Witness Name: Tom LATHAM

Statement No. WITN7040001

Exhibits: WITN7040002 - WITN7040057

Dated: 17 August 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF TOM LATHAM, ON BEHALF OF UNIVERSITY HOSPITALS BRISTOL AND WESTON 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, Tom Latham, will say as follows: -

Section 1: Introduction

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

1. My name is Tom Latham.

2. My date of birth is GRO-C 1971.

3. BSc University of Edinburgh 1993

   MBChB University of Edinburgh 1995

   MRCP Royal College of Physicians Edinburgh 1998

FRCPath Royal College of Pathologists 2003

PhD University of Edinburgh 2007

4. GMC Registration 4206226, registered with a license to practice and admitted to the Specialist Register in Haematology.

2. Please set out your current role at University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) and your responsibilities within that role.

5. I have a joint consultant post between NHS Blood and Transplant and UHBW, with an honorary contract at UHBW. At UHBW I am the consultant with responsibility for the Blood Bank at the Bristol site, chair of the hospital transfusion committee and hospital transfusion team. I am also deputy lead consultant for Haemoglobinopathies and provide outpatient consultation for haemoglobinopathies.

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

6. The joint role is a longstanding post in Bristol, I applied to the post which was advertised by NHSBT in 2010 upon the post becoming vacant due to promotion of the previous incumbent.

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. - Aug 1995 to Feb 1995: Western General Hospital Edinburgh. House Officer in Medicine.

   - Feb 1995 to Aug 1996: Falkirk Royal Infirmary. House Officer in Surgery. - Aug 1996 to August 1998: Senior House Officer on South West Scotland medical

rotation. Posts at Royal Infirmary Edinburgh and Dunfermline hospital. - Oct 1998 to Oct 1999: Western Infirmary Glasgow Research Fellow in Haematology.
- Oct 1999 to Oct 2003: Specialist Registrar in Haematology- SE Scotland Rotation. Posts at Royal Infirmary Edinburgh, Western General Edinburgh, Royal Hospital for Sick Children Edinburgh, St John's Hospital, Livingston. - Oct 2003 to Feb 2008: University of Edinburgh: Clinical Research Fellow. - Feb 2008 to July 2010: Malawi Medical College, Blantyre, Malawi: Lecturer in Haematology.
- July 2010 to present: NHS Blood and Transplant/ UHBW: Consultant in Transfusion Medicine.

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. This evidence is submitted on behalf of UHBW. At the time of the events which are the subject of the Inquiry, Weston was a separate entity. Weston General Hospital (WGH) and University Hospitals Bristol (UHB) merged to form UHBW in 2020. Hospitals which were users of blood within UHB included the Bristol Royal Infirmary, Bristol Childrens Hospital, St Michael's Hospital (maternity), the Bristol Haematology and Oncology centre and Bristol Heart Institute and also Bristol General Hospital (closed 2012).
9. There is no available documentary evidence regarding the formation of the HTC

at UHB. Copies of minutes exist from 2001 onwards, showing that a committee existed then. Minutes from March 2001 refer to Dr Edwin Massey taking over the chair from (the late) Dr Geoffrey Scott. I have contacted Dr Massey who thinks that the HTC was fairly recently formed at that time. It is therefore likely that the HTC was convened in the late 1990s under the chairmanship of Dr Scott, in response to recommendations from the Department of Health "Better Blood Transfusion" circular. The 2005 terms of reference state the objective of the committee as "The promotion of safe & effective blood transfusion practice in the Trust" and it is unlikely the aims were materially different at the inception of the committee.

10. There is no documentary evidence of how transfusion was monitored prior to the inception of the HTC.

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.

11. Minutes from June 2001 state "Regular representatives attend from the departments of surgery, anaesthetics, cardiac surgery, haematology / oncology, bone marrow transplantation, pathology, paediatrics, obstetrics and gynaecology in addition to the transfusion consultant, the heads of blood bank and haematology and a representative of the finance department. The minutes confirm that representatives of these departments did attend or send apologies for absence. The current intended membership of the committee is unchanged but the minutes do record a reduction in attendance from departments between 2001 and 2004, which persists today.

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.

12. There are no surviving Terms of Reference from the time of inception of the HTC. The Terms of Reference from 2005 state the specific roles of committee were: ● Promotion and dissemination of national and local guidelines throughout the Trust.

