Witness Name: Rachel GREEN
Statement No.: WITN7102001
Exhibits: WITN7102002 - WITN7102036
Dated: 17/08/2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR RACHEL GREEN, ON BEHALF OF NHS GREATER GLASGOW & CLYDE

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

I, Dr Rachel Green, will say as follows: -

Section 1: Introduction

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

1. Dr Rachel Helen Ann Green,
   C/O JB Russell House
   NHS GGC HQ
   1055 Great Western Road; Glasgow, G12 0XH
   DoB GRO-C/1958
   BMedBiol, MBChB, CTM, FRCP, FRCPath

2. Please set out your current role at NHS Greater Glasgow & Clyde and your responsibilities within that role.

2. I am now retired from the NHS but am currently reemployed as a Locum Consultant Haematologist since 2019. In this post I perform general Haematology Clinics and Consultant appraisals. I am a trained Haematologist who became the Chief of Medicine for the Diagnostics Directorate within NHS GGC and held this post for 10 years before 2019 when I retired from full time work. I have also held a Consultant post in the Scottish National Blood Transfusion Service for 25 years (1992-2019).

   My employment history is as follows:

House Surgeon General Surgery	01/08/82-31/01/83	Prof. D George Western Infirmary Glasgow
House Physician Haematology	01/02/83-31/07/83	Prof. A S Douglas Aberdeen Royal Infirmary Aberdeen
Senior House Officer (Paediatrics)	01/08/83-31/01/85	Prof. F Cockburn Royal Hospital for Sick Children Glasgow
Registrar (Paediatrics)	01/02/85-31/07/87	Prof. F Cockburn Royal Hospital for Sick Children Glasgow
Research Fellow Haematology	01/08/87-31/07/88	Dr W Crist St Judes Research Hospital Memphis, TN, USA
Registrar (Haematology)	01/08/88-30/09/91	Dr B E S Gibson Royal Hospital for Sick Children Glasgow
Senior Registrar Haematology and Transfusion	01/10/91-17/07/94	Dr D B L McLelland Department of Transfusion Medicine SESBTS

Consultant Haematologist	20/07/94-10/10/98	Consultant in Transfusion Medicine West of Scotland Transfusion Service Law Hospital
Clinical Director	10/10/98-2009	West of Scotland Blood Transfusion Service At Gartnavel Hospital
Associate Medical Director	2012-2019	Scottish Blood Transfusion Service Glasgow
Chief of Medicine (Diagnostics)	2009-2019	Greater Glasgow and Clyde Health Board Gartnavel General Hospital
Retired but returned as Locum Consultant and chief of Medicine	2019- 2021	Greater Glasgow and Clyde Health Board

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

3. Please see answer to question 2 above.

4. Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.

4. Please see answer to question 2 above.

Section 2: Hospital Transfusion Committee history, stricture & relationships

Background

5. NHS Greater Glasgow and Clyde (NHS GGC) is made up of several hospitals which over the past 30 years have amalgamated and changed reporting lines; some have closed. The Greater Glasgow Health Board amalgamated with parts of NHS Clyde in 2006.

6. NHS GGC is made up of five larger acute hospitals - Glasgow Royal Infirmary (GRI), Queen Elizabeth University Hospital (QEUH), Royal Hospital Children (RHC), Royal Alexandra Hospital (RAH) and Inverclyde Hospital - and also smaller hospitals and ambulatory care settings which include Stobhill Hospital, Lightburn, Drumchapel, Gartnavel Hospital which includes the regional Cancer Centre, Victoria Infirmary, and Vale of Leven Hospitals. These smaller hospitals have no laboratory support and hold blood in blood fridges as required. Over the past 30 years the footprint of hospital sites has been rationalised to different and fewer hospitals across the Board area. Hospitals that have closed over that period include the Royal Samaritan Hospital (1991), Yorkhill Children's Hospital (2015), the Queen Mother's Maternity Hospital (2015), Rutherglen Maternity Hospital (1998), Rottenrow Maternity Hospital (2001), Canniesburn Hospital (2003), the Western Infirmary (2015) and the Southern General Hospital (2015).

7. Laboratories were also rationalised with the main transfusion laboratories now located in the larger acute sites i.e. GRI/QEUH and RAH. Other sites may have only satellite fridges or hot labs to service the clinical activity. Gartnavel Hospital had its blood banking delivered from the Regional SNBTS centre at Gartnavel Hospital from 2007-2021.

8. I give this background to explain the difficulties in identifying historic committee meeting minutes and documents. Many of these documents and minutes were held with individuals rather than with corporate groups/processes and so may have been lost when individuals retired or moved on from roles, or with the transfer of staff and functions to other hospital sites. I searched for and obtained personal minutes from the Chair of Glasgow Royal Infirmary Hospital Transfusion Committee going back to 1996. I also obtained material from the Western Infirmary dating from around 2000. In light of the foregoing and in order to enable me to respond to these questions I have sought the help of others (Dr R Soutar and Dr L Anderson) who have been in posts where they were the chairs of the most relevant committees and those with corporate memory from the 1990s to present. The content of some of my answers below has been informed by these discussions. I have also drawn on my own knowledge and experience

based upon 40 years working in haematology including membership of Hospital Transfusion Committees. For these many reasons I am able to be more fulsome in some answers than others depending on the level of evidence that could be found/remembered.

9. I also enclose separately some items of evidence regarding my submission. (WITN7102002 to WITN7102036).

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

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

10. In Scotland the recommendation to set up HTCs was contained within the Management Executive Letter (MEL) 1999 No 9 (WITN7102002). This MEL recommended evidence based transfusion medicine as a way of improving safety in transfusion practice and recommended participation in the National haemovigilance programme the Serious Hazards of Transfusion (SHOT), production of local transfusion policies, in house training in Transfusion and exploration of cell salvage. Hospital Transfusion Committees (HTC) had a scope which included the fresh blood components (Red blood cells (RBC), Fresh Frozen Plasma (FFP), Cryoprecipitate (Cryo), and platelets) and did not include any manufactured products such as Factor 8 and 9. In recent years there has been the inclusion of Novo seven due to its role in major haemorrhage protocols. Hospitals with an obstetric practice may discuss Anti-D but this was not a regular agenda item. Of note, although the risk of transmission of viral infection was known and acknowledged, the HTC was focused on reducing unnecessary transfusion (thereby reducing the risk of viral transmission) but also on what was seen as the greater risks of transfusion such as acute haemolytic transfusion and

acute fluid overload or failure to deliver blood timeously. The frequency of these risks is much greater than viral transmission and were certainly more readily amenable to risk reduction strategies within the scope of practice of the HTCs. It was generally felt that the reduction in the viral transmission from individual blood products was the responsibility in the main of the provider i.e. in Scotland Scottish National Blood Transfusion Service (SNBTS). In overview, it was envisaged that Hospital Transfusion Committees would lead to standardisation of the transfusion process from patient to the lab and back again. In practical terms this was achieved by developing a Hospital Transfusion Policy which was progressively refined over the years. Over time the policy became a Board wide policy.

