Witness Name: Dr Charles Percy
Statement No.: WITN4460005
Exhibits: WITN4460006 - WITN4460033
Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR CHARLES PERCY, ON BEHALF OF THE UNIVERSITY HOSPITALS BIRMINGHAM 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, Dr Charles Llewellyn Percy, will say as follows: -

Section 1: Introduction

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

1. My name is Dr Charles Llewellyn Percy.

2. My address is Department of Clinical Haematology, Queen Elizabeth Hospital Birmingham, Edgbaston, Birmingham, B15 2TH.

3. My date of birth is the GRO-C 1979.

4. My qualifications are: BSc(hons), MB BS, MRCP(UK), PhD, FRCPath, FRCP.

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

5. I am currently a consultant haematologist, Haemophilia Centre Director and Clinical Service Lead (CSL) for Laboratory Haematology.

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

6. I was appointed as a consultant haematologist at the Queen Elizabeth Hospital Birmingham on the 2nd January 2017 by a competitive interview. I became CSL in April 2017. I took on the role of Haemophilia Centre Director by mutual agreement of my consultant haematology colleagues in 2018.

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.

7. My previous employment is as outlined below:

   21st Sept 2015- 19th Dec 2016: Consultant Haematologist, Haemophilia Centre Director and Lead for Haemostasis and Thrombosis, Abertawe Bro Morgannwg University Health Board, Singleton Hospital, Sketty Lane, Swansea

   1st Oct 2014 – 4th Sept 2015: Specialty Registrar 7, All Wales Higher Training Programme in Haematology

   1st October 2011 – 30th Sept 2014: British Heart Foundation Clinical Research Fellow and Honorary Specialty Registrar in Haematology, Cardiff University School of Medicine and University Hospital of Wales, Cardiff.

   4th Sept 2007 – 30th Sept 2011: Specialty Registrar, All Wales Higher Training Programme in Haematology

12th March 2007 – 3rd Sept 2007: Locum Appointment for Training, Haematology, Southmead Hospital, Westbury-on-Trym, Bristol, BS10 5NB.

Feb 2007: Senior House Officer, Hepatology, Bristol Royal Infirmary, Upper Maudlin Street, Bristol.

Aug 2006 – Jan 2007: Clinical Fellow (SHO Level), Haematology Bristol Haematology and Oncology Centre, Bristol, BS2 8ED.

Aug 2004 – Nov 2006: South East Wales Medical Senior House Officer Rotation, Royal Glamorgan Hospital, Llantristant, University Hospital Llandough and University Hospital of Wales, Cardiff.

Aug 2003 – July 2004: PRHO, General and Vascular Surgery, Gastroenterology and General Medicine, Intensive Care, Queen Elizabeth the Queen Mother Hospital, Margate, Kent, CT9 4AN.

Section 2: Hospital Transfusion Committee history, structure & relationships

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

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

8. In response to the questions:

a. I do not know first-hand the date of establishment of a Hospital Transfusion Committee ("HTC") at the Queen Elizabeth Hospital. Minutes and agendas for meetings of the HTC found in filing cabinets in the Haematology Laboratory date back to 1999 and the wording implies the HTC was in existence prior to that year. In this response and in the responses detailed below I direct you to the exhibits of this statement.

b. Similarly, I do not know who established the HTC, nor who the first chair was. In 1999, the chair was Mr Allen Edwards, Consultant Vascular Surgeon, who is now deceased.

c. I do not know why the HTC was established beyond it, presumably being in response to the recommendations in document NHBT0016083_003.