- Support of departmental and hospital audit.
- Promotion of education & training programmes.
- Identification of problems in any aspect of blood transfusion including the delivery of services within the Trust and areas where guidance or

additional resources are needed.

- Participation in national schemes aimed at promoting best practice including Serious Hazards of Transfusion Reporting and Blood Stocks Management Scheme submissions.
- Reporting to the Trust Clinical Risk Assurance Committee and via this route to the Board Governance Committee for governance issues and the Trust Executive Group for ratification of policy and resource issues.
- Liaison with the Regional and National Transfusion Committees. ● To advise on the suitability of and indications for the use of new blood components and products in the trust.
- To assess the impact of haemostatic agents and autologous transfusion techniques providing guidance on their use in relation to blood conservation.

13. Minutes from the HTC meeting in June 2001 [exhibit WITN70390002] show that items discussed include introduction of documentation of hospital practice and procedures (transfusion policy), approval of patient information leaflets, review of blood usage, review of incidents, response to national guidelines (specifically the 2000 SHOT report), response to a report from the National Blood Service and review of audits.

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.

14. The comment that “The responsibilities of these hospital transfusion committees, where they exist and to whom they report' are unclear” is perhaps an unfair

statement when applied to individual HTCs. For example the UHB transfusion committee has clear documentation of its terms of reference and that it reports to the Clinical Risk Action Group. It may be a more precise statement that there may have been inconsistencies in scope, responsibility and reporting arrangements between different hospitals. The Better Blood Transfusion initiatives from the Department of Health had the aim, and in many ways was successful at providing clearer standardisation.

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.

15. Regarding the statement "*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,"* I consider that the assessment of the limited success of HTCs is a fair extent but ascribing this to lack of clinician input is simplistic. It is at least equally likely that clinician input was limited because the transfusion committee was perceived of having low influence. One must also ask what is meant in this context by "input." For example the UHB HTC minutes do document committee attendance by clinicians (both nursing and medical) from a wide range of disciplines. It is less clear what contribution was made by attendees and to what extent they provided genuine representation in terms of communicating the needs of their department to the committee and the decisions of the committee back to their departments. There is reference in the minutes of November 2001 that "the meetings have become very long" and a proposal to deal with incidents "at departmental level",

suggesting that the actual business of the committee may not have been meeting the needs of attendees.

16. The questions around effectiveness of the HTC and of active participation from clinical departments very much remains a problem today although it may be for different reasons to in the 1990 and early 2000s. It should be remembered that transfusion medicine was at the forefront of developing a systematic approach to patient safety in the late 1990s (in very large part, in direct response to the events investigated in the Inquiry). The recommendations to form HTCs was part of this approach. In contrast, HTCs nowadays are simply one of many levels of safety and clinical governance committees in a hospital and priority may be given to committees with a stronger mandate.

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].

17. The terms of reference provide for “up to 4 meetings per year”. Between 2001 and 2005 there were sometimes 3 and sometimes 4 meetings per year as evidenced by minutes. There is reference in minutes from November 2001 to “have 2 full meetings per year and 2 ‘educational updates’ ”.

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.

18. There is no documentary evidence about training provided prior to 2001 or of concerns about the quality of training. Concern about the lack of formal training is noted in the HTC minutes of November 2002 in response the Department of Health circular HSC 2002/009, stating

"Three areas of non-compliance had been identified.

i) The lack of a Hospital Transfusion Team as defined in the document. ii) The lack of training in transfusion for all staff in the Trust.

iii) Lack of an audit trail for intravenous immunoglobulin."

19. From the minutes it appears that training in transfusion was introduced for new junior doctors and for portering staff around 2001 -2002 but the details of the training provided is not recorded.

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?

20. Representation from departments which are substantial users of blood was expected. The role of representatives is not documented but it appears that the

main approach of the HTC towards oversight of transfusion in the hospital was mediated through the development of policies and guidelines and by review of clinical incidents.

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].

21. HTC minutes describe the formation of a South West Regional Transfusion committee on 7 September 2001 and that 2 representatives from UHB attended the committee. NBTS arranged "Zonal blood user group", which were disbanded following the formation of Regional Transfusion Committees but the interaction between the HTC and these groups is not documented. There is no evidence within HTC minutes of the nature of interaction between the HTC and RTC.

