure to follow guidelines, ingrained clinical practice during times of change and lack of clear guidance. This however, was not associated with single unit transfusion, but just transfusion in general. This is the same as platelets.

47. Single-unit transfusions are described in [DHSC0025270, page 3] as a 'waste of resources'. To the best of your knowledge, did the HTC 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.

109. There are no documented views from the HTC on the use of single unit transfusion between 2001 and 2004. In the 2002 Guidelines (WITN7093026) it is suggested that the Hb in anaemia needed to be increased by 2g/dl and this should be achieved by 'giving 2-3 units of blood' once a Hb was 7.0g/dl or 8.0g/dl with additional risk factors. In the 2006 Guidelines (WITN7093027), the HTC appeared to change their opinion and suggested single unit transfusion as being able to 'Occasionally alleviate the symptoms of anaemia'. This is the only time a

direct opinion is mentioned in relation to single unit transfusion of red cells. In the 2002 Guidelines the dose of platelets is listed as one random donor pooled platelet and this should be expected to increase the platelet count by 20-30/μL, and that further doses should be given based on the count after this initial dose.

48. Was the HTC 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?

110. We cannot locate any documentation between 2001 and 2004 relating to the provision to the HTC of guidance from the Department of Health, National or Regional Transfusion Committee concerning the use of single-unit transfusions and/or two unit transfusions.

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 HTC? If so, please describe the nature of them and any conclusions drawn. If possible, please provide copies of the audit reports.

111. There was no documented evidence of audits in single-unit transfusion completed by the HTC between 2001 and 2004. The first recorded single unit transfusion audit was carried out in 2014 (referenced in RLIT0000828: paper entitled "A single unit transfusion policy reduces red cell transfusions in general medical in-patients").

Red Cell concentrates

50. What discussions did the HTC 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?

112. The only reference we can locate in HTC discussions is to the use of red cells.

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

113. There are documented discussions surrounding the general principles of transfusion of red cells, including transfusion reactions.

52. Did the HTC 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.

114. We cannot locate any documentation of the HTC providing policy guidance to clinicians and hospital staff concerning the use of red blood cell concentrate.

53. Was the HTC 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?

115. The HTC were attending Regional Transfusion Committee meetings but there is no evidence of the guidance that was given in relation to the use of red cell concentrates. In the 2002 Policy (WITN7093002) the following are contained within the reference material listed:

a. Department of Health (1998) Better Blood Transfusion, Health Service Circular 1998/224;
b. Kelsey P (chairman) British Transfusion Committee for Standards in Haematology, Blood Transfusion Task Force in collaboration with Murphy M (Convenor) the Royal College of Nursing and the Royal College of Surgeons of England Working Party, (1999) The Administration of Blood and Blood Components and the Management of Transfused Patients.

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.

116. There is no documented evidence of any 'speciality uses' of red cell concentrates, platelets and/or FFP that led to an adverse reaction that required investigation.

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?***
- ***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? Was the HTC aware of why whole blood transfusions were preferred over red blood cell concentrates during the 1970s and 1980s?***

117. We cannot locate any documentation between the 1970s and 1980s surrounding the use of red cell concentrates, pressure around this, preference around this, or any general discussions on this. As a result we are unable to address your questions on this.

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:

56. What discussions did the HTC have about the use of fresh warm blood in

transfusions?

118. There is no documented evidence of discussions surrounding the use of fresh warm blood between 2001 and 2004.

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

119. There is no documented evidence of discussion surrounding the perceived risks, benefits and cost implications of using fresh warm blood between 2001 and 2004.

58. Did the HTC 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.

120. There is no documented evidence of the HTC providing policy surrounding the use of fresh warm blood between 2001 and 2004. It is unclear what the reason for this was, or if fresh warm blood was in use at this point.

59. Was the HTC 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?

121. There is no documented evidence that the HTC was provided with guidance providing policy surrounding the use of fresh warm blood between 2001 and 2004.