d. I do not know what the initial aims of the HTC were when they were established. In minutes from the HTC meeting on the 22nd June 1999 (WITN4460006), item 2 states Terms of Reference were discussed and agreed by those present. However, correspondence dated the 30th September 1999 (WITN4460007) from the then chair of the HTC, Mr Allen Edwards, to Dr Jonathan Wilde, Consultant Haematologist and Clinical Service Lead for Laboratory Haematology, mentions proposed Terms of Reference based on an enclosed document produced by the Royal College of Physicians ("RCP") dated from 1995. The minutes from the meeting of the HTC on the 19th October 1999 (WITN4460008) state that the Terms of Reference were not the RCP document and that those that had been agreed needed to be obtained from Mr Andy Reid to discuss at the next meeting. The minutes of the next meeting held on the 20th November 1999 (WITN4460009) make no mention of this, nor do any of the minutes from meetings held in 2000 (WITN4460010 - WITN4460013). The current HTC is referred to as the Hospital Transfusion Group (HTG) and its Terms of Reference are outlined in exhibit WITN4460012.

e. Prior to the establishment of the HTC, I do not know how hospitals monitored transfusion practice.

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

9. Based on the minutes available, in 1999 to 2010 the HTC was composed of a Chair, a consultant from NHSBT, the Clinical Service Lead for laboratory haematology, a senior biomedical scientist, service users (typically a consultant anaesthetist) and variable nursing staff, some of whom had a role in education of healthcare staff. On occasion, a haematology registrar attended. In the present day, the composition of the HTC is stated in exhibit WITN4460012, and is as follows:
    - Clinical Service Lead for haematology and transfusion
    - BMS Manager for haematology and transfusion
    - Clinical Lead for blood transfusion from all sites
    - Clinical Lead in general surgery or nominated representative
    - Clinical Lead in orthopaedics or nominated representative
    - Clinical Lead in anaesthetics or nominated representative
    - Clinical Lead in cardiac anaesthetics or nominated representative
    - Clinical Lead in liver surgery and/or anaesthetics or nominated representative
    - Clinical Lead in Emergency medicine or nominated representative
    - Clinical lead for trauma or nominated deputy
    - Clinical Lead in general medicine
    - Clinical Lead in elderly care
    - Clinical Lead in renal medicine
    - Clinical Lead in paediatrics/neonates
    - Clinical Lead in obstetrics & gynaecology
    - Blood Bank manager from all sites
    - Pathology quality manager(s) from all sites

- Lead Transfusion practitioner(s)
- NHSBT consultant haematologist
- NHSBT Patient Blood Management Practitioner
- Chief Nurse or nominated deputy
- Operations Director, Div 1 or nominated deputy
- Head of Risk or nominated deputy
- Royal Orthopaedic Hospital transfusion practitioner
- ROH chair of BSAG
- Representative from training and education
- Other individuals may be invited to attend particular meetings or parts of meetings as required to raise any issues within their clinical area, for which support is required from the HTG.

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

a. Awareness of national guidelines for the promotion of good transfusion practices;

b. Development of local hospital guidelines;

c. Transfusion policy induction procedure for new staff;

d. Review of nursing procedures for administration of blood products;

e. Promotion of new information regarding transfusion matters;

f. Ensuring patients are adequately informed of transfusion matters, such as availability of alternative treatments;

g. Blood transfusion record keeping and documentation;

h. Review and notification of post transfusion complications (including adverse reactions and transfusion associated infections);

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

j. Consent for blood transfusion.

You may wish to refer to BCUH0000060 for assistance (See BCUH0000028 for a later, non-draft version of this document. Note this version is incomplete)

What roles, functions and responsibilities did the HTCs carry out from the date established? Please also include any other functions not mentioned above.

10. I do not know the specific roles or responsibilities of the HTC from the date of establishment. It is evident from the minutes available that all issues 7a to 7j were discussed at different times. The current roles and responsibilities are outlined in exhibit WITN4460012.

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

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

11. I am unable to answer this question prior to 2017, when I joined the Trust. In the present day, the HTC (HTG as it is known now) reports to the Trust Board & Clinical Quality Monitoring Group.