11. Given the passage of time the original Chairs of these committees have retired and some minutes, including the most historic, have been lost. Each Acute Hospital site is known to have and can evidence an HTC from 1999 – before that date we can find archives of some minutes back to 1996 for Glasgow Royal Infirmary, but not for all sites.

    Since 1999 within Greater Glasgow HTCs existed in the following hospitals:

    - Glasgow Royal Infirmary
    - Stobhill Hospital
    - Queen Mother's Maternity Hospital and Yorkhill Children's Hospital
    - Western Infirmary and Gartnavel
    - Victoria Infirmary
    - Southern General/Queen Elizabeth University Hospital

12. We have been unable to identify the chairs before these times. A number of chairs of these HTCs have been in post over this period of time and many are retired. The first chair that can be identified was a Dr A Calquhoun in GRI from 1996. We believe, but cannot evidence that this HTC had existed for some time before 1996 and I also believe that other major sites did have HTCs but due to the passage of time we cannot evidence this.

13. In 2001 Overarching Transfusion Committees (OATC) were set up North and

South of the River Clyde reflecting the new governance structure of the Board. The North OATC was made up of Stobhill, GRI, WIG/GGH. Each of these hospitals had their own HTC but fed into this OATC to ensure that there was similarity of purpose and policies and procedures. The South OATC was made up of the SGH and Victoria Infirmary.

In 2006 following amalgamation from Clyde, the Royal Alexandra Hospital, Inverclyde Hospital and Vale of Leven Hospitals were included and they also had an HTC shared between RAH and VoL and then Inverclyde's HTC joined with them in 2009. The chair of the combined HTC was Dr A Todd.

Before this time we do not have records of how transfusion matters were monitored; however incidents/ serious adverse events would have gone through normal reporting channels and been investigated using board policies. Knowledge of good transfusion practice would be disseminated to junior staff through their senior colleagues.

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.

14. The HTCs were composed of the major users of Blood Transfusion and so depending on the hospital would have Surgeons, Obstetricians, Anaesthetists, Haematologists, Laboratory Managers, Transfusion Practitioners (from 2001), Lead Nurse, Laboratory Quality Manager, Consultant in Transfusion Medicine from the SNBTS, Clinical Risk and a general manager. The OATC was made up of the chairs of all the Hospital HTCs, the associated TPs, management representatives, risk managers, laboratory managers and quality managers. There was also a representative of the SNBTS at these meetings. The changes during the period were the addition of Transfusion Practitioners from their inception in 2001/2002 and changes would be made dependent on specialty blood use to ensure the major users were involved. Transfusion Practitioners were employed through the SNBTS to be embedded in Boards with a remit

entirely on Blood Transfusion, including policies, procedures, incident investigation and education and training (WITN7102003 to WITN7102005).

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.

15. The standard agenda at the HTCs covered all of the areas described in the MEL1999(9) and these included everything described in the list above except the transmission of Viral Infection (WITN7102006). The HTC agenda routinely covered Local hospital/board policies for transfusion which included an administration policy, identification policy, labelling of sample policy. Where new guidance was produced nationally this would be adopted into new versions of this policy for transfusion. The transfusion policy was firstly produced hard copy and put in place in every ward area and now is available on the hospital intranet. Other agenda items would be MSBOS, wastage and incidents as well as training

on transfusion and also information giving and consent.

Any suspected Viral Transmission through blood transfusion would have been handled on a physician to blood bank basis. If an individual clinician had a patient who had tested positive for a transmissible infectious agent and there had been transfusion of blood or blood components, then Blood Bank would be alerted to search out units transfused within the timeframe. The Regional Transfusion Centre would have to be involved at that time to find the archive samples from the implicated units and to test each for potential infection. These were not discussed at HTC; however, other blood transfusion complications and incidents were discussed. Wastage of blood and blood products was also discussed as well as any local issues such as blood fridges, portering etc. (WITN7102007 to WITN7102010).

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.

16. Reporting lines of the HTCs in NHS GGC were through general management reporting lines (WITN7102011). Where there was an incident or policy breach this would be reported through the management lines e.g. a ward nurse would report to the most senior nurse on the ward etc. Since 2009 all HTCs report to the OATC which in turn reports to the Diagnostics directorate and through that to the Acute Division Clinical Governance Committee. Any issues from there would feed up to Board level. Traceability of blood products is a regular agenda item at the Acute Services Management meeting which again can be raised to Board level as required.

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.

17. HTCs rely on the attendance of interested users of Transfusion. Meetings are usually scheduled to ensure a majority attendance. However since the advent of the new consultant contract (2003) Consultants have limited time to fulfil non Clinical roles in order that more Consultant time is spent on direct patient care and as a consequence attendance at HTCs has probably suffered. Ensuring a high level of attendance at the meetings continues to present a challenge. However, the involvement of Transfusion Practitioners has been instrumental in ensuring the continued effectiveness of the Hospital Transfusion Committee system. In my experience, Transfusion Practitioners are able to engage with individual clinicians directly on an adhoc basis out with the formal committee structure. Overall, the system works well and the introduction of Transfusion Practitioners has, in my view, been key to this success.

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].

18. The HTCs in GGC have always met on a quarterly basis.

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.***

19. HTCs recognised that everyone involved in the transfusion pathway should have a basic level of understanding of transfusion commensurate with their role. This did not truly progress until training packages were developed by the Better Blood Transfusion Programme Training group – Level 1 in the early 2000s. This basic transfusion teaching was and is still the base on which all learning is performed. Initially this training was carried out in the main by Face to Face learning whilst an e-learning package was developed. Level 1 is mandated for all junior doctors and nursing staff and the number of staff who have successfully completed the module is monitored by the transfusion practitioners. The training for porters is also mandated with those who have not completed being unable to perform blood transfusion collection duties. A laboratory package and more specific training i.e. managing transfusion in certain clinical situations are available but not mandated. These additional packages were role based. Within each module the learner has activities, scenarios and assessments to complete (WITN7102012 to WITN7102014).