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?***

22. NBTS provided *de facto* representation on the HTC since the blood bank consultant (who also acted as committee chair for much of the time period) was jointly employed by NBTS and UHB. This arrangement continues to this day. A regular item in the HTC minutes refers to a report from NBS and documents the HTC response to changes and recommendations from NBS in the report. There is also reference to the Blood Stocks Management Scheme which was able to supply regular reports on the amount of blood issued to hospitals from April 2001.

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.

23. The HTL provided regular attendance on the committee and reports on blood usage trends. As evidenced by the minutes, much of the work of the committee in practice was devoted to discussing logistical issues with the transport of blood around the hospital in response to incidents. This remains true today. In practice, it appears that the HTL was the main conduit of information about changing recommendations in transfusion practice between NBTS and the HTC.

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?

24. Minutes from the early 2000s do illustrate the difficulty of gaining consensus and implementing guidance across a complex organisation, with for example consultation about the introduction of a blood transfusion policy appearing in the minutes over many months. Attempts to standardise practice across the trust and between trusts in the same city are also recurring themes. A very large proportion of the minutes is devoted to incidents arising from logistical difficulties and sample labelling errors. It is of relevance that the number of incidents concerning suspected transfusion transmitted error is very small compared to these other operational challenges. These challenges remain much the same today.

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.

25. Reference is made *passim* in the minutes to "red cells", "platelets", "fresh frozen plasma" and "albumin" as would be expected.

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.

26. There is a discussion in the minutes of November 2002 of a consultation with users to update the MSBOS in response to the introduction of electronic issue. An MSBOS therefore clearly existed prior to 2002 although there is no evidence of when these were introduced. There is reference in the minutes to reducing the number of units crossmatched for certain operations following the introduction of electronic issue in the early 2000s, but there are no details of the changes.

27. There are no surviving copies of the MSBOS from the relevant period

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?

28. There is no direct evidence of a response to these audit findings. There is regular ongoing reference in the HTC minutes to the drafting of a Transfusion Policy, aiming to standardise practices for the administration of transfusion in the

trust. The transfusion policy appears to have been published in the first half of 2002. I do not have a copy of that first version to comment on whether these specific issues were addressed.

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.

29. There is no evidence available as to whether guidance was produced for these specific patient groups. Mention is made in the 2004 HTC minutes to the development of a "Bristol Transfusion Handbook" aiming to standardise guidelines across the city. There is also reference to the Handbook of Transfusion Medicine being distributed to wards and departments.

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?

30. The HTC was not, and is not responsible for individual failures to comply with policies and procedures, although clinical incidents arising from such failures and audits of compliance are recorded as being discussed. There is one recurring

example of discussions relating to a failure to comply with recommended practice. Several minutes record the occurrence of separate incidents where a patient did not receive irradiated blood where irradiated blood would have been recommended. There is no recorded discussion of specific actions in response to these incidents, which may have been dealt with at departmental level as has been noted elsewhere in the HTC minutes.

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.

31. There is no evidence to respond to this comment. Please see response to question 87 below. I would note that the statement remains true today, perhaps even more so than in the late 1990s and early 2000s.

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.

32. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

33. There is no evidence to respond to this comment. Please see response to question 87 below. I would however add that I think it is perhaps unfair to infer that proposals were not listened to; it may be more precise to infer that other issues may have been considered of greater priority.

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?

34. There is no evidence to respond to this comment. Please see response to question 87 below.

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.***

35. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

36. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

37. There are records in the HTC minutes from November 2002 of the results of a hospital- wide consultation on autologous transfusion approaches. The minutes record that autologous predeposit was not available. It is noted "that most patients for cardiac surgery would not be eligible for pre-deposit donation. In fact the cost effectiveness and safety of pre-deposit transfusion has been questioned greatly in recent times, and has become less of a focus for blood conservation."

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.

38. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

39. There is no evidence to respond to this comment. Please see response to question 87 below.

'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?

40. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

41. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

42. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

43. There is no evidence to respond to this comment. Please see response to question 87 below.

Fresh Frozen Plasma ("FFP")

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

44. There are records in the minutes of the need to include more specific guidance on FFP transfusion in the Transfusion Policy being developed in 2001-2, in particular with regard to response to coagulation results. The final guidance provided is not available.