Section 4: Knowledge of risk

60. Please outline any discussions held during the course of the HTC 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?

122. Initial highlighted concerns with transfusion associated infection, namely Human Immunodeficiency Virus, Hepatitis B and C virus and variant CJD occurred before the establishment of HTC and there is very little documented discussion relating to the initial steps or mitigations that were put in place to manage the concerns at the time. However, throughout the HTC minutes and training slides that were available, it was clear that the HTC members were rolling out the recommendations that had been set to protect patients, e.g. the introduction of Solvent Detergent Treated Plasma and the use of Methylene Blue treated plasma components within the NHSBT portfolio. The transfusion practitioners were teaching about the risk ratios of viral transmission in transfusion and the unknown risk factors associated with the variant CJD. The HTC was also implementing recommendations laid out within the 'Better Blood Transfusion' Health Service Circulars from 1998 and 2002 (NHBT0083701_002 and NHBT0062177_001).

61. What, if any, enquiries and/or investigations did the HTC 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?

123. There is no remaining documentation of enquiries/ investigations that were carried out, or had cause to be carried out, in respect of the risks of the transmission of viral infections through blood transfusion. The HTT (Hospital Transfusion Team) began reporting incidents to SHOT in 2001. However, from discussions with colleagues I understand that prior to this, suspected transmission of viral infections were reported to the National Blood Establishment directly.

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

124. The HTC introduced the use of SD FFP to reduce the risk of transmitted pathogens in patients born after 1 January 1996. They also began to use methyl blue treated plasma to reduce the same risk.

63. Did the HTC 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.

125. There is no evidence that the HTC provided guidance on viral transmission risk between 2001 and 2004. There is evidence that the HTT provided teaching that included viral transmission risk.

64. Do you consider that the HTC's decisions and actions, and the steps taken at the Hospital, 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.

126. At the time (already active in 2001) the HTC implemented changes surrounding risks relating to variant CJD in line with government recommendations (i.e. moving to the use of methylene blue cryoprecipitate and Octaplas). This however, was not well documented in policy or guidelines. This may have resulted in a lack of clinical awareness. We cannot locate any documentation that shows whether the HTC had a documented recall process in place to be able to follow up patients who reported to have picked up transfusion related TTI.

65. Please outline any discussions by the HTC 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?

127. We cannot locate any record of discussions held relating to the transfusion of blood components that had a higher risk of infection.

Section 5: Reporting and audits

66. 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.***

128. Section 10 of the 2002 Policy (WITN7093002) has a section relating to the reporting of adverse reactions. Section 10.1 states that reactions should be reported in line with the Trust 'Adverse Incident (AI) Reporting Policy'. It also states that the following must be reported:

a. Severe reactions;
b. Suspected cases of transfusion transmitted infection;
c. Incorrect Blood component transfused;
d. Any 'near misses'.

129. Section 10.2 of the 2002 Policy states that adverse incidents will be reported to SHOT by the Blood Transfusion Nurse Specialist according to their guidelines.

130. There is also evidence of a transfusion reaction form that was in use between 2001 and 2004 but the exact date of its establishment is unknown.

131. We cannot locate any record of discussions relating to whether it extended to discharge between 2001 and 2004.

132. There is evidence stating that patients were asked to report any adverse reaction or symptoms (the 2002 Policy) but it is unclear from the available HTC minutes whether this was within a certain time frame.

133. Within the 2002 Policy clinicians were directed to report transfusion reactions to the Consultant in Transfusion Medicine, the Transfusion specialist registrar or the Blood Transfusion Nurse Specialist and to report the incident via the Trust Adverse Incident Reporting scheme.

134. We cannot locate any documentation to clarify whether the Trust was reporting incidents to the Regional Transfusion Committee.

135. We cannot locate any records to show what process was followed in relation to patient deaths associated with transfusion or how that was reported on death certificates between 2001 and 2004. The Trust was reporting incidents of transfusion associated reactions to SHOT from 2001. This would have included deaths associated with transfusion.