9. In a Penrose Inquiry Submission by NHS Scotland [STHB0000864, page 13], it is noted that 'Hospital transfusion committees were formed to create an interface between the laboratory as provider and the clinicians as users of blood and blood products. Their success was limited due mainly to the lack of clinician input. This problem, to a greater or lesser extent, remains today'. Was this also the position at the Hospitals? Do you think this is a fair assessment of the HTCs? Please explain your answer.

12. Based on minutes of the meetings available, attendance at the HTC has been limited with respect to the full spectrum of clinical users, therefore there is evidence to support this assessment.

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

13. Based on the dates of the minutes available, from 1999 onwards the HTC has met at least once a quarter, apart from August 2001 to August 2002 no meeting took place, for reasons that are unknown. In the minutes of the HTC meeting from the 14th August 2002 (WITN4460014), there is no explanation apart from alluding to time spent preparing a revised "hospital protocol". Prior to 1999 I do not know how frequently the HTC met.

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

Please outline:

a. If the HTCs were aware of this concern;

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

c. Whether as a result of discussion, what, if any, training was implemented. If so, when it was and at what level the training was implemented. If it was not, why it was not?

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

e. A brief overview of what the training included.

14. In response to the questions:

a. The minutes available indicate that the HTC was aware of this concern.

b. On the 12th Sept 2000 (WITN4460012), the HTC discussed nurse training. The departure of the HTC member who had previously conducted this was a major concern. The minutes discuss a letter received from Dr Gabra, Lead Consultant for the Regional Transfusion Advisory Committee which recommended Trusts in the region appoint a Hospital Transfusion Practice Officer (this would nowadays be referred to as a Transfusion Practitioner); the outcome of the discussion was to write to a member of Trust Executive to ask how such a post could be funded. Minutes from the 14th August 2002 (WITN4460014) discuss producing a job description for the role. On the 12th September 2002 (WITN4460015) the minutes state the job description was agreed but funding remained uncertain.

c. Over the years, the minutes do refer to training that was delivered (WITN4460016), either as part of study days or Trust induction. The audience were nursing staff and doctors in training grades.

d. I am unable to comment on whether the training was compulsory or not. In the present day it is and must be completed before anyone is involved in any part of the transfusion process, regardless of their grade or clinical discipline.

e. The minutes indicate the training related to sample collection and administration of blood components, (see exhibits WITN4460016 to WITN4460018).

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

15. From the minutes available, there was repeated discussion about the use of blood products in operating theatres and initiatives to rationalise this with evidence of involvement of the relevant users. For example, the minutes of the 12th September 2002 (WITN4460015) mention a study day focusing on reducing blood product usage in cardiac surgery which was organised by someone who was not a member of the HTC.

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

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

You may wish to refer to [BSHA0000061_029].

16. In response to the questions:
    a. Based on minutes from 1999 to 2010, this person was an HTC member from NHSBT. In the present day, this is who is the lead transfusion consultant for the Trust.

b. I do not know the specifics of these interactions, but can infer from the available documents that it included usage of blood products, changes in national policies or guidance and any particular issues of local or national concern to the Regional Transfusion Committee.

c. There is evidence of discussion of this at the HTC.

d. I do not have any knowledge to assist.

e. For the HTC, a representative NBTS, based at the Regional Transfusion Centre, was in attendance as a matter of routine.

f. I do not have any knowledge to assist.

g. I do not have any knowledge to assist.

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

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

17. In response to the questions:

a. The attendance of a member from NBTS at the HTC meant that the HTC was kept aware of developments in transfusion practice and areas that should be a priority for training and service development.

b. I am not aware of any change occurring over time.

c. It was standard practice for the HTC to include a member from NBTS.

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

18. One or more biomedical scientists from the hospital transfusion laboratory attended HTC meetings from 1999 to 2011 and continue to do so in the present day. They have an essential role in appraising the HTC in relation to incidents that may have arisen, operational considerations and in turn, understanding the clinical needs of the users.