    Level 1 modules include Serious Hazards of Transfusion (SHOT), Blood group serology, Requesting procedure, Sampling and labelling procedure, Collection procedure and Administration procedure as well as a Managing the transfused patient. Level 2 modules included the Role of the Hospital Transfusion Committee, Pre-transfusion procedures, Red blood cells, Platelets, Plasma components and Massive transfusion. Adverse effects of transfusion were also taught.

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?

20. The HTC in general had good relationships with other departments. The greatest area of likely dispute was around the Maximal Surgical Blood Ordering Schedule (MSBOS), and usually at the start of the discussion. Once it was adopted and the surgeon was confident that if required blood could be made available extremely quickly and reliably then they were generally content. The use of evidence with figures of wastage were usually very effective in moving change forward. Given all that has happened over the past 10-20 years the MSBOS and changes receive very little dispute. Often departments would bring discussions to the HTC regarding new techniques and changes in the need for transfusion although this may come after the fact from the laboratory. The MSBOS and the use of guidance was written in cooperation with the users of blood and blood products and so there was ownership of the documents. The HTC did see figures for compliance with MSBOS and wastage of blood and this would be shared with departments.

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].

21. In Scotland there is not a Regional Transfusion Committee. The Effective Use of Blood (EUB) and then the Better Blood Transfusion Programme (BBTP) came into being around 1998-2001. These programmes included national projects to reduce the variation in transfusion practice and to use evidence based medicine to drive forward safer transfusion practice. This programme was managed through the Scottish Clinical Transfusion Committee (SCTAC) and the Transfusion Practitioners (TPs) were employed by the SNBTS to be embedded in the Board to drive through the programmes of work which included training and education, incident management as well as audits of practice and guideline development. SCTAC was attended by chairs of the HTCs and also representatives of the transfusion practitioners and so every hospital was represented. Through this process the annual strategy and guidelines and audit were made known. SCTAC knew what was happening at Board level through the Chair and the transfusion practitioners and there were annual meetings within the board to discuss KPIs. Every HTC in NHS GGC had a Consultant in Transfusion Medicine from the Regional Transfusion Centre invited to the meeting. In that role they could discuss any changes to products being manufactured in the SNBTS or policies as they knew it. NHS Funding for the programme has reduced year on year and recently this has obviously affected the BBTP which has reduced the numbers of and activities provided by the TPs. The precise long term implications of these changes for the operation of the Hospital Transfusion Committee system remains to be seen.

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

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

22. As mentioned above the HTCs commonly had representation from Consultants from the Regional Transfusion Centre (SNBTS) and the Transfusion Practitioners were also SNBTS employees. Their role was to help promote best practice. A joint Consultant appointment between the predecessor of NHS GGC and the SNBTS was made in 1999 to encourage this. Representation from the local transfusion centre was certainly facilitated by the move of the RTC onto the Gartnavel Hospital site in 2002.

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

23. The members of Transfusion Laboratory personnel who sat on the HTC were the very best attendees as they felt that the HTC was their voice to the rest of the hospital. They were useful in describing laboratory practice to the clinicians and vice versa in terms of patient issues in order that solutions best for the patient and safe transfusion could be found.

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

24. I have been able to find little information regarding HTCs before 1999 except for

GRI, which is the only hospital which has not moved site. From reading those minutes I can see no obstacles to the activities of the Transfusion Committee. I know that MSBOS when first being agreed did cause some concern/ anxiety from surgeons, however once the process was explained, evidenced and the laboratory could guarantee quick response times to supply blood when required then these usually were met with a good outcome.

Section 3: Policy and standard practice

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

25. As mentioned previously we are having difficulty evidencing information before 1999. In Scotland the SNBTS delivered blood products and components and these were pretty restricted to RBC with 2 types of additive solutions, Fresh Frozen Plasma, Cryoprecipitate and platelets. Over time, evidence showed that most patients could tolerate Red Cell Transfusion stored in an additive solution which gave the units a relatively long shelf life. Although the other type of red cells in the other additive are still available today they are now restricted to use in very particular clinical circumstances i.e. neonates and intra uterine transfusions. FFP and Cryo are still available today although the use of these has been significantly diminished over time with BCSH Guidelines in FFP restricting much of its use as well as audits of use of Cryoprecipitate demonstrating much reduced indications for use. Platelets were initially prepared as pools of 4-5 adult donors to make an adult dose however over the past 20 years these are now manufactured as one dose i.e. pooled in the SNBTS and not at the bedside and many more units are not collected from donor units but from the donor through pheresis. This was a method of reducing donor exposures. Paediatric red cells became available in the mid1980s. These were adult units split into 4-5 smaller units. These saved wastage of an entire unit for a single child and with a shelf life of 35 days could be used for one child receiving a number of transfusions and only exposing them to a single donor and was an

obvious risk reduction. Similarly, for small children MBT-FFP is a form of viral inactivated FFP that was made available once these technologies had been made available and was seen to be safe. For adults requiring FFP a virally inactivated form (Octaplas) was made available at least 15 years ago for transfusion of large volumes of FFP e.g. plasma exchange.

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

- ***a. When these were introduced;***
- ***b. What the purpose of these schedules were and how they operated; and***
- ***c. Whether the type of blood component and/or the suggested unit amount for each surgical intervention changed over time; If so, please outline how and why.***

Additionally, please provide copies of all available schedules.

26. MSBOS have been around for the best part of 30 years. We can evidence MSBOS on the agenda of a meeting in GRI in 1996. These certainly existed prior to this date. These schedules were put in place to minimise the need for blood to be held cross matched for an individual patient when it was very unlikely that it would ever be transfused. This would vary with the type of surgery and maybe even the surgeon. Every surgical department agreed a level of units that might be needed for a particular procedure (given historical transfusion data) and this was the automatic quota for a procedure. Some operations would not need blood cross matched as the likelihood of use was minimal, again evidenced based. In these circumstances the patient's blood was grouped and screened for any antibodies and this information would be held in the blood bank computer, if the patient needed blood it could then go through the crossmatching phase in a shorter time. O negative blood was also available to respond to the most urgent needs. Over the years evidence has changed as to the requirements for blood in particular due to the different types of surgical techniques and advances. Over time the MSBOS would be reviewed and adjusted accordingly. New procedures would also be added on (WITN7102015 to WITN7102017).