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

45. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

46. There are records in the minutes of the need to include more specific guidance on FFP transfusion in the Transfusion Policy being developed in 2001-2, in particular with regard to response to coagulation results. The final guidance provided is not available.

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?

47. There is no evidence to respond to this comment. Please see response to question 87 below.

Platelets

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

48. There is no evidence to respond to this comment. Please see response to question 87 below.

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

49. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

50. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

51. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

52. There is no evidence to respond to this comment. Please see response to question 87 below.

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

53. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

54. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

55. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

56. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

57. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

58. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

59. There is no evidence to respond to this comment. Please see response to question 87 below.

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

60. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

61. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

62. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

63. There is no evidence to respond to this comment. Please see response to

question 87 below.

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?

64. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

65. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

66. There is no evidence to respond to this comment. Please see response to question 87 below.

'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?

67. There is no evidence to respond to this comment. Please see response to question 87 below.

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

68. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

69. There is no evidence to respond to this comment. Please see response to question 87 below..

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?

70. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

71. There is no evidence to respond to this question regarding activities in the period during the 1980s and 90s. The knowledge of HIV and hepatitis transmission was well established by the period that we have records of HTC discussions. The major sources of knowledge noted in HTC minutes include the SHOT report and the update report provided by NBTS, both of which have discussion evidenced in the minutes.

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?

72. There is no evidence to respond to this comment. Please see response to question 87 below.

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

73. There is no evidence to respond to this comment. Please see response to question 87 below. However it is likely to be the case, as it remains today, that the primary means of minimising exposure to infection was affected by providing guidelines on appropriate use of blood.

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.

74. There is no evidence to respond to this comment. Please see response to

question 87 below.

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.

75. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

76. There is no evidence to respond to this comment. Please see response to question 87 below.

Section 5: Reporting and audits

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

- ***a. What procedure did the 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.

77. There is no evidence to respond to this comment. Please see response to question 87 below.

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

78. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

79. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

80. There is no evidence to respond to this comment. Please see response to

question 87 below.

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

81. The HTC minutes record regular reports on usage and wastage provided by the laboratory manager. Reference is also made to data on blood issues and wastage submitted to and received from the NBTS "Blood Stocks Management Scheme".

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?

82. Audits are mentioned as a regular item in HTC minutes. The HTC does not appear to have conducted audits itself but records audits performed either by individual departments or in response to national audits.

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.

83. The HTC minutes record regular reports on usage and wastage provided by the laboratory manager. Reference is also made to data on blood issues and wastage submitted to and received from the NBTS "Blood Stocks Management Scheme".

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.

84. There is no evidence about whether information on usage from the HTC was disseminated to other bodies. The minutes do record participation in the NBTS Blood Stocks Management Scheme, and that usage and wastage data was submitted to this scheme.

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.

85. There is reference in the June 2001 minutes of an audit of fresh frozen plasma. Other departmental audits are mentioned in minutes but it is not recorded whether these were targeted at specific products.

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.

86. It would be unusual for any audit to have no corrective actions. However corrective actions are not documented in the HTC minutes available.

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?

87. HTC minutes from 2001 welcome the production of an NBTS patient information leaflet "Receiving a blood transfusion" and its distribution in the hospital.

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?

88. There is no evidence to respond to this comment. Please see response to question 87 below.

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, 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?

89. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

90. There is no evidence to respond to this comment. Please see response to question 87 below.

Section 7: vCJD

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

91. There is no evidence to respond to this comment. Please see response to question 87 below.

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

92. Discussion of CJD risk is noted in a number of HTC minutes, including reference to reported CJD cases in 2004, and discussions of the implications of CJD prevention measures including the deferral of previously- transfused donors and withdrawal of UK plasma in 2004. The HTC appears engaged with responding to national communications of risk and their implications.

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].

93. There is no evidence to respond to this comment. Please see response to question 87 below.

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)?***

94. There is no evidence to respond to this comment. Please see response to question 87 below.

Section 8: Look back

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

95. There is no evidence to respond to this comment. Please see response to question 87 below.

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?