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

19. I am only able to comment on the information contained within the HTC minutes from 1999 to the early 2000s and not from my personal knowledge. These indicate concerns about completing audits and implementing any actions.

Section 3: Policy and Standard Practice

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

20. There are no documents to enable me to comment prior to 1999. From 1999 onwards, the documents indicate that the HTC was aware of the full range of blood products available and the circumstances, based on prevailing guidance or publications at the time, as to when they would be used.

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

a. When these were introduced;

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.

21. In response to the questions:

a. I do not know the date the Maximum Blood Ordering Schedule (MBOS) was introduced. Minutes from the HTC meeting on the 22nd June 1999 (WITN4460002) suggest that there were multiple versions which required consolidation in a single document to be held by the Hospital Transfusion Laboratory (referred to as "Blood Bank").

b. The stated purpose was to avoid ordering excessive amounts of blood products that were then unused.

c. I have not located sufficient documentation to be able to comment on this.

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

a. The nature and frequency of patient observations

b. Who wrote local policies

c. The need for two signatures to confirm adequacy of the checking procedure

d. The use of wristbands for patient identification

e. The need for a doctor to be present during transfusion

f. The action to be taken in the event of a transfusion reaction.

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

22. The documentation available indicates that the HTC did operate to try and standardise transfusion practice. For example, exhibits WITN4460007, WITN4460019, and WITN4460020 demonstrate efforts to ensure uniform practice in administration of blood products and attempts to standardise transfusion triggers.

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

a. Obstetrics;
b. Trauma and emergency care;
c. Surgery;
d. Haematological malignancies;
e. Thalassaemia; and
f. Sickle Cell Anaemia.

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

23. There is evidence of involvement in the production of guidance in relation to administering and monitoring blood products and MBOS, but not specific to the subjections specified.

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

24. The minutes indicate that the HTC discussed incidents and made efforts to address them. However, I do not know how the Trust ultimately dealt with these events.

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

25. I have no knowledge to be able to answer this question.

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

Please outline:

a. Any discussions the HTCs had about the Circular in relation to:

i. Obstetrics; trauma and emergency care; surgery; haematological malignancies; thalassaemia; and sickle cell anaemia; and

ii. Use of red blood cells, platelets and Fresh Frozen Plasma ("FFP")

iii. Autologous transfusion

iv. Single-unit transfusion

v. Fresh-warm blood transfusion

vi. Knowledge of risk of transfusion related infections

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

26. This circular was mentioned in minutes of the HTC meeting held on the 22nd June 1999 (WITN4460006). Autologous pre-deposit blood transfusion was

mentioned at the meeting held on the 22nd February 2000 (WITN4460010), where it was noted that in the Trust there was no mechanism in place to allow this to support these transfusions.

24. At a BTSAG meeting on 17 February 2004 [NHBT0060995], it was noted in 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.

27. I am aware of proposals relating to electronic bedside blood sampling and labelling, checking and remote issue fridges not being actioned at the time they were proposed.

Haemoglobin level

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

28. Papers related to HTC meetings on the 22nd April 2004 (WITN4460019) and 17th June 2004 (WITN4460020) contain guidance in development with proposed transfusion triggers. In WITN4460019, the proposed trigger for red cell

transfusion in the absence of symptoms was <7g/dL or 10g/dL if the patient had recently suffered an acute myocardial infarction. Exhibit WITN4460020 is more detailed with platelet transfusion triggers of <10x10^9/L unless there was an infection in which case <20x10^9/L, or major bleeding in which case <50x10^9/L was proposed. A fibrinogen of less than 1g/L was proposed for transfusing cryoprecipitate. In the present day there is clear guidance available on the Trust intranet and within the electronic prescribing system which covers all scenarios.

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

a. Did the HTCs hold any discussions about the frequency of monitoring haemoglobin levels? If so, please provide details and outcomes of any discussions.

b. To the best of your knowledge, were the HTCs aware of excessive or unnecessary transfusion within the Hospitals? If so, please provide details, including any guidance provided to clinicians.