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?

27. Within GGC it was clear that these observations were generally governed by local nursing policy and did have variation across hospital sites. Again, as early as 1996 a transfusion policy was prepared by the HTC in GRI which covered the items such as observations, the checking procedure, the use of wristbands for patient ID and the management of transfusion reactions. Over the years these have been reviewed and changed. These changes were often due to new national guidance from either BBTP, Professional guidance from the BSH. As the Board changed its reporting structure and overarching transfusion committees came into existence then the policies became unified. Since 2015 the entire NHS GGC works to one transfusion policy. The local differences are included in appendices, but the core work activity is unified. The Effective use of Blood (EUB) pilot undertaken in 1998 as a prelude to the Better Blood Transfusion Programme (BBTP) demonstrated that two-person checking was potentially not as safe as a single checker. This was rolled out in the pilot site in the early 2000s at the Western Infirmary and then slowly was rolled out across the entire board (WITN7102018 to WITN7102021).

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.

28. Specific guidance for transfusion has been developed in different medical specialties and conditions (WITN7102022). Many of these are taken from National guidance from professional bodies such as BCSH standards in Haematology, the Transfusion Taskforce and other professional bodies. A transfusion policy has also been developed for Jehovah's Witness patients or other patients who refuse blood transfusion, describing the alternatives to transfusion and the specific consent required following clinical discussion regarding risk/ benefit (WITN7102023). Other specific policies include a Major Haemorrhage policy and transfusion policy in the setting of allogeneic stem cell transplantation.

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?

29. The HTC might be made aware of any noncompliance but failures to follow policy would be managed through the management lines of accountability. Transfusion practitioners were often involved in the investigations and would perform education etc. in light of issues. The HTC was not responsible for dealing with failures of compliance with the policy but would know if there had been breaches.

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.

30. In most cases quality improvement requests are met positively if the cost is net zero. If evidence is given and the benefit can be seen then it is likely that management will accept the changes but larger scale matters can be difficult to get through to successful funding. In terms of personnel it is true that since the new consultant contract sessional time is very much directed towards patient care and the amount of hours given to Consultants for non-clinical time (i.e. committee memberships etc.) has very much diminished as patient care was seen as the priority. Despite this, HTCs have met and managed to deliver their objectives. It may mean that it is slower as departments may have to be contacted individually rather than through the HTC but with email it is becoming easier to work in this manner and still move things forward. Please also see my comments in response to question 13.

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.

31. This circular, referred to as NHBT0083701_002, is an English health service circular and would not have been seen in Scotland. It does cover the same points as the MEL 1999 No9 issued on 14th January 1999 which is the relevant document for Scotland. I can find no evidence of discussion of this MEL however HTC agendas from that date on do have discussion on the Transfusion policy, MSBOS, Transfusion Incidents, Autologous transfusion and massive obstetric haemorrhage and so it would be supposed that this guidance was acknowledged. At no time could I find discussion on fresh warm blood but there were discussion and production of guidelines for use in different clinical settings such as Obstetrics and Trauma in the earliest minutes we can find.

24. At a BTSAG meeting on 17 February 2004 [NHBT0060995], it was noted in a discussion about appropriate use of blood that 'Feedback from Hospital Transfusion Committee Chairs is that they have very limited ability to influence as Chief Executive Officers are not listening to their proposals.' To the best of your knowledge, were there occasions where HTC proposals were not being actioned? If so, please provide details.

32. Our OATC chair feels that they had reasonable power to influence the chief executive but again this would be influenced by the cost of the development but cogent argument and blood safety aspects would influence. The legal requirements leading from the Blood Safety and Quality regulations (BSQR) 2005 also gave leverage to such initiatives.

Haemoglobin level

25. A Scottish Working Group on Blood and Blood Products in 1992 [SCGV0000004_007] noted that patients with a haemoglobin count of <10 g/d would require a blood transfusion. However, in the SHOT annual report 2005 [SHOT0000013] it states that, 'In general, the published data indicates that in adults, red cell transfusions will usually be required when the haemoglobin level

is <6 g/dl, and will rarely be required when it is >10 g/dl. Comparative studies in adults with haemoglobin levels within the range of 6 - 10 g/dl have not shown red cell transfusions to improve outcome in surgical and intensive-care-unit (ICU) patients'. What did the HTCs understand to be the level at which a patient required transfusion and how did this change over time? Was guidance provided to clinicians at the time, and updated guidance once the HTCs became aware of any clinical change?

33. The Transfusion policies across the Health Board reflected the transfusion thresholds that were current in the literature. In 2002 a threshold of transfusion was the subject of several guidelines and reviews including SIGN 54 Perioperative Blood Transfusion in elective surgery (WITN7102023), British Committee for Standards in Haematology (BCSH) guidelines for the clinical use of red cell Transfusion BJHaem 2001;113;24-31 and Transfusion Triggers Carson et al., Transfusion Medicine Reviews 2002;16:187-199. These led to changes in the Adult Blood Transfusion Guideline OATC (WITN7102024) where a figure of <8g/dl was a threshold for transfusion where there were no other confounding issues i.e. cardiac disease/acute blood loss. A figure of above 10 was unlikely to need transfusion. Before this time the Blood Transfusion policy did read that post transfusion Hb should not exceed 10-11g/dl and so was probably not dissimilar but the later guidance was more specific. The transfusion policy has changed over time and in 2002 it begins to state that a single unit may be enough to meet clinical requirements. The policy states that there is always some risk associated with transfusion, younger patients (< 40y) may tolerate anaemia better, young patients are at greatest long term risk and that blood has to be used wisely (WITN7102018 and WITN7102026).

