Witness Name: Catherine Innes
Statement No. WITN7198001
Exhibits: None
Dated: 11th October 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF CATHERINE INNES

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 1 July 2022.

I, Catherine Innes, will say as follows: -

Section 1: Introduction

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

1. Catherine Innes
   GRO-C
   Edinburgh, Midlothian
   Scotland
   GRO-C
   Date of Birth: GRO-C 1966

2. Registered General Nurse and Registered Nurse Level 2 (Enrolled Nurse).

2. Please set out your current role within NHS Lothian and your responsibilities within that role.

3. I was employed by NHS National Services Scotland/Scottish National Blood Transfusion Service (SNBTS) as one of two Transfusion Practitioners (TPs) based in NHS Lothian. I started in that post on Monday 5th May 2008 and was based at Edinburgh Royal Infirmary. I retired in March 2021. I was then employed directly by NHS Lothian, under a one year fixed term contract for one day a week, to assist with the Covid Vaccination roll out. This contract has now finished.

4. I no longer have my Transfusion Practitioner job description, but this can be obtained from SNBTS if required.

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

5. Due to a relocation with my husband's work, I returned to Edinburgh from Aberdeen. I had been working in NHS Grampian before the move. I then had 6 months off work while deciding in which direction I would like my career to go. At that point I felt I needed a change from frontline nursing as a senior nurse. When the SNBTS TP post was advertised, based in NHS Lothian, I thought it sounded interesting and exactly the different career pathway I was looking for. I applied for the role and was successful, starting as a TP in May 2008.

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.

6. March 2021 to June 2022 – Nurse vaccinator for COVID vaccines
   May 2008 to March 2021 – TP NHS Lothian, employed by NHS National Services Scotland (Scottish National Blood Transfusion Service)
   August 2007 to April 2008 – Break in service while moving from Aberdeen to Edinburgh
   August 2005 to August 2007 - NHS Grampian Aberdeen Royal Infirmary, Accident & Emergency Department, Sister, Grade G

October 2002 to August 2005 – NHS Grampian Aberdeen Royal Infirmary, Senior Staff Nurse, Grade F, General Surgical Ward

September 1998 to October 2002 - NHS Grampian Aberdeen Royal Infirmary, Accident & Emergency Department, Staff Nurse, Grade E

April 1998 to October 2002 – NHS Grampian Aberdeen Royal Infirmary, Accident & Emergency Department, Staff Nurse, Grade D

December 1997 to April 1998 – Break in service while moving from Edinburgh to Aberdeen.

April 1993 to December 1997 – NHS Lothian Western General Hospital, General Surgery, Grade D

September 1991 to April 1993 – Bridging course from State Enrolled Nurse to Registered General Nurse

April 1988 to September 1991 – NHS Lothian Princess Margaret Rose Orthopaedic Hospital, Enrolled Nurse Grade D

April 1986 to October 1987 – NHS Lothian, North Lothian College of Nursing and Midwifery, Enrolled Nurse Training

1983 to April 1986 – Long and Gilmour Dental Practice, Bo'ness, West Lothian, Dental Nurse

Section 2: Hospital Transfusion Committee history, structure & relationships

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

a. When the HTCs at the Hospitals were established;

7. The HTCs were already established when I came in to post in 2008.

b. Who established the HTCs and who the first Chair was;

8. I am unsure who established the HTCs, I think the first Chair was Dr Tim Walsh.

c. Why the HTCs was established;

9. Although not in post at this time, my understanding was that the HTCs were established to monitor transfusion practice, provide staff education for all staff involved in transfusion, and to ensure there were policies and guidelines in place for staff guidance.

d. What the initial aims of the HTCs were when it was established; and

10. I am unsure what the initial aims were, other than those mentioned in my response to Question 5 c. above.

e. Before the establishment of the HTCs, how the Hospitals monitored transfusion practice.

11. I am unsure how the hospitals monitored transfusion practice prior to HTCs being established.

RLIT0001079 may also assist.

12. I was an active member of the Edinburgh Royal Infirmary (RIE) Hospital Transfusion Group and the Lothian Transfusion Committee (LTC) from May 2008 to March 2021.

13. In NHS Lothian there are three large acute teaching hospitals, a paediatric hospital (Royal Hospital for Sick Children, RHSC) as well as smaller community hospitals. I was the TP for RIE and RHSC hospitals, and my colleague is the TP for St John's Hospital and the Western General Hospital. We both provided/provide support for the community hospitals and community midwifery services. Prior to me commencing in post in May 2008, Quality Improvement Scotland (QIS) had carried out inspections on all acute hospital sites. One of the recommendations was that each of the large hospitals should establish a Hospital Transfusion Group (HTG) that could address any day to day local

issues, and also to have an overarching Lothian committee which was known as the LTC.

