Witness Name: Caroline Leonard
Statement No.: WITN3449042 Exhibits:
WITN3449043 - WITN3449093
Dated: 23rd May 2022

INFECTED BLOOD INQUIRY

FIFTH WRITTEN STATEMENT OF CAROLINE LEONARD, ON BEHALF OF BELFAST HEALTH & SOCIAL CARE TRUST

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

I, Caroline Leonard, will say as follows: -

Section 1: Introduction

1. As referenced in my second witness statement to the Inquiry, in 2005, the Secretary of State for Northern Ireland announced the Review of Public Administration which was a radical restructure and reduction in public administration structures. As a result, in 2007, the number of Health Trusts in Northern Ireland reduced from 18 to 6, with the Belfast Health and Social Care Trust becoming operational on 1 April 2007. This represented an amalgamation of what are now referred to as the 6 legacy organisations:
    a. Royal Group of Hospitals and Dental Hospital Health and Social Services Trust, established on 1 April 1994;
    b. North and West Belfast Community Health and Social Services Trust, established 1 April 1994;
    c. Belfast City Hospital Health and Social Services Trust, established on 1 April 1993;

d. South and East Belfast Health and Social Services Trust, established on 1 April 1994;
e. Mater Infirmorum Health and Social Services Trust, established on 1 April 1994; and
f. Green Park Healthcare Health and Social Services Trust, established on 1 April 1993

2. As such for the purposes of this Rule 9 response, my reference to hospitals will refer to those hospitals listed above for which the Trust is responsible.

3. The Ulster Hospital is the responsibility of the South-Eastern Health & Social Care Trust and as such, I am not in a position to comment on practice therein.

4. In order to address the questions posed in the Rule 9 request of 18 December 2021, I have spoken with the current members of the Belfast Trust Hospital Transfusion Committee (HTC). I have also received considerable assistance from the Haemovigilance Lead who was able to supply the majority of exhibits referenced herein from historical records held in the Haemovigilance department.

5. In drafting this statement, I have also reviewed the corporate documents supplied to the Inquiry following searches of current and legacy archives as referenced in my second witness statement to the Inquiry. This yielded little in terms of material relevant to the questions posed in the Rule 9 request of 17 December 2021.

6. Review of documentation and discussion with the current members of the Trust Hospital Transfusion Committee has established that pre-2002 there is very little organisational memory and documentation in relation to the matters discussed in the Rule 9 request of 17 December 2021. I have attempted to answer the questions so far as I can based on the information I have been able to obtain from the sources indicated and from my own knowledge and experience of BHSCT.

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

7. My name is Caroline Leonard. My date of birth is known to the Inquiry. My professional address is BHSCT HQ, "A" Floor, Belfast City Hospital, Lisburn Road, BT9 7AB.

2. Please set out your current role at Belfast Health and Social Care Trust and your responsibilities within that role.

8. I am the Director of Cancer and Specialist Services at Belfast Health and Social Care Trust (BHSCT); as such, I have responsibility for services provided at NI Cancer Centre, some medical specialities, renal transplant surgery, laboratories and pharmacy. The Regional Haemophilia Comprehensive Care Centre falls within my Directorate and as such, I was nominated by my Chief Executive, Dr Cathy Jack to undertake a coordinating role in support of the Infected Blood Inquiry on behalf of BHSCT.

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

9. I was appointed to my current role on an interim basis following a competitive recruitment exercise in February 2017 and on a permanent basis following a competitive recruitment exercise in July 2017.

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.

10. I commenced employment in the NHS on 7 September 1990 as an NHS General Management Trainee. This was a 2 year UK NHS Graduate Management Training Scheme in association with the University of Ulster and Manchester Business School. From September 1992 to May 1996, I was employed by the Southern Health & Social Care Board as Primary Care Unit Manager. This role included project manager for the design & development of a GP performance management information system, leading the development & support of GP fundholding in the Southern Board area, managing the General Medical Services contract budget and developing the pharmacy prescribing support programme for Primary Care.

From June 1996 to September 2007, the Royal Group of Hospitals and Dental Hospital Health and Social Services Trust employed me in several roles. As Maternity Project/Services Manager, I had operational management responsibility for Obstetrics, Gynaecology & Neonatology and led the Royal Maternity Hospital (RMH) & Jubilee Maternity hospitals amalgamation project. I redeveloped the RMH to accommodate the move and wrote the first full business case for a new maternity hospital on the Royal Hospitals site. As Commissioning General Manager, I commissioned the £74M Royal Victoria Hospital Phase 1 Hospital Redevelopment Scheme. I led the design team, equipped the building, secured additional revenue funding, appointed & trained staff, transferred services and decommissioned the old facilities. I then held two Divisional Manager roles in the Trust with responsibility for the strategic and operational performance management of the services/hospitals therein. These included Neurosciences, Orthopaedics, Ophthalmology, ENT, and Dentistry from February 2003 to January 2005 and the management of the Royal Belfast Hospital for Sick Children and The Royal Jubilee Maternity Hospital from January 2005 to September 2007. From October 2007 to October 2010 whilst on a 3-year career break from the NHS, I was employed by a NI independent sector healthcare company, 3FiveTwo Healthcare as Development Director. In this role I was responsible for the strategic growth and development of the company including the capital investment programme and developing new business ventures and the acquisition of several healthcare businesses to expand the company portfolio. I returned to the Belfast Health & Social Care Trust in October 2010 and have been in employment there since that time. I was initially placed following my career break in Laboratories as Service Manager for Tissue Pathology & Molecular Services. This role involved the operational & performance management of four Laboratories: Tissue Pathology, Microbiology, Histocompatibility and Immunogenetics (H&I) and Genetics; ensuring services were effective, responsive and accredited with the relevant regulatory authorities e.g. HTA, NCAS etc. From June 2011 to January 2017, I was appointed to two Service Co-Director roles. As Co-Director for Cancer & Specialist Medicine (2011-2014), I was responsible for the leadership and performance management of Cancer treatment (at the NI Cancer Centre) and specialist medical services. I was also responsible for the development, delivery and performance management of cancer pathways in Belfast & across NI Trusts.

As Co-Director for Surgery (2014-2017), I had responsibility for the leadership of the operational, strategic, governance & performance management arrangements for a wide range of local and regional surgical specialties such as, Upper GI, Colorectal, Hepatobiliary, Endocrine, Renal Transplant, Cardiothoracic, Breast, Urology and Ophthalmology. I was appointed to the role of Director of Surgery and Specialist Services in February 2017, a role incorporating the service portfolio of my previous two Co-Director roles together with laboratories and pharmacy. My service portfolio was re-profiled following an internal organisational review in 2021 and my job title amended to Director of Cancer & Specialist Services.

Section 2: Hospital Transfusion Committee history, stricture & 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 Hospital monitored transfusion practice.***

11. The Northern Ireland Regional Transfusion Committee (NIRTC) was set up in October 2003. The first chair of the NIRTC was Dr Damien Carson (Consultant Anaesthetist, South Eastern Health & Social Care Trust). Although I have obtained little documentary or other evidence to confirm the position, I am reasonably confident that prior to 2003, the main hospitals for which the legacy organisations were responsible, had bodies that performed a similar role to that of HTCs and would have had a similar membership. WITN3449043 is a letter from the chair of the legacy BCH HTC dated 2001 in which he refers to updating 1996 regulations and guidelines for the safe administration of blood and blood products. WITN3449044 is a report of the BCH Blood Transfusion Committee for the financial year 1999-2000. It is unlikely that the recommendations referenced

above would not have been adopted in Northern Ireland in some form prior to 2003, and I am aware that the Eastern Health and Social Care Board in 1988 advocated the establishment of Hospital Transfusion Committees (WITN3449045).

12. I am advised NIRTC was renamed the Northern Ireland Transfusion Committee (NITC) at a later date as it was not a regional committee under the England National Transfusion Committee. It may assist the Inquiry to consider WITN3449046. WITN3449046 contains the minutes from the third NIRTC meeting in January 2004, illustrating membership from the Northern Ireland Trusts and the Northern Ireland Blood Transfusion Service (NIBTS). It also records discussions as to how NIRTC would liaise with local Trust HTCs (see item 15 - Correspondence).

13. NIRTC liaised with transfusion colleagues in other parts of the UK and Ireland in establishing the Better Blood Transfusion Network in 2004. This network is still in place today (known as the UK & Ireland Blood Transfusion Network). WITN3449047 contains minutes from the inaugural 2004 meeting of this network and gives a flavour of its role. I am advised the Belfast Trust had HTCs in place for the Royal Group of Hospitals (RGH), Belfast City Hospital (BCH), Musgrave Park Hospital (MPH) and the Mater Infirmorum Hospital (MIH) at the stage when the NIRTC was established however, it is not known exactly when they were first established in these hospitals.