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

136. We cannot locate any documentation of the process of how suspected transfusion–transmitted infections were reported to the service providing blood. However, from discussions with colleagues I understand that there was direct communication between the Trust and National Blood Service when there were suspected transfusion transmitted infections.

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

137. The 2002 Policy (WITN7093002) indicates that the Trust began reporting to SHOT in May 2000.

138. The HTC instructed the Trust to report all transfusion reactions via the 'Adverse Incident Reporting Policy' and then incidents were reported to SHOT by the Blood Transfusion Nurse (as set out in the 2002 Policy). The incidents reported were discussed in HTT and HTC meetings, looking at root cause and key factors. This was to ensure that all incidents were reported to SHOT. Concerns and further incidents were also picked up through the transfusion laboratory and during HTC meetings when other members outside of the HTT attended. It still relied on the clinical areas to report the incident for it to be able to be SHOT reported.

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?

139. From our earliest available HTC minutes from 2001, the HTC at the Trust began discussing transfusion related incidents and investigations at the HTC meetings. The clinical risk management team were included in the membership and were involved in ensuring that transfusion related incidents that had been reported via the trust reporting structure were fed back to the HTC. There was also an expansion of the HTC membership to include high usage areas such as obstetrics, the emergency department, transplantation and surgery. There was also the appointment of the transfusion practitioner in 2001. This role became essential in the following of transfusion-related events, the provision and monitoring of teaching and training and the keeping of training records. These were all part of the recommendations set in document NHBT0001504.

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

140. The HTT minutes from 2001 to 2004 (WITN7093029 to WITN7093044) demonstrate that the transfusion team audited the use of blood in different clinical areas. In the 2002 Risk Report (WITN7093022), audits of platelet usage, irradiation and iron deficiency in elective surgical patients, red cell use in hip and knee replacement and renal anaemia were referenced. The majority of audits were carried out against existing guidelines by reviewing all requests and issues of blood in that area and then feeding back on the compliance. Over time there appeared to be more focus on reauditing of key problem areas such as MSBOS compliance and then more focus on the National Comparative audit schedule. There is reference within the HTC minutes that spot audits were being conducted between 2001 and 2004 (and beyond this period). Initial audits were against guidance like MSBOS (HTC minutes 22 June 2001, WITN7093003). Members that came from the audited areas were given feedback and improvements to take away to their divisions. There were also audits around transfusion sampling, with discussions surrounding the remit of some audits and what areas were responsible for some of the transfusion-related audits. Over time (between 2001 and 2004) some audits became routine, including the HTC involvement in the national comparative audits of transfusion. The minutes suggest that the decision to audit was usually based around matters arising from the clinical areas or from departments e.g. concerns raised by the transfusion laboratory resulted in the auditing of MSBOS in the obstetric setting.

71. Under what circumstances were external and internal audits conducted? How often were internal and external audits conducted by the HTC from the date the HTC was established?

141. Internal auditing was conducted as set out above, external audits were usually conducted in accordance with the national comparative audit (NCA) audit schedule. We cannot locate any documented reference to other external audits.

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

142. The HTC produced yearly reports (such as the 2002 Risk Report (WITN7093022)) which listed the number of units that were being used. The information was initially held by the transfusion team and then the recording of such data was done in collaboration with Blood Stocks Management Schemes from 2003 (HTC minutes 2002). The information consisted of the numbers of units ordered, used and wasted and what disciplines the units were used in.

73. If the HTC 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.

143. The transfusion data collected was disseminated to the HTC members who then fed back to their individual disciplines. There is no documented information on any further methods of disseminating the findings.

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.

144. Our records of audits carried out in the requested areas are as set out in the 2002 Risk Report (WITN7093022): 74.1 Audits of FFP were conducted in relation to usage and wastage.

145. Audits of packed red cell concentrates included surgical use, national comparative audits, renal anaemia, wastage of red cells, MSBOS ordering.