29. In response to the questions

a. There is no available documentation to answer this question.

b. Whilst there is no specific documentation to indicate this was the case, incidents and SHOT reports were routinely discussed, so had such events been reported, the HTC would have been aware.

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

30. I do not have any knowledge to be able to provide the answer to this question.

Autologous transfusion

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

Please explain:

a. What discussions the HTCs had about the use of autologous transfusions; and

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

31. Minutes from the meeting held on the 22nd February 2000 (WITN4460010) mentioned the inability to support pre-deposit autologous red cell transfusion. Autologous red cell transfusion resulting from cell salvage was mentioned within the meeting on 12th September 2002 (WITN4460015), and thereafter discussed on a number of occasions in subsequent years in relation to the theatre areas using this, audits undertaken and the different equipment used.

29. In 'Guidelines for autologous transfusion. Pre-operative autologous donation', written by the British Committee for Standards in Haematology Blood Transfusion Task Force [BSHA0000017_021], the guidelines support predeposit autologous transfusion services within hospitals. In light of this, did the HTCs provide policy guidance to clinicians and hospital staff concerning autologous

transfusions? If so, what was this guidance? If guidance was not provided, please explain why.

32. I do not have the knowledge to be able to answer this question.

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

33. I do not have the knowledge to be able to answer this question.

'Massive Transfusion'

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

34. The current HTC understanding of massive haemorrhage is outlined in the massive haemorrhage policy (WITN4460031). The first mention of a massive haemorrhage policy (defined as a potentially life-threatening bleeding episode) appears in minutes from the 10th December 2008 to 16th March 2011 (see exhibits WITN4460029 to WITN4460031).

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

35. Historically I am unable to answer this question. In the present day, every time the massive haemorrhage procedure is activated, this is audited by the transfusion practitioners and hospital transfusion laboratory. The findings are then reviewed, fed back to the service users and discussed at the HTC where required.

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

36. Please see my response to question 31.

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

37. I am aware of a recommendation that all hospitals should have a massive haemorrhage policy in place relating to the circumstances it should be enacted, how it should be activated, and what actions should follow once activation had occurred, including initial use of blood products.

Fresh Frozen Plasma ("FFP")

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

38. Use of virally inactivated FFP as well as audits of use of FFP were discussed on numerous occasions over the years.

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

39. There was concern about viral transmission and how this might be reduced by using virucidally treated FFP. The costs and indications for use were discussed repeatedly between the 22nd June 1999 and 20th January 2001 (see exhibits WITN4460006 - WITN4460013).

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

40. Aside from a document proposing that FFP should only be given if the INR (International Normalised Ratio) or APTTR (Activated Partial Thromboplastin Time Ratio) was over 1.5 (see exhibit WITN4460020). I have not located any specific guidance regarding this.

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

41. I have not located any documentation to be able to answer this question.

Platelets

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

42. I have not identified any historical discussion about platelet transfusions aside from the overall amounts used and the triggers for transfusion mentioned previously.

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

43. I do not have the knowledge to be able to answer this question.

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

44. There was a policy on triggers for platelet transfusion (see exhibit WITN4460020).

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

45. I do not have any knowledge to be able to respond to this.

Single-unit transfusion

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

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

46. I do not have any knowledge to be able to respond to this.

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

47. I do not have any knowledge to be able to respond to this.

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

48. I do not have any knowledge to be able to respond to this.

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

49. I do not have any knowledge to be able to respond to this.

47. Single-unit transfusions are described in [DHSC0025270] as a 'waste of resources' (p3). To the best of your knowledge, did the HTCs have specific views on the use of single-unit transfusion in relation to potential waste and did this change over time? Please explain your answer.