14. The NIRTC minutes in WITN3449046 indicate the presence of HTCs in Belfast and in other NI Trusts. The Belfast Trust legacy organisations had four HTCs. The first chair of the RGH HTC was Dr Susan Atkinson, Consultant Anaesthetist RVH. The first chair of the BCH HTC was Dr John McCollum, Consultant Anaesthetist BCH. The first chair of the MIH HTC was Dr John O Hanlon and the first chair of the MPH HTC may have been Dr Pamela Bell. A single BHSCT HTC was formed following the amalgamation of the legacy Trusts in 2007. Dr Susan Atkinson was the first chair of the BHSCT HTC.

15. The NIRTC were following *National Guidance HSC 1998/224 - Better Blood Transfusion* (NHBT0083701_002) which determined the need to have HTCs. Item 15 of the NIRTC minutes contained in WITN3449046 contains discussion regarding implementing Better Blood Transfusion in Trusts. It appears from the minutes that Trusts had already established HTCs prior to the NIRTC convening which supports my belief that HTCs or similar bodies existed prior to 2003. Given the paucity of information available, I am unable to say when these HTCs commenced. However, it would be a reasonable assumption that they were created following policy correspondence from DHNI directly to Trusts. Current practice is that all such guidance is distributed from the NI Department of Health to the NITC and the Trusts.

16. The initial aims of the HTCs appear to be contained within the WITN3449046 minutes of the NIRTC in relation to the role of Trust HTCs as follows:
    a. Implement HSC 1998/224 - Better Blood Transfusion collectively through the NIRTC;
    b. Establish a Northern Ireland Haemovigilance service, including training of new Haemovigilance staff;
    c. Establish a Cell Salvage service;
    d. Encourage use of Patient Information Leaflets;
    e. Establish a Bloodless Pathway for patients who refuse blood transfusion;
    f. Standardise transfusion practice as much as possible in NI Trusts by coordinating all Trust HTC work;
    g. Share information from NIBTS regarding risks including infections in transfusion;
    h. Establish if red cell transfusions were appropriate by undertaking a regional audit on the appropriate use of Red Cells, audits of Fresh Frozen Plasma use, Neonatal Donor Exposure, Obstetric Transfusion to establish current practice with a view to setting NI guidance and action plans for appropriate use; and
    i. The recommendations of these audits informed the CREST 2001 NI Guidance for Blood Transfusion Practice that was used by all NI Trusts (DHNI0000013_065).

17. My enquiries have established that there is no one in the current employment of BHSCT with organisational knowledge who can comment meaningfully on how the Hospitals monitored transfusion practice before the establishment of HTCs, nor have we secured any relevant documents from the legacy organisation archives that would assist.

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.

18. WITN3449050 is a copy of the Terms of Reference detailing the functioning of the BHSCT Transfusion Committee in 2010 and contains the composition of the committee that remains largely unchanged to this day. We have been unable to locate documents in relation to committee composition prior to 2010.

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.

19. WITN3449051 is a copy of the NI Regional Transfusion Policy 2005 containing the roles, functions and responsibilities of HTCs and practitioners. I have been unable to locate any material prior to 2005 that would assist in answering this question but I doubt the position would have differed significantly.

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.

20. No information has been found in relation to the reporting arrangements for the BHSCT legacy organisations' HTCs. However, the BHSCT HTC is a subcommittee of the BHSCT Trust Board Assurance Committee. It produces a quarterly assurance summary and an Annual Report for the BHSCT Trust Board. The Trust's Medical Director is responsible for ensuring the committee meets its delegated function. NI HTCs follow the UK guidance and terms of reference for HTCs. Based on my enquiries and personal experience, I would be hesitant about accepting the quotation above as a fair assessment of HTCs within the BHSCT.

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.

21. WITN3449050 details that membership of the BHSCT HTC is drawn from a range of medical specialties. The BHSCT HTC has always been chaired by a doctor, who is usually from a specialty independent of the laboratory service, (that is, a user of the Blood Bank service). WITN3449046 would indicate that all legacy HTCs were chaired by a doctor. This points to significant clinician input. To that extent, I would not agree that the submission represents a fair assessment of the position in relation to BHSCT HTCs.

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].

22. WITN3449050 detailing the BHSCT HTC Terms of Reference states "Frequency of Meetings: 3 per year of the HTC. Various working parties or subcommittees (e.g. cell salvage committee) may meet more frequently."

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.

23. From the time the NIRTC was set up in 2003/4, it was acknowledged that training for all staff who took part in the transfusion process, but particularly medical staff, must be established/improved. The NIRTC Minutes in WITN3449046 illustrate plans for education for medical undergraduates and postgraduates and for nursing staff. Furthermore, WITN3449052 obtained from a search of legacy corporate records is a letter from the then Belfast City Hospital Trust Medical Director to the Chief Medical Officer advising of the training given to Senior House Officers (junior doctors) in 2002. These examples indicate that HTCs within the BHSCT were aware of concerns about the adequacy of training.

24. I am advised this matter would have been discussed at NITC to be then incorporated into HTC agendas. WITN3449053 is a minute of the BHSCT HTC in Sept 2008 wherein item 2 details plans to incorporate 'Right Patient Right Blood' (RPRB) training to medical staff – training is a standing agenda item.

25. A key responsibility of the Trust Haemovigilance team is to deliver educational sessions to medical and other key staff. The provision of this training would have been included in annual HTC plans from 2005 onwards. This training included awareness of the guidelines, any changes to practice, feedback on audits etc. Undergraduate medical staff received a 'preparation for practice' training session prior to registration and had core training in their Haematology 3rd year rotation.

26. Training became compulsory in 2008 for all staff who practice transfusion roles. The requirement is to have 3-yearly theory and practical 'Right Patient Right Blood' assessments for their roles. Medical staff who authorise blood components must have 3-yearly updates in 'Blood Components Indications for Use' theory. Training in consent for transfusion will be mandatory for all staff who undertake transfusion roles from August 2022.

27. I am advised a summary of the training is as follows:

- RPRB guidelines awareness and when to authorise blood components;
- Safe Transfusion Practice particularly in Patient Identification for transfusion sampling and administration of a blood component;
- Feedback from local, regional and national audits carried out in the Trusts;
- Feedback from national bodies e.g. SHOT;
- Awareness of how to implement Massive Transfusion Protocols;
- Demonstrations and presentations on new Trust documentation (e.g. Transfusion Records);
- Updating on any new changes to national, regional or Trust transfusion practice;
- Since 2008 all staff, including medical staff have to have updated transfusion theory in safe transfusion practice followed by a 3-yearly practical competency assessment. All medical staff who decide to transfuse blood also need to have 3-yearly updates on Blood Components Indications for use; and
- A 3-yearly update on Consent for Transfusion will be implemented as mandatory training for those who take part in transfusion consent from August 2022.

28. WITN3449054 contains appendix 1 of the BHSCT Clinical Transfusion Training policy. It includes a decision making tool for medical staff to determine the level of training required to carry out transfusion duties appropriate to their role.

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?

29. I am advised practice today is that the BHSCT Haemovigilance team via the BHSCT HTC have set up 'Blood Interest Meetings' (BIMs) for specialities that use

a lot of blood components. The role of the BIMs is to address local speciality or location transfusion issues. These meetings involve the specialty clinicians, Haemovigilance and Blood Bank managers. Any issues are reported to, or escalated to, the HTC. Specific meetings are held if concerns are noted or new practice is to be implemented. By way of illustration, WITN3449055 contains the 2017 Terms of Reference for a Blood Interest Meeting for Maternity and Paediatric services.

30. As part of the HTC work programme, there are local nursing staff who are trained to carry out Right Patient Right Blood (RPRB) assessments in their clinical areas. These assessors are updated in assessment practice every 3 years. They operate as the communication links for the Haemovigilance team and as advocates for good transfusion practice in their clinical areas.

31. The Haemovigilance team have noted improvements in compliance with RPRB guidelines following the introduction of Blood Interest Meetings (BIMs). They have also been aware of greater learning from feedback given when the Massive Transfusion policy is invoked. Furthermore, they have found specialty clinical groups have become more proactive in requesting specific on-site training or drills.

32. The practice is that BIMs report any issues or queries to HTC. In addition, the Hospitals Transfusion Team (HTT), comprising Haemovigilance and Blood Bank colleagues, set up at the same time as the HTCs, discuss any requests or issues from different clinical departments and report or escalate to the HTC as required.

33. Problems or queries are sent to the Blood Bank or the Haemovigilance team. They are discussed at HTT meetings if relevant and then at HTC. Transfusion practice is audited and any emerging issues follow the same pathway as outlined in paragraph 32 above.

34. The aim of the HTC's oversight can be stated as follows:
    - to ensure safe transfusion practice;
    - to standardise practice as much as possible;

- to share good practice; and
- to agree if any changes or additions are required to Trust policy or procedures.

35. The Haemovigilance team describe challenges maintaining consistent commitment on the part of clinical teams to regular training. Implementing a change in practice is also noted to be challenging given the scale of the BHSCT organisation. Action taken by the Haemovigilance team to ensure staff desist from practice noted to be unsafe practice can occasionally result in operational challenges for busy clinical teams. However, the experience of the Haemovigilance team has been that clinical teams acknowledge the importance of this safety intervention.

