Witness Name: Dr Andrew Goringe

Statement No.: WITN7083001

Exhibits: WITN7083002 - WITN7083013

Dated:

25/04/2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ANDREW GORINGE, ON BEHALF OF CARDIFF & VALE UNIVERSITY HEALTH BOARD

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

I, Dr Andrew Goringe MBCh, 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 Andrew Goringe.

2. My professional address is Haematology Department, University Hospital of Wales, Heath Park, Cardiff.

3. My date of birth is GRO-C 1967.

4. My professional qualifications are:

University of Wales College of Medicine

Degrees: - Bachelor of Medicine, Bachelor of Surgery – 1990

Postgraduate Diplomas

Membership of the Royal College of Physicians (U.K) June 1993

Membership of the Royal College of Pathologists October 1999

CCST awarded April 2000

2. Please set out your current role at Cardiff and Vale University Health Board and your responsibilities within that role.

5. I am currently employed by Cardiff and Vale University Health Board as a Consultant Haematologist having been appointed to the role in November 2001. I am the Clinical Lead for the Haematology Laboratory including Transfusion.

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

6. I was a Specialist Registrar in Haematology – South Wales programme between 1994-2000, with Locum Consultant posts in Cardiff during 2000-2001.

7. Having an interest in laboratory diagnostics and clinical haematology, I took the opportunity within the health board to apply for my current position to progress and take on clinical responsibilities in 2001.

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.

8. As a junior doctor 1990 – 1993 I completed my House Jobs in medicine and surgery in Cardiff and Swansea, undertook a 2-year medical rotation between Cardiff and Merthyr Tydfil and a 6-month job in intensive care based in Cardiff.

Section 2: Hospital Transfusion Committee history, stricture & relationships

9. I would like to make it known to the Inquiry that in preparation for this Rule 9 response I have been unable to access any written (paper or electronic) evidence prior to 2003, although at this time the Hospital Transfusion Committee (HTC) appears established and active. My evidence therefore reflects the position in 2003-2006. I am unable to comment before this period.

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

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

10. I am unable to answer due to lack of evidence from which to draw upon.

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. In 2005 the membership was to include:

- Chairperson
- Blood Bank Manager
- Consultant Haematologist
- Transfusion Practitioner
- Welsh Blood Service (WBS) representative
- Trust Clinical Governance representative
- Representation from high blood use clinical directorates
- Senior Nurse representation

12. This remains the core expected representation.

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.

13. The stated functions and responsibilities of HTC's at points a to i (copied below) were similar to those listed. The responsibility for consent was held within the Trust's over-arching consent policy. In addition, the HTC was responsible for oversight of the cell salvage working group.

    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

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. At Cardiff and Vale University Health Board the HTC reported to the main Trust governance committee the 'Clinical Standards and Patient Experience Committee' which in turn, reported to the Trust Board. There is evidence of interaction between the HTC and the Clinical Standards and Patient Experience Committee and/or the Trust's Medical director (see exhibits WITN7083002 to WITN7083006). Therefore, there is evidence that in 2005/6 the HTC were aware of their role and to whom they reported to.

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. The minutes of HTC and HTC annual report (Exhibit WITN7083007) suggest that representation was below that expected, most notably clinical representation from high use areas. There is evidence of the HTC discussing this with the Trust Medical director (Exhibit WITN7083006) and having his support to improve attendance. My own experience is that despite this support, regular attendance at the HTC by clinical representation from high use areas has remained patchy.

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].

16. In 2005-6 the HTC met 3 times per year. Currently, the HTC meets 4 times per year.

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.***

17. Education was discussed at the HTC (Exhibits WITN7083004 to WITN7083006). The Trust had participated in the National Comparative Audit of Blood Transfusion – report Sept 2003. The trust had appointed a Transfusion Practitioner to improve education and training and was developing a strategy to link nurses within clinical areas to train and promote best practice. The HTC also noted the requirement that staff accessing transfusion fridges be trained. There was also access to the All Wales e-learning package. At this stage, this did not include a formal competency assessment or central documentation of training.

18. All staff involved in transfusion practice must now be trained and assessed as per the All Wales competency assessment and these results are centrally recorded on their Electronic Staff Record. Discussions have been had within the HTC regarding the status of agency staff and the ability to ensure they are trained and

assessed to the All Wales standards; a resolution to this topic has not been reached.