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

Please address the following:

a. ***Did the HTCs hold any discussions about the frequency of monitoring haemoglobin levels? If so, please provide details and outcomes of any discussions.***
b. ***To the best of your knowledge, were the HTCs aware of excessive or unnecessary transfusion within the Hospitals? If so, please provide details, including any guidance provided to clinicians.***

34. We cannot find evidence of discussion specifically about the frequency of Hb level monitoring in advance of transfusion. The HTC felt that strict appliance of MSBOS and the thresholds in the Transfusion policy would drive down Transfusion at higher Hb levels. Transfusion at higher Hb would only be discussed if it had been recorded on our adverse incident reporting system (Datix). I could find no evidence of discussion about excessive transfusion within the HTC agendas. The Transfusion Policy did describe levels of haemoglobin that patients should be transfused at, the purpose of which was to drive down unnecessary or excessive transfusion (WITN7102018 and WITN7102019).

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

35. Guidance on Hb levels would have been from Guidelines from professional bodies and these were not directed by SG. SCTAC may have endorsed professional guidance (WITN7102027 to WITN7102029).

Autologous transfusion

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

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

36. Discussion on Autologous Transfusion was evidenced in transfusion policies dating from 2002.

The service was offered to clinicians with strict criteria for referral as per the BCSH standards for autologous transfusion. At the instigation of the service it seemed a potential risk reduction programme however the criteria that had to be met made it difficult to identify large numbers of patients and the cancellation of surgery added to the difficulty in the success of the programme. The use of pre-deposit did not achieve large throughput because of these difficulties and over the course of the next 10 years it was only offered to individuals who had rare blood types where it may be difficult to identify donor units.

29. In 'Guidelines for autologous transfusion. Pre-operative autologous donation', written by the British Committee for Standards in Haematology Blood Transfusion Task Force [BSHA0000017_021], the guidelines support predeposit autologous transfusion services within hospitals. In light of this, did the HTCs provide policy guidance to clinicians and hospital staff concerning autologous transfusions? If so, what was this guidance? If guidance was not provided, please explain why.

37. Policy guidance was included in hospital and subsequently Board Transfusion policies.

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

38. The HTC used the professional guidance from the BCSH Transfusion Task Force Guidelines for Autologous Transfusion 1. Pre-operative autodonation.

Trans Med 1993(3) 307-16. The local Blood Transfusion Service offered a pre deposit service for the patients as required. The guidance for that came from the BCSH standards.

Massive Transfusion

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

39. The hospital transfusion policies and laterally the Boards transfusion policy described the clinical setting of massive transfusion and this was drawn from the descriptions in professional guidance such as BCSH guidance on the management of Massive haemorrhage (WITN7102022 and WITN7102030 to WITN7102032). These were laid out in the Transfusion policy as well as the plan on how to activate the process. The original document was produced by SCTAC (2010) and includes the following definitions – a blood loss of 50% within 3 hours or a rate of > 150 mL/ minute. Or 4 units of red cells in less than 4 hours. It was recognised that there may also be a subjective assessment that the clinician felt the patient was having a major bleed.

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

40. The HTC reviews the Massive Transfusion Activation policy and any incidents surrounding this. Education was given as appropriate. Transfusion practitioners were usually involved in investigating these incidents.

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

41. The guidance on Massive Haemorrhage protocol was produced by the HTCs

e.g. at the Western/ Gartnavel from the early 2000s (WITN7102030). This document was regularly reviewed and has an activation flow chart. Initially this would be given as hard copy to departments likely to need to use it i.e. A&E, cardiac surgical units, Theatres etc. Laterally these have been updated and placed on the hospitals intranet as well as being in hard copy. New protocols are given billing on the Hospitals Intranet to alert users to the new policy (WITN7102022). In the early massive haemorrhage policies some hospitals released FFP, Cryoprecipitate and platelets along with the red cells in an agreed formula. It became apparent when the coagulation screens were reviewed that the need for Cryoprecipitate was not required and this was dropped from the standard issue in massive haemorrhage unless driven by the coagulation results or clinical condition.

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

42. Initially the Board used professional guidance such as BCSH Standards Transfusion Task force Transfusion Guidelines for transfusion in massive blood loss. Clin Lab Haemat 1988(10) 265-73. In 2010 SCTAC produced a template document which could be used.

Fresh Frozen Plasma

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

43. FFP was discussed at the HTC on a number of occasions and guidance on the use was certainly found in the earliest Transfusion policies. BCSH guidance on the use of FFP was also used as a basis of the early transfusion policies (Transfusion Task Force Guidelines for the use of fresh frozen plasma Transfusion Medicine 1992 (2) 57-63). A regional audit on use was carried out in 2000 to identify the clinical indications for use. The results were discussed at the HTC and framed modifications of the guidance. Over time further audits and refreshed national guidelines were discussed and the reviews led to changes in

the Transfusion policy. There is a separate GGC FFP policy (since July 2008 and has been regularly reviewed) (WITN7102033).

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

44. By the mid 1990s it was well recognised that FFP was of a higher risk than other fresh products as it was given in a dose of 4 donations i.e. it exposed the patient to 4 donors. This is why in particular audits were done on use and even the earliest published transfusion policies gave guidance on its use. The cost was not considered in Scotland as these products are free of charge at the point of use.

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

45. This has been answered in response to questions 35 & 36 above.

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

46. Guidance came from professional sources such as the BCSH guidelines from 1992 with further guidance last updated 2018.

Platelets

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

47. Please see answer to question 42 below.

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

48. Please see answer to question 42 below.

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

49. Please see answer to question 42 below.

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

50. Platelets too had guidance on their use in the Hospital Transfusion Policy from the earliest ones found. They were a short shelf life product (5 days) and required to be stored in an incubator at 37°C so more difficult for many labs at the beginning. By the mid-1990s laboratories where patients were receiving regular chemo and those with significant cardiac work began to hold stock of platelets to reduce the time from need to supply. Again these were products which were made from a pool of 5 donors and so were seen as higher risk products for that reason. Platelets were in relatively short supply as they were often not stored in the hospital blood bank and so requests for platelets in the early 1990s were vetted by haematology staff in the hospital and they had to order individually from the regional transfusion service. By the time the RTC moved into the City of Glasgow in 2001 most major using hospitals had a stock of platelets where wastage was scrutinised by the hospital and the transfusion service as part of the wastage summary which was sent monthly to the regional hospitals. BCSH guidelines on the use of platelets were published in Transfusion Medicine 1992(2) 311-318 and they were used to guide local policy and use as well as the outputs from the consensus conference in Edinburgh on platelets use in 1998 (Consensus statement on Platelet transfusion. Transfusion Medicine 1998:9:149-151). Apheresis platelets became a larger component manufactured in SNBTS from the time the potential risk of vCJD transmission was understood. This product was a general risk reduction in that it came from only one donor;

however, these products were provided by SNBTS. Clinicians did not specifically request which type of component was provided.