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].

36. WITN3449056 contains the NI Transfusion Committee Terms of Reference from 2014 that includes membership of same, and illustrates the relationship between

Trust HTCs and the NITC. WITN3449057 is an organisational chart of the NI Transfusion Structure.

37. WITN3449058 contains a copy of an example of a typical NITC agenda from October 2015 with topics ranging from audit, education, standardisation of documentation and update on national guidelines.

38. The Haemovigilance team advise that the policies agreed at NITC are usually written by an NITC working group and then shared as a regional template for Trusts to use. Trusts are in a position to develop policies particular to their Trust and may communicate same to NITC for information only.

39. The Haemovigilance team note that at times guidance or directives are issued from the Department of Health via the CMO's office, the Health and Social Care Board (HSCB) and/or the Public Health Agency (PHA) to Trust Chief Executives. These are directed to either the Trust HTCs for implementation or are directed for coordination through the NITC.

40. The Haemovigilance team advise there is a two way reporting system. Anything of concern that warranted regional consensus or change was escalated through the regional Haemovigilance team or the regional Blood Bank team to NITC or on behalf of the Trust HTC. If NITC or NIBTS had an issue that required a change of practice, or information from Trusts, it was brought to the Trust HTC for consideration.

41. I understand that a Blood Advisory Committee was set up in which the NITC officers, the NI Haemovigilance Coordinator and the NIBTS Haematologist met annually with the CMO and the service commissioners, the HSCB. Reference to such a meeting, known as the annual Blood Safety Meeting is contained in point 9 of the NITC minutes of January 2009 (WITN3449059 refers). The NITC chair, the NITC Audit and Implementation lead and the Regional Haemovigilance Coordinator all are responsible to the Chief Medical Officer.

42. All Trust HTCs have an NIBTS representative as a member. This is included in the BHSCT HTC's terms of reference in WITN3449050.

43. I understand there is NI representation in most UK Transfusion policy and working groups. Information and updates on national policies, audits, directives, etc. are circulated to NITC members and if necessary, approved for Trust implementation or for discussion at the local HTC. The team advise NITC have organised many regional education events and have an Education for Transfusion Practice fund in place to help fund this. NITC also shares information on UK and international conferences/sessions with Trust HTCs. The Regional Haemovigilance coordinator guides the Regional Haemovigilance team in updating and promoting transfusion practice along with standardising practice, training and policies in all Trusts. NIBTS and the NI Blood Bank managers make up the regional Blood Bank speciality forum that also reports to the NITC. The NI Transfusion structure (WITN3449057) diagrammatically shows the links to and from NITC including to the CMO's office.

44. The Haemovigilance team advise that in 2009 the Department of Health commissioned a Blood Safety review in all NI Trusts, which was conducted by the NI Regulation and Quality Improvement Authority. The recommendations from these reviews, designed to update and promote safe transfusion practice, were discussed and actioned at the BHSCT HTC. A Blood Safety Project group was established by the BHSCT HTC to manage an action plan to implement the recommendations.

45. The Haemovigilance team advise that the absence of a NITC chair on occasion has led to a delay in NITC projects, meetings and resultant standardisation decisions. However, the NITC Audit and Implementation Lead and the Regional Haemovigilance coordinator meet regularly and update NITC members on any ongoing transfusion matters.

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?***

46. The NITC does not report to the NBTS as the NI structure as set out in WITN3449057 applies. NIBTS staff, like Trust HTC staff, are on the NITC and also on the national networking group (UK&Ire BTS). NIBTS consultant staff have presented at regional NITC educational meetings and help deliver transfusion courses (e.g. the non-medical authorisation of blood course).

47. The relationship between NIBTS and the Trust HTC remains positive and mutually supportive.

48. A member of staff from the NIBTS, not the National Blood Service, is a member of the BHSCT HTC and I understand this is the case in all NI Trust HTCs and has been standard practice since the inception of the HTCs.

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.

49. The Trust HTLs have their own meetings to discuss matters specific to Blood Banks as part of the Regional Blood Bank Specialty forum. In BHSCT, there is a monthly Blood Bank Quality meeting that includes staff from both the Laboratory and Haemovigilance team. Matters of common interest and any actions that require the Haemovigilance team to liaise with clinical teams regarding HTL matters are discussed and agreed. All incidents are discussed at this meeting, particularly those that are reported to SHOT or SABRE.

50. Any HTL matters that require clinical liaison or updates are brought to the Hospital Transfusion Team and if relevant, they are reported or escalated to the BHSCT

HTC. The HTL managers also attend the Trust Blood Interest Meetings (BIMs), the HTC and the NITC meetings. Any matters that are solely relating to the HTLs are escalated to Blood Bank control meetings instead of the HTC. Having HTL staff present in discussions and decisions at the HTC & BIMs results in a mutual appreciation and understanding of blood bank operations and those of the other clinical teams. The regional Blood Bank speciality forum is part of the NITC structure detailed in WITN3449057.

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?

51. As referenced previously, I have not been able to determine the date at which the Trust legacy organisations' HTCs or similar bodies were established. Likewise, I have been unable to find out what obstacles they may have faced at that time. However, the Inquiry may gain some assistance from WITN3449060. WITN3449060 is the minutes of the BHSCT HTC meeting of 2 June 2009. These give an indication of some of the issues being encountered then.

Section 3: Policy and standard practice

52. It may be helpful to preface the answers to Section 3 by clarifying terminology. In NI we use the definitions from the MHRA regarding nomenclature for blood components and products. Thus -
    - "blood component" means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods";
    - "blood product" means any therapeutic product derived from human blood or plasma".

    All references in the questions in this Section to blood products I have interpreted as blood components as is used regarding transfusion.

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.

53. As outlined in paragraph 6, the review of documentation and discussion with the current members of the Trust Hospital Transfusion Committee has indicated that there is very little organisational memory and documentation in relation to transfusion practices pre-2002. I cannot, therefore, assist beyond what appears in the following paragraphs.

54. Prior to the formation of the HTCs and NIRTC, the team advise there was no standard threshold or criteria for transfusion of any of the blood components. Transfusion was decided by the clinician from experience or on guidance from senior colleagues, with some local guidance in place. Retired Nursing colleagues anecdotally recall whole blood being transfused up to the mid-1980s.

55. The blood components used were:

- Red Blood Cells for patients with low Haemoglobin or who had lost a lot of blood in surgery or during obstetric delivery. It was common to transfuse two units as the standard dose.
- Fresh Frozen Plasma to correct coagulation or when there had been a massive blood loss situation. It was common to transfuse two units as the standard dose, even though policy and guidelines advise the standard dose should be approx. 4 units.
- Platelets for treatment of patients with low platelets due to their condition, their treatment (e.g. chemotherapy) or to cover patients pre and during surgery. It was common to transfuse two units as the standard dose.
- Cryoprecipitate mainly for patients with low fibrinogen and in a massive blood loss situation.

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.

56. The Haemovigilance Lead recalls that an audit on blood ordered, based on the patient's reported Haemoglobin levels pre and post surgery, was carried out with the introduction of Haemovigilance in 2004. Maximum Surgical Blood Ordering Schedules (MSBOSs) were then produced by the RVH HTC and the BCH HTC from the results as guidance.

57. The purpose of the schedules was to give clinicians an indication of how much, if any, blood to order for a specified procedure based on review of the audit results and on principles of good practice. The MSBOS was used at patient admission to order the required amount of red cell units to be ready for the time of surgery.

58. MSBOSs were audited and adapted particularly for those specialties and clinicians who were noted to order much more blood than is commonly used for procedures. Advancements in surgical techniques meant some surgeries no longer required blood, whereas other new surgeries may have been noted to require more. Types of procedures, joint operative procedures and new procedures required MSBOS review. Initially there were single MSBOSs for a hospital site that formed part of the Laboratory handbook. Unfortunately, no hard or electronic versions of the originals remain available. However, the Haemovigilance team report that over time the MSBOSs were adapted for more specialities and procedures as the range of surgical services increased.

59. WITN3449061 contains the current MSBOS schedule. Hopefully, this will provide the Inquiry with a useful indication of the nature and scope of the schedule as it currently operates. For the reason just stated, I am unable to provide earlier versions.

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?

60. The information available to prepare this response is limited to the period from 2002 onwards and should be read accordingly. I am advised the clinical observations for transfusion that were included in the NI Transfusion policy in 2005 (WITN3449051) were referenced from the UK BCSH guidelines. These guidelines were used to complete the observation guidance in the Trust policies that were approved by the HTCs. When the first HTC-led Trust policies were available, patient observations were included in Haemovigilance nursing teaching sessions on Safe Transfusion and in policy awareness sessions. The BHSCT HTC has carried out local audits and participated in national audits on patient observations.

61. The Haemovigilance Practitioners generally wrote the Trust transfusion policies for the HTC, from 2002 onwards. Prior to this, the Trust's policy committee would likely have ratified any local policy developed.