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

19. The Hospital Blood Transfusion Policy 2003 (the Policy) (see Exhibit WITN7083008) states that the 'following recommendations are based on the guidelines published by the British Council for Standards in Haematology and the Royal College of Anaesthetists in 2001'. The relationship between the HTC and hospital departments appears to be collaborative with promotion of best practice and support of local audits by provision of transfusion data rather than specific oversight. Over the subsequent years there has been a significant reduction in blood usage in high use areas such as Cardiac Surgery and Obstetrics. Usage figures broken down to clinical directorates were produced in the 2005 and 2006 annual HTC reports.

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

- ***a. Who, if anyone, from the HTCs primarily interacted with the Regional Transfusion Centre, and subsequently the Regional Transfusion Committee;***
- ***b. The topics covered by the interactions;***
- ***c. How policy and guidance was cascaded from the Region to the Hospital Transfusion Committee;***

d. ***What oversight the Region had over the Hospital Transfusion Committee;***
e. ***Whether it was standard practice to have someone from the Regional Transfusion Centre sit on the HTCs;***
f. ***The input, if any, that the Region provided to the HTCs in relation to updating and promoting transfusion practice; and***
g. ***How the relationship changed over time.***

You may wish to refer to [BSHA0000061_029].

20. There is evidence of limited attendance at the Cardiff and Vale HTC by a representative from the Welsh Blood Service (WBS) (Exhibit WITN7083003). It appears that the WBS played an advisory role, updating the HTC on national issues with no oversight role. In 2005-6 the extent of their input appears limited compared to the present day.

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?***

21. See answer to question 13.

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.

22. The transfusion laboratory manager attended the HTC and reported to the committee. Topics discussed within the 2005/6 minutes include updates on analysers (related to capacity), blood wastage figures, cold chain validation issues (blood transport boxes), the use of satellite fridges, traceability data and MHRA/BSQR compliance.

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?

23. One of the main obstacles faced by the HTC in the early 2000's appears to be the relative lack of clinical input as previously noted. Also, although there were clear reporting lines and interaction with the Trust's governance committee, the HTC would have been one of many groups interacting with this committee and lacked any 'independent' authority.

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.

24. The Policy specifically only mentions Red Blood Cell (RBC) transfusion. This policy was replaced by the Blood and Component Transfusion Policy (Exhibits WITN7083009 and WITN7083010) which included Fresh frozen plasma (FFP), cryoprecipitate, platelets and Beriplex (for emergency reversal of warfarin) and there is evidence of participation with the National Comparative Audit for platelet use 2006.

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.

25. The Maximum Blood Ordering Schedule (MBOS) (see exhibit WITN7083011) was discussed in the HTC minutes (Exhibits WITN7083002 and WITN7083004) but appeared to have difficulty gaining information from the clinical teams. I have access to an undated/uncontrolled copy likely from this time period. The MBOS longer uses an electronic issue that allows blood to be available without crossmatching (and pre-allocation).

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?

26. The Policy clearly states the requirement for pre, 15 minute and post transfusion observations and the trust took part in the National Comparative Audit – Sept 2003.

    a. The policy did not require a second check or signature.
    b. Wristbands for transfusion were clearly required.
    c. There was no requirement for a doctor to be present during transfusion.
    d. The policy contains a section on transfusion reactions clearly stating the actions required which would include access to medical review.

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

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

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

27. Specific advice to these areas is not contained within the Policy. There is evidence of discussion with specialist areas within the HTC minutes (Exhibits WITN7083005 and WITN7083006) but this is limited.

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

28. The HTC would provide support to clinical areas but report any failure to comply with policies and practices to the Trust's Clinical Governance committee who would act as appropriate in response to such failures.

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.

29. The Policy states that 'there is increasing evidence that a conservative policy of perioperative red cell transfusion does not compromise clinical outcome, and some evidence that it may improve outcome in certain circumstances' and stated the transfusion thresholds as recommended by the British Council for Standards in Haematology and the Royal College of Anaesthetists in 2001. It would therefore appear that by 2003 Cardiff and Vale University Health Board were working in such a way to avoid unnecessary transfusion.