Single Unit Transfusion

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

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

51. The potential to use a single unit can be evidenced in the transfusion policy from 2000 but may have been before, it is just difficult to find a historic copy of policies before that date (WITN7102020 and WITN7102034 to WITN7102035).

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

52. As above, the fact that transfusion could carry a risk was known by clinicians and methods of reducing exposure were written into the transfusion policies.

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

53. As above the hospital policy on the use of blood included mention of the use of a single unit to increase Hb and also that the target level at the end of transfusion should not be greater than 100-110g/L.

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

54. We cannot find evidence for discussions on unnecessary or excessive single unit transfusion.

47. Single-unit transfusions are described in [DHSC0025270, page 3] as a 'waste of resources'. To the best of your knowledge, did the HTCs have specific views on the use of single-unit transfusion in relation to potential waste and did this change over time? Please explain your answer.

55. Although we can find no evidence to confirm this view I believe many clinicians were concerned about unnecessary transfusion in the setting of single unit transfusion and would probably consider whether one unit was required at all. Thus single unit transfusion may have been less popular in the distant past; however more recently when the thresholds are lower than previously used, then clinicians would have been happier to give a single unit and recheck the Hb. I also think that the SHOT reports from 2016, where the pre-transfusion checklist for TACO was first introduced have caused clinicians to actively consider the risk benefit from large volume transfusions.

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

56. The guidance for single unit transfusion came from discussions around SHOT reports on Transfusion Associated Circulatory overload (TACO). The number of TACO cases have been collected by SHOT since 2008 and the pre-transfusion TACO checklist was introduced in 2016 as a consequence.

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

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

57. We can find no evidence for this or in fact any documentation from 1990.

Red Cell concentrates

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

58. SNBTS was and is the single provider of blood in Scotland. The collective history cannot remember the provision of whole blood in the past 30-40 years. SNBTS provided red cell concentrates in two different storage media and these were used in different clinical scenarios. Both had the majority of their plasma removed. There was no discussion that can be remembered with the SNBTS regarding the type of blood and components that would be issued.

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

59. Again these blood products have always been free. SNBTS received central funding to provide blood and blood components. The risks of red cells have been known by clinicians through publications. In the HTC the risks that would be discussed were those such as haemolytic transfusion reactions i.e. those that happen from the administration of the wrong blood to a patient and these drove the considerations of reducing use and the strict administration guidelines.

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

60. The Hospital Transfusion Policy described the use of red cell transfusions. The policy was updated on a regular basis over the years.

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

61. Guidance on the use of red cell concentrates were provided in professional guidance through BCSH Blood Transfusion Task Force. The administration of blood and blood components and the management of transfused patients. Transfusion Medicine 1999(9) 227-38.

54. To the best of your knowledge, were there any specialty uses of red cell concentrate, platelets and/or FFP that lead to an adverse reaction that required investigation? Please provide details. You may want to refer to [NHBT0090084] for assistance.

62. We cannot find evidence of when NHS GGC started having guidelines for FFP. However, there is evidence of local hospital guidance since 2008. Up until this date FFP required clearance from a haematologist for release. By 1996 we know that FFP guidance was available to transfusion users through the Transfusion Policy. Unfortunately, we are unable to find any records of individual adverse events however we can evidence audit of use both locally and also regionally around 2000.

55. In relation to red blood cell concentrates:

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

the HTCs aware of why whole blood transfusions were preferred over red blood cell concentrates during the 1970s and 1980s?

63. I can only speak personally of this and can remember no coercion to increase the use of RBC at any time in my career. I have never used Whole Blood in any of my practice in Scotland and do not remember this ever being a product made available by the SNBTS. I would have first prescribed blood and components as a clinician from 1982.

Fresh Warm Blood

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

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

64. Please see answer to question 59 below.

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

65. Please see answer to question 59 below.

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

66. Please see answer to question 59 below.

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

67. Again from personal recollection from the 1980s I cannot remember ever being offered fresh warm blood as a transfusion component at any point in my career. I cannot find any evidence of requests to the HTCs nor any discussion on this. Fresh warm blood would not have been tested for transfusion-transmitted infectious agents and so clinicians would be aware of this as an increased risk but again I can see no desire amongst our records for such a product.

Section 4: Knowledge of risk

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

68. The risks of viral infection for HIV and Hepatitis B would have been known in the 80s, and HCV and vCJD in the 1990s. These were not an agenda item for HTCs. The HTC was more directed in driving down inappropriate use which would reduce all risks but the HTC was more focused on preventing the wrong person from getting blood and ensuring administration was appropriate against medical evidenced guidelines. The HTC believed the safety of the blood in terms of Viral transmission was the responsibility of the provider and there was little they could do except reduce unnecessary transfusion.

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

69. I don't know of any discussions at the HTC about this and I can find no evidence. Lookback process, which would have been triggered via SNBTS, was assisted

and performed in the hospital blood bank who would use the Laboratory IT systems to identify which individual patients had received implicated donations.

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

70. As above the HTC drove down risk by ensuring that transfusions were medically evidenced against clinically appropriate guidance and that inappropriate transfusions were reduced. The HTC promoted good practice.

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

71. The risk of blood transfusion would have been communicated to patients on an individual basis (WITN7102036) but it was not formalised until the use of the PIL produced by the SNBTS in 2003 following on from HDL. This leaflet progressed to having a label that could be placed in the notes to confirm the discussion on risk. At the same time as a patient leaflet there was a partner leaflet for clinical staff outlining the issues and risks that needed to be discussed.

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

72. I think the actions taken as risks became known were appropriate. There is a pressure to ensure that surgery can proceed and chemotherapy can be given because blood and blood components will be available. Also no patient should bleed to death from lack of blood products and timely provision is a necessity. The SNBTS provided a changing range of products and tested blood for new and emerging infections as was agreed nationally and with government bodies. i.e. Leucodepleted products, MBT FFP being made available for neonates with the CJD concern and the increase in apheresis products to reduce donor exposures.

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

73. Components made of more than a single donor were known to be higher risk and so this led to the need for guidance as is seen in the examples in our transfusion policies and also national professional guidance from BCSH.