62. As the need for two signatures was in the UK BSH guidance, this is what was stipulated in the original Trust transfusion policies and included in Haemovigilance training which stated: "Two members of staff, one of whom must be a doctor or registered nurse must check the identity of the patient and the unit of blood. The

second member of staff checking must be trained and assessed for this role. The checks must be independent".

63. Although the BSH guidance changed to allow the option of a single checker for administration of blood, BHSCT practice continued to require a second trained member of staff to check the procedure. This only changed in September 2020 when current BSH guidance was introduced.

64. As the use of wristbands for patient identification was in the UK BSH guidance, this is what was in the original Trust transfusion policies and included in Haemovigilance training programmes. The Trust policy states: "It is essential that any patient having a blood transfusion has an identification wristband (or validated alternative) with the patient's surname, first name, gender, date of birth and patient identification number." Checking that an armband was used is included as a core question in any Haemovigilance investigation into a transfusion incident. In March 2005, the NI Haemovigilance team contributed to NHSBT's 2006 'No Wristband' poster campaign.

65. I am advised that the need for a doctor to be present during transfusion was not stipulated in policy or in practice. The initial NI 2005 policies stated: "Visual observation of the patient throughout transfusion is an essential assessment" and "Qualified nursing staff are responsible for the care and monitoring of patients receiving a transfusion. In addition they are responsible for measuring the patient's vital signs throughout the transfusion." In addition, medical and/or nursing staff responsibilities were stated to include: "monitor patients during the blood transfusion, and carry out appropriate actions in the event of adverse events."

66. As this was detailed in the UK BSH guidance, the recommended action to be taken in the event of a transfusion reaction was included in the original Trust transfusion policies and included in Haemovigilance training. The NI 2005 (WITN3449051) policy required Medical and nursing staff to "report transfusion reactions or other incidents related to transfusion". It also stated: "If a transfusion reaction is suspected a member of the medical staff must be contacted

immediately. The patient's temperature, pulse, blood pressure and respirations must be recorded." Furthermore, the NI 2005 policy included detailed guidance on management of a suspected transfusion reaction.

67. The management of a Transfusion reaction was included in all nursing and medical transfusion training presentations. All reactions were recorded for discussion at HTT and HTC and reported to SHOT if relevant.

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.

68. From 2006, Blood Interest Meetings (BIMs) were established by the BHSCT Haemovigilance practitioners for Obstetrics, Trauma and Emergency Care, Surgery and Haematological malignancies. The management of Thalassaemia and Sickle Cell Anaemia was maintained via the Haematology department rather than through the HTC.

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?

69. The Haemovigilance team advise that all incidents and sample errors were recorded and followed up and trend analysis made by Haemovigilance as part of the role of the HTC. When appropriate, staff and their managers were made

aware of serious or multiple minor errors for action. All reported incidents and errors were discussed at HTT and reported to HTC where any relevant actions were discussed and agreed. Since the advent of Right Patient Right Blood (RPRB) in 2008, the BHSCT HTC have adopted a policy of requiring staff to desist from transfusion practice if serious or multiple minor errors by them are noted. Also, Trust Incident investigations and reports are written when errors created a risk or potential risk to patients.

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.

70. BHSCT are committed to reducing unnecessary transfusion and have taken steps to achieve that objective. BHSCT have taken part in local, regional and national audits on appropriate transfusion. Agreed guidelines and recommendations form an integral part of BHSCT transfusion policies. Transfusion request forms and Transfusion Records reflect these recommendations and guidelines. For example, the NI Transfusion request form includes a specific section which staff complete stating what red cell criteria their request meets. As transfusion practice is guided by the NITC, the foregoing is standardised practice in all NI Trusts, not just BHSCT.

71. The rationale for reducing unnecessary transfusion is included in undergraduate medical training (preparation for practice session and in 3rd year Haematology rotation).

72. If any increase in blood usage is noted at the HTT, reasons for this are explored by the Haemovigilance team to determine if there are any actions to be taken. Actions include feedback and presentation at medical audit sessions and

discussions at BIMs or with the medical speciality leads. Good practice is shared between Trusts and within Trust specialities.

73. The Haemovigilance team believe that the combined effect of these measures has contributed significantly to NI having one of the lowest transfused numbers per capita in the UK if not Europe.

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.***

74. I have been unable to confirm whether HTCs had discussions specifically about the Circular but I have established that much of its content is reflected in various Haemovigilance training presentations given to staff with the exception of Fresh-warm blood transfusion. WITN3449062 contains a sample of the slides prepared at that time by the Regional Haemovigilance Coordinator.

75. Neither the NITC nor the HTCs (in their present form) were in place in Northern Ireland at the time of publication of the circular. However, this document was a key element in the establishment of the NI Transfusion structure. BHSCT Consultant Haematologist, Frank Jones, and the newly appointed Haemovigilance Coordinator, Shirley Murray, prepared a business case that resulted in the funding

of the regional Haemovigilance service. This service was recognised as an essential new staff group to enable HTCs to implement the NI version of the Better Blood Transfusion circular. The content of this document was used as a template to determine NITC and HTC membership functions and activity.

76. The terms of reference and scope of the various committees in the NI Transfusion structure addressed items i-vi as detailed in question 23 with some exceptions. In particular, thalassaemia and sickle cell anaemia guidance was left to the Regional Haematology unit to determine, mainly due to a very small number of cases in NI at the time. Patient information booklets from NHSBT were used to provide information for these patients.

77. Regarding Autologous Transfusion, I am advised Cell Salvage was set up by the newly-appointed Haemovigilance coordinator around 2003 along with operating theatre colleagues. Awareness sessions on all autologous transfusion and training in cell salvage took place at that time. A committee was established in 2010 under the BHSCT HTC (the only NI Trust where it was deemed feasible to undertake autologous transfusion). Dr Sheena Gormley, Consultant Anaesthetist, was the chair. This committee participates in the UK Cell Salvage Action Group, a group involved in establishing UK competencies, supporting working groups, developing fact sheets and taking part in audits. WITN3449063 is a copy of a presentation on Cell Salvage given to Anaesthetists in RVH in 2010. As regards pre-operative autologous transfusion, see paragraph 91 below.

24. Please consider 'Better Use of Blood In Northern Ireland' Guidelines for Blood Transfusion Practice, issued by CREST in 2001 [DHNI0000013_065]. Please outline:

a. Any discussions the HTC had about the Guidelines in relation to:

i. Red Cell Transfusions

ii. Massive Transfusions

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

iv. Neonatal Transfusions.

v. 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 guidelines.

78. The newly formed NIRTC and HTCs conducted a regional audit in 2005 of appropriate use of red cells based on these 2001 CREST Red Cell Guidelines and from the audit results updated the NI Red Cell guidance. WITN3449064 is a copy of the Regional Appropriateness of Blood Transfusion Audit and recommendations. This audit resulted in an action plan for Trusts to reduce the reported level of 19% of transfusions being inappropriate. The action plan also resulted in the creation of the NI guidelines for red cell transfusion, which were accepted and published by Guidelines & Audit Implementation Network (GAIN) (WITN3449065). The HTCs collectively through NITC adopted the new guidelines. It is estimated that inappropriate red cell transfusion fell by nearly 20% in the following year. The HTCs continued to monitor the use of red cells then and now. These GAIN guidelines also included provision for massive transfusion, obstetric, trauma, and surgical blood use.

79. Neonatal transfusion guidelines were taken from the BSCH National guidelines and CREST and were included in the Trust's local policy along with the GAIN adult red cell guidelines.

80. In line with these policies, knowledge and risk of transfusion related infections are discussed with patients or their carers. Patients or their carers are also given patient information leaflets regarding their transfusion.

25. 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.

81. The Haemovigilance team were unable to provide any feedback or documentation on any occasions since 2004 when HTC proposals were not actioned. Given the BHSCT HTC reporting arrangement to the Trust Board Assurance Committee there is strong support from the BHSCT Chief Executive and the senior executive team to ensure all RPRB requirements are met.

Haemoglobin level

26. 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?

82. The guidelines produced in the 2005 Regional Appropriateness of red cells audit (WITN3449064) were used in NI from the time of the audit (2005) and then published as GAIN guidelines in 2009, effective 2007 (WITN3449065). For ease of reference, these are replicated in the table below:

Patient Criteria	**Consider transfusion when Hb below**	**Upper Hb limit (post transfusion)**
Healthy, stable patient < 65	7 g/dl	8.5-9 g/dl
Healthy, stable patient > 65	8 g/dl	9.5-10g/dl
Evidence of	9 g/dl	10.5-12g/dl

cardiac/cerebral disease		
Symptomatic of anaemia	10 g/dl	11.5-12g/dl
Evidence of on-going bleeding	10 g/dl	11.5-12g/dl
Patients on radiotherapy, chemotherapy or other marrow failure	10 g/dl	11.5-12g/dl

83. The Haemovigilance team state changes made to the guidelines since then include changing the unit of measurement to g/L from g/dl in line with a UK change. Also for patients on radiotherapy, chemotherapy or other marrow failure the criteria to consider transfusion has changed to patients having Haemoglobin below 9 g/L. Staff are encouraged to consider transfusion for these levels, not to automatically decide to transfuse on receipt of result. In NI, there is also guidance aimed at preventing over-transfusion or further unnecessary transfusion by giving a target Upper Haemoglobin Limit post transfusion.