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

- *a. Any discussions the HTCs had about the Circular in relation to:*
  - *i. Obstetrics; trauma and emergency care; surgery; haematological malignancies; thalassaemia; and sickle cell anaemia; and*
  - *ii. Use of red blood cells, platelets and Fresh Frozen Plasma ("FFP")*
  - *iii. Autologous transfusion*
  - *iv. Single-unit transfusion*
  - *v. Fresh-warm blood transfusion*

vi. Knowledge of risk of transfusion related infections

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

30. HTC minutes for the period 1999-2004 are unavailable and discussions regarding the circular 'Better Blood Transfusion' Health Service Circular 1998/999 are not available to comment upon. Although I was present at HTC meetings from Spring 2002, I do not have any recollection of what was discussed in those meetings due to the twenty year passage of time. I haven't been able to access pre 2003 records as there aren't any within our systems corporate or transfusion service repositories for this period. The reason for this is unclear but is most likely due to historic archiving practices which have improved over recent years.

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.

31. There is no evidence that specific proposals were not being actioned from the 2005-6 minutes.

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?

32. The Policy, available to all clinicians, stated that in 'Acute or perioperative blood loss where the decision to transfuse is based on the measured haemoglobin

a. When the haemoglobin is >10g/dl blood transfusion is generally not indicated
b. When the haemoglobin level is 7-10g/dl blood transfusion may be indicated, but the decision to transfuse should not be based on the measured haemoglobin alone
c. When the haemoglobin is <7g/dl (or 8g/dl in patients with cardiopulmonary compromise) transfusion of red cells is generally indicated.

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.

33. See above response to question 25 for HTC guidance. The frequency of haemoglobin (Hb) measurement is not mentioned in the policy or minutes of HTC 2005-6.

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?

34. The guidance concerning haemoglobin levels and transfusion within the Policy was based on the British Council for Standards in Haematology and the Royal College of Anaesthetists in 2001.

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.

35. The trust had developed an active cell salvage programme supported by the WBS which reported to the HTC. This included intra operative cell salvage and

post-operative wound drainage. There is no evidence of pre-operative donation of autologous blood.

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.

36. By 2005 pre-operative transfusions could only be undertaken at Blood Establishments such as the WBS.

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?

37. I am not aware of any guidance regarding this from 2005-6. The WBS actively and financially supported the development of the intra operative cell salvage programme.

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?

38. The HTC minutes (Exhibits WITN7083003 and WITN7083004) show discussion of massive haemorrhage. I am unable to provide the working definition at this time or as to whether there were bespoke pathways for specialities. The definition of what

constitutes a massive haemorrhage has been much debated and still often relies on the clinical assessment/judgement by a senior clinician. The balance lies between unnecessary activation of the pathway and that of delayed transfusion. This, especially with internal bleeding can represent a difficult clinical challenge. We presently have specific massive haemorrhage pathways for Obstetrics, Emergency Department both adult and paediatric, Cardiac Surgery, Neonatal and General.

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?

39. See above response. All massive haemorrhages are presently audited and reported to the HTC.

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.

40. The Policy 2003 did not specifically mention massive haemorrhage but there was clearly an understood pathway within the hospital.

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?

41. The Policy did not specifically mention massive haemorrhage but there was clearly an understood pathway within the hospital.

Fresh Frozen Plasma

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

42. The Policy does not discuss the use of FFP and this is not discussed within the HTC minutes.

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

43. See response at question 35.

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.

44. See response at question 35.

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?

45. See response at question 35.

Platelets

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

46. The Policy does not discuss the use of platelets. However, there is evidence (Exhibit WITN7083006) of participation in the National comparative audit examining platelet usage in haematology, critical care, cardiac and miscellaneous use. The HTC therefore presumably had a position to follow national guidance on platelet use but this is not otherwise evidenced within the HTC minutes or the Policy.

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

47. See response at question 39.

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

48. See response at question 39.

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?

49. See response at question 39.

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?

50. There is no mention of single unit transfusions with the Policy or HTC minutes 2005-6. My own experience was as a registrar in haematology (1994-2000) being taught that 'if you only need one unit, you don't need a transfusion'.

51. At this time all blood was crossmatched and so logistically it was much more efficient for the laboratory to crossmatch several units rather than one unit on several occasions and the latter could lead to clinically significant delays in transfusion in cases of unexpected ongoing bleeding.

52. Electronic issuing of Red blood cells without the requirement for cross matching was introduced in the early 2000s.

53. The standard today is reversed with a single unit transfusion being recommended.

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

54. See response at question 43.

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.

55. See response at question 43.

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?

56. See response at question 43.

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

specific views on the use of single-unit transfusion in relation to potential waste and did this change over time? Please explain your answer.

57. See response at question 43.

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?

58. See response at question 43.

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.