50. I do not have any knowledge to be able to respond to this.

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

51. I do not have any knowledge to be able to respond to this.

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

52. I do not have any knowledge to be able to respond to this.

Red blood cell concentrates

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

53. I do not have any knowledge to be able to respond to this.

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

54. I do not have any knowledge to be able to respond to this.

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

55. There was a policy in place in relation to transfusion triggers (see exhibits WITN4460019 and WITN4460020).

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

56. I do not have any knowledge to be able to respond to this.

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.

57. I do not have any knowledge to be able to respond to this.

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

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

58. I do not have any knowledge to be able to respond to 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 was administered to patients. Please address the following:

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

59. There is no mention of fresh warm blood in any of the documents I have located.

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

60. Please see my response to question 56.

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

61. Please see my response to question 56.

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

62. Please see my response to question 56.

Section 4: Knowledge of risk

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

63. Aside from the discussions relating to virucidally treated FFP mentioned previously (exhibits WITN4460006 to WITN4460013), HTLV-1 was discussed at the HTC meeting held on the 17th June 2004 (WITN4460020), and a look back exercise was described in the associated papers.

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

64. Aside from the look back exercise mentioned above, there is no specific mention of this in the documentation available. However, given the active discussion of incidents that should be reported or had been reported to SHOT, it can be assumed that any instance where viral transmission was suspected would have been investigated.

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

65. As outlined previously, there was repeated discussion regarding reducing the risks related to FFP transfusions.

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

66. I do not have specific knowledge to respond to this, but given the evidence of education of clinical staff involved in the transfusion process, it is possible such matters were discussed.

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

67. The documentation referred to thus far and contained within the exhibits in my opinion constitutes an appropriate

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

68. I do have the knowledge to be able to respond to this.

<u>Section 5: Reporting and audits</u>

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

a. What procedure did the Hospitals 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 Hospitals to report any adverse reactions or symptoms to the Regional Transfusion Centre?

f. In the event of a patient's death after receiving a blood transfusion, what process was followed? Specifically, please address the position in relation to the registration of the death and/or any consideration of what was recorded on the death certificate.

69. My interpretation is this applies to historical events rather than the present day. Therefore, I do not have any knowledge to be able to respond to this.

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

70. I do not have any knowledge to be able to respond to this.

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

71. The documents I have located indicate this was a regular, if not a standing agenda item, at the HTC meetings. I do not have any knowledge as to the specific mechanisms in place to ensure all reportable events were reported to the HTC.

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

72. I do not have any knowledge to be able to respond to this.

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

73. This was routinely reviewed at the HTC meeting using figures obtained from the Hospital Transfusion Laboratory and compared against the usage figures provided by the NBTS. Over time this process has become more robust through better electronic documentation of the fate of units transfused.

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

74. I do not have any knowledge to be able to respond to this in relation to historical events. In the present day there is a rolling programme of audits which is discussed and results reviewed at the HTC meetings.

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

75. The total number of units of different components used by the hospitals was reviewed. The data was obtained as outlined in question 70.

73. If the HTCs did record any information on the volume or number of transfusions as described in your answer to question 72 above, was this

information ever reported or disseminated to any other institution or body? If so, please explain the reporting process involved.

76. This data was reported to the NBTS. I do not have knowledge of the specifics of the reporting process.

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.

77. Audits were and still are regularly conducted in relation to all these.

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

78. The documentation available indicates that action was required over the years. I am not able to comment on the exact process followed historically as I do not have direct knowledge of it. In the present day, corrective action is agreed by all those involved and then a repeat audit is undertaken to ensure it has been effective. This is documented within the Hospital Transfusion Laboratory quality management system and where necessary (for example in relation to any clinical incidents) the quality and governance processes of the Trust.

Section 6: Treatment of patients

Provision of information to patients

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

79. I do not have any knowledge to be able to respond to this.

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

80. I do not have any knowledge to be able to respond to this.

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

81. There is discussion of patient consent in the minutes of the HTC meeting from the 19th October 1999 (WITN4460008). Documentation of verbal consent was recommended.