146. Audits of platelets included wastage, appropriate use and irradiation.

147. We cannot locate any documentation referencing audits of massive transfusion between 2001 and 2004.

148. There were audits around the use of cell salvage and the compliance of surgical area use. There is evidence in the 2002 Risk Report that autologous pre-deposits were being collected at the Trust and simple audits of the number of units collected were carried out. There is no other documentation that we can locate of existing audits surrounding autologous blood.

75. Did the HTC 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.

149. We cannot locate any available documentation to confirm whether the HTC ever had to take corrective action as a result of an audit relating to blood transfusion practice. Most of the referenced HTC actions in response to auditing was retraining and presenting evidence of the audit findings to the clinical area. There were suggestions of changed practice. These were often not completed due to poor clinical engagement or failure to reach the relevant leads to help implement the changes suggested. Within the 2002 Risk Report (WITN7093022), there were conclusions and proposals set after the audit period but we cannot locate any documentation clarifying how or if the proposals were met.

Section 6: Treatment of patients

Provision of information to patients

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

150. There is no documented evidence within the HTC minutes between 2001 and 2004 regarding the risks of infection in consequence of treatment with transfusion.

77. Did the HTC 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 HTC take?

151. There is no documented evidence within the HTC minutes between 2001 and 2004 regarding discussions of patient education and surrounding risk of infection in consequence of treatment with transfusion. However, there is evidence that the HTT had been providing the Trust with National Blood Service Patient information leaflets (earliest copies retrieved dated March 2007) and had provided patients with transfusion information as required by the Health Services Circular 2002.

Consent

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, was the HTC aware if patients under the care of the Hospital were treated with blood transfusions without their express or informed consent? If so, how and why did this occur?

152. There is no documented evidence that the HTC was aware if patients were treated with transfusion without their consent between 2001 and 2004. However the HTC referenced the 'The Administration of Blood and Blood Components and Management of Transfused Patients, 1999' in the 2002 Policy (WITN7093002), and I understand that referenced document informed readers that there was no requirement to take consent for blood transfusion.

79. Did the HTC 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.

153. There is reference to consent for blood transfusion within section 5.5 of the 2002 Policy. The Trust issued their first full consent for blood transfusion guidelines in 2013 (WITN7093049).

Section 7: vCJD

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

154. There is no clear documented evidence of when the HTC became aware of the risks associated with the transmission of vCJD. The 8 February 2002 HTC Minutes (WITN7093013) mention the NBS was planning to introduce the use of methylene blue ("**MB**") pathogen inactivated plasma components for use in children born after 1 January 1996. The minutes state that the Trust is already using solvent detergent treated plasma (Octaplas) in this patient group. This is also referenced in the 2002 Guidelines (WITN7093026). Training slides from 2002 (WITN7093045) list vCJD under the 'Risks of Blood Transfusion in the UK' with the comment – 'no proven transmission' next to it. We have a record of the HTC receiving an announcement by the Secretary of State for Health regarding vCJD dated 17 December 2003 (WITN7093046). An update on the Trust's intranet from the HTC dated 28 June 2007 states that vCJD has been 'a key topic of discussion for the past three years'.

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

155. There is no clear documented evidence that lays out the extent to which the HTC was involved in assessing and managing the risk of vCJD transmission by blood transfusion but the HTC did discuss the introduction of MB plasma on 8 February 2002 (WITN7093013) and from subsequent minutes that report using the MB plasma, it appears to have been brought into use in 2002.

82. Please confirm if policies, guidance, standards, or protocols were formulated at the HTC at the Hospital with regard to the transfusion of vCJD. If so, please describe what these were. You may be assisted by [NHBT0001719].

156. The only documentation that we can locate on formulations by the HTC with regard to the transfusion of vCJD is the reference in the 2002 Guidelines (WITN7093026) into the selection of MB for children born after 1996.