14. As clinical staff potentially could move to any of the hospitals within NHS Lothian to work, policies, procedures and guidelines for transfusion were applicable for all sites, other than there being small differences like telephone numbers and locations of transfusion laboratories for each of the local sites.

6. In 1989, the Working Group on Transfusion Practice and HIV Infection in Scotland also recommended HTCs [NHBT0010270_003]. What influence, if any, did this recommendation have on the establishment of HTCs at the Hospitals?

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

7. 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. SCGV0000099_142 and SCGV0000099_017 may also assist.

16. The membership included clinical staff, both medical and nursing, theatre staff, laboratory staff from both SNBTS and non SNBTS laboratories and a compliance manager. There were a wide range of specialities in attendance, to represent the various areas that were involved in transfusion.

17. The composition of the committee was reviewed periodically, or if someone left the group

8. 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.

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

18. During my time as a member of the LTC, the committee oversaw all matters relating to transfusion, which included all the above. Previous LTC minutes and agendas will support this.

19. I am unable to access any documents now that I have left the organisation, to support answering the above questions. However, the Chair of the LTC, or current TPs will be able to assist with these.

9. **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. During the time I worked as the TP in NHS Lothian there was a clear pathway for introducing recommendations. For example, if an incident/event or transfusion reaction was raised by clinical staff, or the transfusion laboratory, the TP would automatically be alerted by email when it was reported on the local incident/event reporting system. If it required TP input we would follow up with relevant staff involved, identify root cause and assist staff with implementing learning outcomes, if required. It would also be reported to the relevant authorities if applicable (e.g. SHOT Serious Hazards of Transfusion and MHRA). This would then be tabled at the next HTG and LTC meeting for further discussion, and further escalation if required.

10. **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 position at the Hospitals? Do you think this is a fair assessment of the HTCs? Please explain your answer. DHSC0038527_092 may also assist.**

21. From my experience, the LTC meetings had positive clinical input from a full range of specialities including laboratory staff (which on the RIE site was operated by SNBTS transfusion laboratory staff and a SNBTS Compliance Manager. I found the meetings positive, and felt it was clear that the clinicians attending were proactive and keen to ensure they influenced safe transfusion practice in their own areas.

11. **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. Routinely the LTC met quarterly. Occasionally this could change depending on clinical commitments, however if this did happen the date of the next meeting was changed, as opposed to having no meeting at all. The local HTGs tried to meet before the LTC, so if there were any local issues these could then be raised at the LTC if required.

12. 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.

SBTS0004340_136 and SCGV0000099_016 may also be of assistance.

23. I have no access to the relevant documents to support my answer, however, from memory, the HTC was aware of these concerns. This was discussed at LTC meetings and learning agreements were introduced for all levels of staff. These were introduced prior to me starting in 2008. It was mandatory for all

staff involved in any part of the transfusion process to complete the relevant mandatory transfusion training every two years. Again, from memory, this would be checked as part of the staff member's annual PDP, including medical staff.

24. Previous LTC minutes will have discussions about these issues. The LTC Chair and the current TPs will also be able to support this.

13. Please consider RLIT0001094. Please explain who undertook the work described in this article, why it was undertaken and what the key issues were that were addressed. Why do you consider this work was so successful? Was it one particular intervention that was the primary reason for success or were there several?

25. Dr Matt Reed, Emergency Department (ED) Consultant at Edinburgh Royal Infirmary was the lead on this article, along with an ED senior medical student. My role was to provide the data requested by Dr Reed, which was obtained from the Transfusion Laboratory database. The objective was to review clinical indications for blood components requested, transfused, discarded, and the traceability of the unit.

26. This was a follow up audit to compare results from a previous audit in 2008. The outcome showed there had been a significant improvement in ED with regards to local issues that they were striving to improve upon, such as reducing any unnecessary blood component wastage, full traceability/final fate of blood components that had been delivered to ED, and ensuring the blood components were being ordered appropriately. Simple strategies were implemented within the ED department such as the introduction of transfusion link nurses, checklists that were used in ED during traumas had a transfusion section added to them, to remind staff to return blood components if no longer required and complete the traceability tag that is returned to the transfusion laboratory to confirm the date, time and name of the person receiving the blood components.

14. Please consider RLIT0001081. Please explain who undertook the work described in this article, why it was undertaken and what the key issues were that were addressed. Why do you consider this work was so successful? Was it one particular intervention that was the primary reason for success or were there several?