Section 5: Reporting and audits

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

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

74. All adverse events during a hospital stay should be reported on the Datix system, the national incident reporting system. This has been in place for decades. Any incident that is flagged up as blood transfusion related would have been investigated by the Transfusion Practitioner and Corrective Actions and

Preventative actions (CAPA) agreed. Since the development of the SNBTS Transfusion Team (2019), TPs are no longer the primary investigator for clinical blood transfusion events, but tools have been developed to help ward managers complete the investigation and the TPs are available to help as subject experts.

75. Outpatient transfusion patients are given cards with a number to phone if they have any adverse events in the period post transfusion. I don't think patients are given a timescale to report in. Within clinical areas both nurses and clinicians know to seek help from blood bank and also to use the Datix system. Reporting to the RTC would depend on the reaction. Some issues such as potential viral transmission and delayed haemolytic transfusion reactions may need further investigation that can only be performed at the RTC. Febrile Haemolytic Transfusion Reactions and TACO would be managed within the hospital. Any potential bacterial infection of blood components would also be investigated by the Transfusion Centre. (SNBTS)

76. SHOT and the Serious Adverse Events and Reactions Reporting system of the BSQR mean that reports of certain adverse events must be shared with the component authority and voluntarily reported to SHOT dependent on the reaction.

77. An investigation into a death where transfusion was identified as a likely contributing factor would have an internal investigation (Level 4/5 Datix i.e. serious incident). In Scotland any sudden and unexpected death should be reported as soon as it is known to the Procurator Fiscal who may instruct the police to perform an investigation. Depending on the cause the hospital may involve the RTC as the manufacturer i.e. if it was thought to be an issue with the manufactured component, bacterial contamination etc.

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

78. The HTCs were not involved in informing the RTC of potential viral transmissions. The Individual clinician who suspected a transmission would contact the Blood Bank/ local Haematologist and possible implicated units identified. The Consultant Haematologist would send these details to the RTC for investigation and the result of that investigation would be returned to the clinician and Haematologist within the hospital.

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

79. Reporting to SHOT was a final process at the end of investigations. The blood bank coordinated this as well as reporting of SAER through the BSQR regulations. The annual SHOT report was discussed at the HTC. Individual incidents/ investigations would be discussed at the HTC. Investigations and incidents have been a standard item for the agenda of HTCs since the earliest we can find (1996). I think the reporting with SHOT and BSQR merely formalised this reporting mechanism.

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

80. I think it would be fair to assume that we had under reporting in the early days but once we had Transfusion Practitioners who investigated transfusion reactions it became a much more robust process. The development of TPs, SHOT and the BSQR made this a much more formalised reporting system.

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

81. Blood use and wastage was a regular item on the agenda. Internal wastage

formed much of the discussion within the MSBOS preparation and hospital wastage figures were provided by RTC. Audit was undertaken within the hospital and figures for the transfusions /100000 population were reviewed as were the use of cross grouping and O negative. Many of these comparative audits were national in Scotland and also across the UK. Following on from the output of these audits, change in clinical practice may evolve after discussion at HTC.

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

82. The MSBOS was reviewed every two years. Units would review their own blood use and wastage. External audits and national audits were done as part of a wider strategy from the BBT programme and national comparative audits requested sites to participate. In the early 2000s audit was performed in the Region and audits of FFP/Cryo and platelets were performed to identify areas of variation in practice and lead in part to the development of guidance.

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

83. The total number of units transfused and wasted was calculated by the blood bank as well as a more global and comparative figure from the RTC. The hospital figures were shared at the HTC. More sophisticated measures were able to be pulled from the laboratory IT system over time as the world moved into the electronic era.

73. If the HTCs did record any information on the volume or number of transfusions as described in your answer to question 72 above, was this information ever reported or disseminated to any other institution or body? If so, please explain the reporting process involved.

84. Some of the information was provided by the RTC and shared with us. This usually showed comparative figures for the local hospitals. With the BBT programme these use/ wastage figures were shared with them and national comparisons drawn. These figures were used to drive down variation in practice. The Scottish Transfusion Epidemiology database was established in 2009 and provided vast amounts of information on how blood and components were being used clinically. In addition comparisons could be made between specific regions and hospitals for blood use for any given procedure. This was limited by coding and the ability to link databases but has, over the years, come to cover almost every Health Board and has driven improvements in practice.

74. Were audits specifically conducted in relation to the use of:

- ***a. FFP;***
- ***b. red blood cell concentrate;***
- ***c. platelets;***
- ***d. massive transfusions; and/or***
- ***e. autologous transfusion.***

If audits were not conducted, why not? [NHBT0090084] may be of assistance.

85. Audits on all of these areas were performed within hospitals, regionally, Scottish nationally and UK nationally over time. We did not audit autologous transfusion as the figures were so small.

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

86. The HTC did review audit data and changes required formed the new guidance in transfusion policies. Massive Haemorrhage is a good example where some hospitals issued different blood components in their crash pack and over time wastage of certain components came to light through audit and so the components of the crash pack changed and was highlighted to clinicians and in the Transfusion Policy. The MSBOS is another good example where over time the use of blood diminished and more procedures could be performed on a group

and screen only and also new procedures were added to the list.

Section 6: Treatment of patients

Provision of information to patients

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

87. Please see answer to question 77 below.

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

88. I can identify no specific reference to discussion of consent in the minutes of the HTCs available to me before 2004, where the SNBTS provided a Patient Information Leaflet. This addressed the risks of transfusion. The roll out of these was discussed and endorsed at the HTC. A further PIL was produced where a sticker from the leaflet could be stuck into the notes and signed by the consenting clinician to demonstrate that the discussion had taken place. The HTC took steps to make the clinicians aware of these documents and made sure they were distributed to the clinical areas.

Consent

78. An audit of transfusion practice across the United Kingdom by the Royal College of Physicians in 1998 [NHBT0042247] indicated that none of the participating 47 hospitals required informed consent for blood transfusions. In light of this, were the HTCs aware if patients under the care of the Hospitals were treated with blood transfusions without their express or informed consent? If so, how and why did this occur?