27. 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.

84. Following NITC discussion and agreement, HTCs require authorisers of blood requests to include a recent Haemoglobin level in their decision to transfuse. The NI Transfusion Request Form includes a section to be completed that records the Haemoglobin result and also a tick chart indicating why the transfusion is being considered.

85. The Haemovigilance Lead advises me that periodic local audits are done to check appropriate use of red cells. Any investigation into a transfusion incident also routinely includes confirmation of the reason for the transfusion. If any concerns are identified, awareness and training sessions are arranged for the particular area or staff group. Appropriate use of blood components and the need to avoid unnecessary transfusion are integral parts of medical transfusion training.

86. The NITC and HTCs monitor blood component usage trends in NI. The data obtained have shown continuous decrease until recently. Determining decreases and changes since Dec 2019 is more difficult because of changes in surgery provision and other factors linked to Covid-19.

87. WITN3449066 is a chart showing the decrease in red cell transfusions per capita in NI since NITC commenced monitoring. Superimposed on the chart is the timeline of the interventions made by the NITC and HTCs in this period to drive this overall reduction in red cell transfusions. Red cell transfusions per capita in NI have decreased from 37 units issued per 1000 of population in June 2004 to 19.5 units issued per 1000 of population in June 2020.

28. 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?

88. A NI Blood Advisory Committee has been established. This committee, comprising the Chief Medical Officer, HSCB commissioners, NIBTS, NITC officers and the regional Haemovigilance Coordinator, meets to share information and to discuss and plan transfusion activity in Northern Ireland. I understand provision of guidance concerning haemoglobin levels and transfusion would come within its scope, for example, those contained in the GAIN guidelines of 2009. Northern Ireland does not come under the remit of the National or Regional Transfusion Committees.

Autologous transfusion

29. 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.

89. Autologous transfusion primarily involves cell salvage from the patient for transfusion back to the patient during operating procedures. I am advised that a Cell Salvage subcommittee of the Belfast HTC was established in or around 2009/2010. Pre-operative Autologous donation for transfusion, which is relatively rare, was discussed with the Northern Ireland Blood Transfusion Service (NIBTS) and is potentially available to some patients. However, any pre-operative autologous donation for transfusion is organised through NIBTS. There is no knowledge of such a transfusion having taken place in recent years. Beyond those general observations, I have been unable to confirm whether autologous transfusion was discussed specifically by HTCs.

90. These matters were all considered in the setting up of the Cell Salvage Committee and remain within its remit. It is worth noting that members of the BHSCT Cell

Salvage committee have been members of the UK Cell Salvage Action Group since 2010 and continue to be so.

30. 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.

91. Pre-operative autologous donation for transfusion was discussed by the Cell Salvage Sub-committee of the BHSCT HTC with NIBTS and, as stated, is potentially available to some patients but is organised through NIBTS. In Northern Ireland, pre-operative autologous donation for transfusion is only available in very specific circumstances and would be a matter for the NIBTS Haematology Consultants, not the Trust HTCs.

31. 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?

92. I have limited information on this beyond what is stated above. I have asked for further checks to be made of any relevant records that are still available. I will advise the Inquiry if these checks yield any substantive results.

Massive Transfusion

32. 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?

93. There are currently three distinct massive transfusion protocols in Belfast Trust, one each for:

- adults;
- paediatrics; and
- trauma.

The protocols and the details on instigation and on what blood components are provided automatically are included as appendices in the Trust's Massive Transfusion Policy (WITN3449067).

33. 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?

94. WITN3449068 is a copy of the massive blood loss policy for the legacy Royal Group of Hospitals (RGH) in 2004. Massive transfusion is a standing item on the HTC and HTT agendas.

95. In April 2016, the Haemovigilance team commenced preparing Massive Transfusion feedback reports on every incident called. Preparation of these reports operate as a continual form of review. Reports include: reason for instigation; components used; feedback from the clinical team, blood bank, and porters. Any relevant actions or recommendations are included. Clinical areas are advised to use these reports to implement any relevant changes or to include in incident reviews.

96. All massive blood loss/transfusion incidents called are discussed in HTT and HTC meetings as part of the Haemovigilance incident report. Drills for massive transfusions are organised by the Haemovigilance team on request of the clinical areas or on suggestion from the HTT and all incidents, including recommendations for change to practice or policy are discussed at HTT and HTC.

97. The annual activity for massive transfusion incidents and drills are included in the Haemovigilance annual reports, which form part of the HTC annual report. WITN3449069 is an example copy of the Haemovigilance annual report for 2019/20.

34. 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.

98. Belfast HTC did provide such policy guidance. I would refer to WITN3449067 and WITN3449068 detailing current and legacy massive transfusion policies respectively. The Belfast Trust also took part in a 2018 National Comparative Audit of the Management of Major Haemorrhage (WITN3449070) and the HTC included any relevant recommendations in Trust policy as required.

35. 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?

99. Such guidance has been provided. The 'Better Blood Transfusion 3' NI directive (WITN3449071) included massive transfusion guidance at paragraphs 2.19 and 2.20. The BHSCT HTC also receives policy updates from the NHS National Patient Safety Agency (WITN3449072).

Fresh Frozen Plasma

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

100. Technical advice on administration of FFP was included in the initial 2005 NI Transfusion policy (WITN3449051) and used to inform Trust policies. An audit on FFP use was conducted by two BHSCT consultants (a Haematologist and an Anaesthetist) for the NIRTC. The findings were used in conjunction with BCSH guidelines to produce NI Regional FFP appropriate use NI guidelines in June 2009 (WITN3449073).

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

101. The NI FFP guidelines include advice on when not to use FFP. This advice was based on the recommendations from the 2009 National Comparative Audit in Appropriate Use of FFP (WITN3449074).

102. The guidelines state: "FFP is NOT indicated in the following situations:

a) Reversal of warfarin induced coagulopathy in the absence of bleeding or when Prothrombin Complex Concentrate is available
b) Correction of coagulopathy in the absence of bleeding or anticipated peri-operative blood loss
c) Volume or plasma expansion in adults
d) Routine volume expansion in preterm infants"

38. 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.

103. I am advised that all NI HTCs adopted the new NI FFP 2009 guidelines (WITN3449073) and HTCs incorporated them into Trust use.

39. 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?

104. Such guidance was provided. Paragraph 2.17 of BBT3 NI (WITN3449071) states: "Trusts must develop, update and monitor implementation of evidence based local policies for the appropriate use of red cells, fresh frozen plasma, cryoprecipitate and platelets, based on regional and national guidance (see BCSH guidance)."

Platelets

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

105. The Haemovigilance team advise the BCSH Guidelines for the Use of Platelet Transfusions (2003) and recommendations from the 2007 and 2010 National Comparative Audits of platelet transfusions were adopted by the NIRTC and the Trust HTCs included them in their transfusion policies.

106. I understand that trend data of platelet volume purchased by each Trust was a standing agenda item at the NIRTC meetings and remains so to date. A regional audit on Appropriate use of Platelets in NI was carried out by the NITC, endorsed by GAIN in 2015 (WITN3449075). The recommendations made were agreed for implementation by NITC and the Trust HTCs.

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

107. In addition to the discussion contained in WITN3449075, I am advised that since the inception of the NITC and HTCs, provision of information to patients about the risks and benefits of any planned transfusion of blood components is included in the NI regional and Trust policies.

108. The Haemovigilance lead advises that importance is attached to ensuring patients receive appropriate information prior to a blood component transfusion. Receipt of such information is documented in the specific patient information section in the updated BHSCT Transfusion Record re-designed in 2015 (WITN3449076).

42. 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.

109. The BHSCT HTC did provide policy guidance to clinicians and hospital staff. It introduced a Trust policy on Appropriate use of Platelets following the 2015 publication of the GAIN report on the Appropriate use of Platelets in NI (WITN3449075).

43. 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?

110. I am advised the NITC used the BCSH Standards for Platelet Transfusion as the NI guidelines for implementation in Trusts.

Single Unit Transfusion

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

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

111. The NITC audit on Appropriate Use of Transfusion in 2005 (WITN3449064) noted how many units were transfused in each transfusion episode. It reported the overall inappropriate transfusion rate for all the transfusion episodes was 19%. The audit recommended: "Over-transfusion should be avoided. When deciding how many units to transfuse, consideration should be given to the transfusion threshold for the patient, the size of the patient and whether or not significant active bleeding is present. Single unit transfusions may be appropriate in some cases." The recommendations of the 2005 audit would have informed discussions within the HTCs.