59. See response at question 43.

Red Cell concentrates

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

60. By 2003 Red cell concentrates were the only RBC product supplied by the WBS. I cannot comment on the situation in the 1970s-1990s.

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

61. See response at question 50.

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.

62. See response at question 50.

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?

63. See response at question 50.

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.

64. See response at question 50.

55. In relation to red blood cell concentrates:

a. *Were attempts made to persuade clinicians to increase their usage of red blood cell concentrates in transfusions during the 1970s and 1980s?*
b. *To the best of your knowledge, did the Hospital come under pressure during the 1970s and 1980s to increase usage of red blood cell concentrates? If so, where did this pressure come from?*
c. *According to [HSOC0020283], British clinicians had a "traditional preference" for the use of whole blood in comparison with other*

countries. Is this an accurate representation of the position? Were the HTCs aware of why whole blood transfusions were preferred over red blood cell concentrates during the 1970s and 1980s?

65. See response at question 50.

Fresh Warm Blood

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

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

66. By 2003 Red cell concentrates were the only RBC product supplied by the WBS. I cannot comment on the situation in the 1970s-1990s.

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

67. See response at question 56.

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

68. See response at question 56.

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

69. See response at question 56.

Section 4: Knowledge of risk

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

70. There are no discussions within the minutes of the HTC 2005/6 meetings regarding the risk of viral infection associated with blood transfusion. The risk of HIV and Hep C would have been well established by this time point. The sources of knowledge that developed over time would be data from the SHOT reports and reports from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO).

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?

71. As above, during the 2005/6 time period there is no evidence of the HTC carrying out or initiating investigations into the risk of transmission of viral infections through blood transfusion.

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

72. The HTC supported a 'conservative policy' of red cell perioperative transfusion as stated in the transfusion policy and referred to at question 25.

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.

73. The policy states that the risk of transfusion transmitted virus infection is 'rare, but notification is important'. Safety data from SHOT along with the established donor testing for HIV and Hep C has confirmed that the risk of viral infection from blood products in this time period was rare. However, given the historical risks from HIV and Hep C this statement appears minimal. The possibility of an unknown virus is not mentioned. There are now well-established patient information leaflets provided by the WBS available to all patients receiving blood transfusion.

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.

74. I do not have minutes of HTC meetings at the relevant time points to comment on the response to HIV and Hep C infection.

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?

75. There is no evidence of discussion of this within the 2005/6 minutes but as described at question 60, the risk of HIV and Hep C were by 2005/6 well established.

Section 5: Reporting and audits

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

a. **What procedure did the Hospital have in place?**
b. **Did this procedure extend to a time after a patient had been discharged from Hospital?**
c. **Were patients asked to report any adverse reactions or symptoms within a certain timeframe?**
d. **If clinicians were informed and/or became aware of a patient having suffered any adverse reactions or symptoms, who were they required to report this to?**
e. **Was there any mechanism for the Hospital to report any adverse reactions or symptoms to the Regional Transfusion Centre?**
f. **In the event of a patient's death after receiving a blood transfusion, what process was followed? Specifically, please address the position in relation to the registration of the death and/or any consideration of what was recorded on the death certificate.**

76. The Policy has a section on the management of transfusion reactions, including recommendations to contact haematologists and the transfusion laboratory. There does not appear to be advice to specifically ask patients to report adverse reactions or symptoms after discharge. The Policy does not state when and how the WBS should be informed, though this is now standard policy through the transfusion laboratory. From 2005 I am not aware of a death contributed to by the transfusion of a blood component (RBC, FFP or platelets). If there had been such an occurrence or suspicion the case would be referred to the coroner and reported to the Welsh government as a potential serious incident. The HTC

annual reports (Exhibits WITN7083007 and WITN7083012) and HTC minutes (Exhibits WITN7083002 to WITN7083006, and WITN7083013) provide evidence of reporting to the Serious Hazards of transfusion (SHOT). The number of SHOT reportable incidents increased following the introduction of a mandatory reporting requirement in 2005 and so it is probable that there was some degree of under-reporting prior to this time. I am unable to comment on practice from 1970-1990s. The SHOT process of reporting has been hugely beneficial with excellent data and recommendations produced.

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

77. See response at question 66.

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?

78. See response at question 66.

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?

79. See response at question 66.

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

80. There is evidence of an audit of blood usage and wastage in the HTC minutes (Exhibit WITN7083005) and annual reports (Exhibits WITN7083007 and WITN7083012).

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?