89. I am unaware of the state of knowledge of the HTC's in relation to this at the material times. However, I am aware that consent became part of the Hospital Transfusion Policy. The need to discuss whether a patient was likely to need a transfusion and the risks was introduced into the Glasgow University final year medical student curriculum around 2000. Transfusion Policies stated the need for information giving to the patient. We did not and still do not ask the patient to sign any consent form for blood. The recent Advisory Committee on the Safety of Blood, Tissues and Organs (SABTO) guidelines have stated that a discussion of risks, benefits and any alternatives should take place and be documented but there is still no written consent from the patient required.

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

90. Guidance on consent for transfusion is described in the Hospital Transfusion policy. Quite specifically in the Western Infirmary Transfusion policy from 2001 and 2002 North Glasgow Trust Transfusion policy there was a paragraph describing the need for informed consent for patients receiving a transfusion. This was produced in the policy in order to ensure information giving and the use of the Patient Information Leaflets. Consenting and information giving has developed into a more formal affair since HIV was found to have been transmitted in blood. Formal policies for Jehovah's Witnesses were also produced around the same time.

Section 7: vCJD

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

91. The HTC was made aware by the SNBTS in 1999 that a precautionary measures

were being put in place to reduce the risk of transmission of vCJD through blood – i.e. the provision of Leucodepleted RBC's, the provision of MB FFP for those born after 1.1.1996 and increasing production of apheresis platelets. vCJD was not overtly discussed in the HTC except to discuss the new types of components being made available as a risk reduction. The PIL was changed to state this new risk and the blood bank was made aware to document those transfused with >80 units of blood or blood components who were deemed high risk and changes to sterilisation of surgical equipment was to be organised. This was circulated to hospitals through a Scottish Executive letter 2004 (March) protecting the blood supply from Variant CJD: Deferral of donors who have received a transfusion. Following this, as medical and Scientific evidence accumulated, new policies and strategies were developed.

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

92. As above, vCJD was not discussed at the HTC. Instead there was continuing transfusion avoidance and good practice guidance driving the agenda forward. The risk reduction measures for avoidance of vCJD were centralised and mitigation measures put in place by SNBTS and these measures were then put in place at a hospital level.

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

93. The PIL changed to describe the potential risk of transmission of vCJD. The Transfusion policy named the new products available from the blood bank – leucodepleted RBC/Apheresis platelets/ MBTFFP.

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

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

You may be assisted by BART0002418, NHBT0001123_002, HCDO0000643.

94. No, the HTC did not have involvement in these matters. The HTC did facilitate the roll out of the PIL with the risk statement on VCJD throughout the hospital.

Section 8: Look back

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

95. No, the HTCs in Glasgow were not involved in any look back exercise policies nor procedures.

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

96. As above the HTC had no involvement.

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

97. This was not an HTC action and so I cannot add to the response.

Section 9: Other

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

98. I have no other comment to add.

88. In addition to any documents exhibited in support of your statement, the Inquiry would be grateful to receive copies of any potentially relevant documents you possess relating to the issues addressed in this letter.

99. I have enclosed evidence I believe pertinent to my submission.

Statement of Truth

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

Signed GRO-C

Dated 17TH August 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
14/01/1999	NHS MEL (1999)	WITN7102002
17/01/2001	First meeting of Over Arching Transfusion Committee with remit	WITN7102003
Undated	Remit and membership of North Glasgow University Hospitals NHS Trust Transfusion	WITN7102004

	Committee	
2002	Distribution List of Over Arching Transfusion Committee	WITN7102005
13/08/1996	Agenda for meeting of Glasgow Royal Infirmary's Hospital Transfusion Committee	WITN7102006
09/09/2004	Royal Alexandra Hospital HTC, meeting minutes	WITN7102007
09/09/2004	Western Infirmary Glasgow's HTC, meeting minutes	WITN7102008
11/10/2007	Vale of Leven Hospital HTC, meeting minutes	WITN7102009
24/05/2005	Inverclyde Royal Hospital HTC, meeting minutes	WITN7102010
March 2013	Overarching Transfusion Committee GGC - Clinical Governance summary	WITN7102011
27/02/2006	Staff training record	WITN7102012
March 2011	Better Blood Transfusion Training Report, April 2009 to March 2011	WITN7102013
08/12/2003	Letter from Dr Anderson to Dr Soutar re Training in Transfusion Medicine	WITN7102014

1998	Maximum Surgical Blood Ordering Schedule - Glasgow Royal Infirmary	WITN7102015
July 2000	Maximum Surgical Blood Ordering Schedule - Glasgow Royal infirmary	WITN7102016
January 2020	Maximum Surgical Blood Ordering Schedule - Queen Elizabeth University Hospital	WITN7102017
January 2001	Blood Transfusion Protocol – Glasgow Western Infirmary	WITN7102018
July 2000	Blood Transfusion Protocol – Glasgow Royal Infirmary	WITN7102019
January 2002	North Glasgow Transfusion Policy	WITN7102020
Undated	Management of Princess Royal Maternity Hospital	WITN7102021
Undated	Victoria Infirmary Blood Transfusion Committee - Jehovah's Witness Blood Transfusion Policy	WITN7102022
October 2001	Scottish Intercollegiate Guidelines Network - Issue 54	WITN7102023
September 2002	Adult Blood Transfusion Guideline	WITN7102024

June 2004	Perioperative Blood Transfusion for Elective Surgery - target levels	WITN7102025
Undated	Sources of Information for Transfusion Practice	WITN7102026
18/11/2002	Agenda for meeting of the Overarching Transfusion Committee	WITN7102027
31/03/1998	GRI Trust Transfusion Committee, meeting notes	WITN7102028
December 2007	Western Infirmary Glasgow Major Haemorrhage Policy	WITN7102029
26/01/2009	West of Scotland Consultant Haematologists Group/ SNBTS Better Blood Transfusion - Regional Audit	WITN7102030
28/07/2010	Scottish Major Haemorrhage Template cover	WITN7102031
25/07/2008	Guidelines for Use of Fresh Frozen Plasma	WITN7102032
2002	West of Scotland Blood Transfusion Centre - RBC Issues and Returns - 2001-02	WITN7102033
July 2005	Glasgow & West of Scotland Blood Transfusion Service Clinical Directorate: Summary of Blood Component	WITN7102034

	Transactions with West of Scotland Hospitals	
November 1995	British Blood Transfusion Audit in Transfusion Practice cover	WITN7102035
Undated	Red Cell Transfusion Information Leaflets covers	WITN7102036