112. A post transfusion Haemoglobin target guidance in the NI red cell guidance was included in the 2009 GAIN guidelines (WITN3449065).

113. Similarly, that guidance would also have informed HTC discussions and was adopted by all HTCs. It was also included in Trust policy and Haemovigilance teaching. A more recent audit in BHSCT HTC entitled 'Don't give two without review' concluded that at least half of routine red cell transfusions were single unit transfusions. That audit would also have informed HTC discussions.

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

114. The NITC audit on Appropriate Use of Transfusion in 2005 (WITN3449064) and the 2009 GAIN guidelines (WITN3449065) reflect considerations given to the perceived risks, benefits and cost implications of single-unit transfusions.

46. 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.

115. I am advised all HTCs incorporated and included in Trust policy and in Haemovigilance teaching to clinicians and hospital staff, the recommendations of the NITC audit on Appropriate use of Transfusion in 2005 (WITN3449064) and of the 2009 GAIN guidelines (WITN3449065) on the use of single-unit transfusions.

47. 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?

116. The Haemovigilance team advise that internal audit work indicated there were no incidents detected where under-transfusion was indicated.

117. As regards, over-transfusion, the team advise that through training and through policy guidelines supported by HTCs staff are required to consider the need for individual red cell unit transfusion in each case with the exception of emergencies. Evidence suggests these steps have had a significant positive effect on over-transfusion.

118. The NIRTC audit in Appropriate Use of Blood 2005 (WITN3449064) illustrates the point. In a single year following implementation of the audit's recommendations and the introduction of new Haemovigilance staff in Trusts, an

approximate 20% reduction in the number of red cell unit transfusions was reported.

48. 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.

119. The Haemovigilance lead advises that in NI, the approach to single unit red cell transfusion has evolved from simply recognising inappropriate use and over-transfusion. Central to NI guidance is proactively assessing whether a patient requires transfusion and, if so, to what extent rather than stipulating single units. The focus in NITC and in the HTCs has been and remains to ensure the right amount of blood is given to cover patient requirements.

49. 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?

120. The NITC provided updates on blood use and reports to the Blood Advisory Committee (BAC), membership of which includes the Chief Medical Officer and HSCB commissioners. DHNI, in conjunction with the BAC, issued Northern Ireland versions of the national guidelines in 'Better Blood Transfusion' (BBT), 'Better Blood Transfusion 2' (BBT2) and 'Better Blood Transfusion 3' (BBT3).

50. 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.

121. The Haemovigilance team cannot confirm whether HTCs or similar bodies were operating in NI in 1990, nor has much documentation been found in relation to legacy HTC work pre-2002. The recommendations made in the NITC audit on Appropriate use of Transfusion in 2005 (WITN3449064) and the 2009 GAIN guidelines (WITN3449065) on the use of single-unit transfusions were based on the audits conducted on this aspect of transfusion. While the work of these bodies was not undertaken with, or under the auspices of, HTCs in NI, the conclusions reached have informed discussions within HTCs and the relevant recommendations and guidance adopted.

Red Cell concentrates

51. 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?

122. The Haemovigilance Lead advises the team cannot assist with any confidence on the nature of discussions on this matter before 2005. They report their Nursing colleagues do recall use of whole blood up until the mid-1980s in the Royal Victoria Hospital. They are clear, however, that by 2005 only separated blood components including red cell concentrates were the options for transfusion. It seems likely that the issue would have been discussed by HTCs and would have contributed to the transition to the use of separated blood components only.

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

123. The team are unable to confirm what considerations may have been given to these aspects before 2005. The matters discussed earlier in this section relating to the transfusion of other blood components also apply to red cell concentrates. Furthermore, adoption of SHOT categories of risks of transfusion, and the national BSCH guidance on managing transfusion reactions are always included in HTC investigations and reporting.

124. Risks of transfusion were automatically included in Haemovigilance teaching presentations and in Trust policies. The initial NITC transfusion policy (2005) details the responsibility of medical staff to discuss risks and benefits of a transfusion to a patient.

53. 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.

125. The policy guidance referenced previously in paragraphs 78 to 80 makes reference to the use of red blood cell concentrates.

54. 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?

126. Regional guidance contained in NHBT0083701_002, DHNI0000013_065, WITN3449051 and WITN3449065 makes reference to the use of red blood cell concentrates.

55. 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.

127. The Haemovigilance lead advises that any unnecessary or excessive transfusion of any of the blood components would be regarded as an unnecessary risk to patients and would trigger an investigation. An "adverse reaction" is not a prerequisite. All transfusion reactions and incidents are reported to Blood Bank or Haemovigilance for investigation as per Trust incident reporting processes or through national reporting systems, e.g. SHOT. If inappropriate use was determined in any speciality, this was discussed either at Trust HTC or at NITC and decisions for appropriate action were taken.

56. 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?***

128. With regards to attempts to persuade clinicians to increase their usage of red blood cell concentrates, I am unable to assist on this point. I do not have any relevant information or documentation of matters pre-dating 2002.

129. With regards to hospitals coming under pressure to increase their usage of red blood cell concentrates, I am unable to assist on this point. I do not have any relevant information or documentation of matters pre-dating 2002.

130. The Haemovigilance lead advises Nursing colleagues have reported anecdotally that whole blood had been used in the RVH until the mid-1980s. However, for the reasons already indicated I am unable to comment further.

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:

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

131. The Haemovigilance team advise they do not have any knowledge of the use of fresh warm blood in BHSCT hospitals or in legacy organisation hospitals.

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

132. See paragraph 131 above.

59. 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.

133. See paragraph 131 above.

60. 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?

134. See paragraph 131 above.

Section 4: Knowledge of risk

61. 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?

135. I have not been able to find any information or documentation relating to these matters pre-dating 2002. I am advised that since the NITC and HTCs commenced, members (who included the Trusts' HTC chairs) were regularly updated on any concerns about viral or other infection transmission through the Medical Director in NIBTS. The Medical Director of the NITC was in communication with other UK Transfusion Services. Members from the NITC were

members of the UK & Ireland Better Blood Transfusion Network, a forum where national transfusion concerns or updates were shared.

62. 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?

136. The Haemovigilance team report they have not been able to confirm the position in relation to these matters prior to 2005, nor are they aware since 2005 of any investigations commissioned by the BHSCT HTC regarding transmission of viral infections through blood transfusion.

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

137. Trust HTCs adopted and followed NITC advice and recommendations for NI practice to minimise or reduce exposure to viral infection. Such advice recommended, for example, the current practice of NIBTS screening all donated blood and issuing units with labels indicating negative pathogen/viral test results (e.g. CMV neg). The BHSCT HTC gives guidance on the appropriate use of special requirements components for patients vulnerable to particular viral infection (e.g. neonates, stem cell recipients etc.) The HTC policy has always been to reinforce communicating the avoidance of any unnecessary transfusion.

138. I am advised that at a point in time in the 1990s, UK sourced FFP was not given to patients born after 1996 to limit the risk of vCJD transmission. As this FFP could be from pooled or paid donors, to mitigate any anticipated additional risk of viral infection, this FFP was treated with anti-viral solvent detergent (methylene blue). While this process was managed by NIBTS, the provision for this was in the NITC policy/HTC policy.

64. 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.

139. As outlined in paragraph 137 above, guidance to clinicians on these matters formed part of the BHSCT Blood Transfusion Manual.

65. 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.

140. From the information secured to inform this response, it would appear that since the inception of NITC, local HTCs have been active in anticipating and responding to issues as they emerge, reducing unnecessary blood transfusions, implementing and regularly auditing the guidelines and communicating effectively with clinical teams.

66. 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?

141. The documents and supporting evidence secured to inform this response do not appear to contain evidence of HTC discussions on these matters. Given that policy and guidance issued since 2003 reference the range of risks associated with transfusion, this would indicate some discussions had taken place.

Section 5: Reporting and audits

67. 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.**

142. The details of procedures prior to 2005 are not known by the Haemovigilance team, however they would advise they are confident there were procedures in place, although no historical documents have been secured. The Haemovigilance lead advises that from 2004/05, NITC organised supplies of the NHSBT Transfusion Patient Information Leaflets for use in NI Trusts for adults and for paediatrics (WITN3449046 minutes).

143. Haemovigilance staff were trained to include the importance of patient information in transfusion teaching sessions. This included informing the patient to report any unusual feelings or reactions during the transfusion. It will be noted that the legacy 2005 BCH policy for the administration of blood and blood components (WITN3449077) states 'The patient must be informed about possible adverse effects of transfusion and the importance of reporting immediately any symptoms.'

144. With regards to the procedure after a patient had been discharged, I am unable to confirm the position prior to 2005. I am advised core clinical practice for many years for patients attending as hospital day-cases who were transfused is to give information to call the clinical team if they had any unusual symptoms following their transfusion at any time.

145. The current team are unable to confirm the detail of what patients were asked to report prior to 2005. The legacy 2005 BCH policy (WITN3449077) states that patients should report any adverse reactions or symptoms within 48 hrs. Current policy does not indicate a time frame for patients to report any adverse reactions or symptoms.