81. The HTC has participated in the majority of National comparative audits since their inception in the early 2000s. Local audits within high use areas were undertaken by the relevant clinical teams and supported by data provided by the transfusion laboratory (Exhibits WITN7083007 and WITN7083012).

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.

82. The HTC annual report 2005 (Exhibit WITN7083012) provides data on RBC transfusion for the years 2004 and 2005, broken down into directorate use. The HTC also contributed to the WBS audit 'where does blood go' and provided data to individual directorates auditing their own blood use. Annual blood usage is discussed with the WBS.

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.

83. The annual report 2005 (Exhibit WITN7083012) and 2006 report (Exhibit WITN7083007) include blood usage at the directorate level. It is not clear whether

this information was disseminated to any other institution or body though annual usage figures are part of the SLA meeting held each year with the WBS.

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.

84. There is evidence of audits being undertaken in RBC, platelets and massive transfusion. WBS collected extensive data on the use of cell salvage. I am not aware if this data is still available.

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.

85. The National comparative audit of Blood Transfusion – Reported Sept 2003 was a very significant audit. I do not have access to HTC minutes from this time period but the results gave significant impetus to transfusion education within the clinical area and the eventual development of Link nurses within the clinical areas to promote best practice, education and competency assessment.

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 as a consequence of treatment with blood?

86. There is no discussion in the HTC minutes available regarding providing patients with written information about the risks of infection as a consequence of treatment with blood. There are now specific transfusion leaflets provided centrally by the WBS as standard across Wales.

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?

87. See response at question 76.

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?

88. There is discussion in the HTC minutes (see Exhibits WITN7083006 and WITN7083013) regarding consent for Jehovah's witness patients and reference to the 'Trust consent policy' which appears to be a reference to consent which is not specifically mentioned in the Policy. There is no evidence of an audit of the effectiveness of the consent process regarding transfusion between 1970 and the early 2000's.

89. There is discussion in the HTC minutes (see Exhibits WITN7083006 and WITN7083013) regarding consent for Jehovah's witness patients and reference to the 'Trust consent policy' which appears to be a reference to consent which is not specifically mentioned in the Policy. There is no evidence of an audit of the effectiveness of the consent process regarding transfusion between 1970 and the early 2000's. An audit is available from 2014 (Exhibit WITN7083014). Following this audit the Welsh Blood Service introduced patient information leaflets and also the transfusion prescription form had consent Yes / No added.

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. During this time period (1970 to the early 2000's) consent for transfusion fell within the 'Trust consent policy'. A copy of this document is not currently available.

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. Knowledge of vCJD and the risk of its transmission associated with the use of Blood Transfusions will have occurred prior to my employment and before the recording of the HTC minutes 2005/6 and beyond that are available.

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

92. See response at question 80.

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

93. See response at question 80.

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

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

You may be assisted by BART0002418, NHBT0001123_002, HCDO0000643.

94. See response at question 80.

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. My understanding is that the look back exercise was centrally co-ordinated by the WBS prior to my employment and before the recording of the HTC minutes that are available. A copy of the literature for this exercise has not been located for review or comment.

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. See response at question 84.

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

97. See response at question 84.

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 have tried to give information as to the state of practice in 2005/6 that would be of some help in looking at events in the 1970-1990s but am aware that the information I have provided is limited given that our electronic records start from 2005.

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.

99. The Glamorgan Archives have been considered and searched in response to this Rule 9, however no information relating to HTCs was found. The relevant HTC documents in the Glamorgan Archives were searched but nothing was found.

Statement of Truth

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

Signed GRO-C

Dated 25/04/2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
14 April 2005	HTC Minutes April 2005	WITN7083002
12 July 2005	HTC Minutes July 2005	WITN7083003
29 November 2005	Blood Transfusion Committee Minutes 29 November 2005	WITN7083004
1 March 2006	TTC Minutes March 2006	WITN7083005
9 June 2006	TTC Minutes June 2006	WITN7083006

March 2007	TTC Annual Report 06-07	WITN7083007
August 2003	Transfusion Policy 2003	WITN7083008
2021	Blood and Compound Transfusion Policy 2021	WITN7083009
Undated	Blood and Compound Transfusion Policy	WITN7083010
Undated	MBOS Schedule	WITN7083011
May 2006	TTC Annual Report 05-06	WITN7083012
14 September 2006	Blood Transfusion Committee Minutes 14 September 2006	WITN7083013
Undated	NCA of Blood Transfusion	WITN7083014