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

82. I do not have any knowledge to comment on the historical situation regarding this.

Section 8: vCJD

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

83. The first record of discussion of this risk I have located was in the minutes of the HTC meeting on the 14th August 2002 (WITN4460014). Over time, subsequent minutes indicate awareness of the impact this might have on the availability of blood products and the public health considerations.

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

84. I do not have any knowledge to comment on this.

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

85. I have not located any documentation to be able to respond to this question.

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

a. What steps were taken/put in place by the HTCs for informing patients about the risks of or possible exposure to vCJD before transfusion?

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

You may be assisted by BART0002418, NHBT0001123_002 and HCDO0000643

86. I do not have any knowledge to respond to this question.

Section 9: Look back

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

87. A look back exercise in relation to HTLV1 is mentioned and described in WITN4460020 and WITN4460021.

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

88. I do not have any knowledge to respond to this question.

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

89. I do have the knowledge to be able to respond to this in relation to any look back exercises conducted prior to 2017.

Section 10: Other

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

90. I have nothing further to add.

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.

91. I have included minutes of the Zonal Blood User Group (ZBUG) meetings (WITN4460021).

92. Exhibits WITN4460022 to WITN4460033 have been added for additional context.

Statement of Truth

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

Signed GRO-C

Dated 29/04/2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
22nd June 1999	Minutes and associated papers of HTC meeting	WITN4460006
30th September 1999	Correspondence and associated papers in relation to HTC, including letter from Allen Edwards to Dr Jonathan Wilde and attachment of	WITN4460007

	'Audit for Good Practice in Blood transfusion measure'	
29th October 1999	Minutes and associated papers of HTC meeting	WITN4460008
30th November 1999	Minutes and associated papers of HTC meeting	WITN4460009
22nd February 2000	Minutes and associated papers of HTC meeting	WITN4460010
6th June 2000	Minutes and associated papers of HTC meeting	WITN4460011
12th September 2000	Minutes and associated papers of HTC meeting	WITN4460012
30th January 2000	Minutes and associated papers of HTC meeting	WITN4460013
14th August 2002	Minutes and associated papers of HTC meeting	WITN4460014
12th September 2002	Minutes and associated papers of HTC meeting	WITN4460015
5th December 2002	Minutes and associated papers of HTC meeting	WITN4460016
20th March 2003	Minutes and associated papers of HTC meeting	WITN4460017
25th September 2005	Minutes and associated papers of HTC meeting	WITN4460018

22nd April 2004	Minutes and associated papers of HTC meeting	WITN4460019
17th June 2004	Minutes and associated papers of HTC meeting	WITN4460020
18 January 1999	Zonal Blood User Group meeting minutes	WITN4460021
16th September 2004	Minutes and associated papers of HTC meeting	WITN4460022
3rd February 2005	Minutes and associated papers of HTC meeting	WITN4460023
11th May 2005	Minutes and associated papers of HTC meeting	WITN4460024
5th October 2005	Minutes and associated papers of HTC meeting	WITN4460025
11th January 2006	Minutes and associated papers of HTC meeting	WITN4460026
6th December 2006	Minutes and associated papers of HTC meeting	WITN4460027
6th June 2007 to 3rd September 2008	Minutes and associated papers of HTC meetings	WITN4460028
10th December 2008	Minutes and associated papers of HTC meeting	WITN4460029
4th March 2009 to 9th December 2009	Minutes and associated papers of HTC meetings	WITN4460030

15th December 2010	Minutes and associated papers of HTC meeting	WITN4460031
4th June 2019	Blood Transfusion; Procedure 5 Queen Elizabeth (QEHB) Major Haemorrhage Procedure (MHP) and Urgent Transfusion	WITN4460032
Undated	Terms of Reference of HTC/HTG	WITN4460033