146. The team advise that since the NI Transfusion policy of 2005, staff have reported any unusual reactions during a transfusion to Blood Bank. Blood Bank would follow their testing procedures and also forward the incident details to Haemovigilance to investigate the reaction. Each reaction incident would be approved or discarded by the Consultant Haematologist and if relevant, the reaction reported to SHOT and/or reported via the Trust's incident management system. If clinicians required specific advice, the Blood Bank would direct them to the Haematologist on call.

147. WITN3449078, the 2004 legacy RGH Blood/Blood component Transfusion policy, contains a section on reporting Adverse Incidents, as does the 2005 BCH policy (WITN3449077) in sections 13 and 14.

148. WITN3449076, the BHSCT Transfusion record includes advice and a recording sheet for noting any reactions. The record also includes instructions to send the completed form to Blood Bank – see page 7.

149. The Haemovigilance team advise that since 2005 the process is that if clinicians report a transmissible infection or a transfusion related acute lung injury (TRALI) to Blood Bank, Blood Bank forward the details to NIBTS for noting and/or investigation.

150. The Haemovigilance lead advises this matter would be outside of scope of the Haemovigilance team except for producing any relevant Haemovigilance incident report on the practicalities of the transfusion reaction and the Haemovigilance team, including a death due to transfusion in a SHOT report if applicable. Clinical teams follow the BHSCT 'Guidance on Actions to be Taken after a Patient's Death

in Hospital' (WITN3449079) which includes at pages 9 and 10 a flow chart and protocol for action to be taken as appropriate.

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

151. SHOT was established in 1996 and we do not have information or documentation which would indicate reporting procedures for such events prior to 2002. The team advise it is assumed Blood Bank would have reported back to the supply centre (NIBTS) as is currently the case.

69. 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?

152. The NITC adopted SHOT recommendations for NI and incorporated SHOT reporting criteria into the 2005 NI Transfusion Policy. The practice prior to 2005 is unknown. Since 2005, reporting reactions to Blood Bank and to SHOT has been included in the Trust's transfusion policy (as in the WITN3449078 legacy RGH example).

153. Haemovigilance Practitioners in Trusts were trained in SHOT criteria and SHOT reporting to use for their investigations. The Haemovigilance team provided training to clinical teams on Transfusion Reactions. Management and reporting of Transfusion reactions was an essential section in Nurse Haemovigilance Training and is included in the 'Learnbloodtransfusion' E-learning modules which medical staff complete.

70. 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?

154. The Haemovigilance team have no knowledge or evidence of this 2001 document being used in Northern Ireland.

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

155. Practice prior to the establishment of NIRTC in 2003 cannot be confirmed. Since 2005, NITC has trended data on blood components purchased by the Trusts and this is presented as a standing item on the NITC agenda. Along with regular monitoring, regional audits highlight areas for recommendations to audit locally through HTCs. The Haemovigilance lead advises when trends were noted at HTTs in clinical areas, local audits were sometimes recommended and were conducted by either Haemovigilance or the clinical staff.

156. Blood Banks use a UK-wide Blood Stock Management System to report and view blood component use and wastage and report any deviations to HTT and, if relevant, to the HTCs. Data on blood use has demonstrated a consistent decrease in use (WITN3449066). Appropriate use of component audits continued to show high appropriate use and therefore follow-up audits are only repeated or done when areas of trend change are noted in Blood Bank, HTT, HTC or NITC.

72. 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?

157. I am advised the position since 2005 has been that audits are undertaken either as a result of noting trend deviation, or to support the introduction of new practice or guidelines. These can be local hospital audits, Trust-wide audits or regional NI audits. Audits are also carried out following invitations to take part in the UK National Comparative Audits (UK NCA). The NITC have an Audit and Implementation Lead who is a member of the UK NCA group.

73. 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.

158. The position since 2005 is the HTTs collate data on transfusion activity in the clinical areas and a summary report is prepared for the HTC. WITN3449069, the BHSCT annual Haemovigilance report for April 2019 to March 2020 contains a summary of blood usage.

74. If the HTCs did record any information on the volume or number of transfusions as described in your answer to question 73 above, was this information ever reported or disseminated to any other institution or body? If so, please explain the reporting process involved.

159. HTCs sit within a wider data collection and dissemination structure. An outline of that structure and how various bodies within it interact is provided in the following paragraphs.

160. The Haemovigilance team continually monitors numbers of transfusion and presents this to HTT and to HTC. WITN3449080 is an extract of one of the monitoring spreadsheets used by the team for a 4-month period in 2021. This data is available for all BHSCT staff to view via a link on the Haemovigilance page on the BHSCT Trust intranet site.

161. Any matters of concern in addition to routine audit reports are presented to the Trust Executive team, and/or the Board Governance Assurance Committee and/or through Medical and Nursing professional management lines.

162. NIBTS report monthly usage figures to the NI Trust Blood Banks and also to the regional Haemovigilance coordinator and NITC Audit Lead. Usage figures are a standing agenda item at NITC meetings to note trends and discuss if any actions are required and for onward use at HTCs.

163. The regional Haemovigilance Coordinator and the NITC Audit Lead share NI component blood use data and an update on NI transfusion activity at the UK and

Ireland Blood Transfusion Network. WITN3449081 is a copy of the presentation given in February 2021.

75. 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.

164. In 2005, an audit of fresh frozen plasma (FFP) transfusion episodes in the legacy Royal Group of Hospitals Trust was undertaken (WITN3449082). In 2018, BHSCT participated in a UK National comparative Audit of the use of Fresh Frozen Plasma, Cryoprecipitate and of Transfusions for Bleeding in neonates and children (WITN3449083).

165. A regional Audit of red blood cell concentrates was undertaken in 2005. In 2017, the NITC via the RQIA undertook a Regional NI Audit of transfusion, published in 2018 entitled 'Where Does the Blood Go In Northern Ireland?'. WITN3449084 is a copy of this report.

166. The Trust continues to participate whenever possible in National Comparative Audits. For example, WITN3449085 is the BHSCT report of the NCA Audit of Red Cell and Platelet Transfusion in Haematology in 2016. WITN3449086 is the BHSCT report of the NCA 2017 Transfusion Associated Circulatory Overload Audit.

167. WITN3449085 is the BHSCT report of the NCA Audit of Red Cell and Platelet Transfusion in Haematology.

168. A review of every massive transfusion event that is called is carried out by Haemovigilance to follow up the communication and the timely provision of blood to the patient. Each event is tabled at Blood Bank quality meetings, HTT and HTC

meetings for discussion and learning. To the best of the team's knowledge, to date there has not been a regional audit of appropriate calling of the massive transfusion protocol. Summations of the event including components used and wasted are communicated back to the clinical teams for their attention thereafter.

169. WITN3449070 is the BHSCT report of the NCA 2018 audit on the Management of Major Haemorrhage.

170. The Haemovigilance team advise the BSHCT Cell Salvage committee are members of the UK Cell Salvage Action Group (UKCSAG) and participate in their UK audits. WITN3449087 is a copy of the 2014 UKCSAG Intra-operative Cell Salvage Survey of Equipment and Practice across the UK in which BHSCT were active participants.

76. 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.

171. I am unable to give a specific example of corrective action taken as a result of an audit relating to blood transfusion practice. However, I have outlined below the process, which, depending on the nature and scope of the audit, is followed in the event such action is required.

172. The Haemovigilance team advise that audit findings are tabled at HTC for discussion and action. Audit findings where required are forwarded to senior clinical and managerial teams in the specialty for dissemination and awareness of findings. Corrective action is mandated by the specialty leadership team, and where necessary, the impact of the action is re-audited at a later date to provide assurance on improvement.

173. Information and audit feedback generally is disseminated to clinical areas and at Blood Interest Meetings, and included at the rolling training programme. Any process found to be deficient will have corrective action mandated with a view to a re-audit of the process to demonstrate improvement.

174. As outlined previously, since the advent of RPRB in 2008, the BHSCT HTC operate the NI policy of desisting staff from transfusion practice if serious or multiple minor errors were noted from a staff member. Incidents are raised via the Trust's incident reporting system, investigations undertaken and reports written when errors create a risk or potential risk to patients.

Section 6: Treatment of patients

Provision of information to patients

77. 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?

175. I am unable to confirm the position prior to 2005, however, all NITC and HTC policies post 2005, and referenced in this statement, include that patients must be provided with information about the risks of infection in consequence of treatment with blood.

78. 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?

176. I have been unable to confirm the position in relation to the role of the HTC in ensuring patients were informed and educated about the risks of viral infection, save for ensuring policy reflected this requirement.

177. Since 2005, patient information processes have been in place although whether these are the result of steps taken by the HTC or NITC is unclear. I am advised that changes to local information given to patients on viral infection risks are made if risk data or information is updated in the NHSBT Patient Information Leaflets. These leaflets continue to be the primary source of information given to patients.