83. Did the HTC 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 HTC for informing patients about the risks of or possible exposure to vCJD before transfusion?***
- ***b. What steps were taken/put in place by the HTC 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.

157. We cannot locate any documentation on whether the HTC had involvement in decisions as to what information should or would be provided to patients about vCJD, or steps being put in place to inform patients of their risks.

Section 8: Look back

84. Was the HTC 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.

158. We cannot locate any documented policy for look back exercises for suspected transfusion transmitted infection. However, look back exercises have been carried out for patients with suspected transfusion transmitted infections

(TTI). I understand from discussions with colleagues that the process is as follows:

a. An adverse incident, laying out the suspected TTI and suspected acquisition period;
b. The submission of a SABRE notification of the suspected TTI;
c. A meeting with the patient/clinical team caring for the patient to discuss the suspected TTI, the transfusion history of the patient and rule out other more likely modes of transmission where possible;
d. Notification to the clinical risk and HTC by the HTT;
e. A look back of the patient's virology testing that was available prior to the event and after diagnosis to be able to determine the potential infection window;
f. A review of the patient's transfusion history to collate a list of all transfused units within the suspected time frame;
g. Completing the NHSBT Look Back form complete with the units, relevant current and historical blood tests and virology testing results so that the donors can be investigated;
h. On completion of the testing by the national blood service:
    i. Duty of candour with patients/family and clinical team if confirmed to be a TTI;
    ii. Continue to provide support to the patient and clinical team to manage patient care and follow up procedures as a result of a confirmed TTI; and
    iii. Completion of SHOT and SABRE reporting; and
i. Discussion at clinical risk and governance meeting and HTC to conclude the investigation,

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

159. We cannot locate any record relating to any actions or decisions taken by the HTC as part of the HCV 'look back' programme that commenced in 1995 to trace those infected with HCV through the use of blood transfusions.

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

160. We cannot locate any record of the obstacles or exercise of the HCV 'look back' programme that commenced in 1995.

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.

161. The majority of the information that has been provided from the records kept are based on paper copies of minutes kept between 2001 and 2004. There were other minutes, guidelines and records that are no longer available that may have held the information sought.

162. The HTC came into formation in 2000 but it is clear in the earliest minutes that there were discussions happening within the Trust in relation to transfusion practice and safety. Transfusion guidelines were already published before HTC establishment and were being discussed within meetings. A use of blood components guideline, dated 1999 and therefore prior to the HTC, was written by haematology within the Trust. However, we no longer have a copy of this. The content of HTC/HTT minutes alone is unlikely to be enough to establish if certain discussions were being had or if policy and procedure were in place as there is evidence of improvements and changes to practice that would have been in direct response to the recommendations set but cannot be evidenced.

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.

163. WITN7093002 to WITN7093049 are all exhibits referenced in this statement. Other documents were recovered and used in preparation of this statement and we exhibit them as WITN7093050 to WITN7093068.

Statement of Truth

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

Signed GRO-C

Dated 24 May 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
January 2002	KCH Blood Transfusion Policy and Procedure	WITN7093002
22/06/2001	KCH HTC Minutes	WITN7093003
11/12/1998	Health Service Circular 1998/999 - Better Blood Transfusion	NHBT0083701__002
September 2003	KCH HTC Terms of Reference	WITN7093005
July 2007	KCH HTC Terms of Reference	WITN7093006
02/12/2013	KCH HTC Terms of Reference	WITN7093007

November 2016	KCH HTC Terms of Reference	WITN7093008
04/07/2002	Health Service Circular 2002/009 - Better Blood Transfusion	NHBT0062177_001
October 2019	KCH HTC Terms of Reference	WITN7093010
28/09/2001	KCH HTC Minutes	WITN7093011
14/12/2001	KCH HTC Minutes	WITN7093012
08/02/2002	KCH HTC Minutes	WITN7093013
10/09/2002	KCH HTC Minutes	WITN7093014
08/04/2003	KCH HTC Minutes	WITN7093015
10/06/2003	KCH HTC Minutes	WITN7093016
09/09/2003	KCH HTC Minutes	WITN7093017
11/11/2003	KCH HTC Minutes	WITN7093018
11/02/2004	KCH HTC Minutes	WITN7093019
20/04/2004	KCH HTC Minutes	WITN7093020
22/06/2004	KCH HTC Minutes	WITN7093021
2002	KCH HTC Clinical Risk Report	WITN7093022