96. There is no evidence to respond to this comment. Please see response to question 87 below.

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

97. There is no evidence to respond to this comment. Please see response to question 87 below.

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.

98. I wish to comment on the approach taken to attempt to provide answers to the questions asked. The events referred to in these questions are of course long before my personal involvement with the Hospitals. Some members of staff who were involved in the Hospital Transfusion Committee in the late 1990s are still employed by the trust but staff who were involved at a sufficiently senior level prior to this have long retired and some are known to have died.

99. Bearing in mind potential inaccuracies in recall over this length of time, the report therefore concentrates on answers to the questions for which we have some documentary evidence. Accordingly, where the response states that "there is no evidence to respond to this comment", this indicates a lack of documentary evidence covering the relevant period, rather than evidence that the issue in question was not being addressed in the Hospitals.

100. I am grateful to Eric Sanders, Director of Corporate Governance at UHBW who has requested the following documents from archive records, the electronic document system, and personal requests via departmental governance leads. ● Minutes from the Hospital Transfusion Committee;

- Minutes from blood bank or haematology laboratory meetings;
- Minutes from any committees which the HTC reported to;
- Earliest available policy or procedure documents relating to transfusion (both clinical/ hospital or laboratory); and
- Documents relating to clinical staff training.

101. I refer to the NHS England Corporate Records Retention and Disposal Schedule 2019. A 20 year retention time is stated for board level minutes, terms

of reference, and serious incident reports; a 6 year retention time is stated for minutes and terms of reference for meetings below board level. A 10 year retention time is stated for standard operating procedures and policies.

102. There are a full set of HTC minutes for UHB from 2001 onwards, which do help to answer some of the questions relating to the later part of the relevant period. For the purposes of this response I have limited the "relevant period" as extending up to the date of the Blood Safety and Quality regulations in 2005. It is recognised that many of the issues under investigation by the Inquiry were well established by the 2000s and responses based on later minutes may not be informative about earlier practices.

103. There are no surviving documents for the relevant period relating to Weston General Hospital.

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.

104. I enclose a copy of the Minutes from the June 2001 UHB Hospital Transfusion Committee meeting [WITN7040002]. This meeting is a particularly useful record of the business of the HTC since this meeting is the first meeting of the newly appointed transfusion consultant and committee chair, and as such documents discussion to understand the work of the committee.

Statement of Truth

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

GRO-C

Signed _____

Dated 17 August 2022

Table of exhibits:

Table of exhibits:

Date	Description	Exhibit number
07/06/2001	UBHT Hospital Transfusion Committee Meeting Minutes June 2001	WITN7040002
09/08/2001	UBHT Hospital Transfusion Committee Meeting Minutes August 2001	WITN7040003
29/11/2001	UBHT Hospital Transfusion Committee Meeting Minutes November 2001	WITN7040004
09/05/2002	UBHT Hospital Transfusion Committee Meeting Minutes May 2002	WITN7040005
12/09/2002	UBHT Hospital Transfusion Committee Meeting Minutes September 2002	WITN7040006
14/11/2002	UBHT Hospital Transfusion Committee Meeting Minutes November 2002	WITN7040007
26/02/2004	UBHT Hospital Transfusion Committee Meeting Minutes February 2004	WITN7040008

27/05/2004	UBHT Hospital Transfusion Committee Meeting Minutes May 2004	WITN7040009
09/09/2004	UBHT Hospital Transfusion Committee Meeting Minutes September 2004	WITN7040010
18/11/2004	UBHT Hospital Transfusion Committee Meeting Minutes November 2004	WITN7040011
24/02/2005	UBHT Hospital Transfusion Committee Meeting Minutes February 2005	WITN7040012
09/06/2005	UBHT Hospital Transfusion Committee Meeting Minutes June 2005	WITN7040013
22/09/2005	UBHT Hospital Transfusion Committee Meeting Minutes September 2005	WITN7040014
17/11/2005	UBHT Hospital Transfusion Committee Meeting Minutes November 2005	WITN7040015
18/05/2006	UBHT Hospital Transfusion Committee Meeting Minutes May 2006	WITN7040016
14/09/2006	UBHT Hospital Transfusion Committee Meeting Minutes September 2006	WITN7040017