178. The BHSCT transfusion record (WITN3449076) includes a compulsory section for completion on patient information and consent, which includes that they receive written information and have the opportunity to ask questions.

Consent

79. 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?

179. I have no information about the situation in relation to consent, including the state of knowledge of HTCs or similar bodies, at the time of this 1998 document.

80. 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.

180. In 2015, the BHSCT Transfusion Record was introduced to clinical staff, which contained a section on capturing the patient information discussion. In training and information sessions on the completion of this record, staff were advised to be familiar with the content of the NHSBT patient information leaflets. WITN3449088 is a copy of a training presentation for clinical staff on the new BHSCT Transfusion record from March 2015. Slides 9 and 10 address the requirements for completing the section of the record relating to patient consent.

181. Updated SaBTO guidance on patient consent for blood transfusion was issued through the NI CMO's office in August 2021 (WITN3449089). The NITC agreed to have an implementation date of August 2022 for the Trust HTCs to action the new guidance. WITN3449090 is a post-meeting note from an NITC update meeting in

November 2021. Item 5 includes actions required for HTCs and for regional coordinators to implement the guidance.

Section 7: vCJD

81. 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].

182. I am unable to confirm when and in what circumstances HTCs first became aware of the transmission risks associated with vCJD. I have established that from 2005, vCJD risk and actions to prevent transmission in blood were included in Haemovigilance training. (See slide 13 from 2005 Haemovigilance induction training slides in WITN3449091). It is, therefore, reasonable to conclude that HTCs were aware of the risk and had taken steps to ensure that appropriate training for staff was provided.

183. WITN3449092 is a copy of the minutes of a NITC meeting in January 2011 where vCJD was discussed at point 7. WITN3449093 details the proposed updating of the NI BBT3 guidance to incorporate the need to inform staff and patients of the revision of the risk factors of contracting vCJD after being transfused donated blood components. It is, therefore, reasonable to conclude that NITC and HTCs were aware that the vCJD risk factors were changing over time as more information became available and they had taken steps to ensure that appropriate updating for staff was provided.

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

184. All HTCs took guidance from NIBTS on what measures the UK Transfusion services had in place to reduce the risk of vCJD. As slide 13 from the presentation in WITN3449091 illustrates. I am advised that Trust HTCs did not take any actions

apart from explaining these preventative measures in transfusion presentations and discussions.

83. 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].

185. As referenced in paragraph 184, my understanding is there were no specific actions or advice formulated by Trust HTCs on managing risk of vCJD. NIBTS were seen as having addressed these matters prior to blood being issued to Trusts. Discussion of the risk and preventative measures were, however, included in patient discussions and in Patient Information Leaflets.

84. 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.

186. See reply to Q 83 above.

187. See reply to Q 83 above. Patient discussion about transfusion risk post an emergency transfusion was also included in Trust guidance.

Section 8: Look back

85. 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.

188. I am not aware of HTCs ever being involved in establishing policy or procedure in relation to lookback exercises and think it is unlikely that they would have been. My experience is that Blood Banks, but not HTCs, have policies to recall units of blood or components when requested by NIBTS.

86. 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?

189. I do not have this information but I understand the 1995 HCV "lookback" programme was undertaken in NI by NIBTS. BHCT0004009_001 is a letter from the Deputy CMO to Acute Trusts in NI in July 1996 providing an update on the lookback exercise.

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

190. I do not have this information and would refer to my previous answer to Q 86.

Section 9: Other

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

191. None.

89. 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.

192. Within the limitations of the documentation and other evidence available, I have endeavoured to assist the Inquiry to the best of my ability with the issues addressed in this Rule 9 request of 17 December 2021. The inquiry may also find the range of material previously supplied by BHSCT to be helpful.

Statement of Truth

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

Signed GRO-C

Dated 23/05/22

Table of exhibits:

Date	Notes/ Description	Exhibit number
11/07/2001	Letter from Mr Brian Fisher, Chair BCH Transfusion Committee to Director of Clinical Services	WITN3449043
Undated	Blood Transfusion Committee, report for financial year 1999-2000	WITN3449044
07/12/1988	Eastern Health and Social Services Board, Pathology Sub-Committee Minutes	WITN3449045
30/01/2004	3rd N I Regional Transfusion Committee Minutes	WITN3449046
28/06/2004	UK & Ireland Better Blood Transfusion Network Minutes	WITN3449047

11/12/1998	Health Service Circular 1998/224 - Better Blood Transfusion	NHBT0083701_002
January 2001	CREST, Better Use of Blood in Northern Ireland - Guidelines for Blood Transfusion Practice	DHNI0000013_065
01/11/2010	BHSCT Transfusion Committee Terms of Reference	WITN3449050
27/05/2005	NI Regional Blood Transfusion Policy	WITN3449051
18/05/2002	Letter from Dr K. J. Fullerton, medical staff training for safe administration of blood & blood products	WITN3449052
09/09/2008	BHSCT Transfusion Committee Minutes	WITN3449053
August 2020	NI Transfusion Training Requirement: Decision making tool for Medical Staff	WITN3449054
2017	RMH + RBHSC Terms of Reference	WITN3449055
May 2014	NI Transfusion Committee Terms of Reference	WITN3449056
Undated	NI Transfusion Structure	WITN3449057
02/10/2015	NI Transfusion Committee Agenda	WITN3449058

30/01/2009	NIRTC Minutes	WITN3449059
02/06/2009	BHSCT Transfusion Committee Minutes	WITN3449060
September 2017 - January 2021	BHSCT Maximum Surgical Blood Ordering Schedules currently in operation	WITN3449061
2003 - 2005	Slides from Haemovigilance lead for teaching new Haemovigilance Staff and for Clinical Staff Awareness	WITN3449062
2010	Presentation Slides, 'Intraoperative Cell Salvage', given to Anaesthetists in RVH by Dr S Gormley	WITN3449063
2005	NIRTC, Regional Appropriateness of Blood Transfusion Audit	WITN3449064
March 2009	GAIN, Better Use of Blood in Northern Ireland, Guidelines for Blood Transfusion Practice	WITN3449065
June 2004 - December 2020	Chart of Red Cell Issues in NI	WITN3449066
05/08/2020	BHSCT Massive Transfusion Policy	WITN3449067
August 2004	RGH Trust Policy, Guidelines for the Management of Massive Blood Loss	WITN3449068

September 2020	BHSCT Haemovigilance Team Annual Report 2019/2020	WITN3449069
2018	National Comparative Audit of Blood Transfusion, Audit of the Management of Major Haemorrhage Interim Report	WITN3449070
24/08/2011	Better Blood Transfusion 3 Northern Ireland, HSS(MD) 17/2011	WITN3449071
21/10/2010	Rapid Response Report NPSA/2010/017 The Transfusion of Blood and Blood Components in an Emergency	WITN3449072
June 2009	NIRTC Guidance on the use of Fresh Frozen Plasma and Cryoprecipitate	WITN3449073
February 2009	National Comparative Audit of the Use of Fresh Frozen Plasma	WITN3449074
March 2015	GAIN, Appropriate Use of Platelets in NI audit	WITN3449075
2015	BHSCT Transfusion Record Forms	WITN3449076
July 2005	Belfast City Hospital Trust, Policy and Procedure for Administration of Blood and Blood Components	WITN3449077
August 2004	Blood/Blood Component Transfusion (Adult) Procedure	WITN3449078

October 2018	BHSCT Guidance on Actions to be Taken after a Patient's Death in Hospital	WITN3449079
June - September 2021	Extract of spreadsheet used to monitor issue of blood and components in BHSCT	WITN3449080
26/02/2021	Northern Ireland UKBTN Report	WITN3449081
2005	Audit of Fresh Frozen Plasma Transfusion Episodes in RGHT	WITN3449082
2018	Audit of the use of Fresh Frozen Plasma and of Transfusions for Bleeding in neonates and children	WITN3449083
July 2018	Where Does the Blood Go In NI? A Regional Audit by The Northern Ireland Transfusion Committee & RQIA	WITN3449084
2016	Audit of Red Cell and Platelet Transfusion in Adult Haematology Patients	WITN3449085
2017	Transfusion Associated Circulatory Overload Audit, BHSCT	WITN3449086
2014	Intra-operative Cell Salvage: A Survey of Equipment and Practice across the UK	WITN3449087
2015	BHSCT Training presentation on completing the new BHSCT Blood Component and Transfusion Record	WITN3449088

10/08/2021	Update to UK Guidance on Patient Consent for Blood Transfusion, HSS(MD) 58/2021	WITN3449089
26/11/2021	NITC Update, Post-Meeting Notes	WITN3449090
2005	Presentation Slides, 'Blood Transfusion Practices'	WITN3449091
28/01/2011	NIRTC Minutes	WITN3449092
24/08/2011	Revision of advice in BBT3 NI concerning risk of contracting vCJD following transfusion of donated blood components	WITN3449093
19/07/1996	Letter from Dr C. E. Hall, Deputy CMO, Update on Hepatitis C and Blood Transfusion Lookback	BHCT0004009_001