2003	Elective Surgical Blood Order Schedule	WITN7093023
May 2010	Maximum Surgical Blood Order Schedule (MSBOS)	WITN7093024
May 2006	KCH Blood Transfusion Policy and Procedure	WITN7093025
July 2002	KCH Guidelines for the use of Blood Components	WITN7093026
July 2006	KCH Guidelines for the use of Blood Components	WITN7093027
21/07/2017	Paper on single unit transfusion policy	RLIT0000828
02/06/2003	KCH HTT Minutes	WITN7093029
16/06/2003	KCH HTT Minutes	WITN7093030
23/06/2003	KCH HTT Minutes	WITN7093031
30/06/2003	KCH HTT Minutes	WITN7093032
14/07/2003	KCH HTT Minutes	WITN7093033
08/09/2003	KCH HTT Minutes	WITN7093034
15/09/2003	KCH HTT Minutes	WITN7093035
03/11/2003	KCH HTT Minutes	WITN7093036

24/11/2003	KCH HTT Minutes	WITN7093037
22/12/2003	KCH HTT Minutes	WITN7093038
12/01/2004	KCH HTT Minutes	WITN7093039
26/01/2004	KCH HTT Minutes	WITN7093040
16/03/2004	KCH HTT Minutes	WITN7093041
29/06/2004	KCH HTT Minutes	WITN7093042
20/07/2004	KCH HTT Minutes	WITN7093043
27/07/2004	KCH HTT Minutes	WITN7093044
2002	Blood Transfusion at King's (Midwives training)	WITN7093045
17/12/2003	Announcement by SOS regarding vCJD 17 Dec 2003	WITN7093046
27/01/2011	KCH Code Red Policy	WITN7093047
13/02/2017	KCH Platelet Usage and Administration Guidance	WITN7093048
January 2013	KCH Consent for Blood Transfusion Support and the Management of Patients who Refuse	WITN7093049
04/10/2001	KCH Meeting Minutes on use of anti-D immunoglobulin	WITN7093050

2002/2003	Blood Transfusion - Information for CNST (Maternity Services)	WITN7093051
31/08/2007	Use of Blood Products	WITN7093052
January 2005	Guidelines for the Use of Erythropoietin Outside the Setting of Renal Failure	WITN7093053
February 2007	Guidelines for use of Recombinant Activated Factor VII	WITN7093054
Undated	Investigation of Suspected Transfusion Reaction form	WITN7093055
Undated	KCH Investigation of Suspected Transfusion Reaction form	WITN7093056
08/03/2001	Severe Sepsis, The New England Journal of Medicine	WITN7093057
06/06/2002	RCP National Comparative Audit of Blood Transfusion	WITN7093058
Undated	Out of Hours ordering RBCs	WITN7093059
October 2001	Transfusion Episodes	WITN7093060
2003-2005	Blood Transfusion AI reports / Training Lists 2002 to 2005	WITN7093061
Undated	Trigger Events for Blood Transfusion Incident Reporting	WITN7093062
August 2007	KCH Elective Surgical Blood Ordering Schedule	WITN7093063

Undated	KCH Blood Component Prescription and Transfusion Record	WITN7093064
Undated	KCH Pilot Study of Transfusion Record	WITN7093065
07/12/2005	Amendments and Corrections to the “Transfusion guidelines for Neonates and older Children”	WITN7093066
07/02/2002	Sepsis: A significant Healthcare Challenge	WITN7093067
Undated	Use of Blood Products	WITN7093068