16/11/2006	UBHT Hospital Transfusion Committee Meeting Minutes November 2006	WITN7040018
22/02/2007	UBHT Hospital Transfusion Committee Meeting Minutes February 2007	WITN7040019
24/05/2007	UBHT Hospital Transfusion Committee Meeting Minutes May 2007	WITN7040020
26/09/2007	UBHT Hospital Transfusion Committee Meeting Minutes September 2007	WITN7040021
19/12/2007	UBHT Hospital Transfusion Committee Meeting Minutes December 2007	WITN7040022
27/02/2008	UBHT Hospital Transfusion Committee Meeting Minutes February 2008	WITN7040023
13/05/2008	UBHT Hospital Transfusion Committee Meeting Minutes May 2008	WITN7040024
11/09/2008	UBHT Hospital Transfusion Committee Meeting Minutes September 2008	WITN7040025
13/11/2008	UBHT Hospital Transfusion Committee Meeting Minutes November 2008	WITN7040026

12/02/2009	UBHT Hospital Transfusion Committee Meeting Minutes February 2009	WITN7040027
30/04/2009	UBHT Hospital Transfusion Committee Meeting Minutes April 2009	WITN7040028
10/09/2009	UBHT Hospital Transfusion Committee Meeting Minutes September 2009	WITN7040029
12/11/2009	UBHT Hospital Transfusion Committee Meeting Minutes November 2009	WITN7040030
11/02/2010	UBHT Hospital Transfusion Committee Meeting Minutes February 2010	WITN7040031
13/05/2010	UBHT Hospital Transfusion Committee Meeting Minutes May 2010	WITN7040032
05/08/2010	UBHT Hospital Transfusion Committee Meeting Minutes August 2010	WITN7040033
11/11/2010	UBHT Hospital Transfusion Committee Meeting Minutes November 2010	WITN7040034
10/02/2011	UBHT Hospital Transfusion Committee Meeting Minutes February 2011	WITN7040035

09/06/2011	UBHT Hospital Transfusion Committee Meeting Minutes June 2011	WITN7040036
13/10/2011	UBHT Hospital Transfusion Committee Meeting Minutes October 2011	WITN7040037
28/06/2012	UBHT Hospital Transfusion Committee Meeting Minutes June 2012	WITN7040038
25/10/2012	UBHT Hospital Transfusion Committee Meeting Minutes October 2012	WITN7040039
28/02/2013	UBHT Hospital Transfusion Committee Meeting Minutes February 2013	WITN7040040
27/06/2013	UBHT Hospital Transfusion Committee Meeting Minutes June 2013	WITN7040041
14/11/2013	UBHT Hospital Transfusion Committee Meeting Minutes November 2013	WITN7040042
29/06/2014	UBHT Hospital Transfusion Committee Meeting Minutes June 2014	WITN7040043
07/10/2014	UBHT Hospital Transfusion Committee Meeting Minutes October 2014	WITN7040044

11/06/2015	UBHT Hospital Transfusion Committee Meeting Minutes June 2015	WITN7040045
26/11/2015	UBHT Hospital Transfusion Committee Meeting Minutes November 2015	WITN7040046
28/04/2016	UBHT Hospital Transfusion Committee Meeting Minutes April 2016	WITN7040047
13/10/2016	UBHT Hospital Transfusion Committee Meeting Minutes October 2016	WITN7040048
23/02/2017	UBHT Hospital Transfusion Committee Meeting Minutes February 2017	WITN7040049
27/07/2017	UBHT Hospital Transfusion Committee Meeting Minutes July 2017	WITN7040050
17/12/2017	UBHT Hospital Transfusion Committee Meeting Minutes December 2017	WITN7040051
15/08/2018	UBHT Hospital Transfusion Committee Meeting Minutes August 2018	WITN7040052
17/04/2019	UBHT Hospital Transfusion Committee Meeting Minutes April 2019	WITN7040053

10/12/2019	UBHT Hospital Transfusion Committee Meeting Minutes December 2019	WITN7040054
09/04/2020	UBHT Hospital Transfusion Committee Meeting Minutes April 2020	WITN7040055
16/10/2020	UBHT Hospital Transfusion Committee Meeting Minutes October 2020	WITN7040056
01/04/2022	UBHT Hospital Transfusion Committee Meeting Minutes April 2022	WITN7040057