27. Dr Matt Reed, Emergency Department (ED) Consultant at RIE was lead for the audits and both articles. My role was to provide the transfusion data requested by Dr Reed, which was obtained from the Transfusion Laboratory database.

28. This audit was undertaken to address various issues around transfusion within the ED department e.g., traceability of the blood component (final fate of the unit if transfused, discarded, returned to the transfusion laboratory) and ordering units that weren't transfused, which could then lead to wastage.

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

29. I always found the HTGs and the LTC meetings to be positive, well attended and proactive. I personally felt as the TP that I was well supported by the group, especially when involved with any large projects or audit. The HTG and LTC were well known and respected by hospital staff and at senior management level.

16. Please describe the nature of the HTC's 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] and [SCGV0000099_018].

30. I am unable to answer the above, not now being able to look back at minutes from over the years, my personal notes, emails etc regarding the various projects, as a reminder.

31. I always found the HTGs and the LTC to be supportive, approachable and well known amongst staff in the hospitals and community settings. The NHS Lothian intranet had a Transfusion Page, which included information such as the structures of HTG and LTC, audit information, blood use reports, education, policies and guidelines and staff information.

17. Please describe the HTC's 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 HTC?

32. During the time I was employed as a TP (2008 to 2021) the LTC had a good working relationship with SNBTS. SNBTS were represented at the LTC meetings, from both the local SNBTS transfusion laboratory and the local SNBTS Compliance Manager, both of whom were based at Edinburgh Royal Infirmary.

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

33. As far as I was aware there was a good working relationship between the LTC and the SNBTS transfusion laboratory.

19. 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?

34. I am unable to answer this question as I was not in post until 2008.

<u>Section 3: Policy and Standard Practice</u>

20. Please outline the HTC's 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.

35. This question relates to a period out with the time frame of my employment.

21. 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.

36. This was already in place prior to my employment as a TP.

37. The blood ordering schedules for adults and children were in place to guide clinical staff as to what operations and procedures required patients to be cross matched for, or not, and, if so, how many blood components were required for each surgical operation or procedure.

38. Yes, this did change over time, when the policy was due for an update it was done through collaboration with the HTGs, the LTC, clinical staff and the transfusion laboratory.

39. I am unable to provide copies, if required these can be provided by the LTC Chair or TPs.

22. 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?

40. Local policies are written by various members of staff or small working groups, which would include staff who have the expertise, experience and knowledge required to write the policy. They would then be circulated to the HTGs, and or the LTC, for feedback, tabled at the meetings and final sign off was performed by the NHS Lothian Policy Group.

41. During the time I was working as a TP, the other issues mentioned in Question 22 above were addressed, with the introduction of a transfusion document called 'NHS Lothian documentation for transfusion of blood components' (WITN7104008). This version is from 2011, the document was updated every two years or when going for reprint. This was a 4-page document that included consent checklists, pre-administration of blood component checklists and prescription, prompts and advice for clinical staff involved with transfusion in the clinical areas.

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

a. **Obstetrics;**
b. **Trauma and emergency care;**
c. **Surgery;**
d. **Haematological malignancies;**

e. Thalassaemia; and

f. Sickle Cell Anaemia.

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

42. Yes, guidance regarding the above was included in the NHS Lothian Transfusion Policy and Procedures and, from memory, some areas also had their own local guidelines and policies.

43. I have no access to these documents but the Chair of the LTC will be able to help with this or the TPs.

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

44. The HTGs, and or LTC, would be involved if made aware of any instance of failure to comply, via the local incident/event reporting system. This would then be followed up with the area involved/staff involved.

25. 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.

45. I am unable to remember full details around this during the time I was a TP, however, if it was discovered that there had been an unnecessary transfusion this would be reported via the NHS Lothian local reporting system, tabled and

discussed at the HTG and LTC and reported to SHOT (Serious Hazards of Transfusion).

26. Please consider '*Better Blood Transfusion*' Health Service Circular 1998/1999, issued on 11 December by Dr Graham Winyard, NHS Executive (NHBT0083701_002). Please outline:

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

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

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

iii. Autologous transfusion

iv. Single-unit transfusion

v. Fresh-warm blood transfusion

vi. Knowledge of risk of transfusion related infections

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

46. I can remember conversations about the above taking place at various times throughout my employment, but can't remember when or what the outcomes of these were. Previous LTC minutes or the LTC Chair should be able to assist with this.

27. 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.

47. During my employment, I don't recall any proposals not being actioned. The previous and current Chair of the LTC had a very positive relationship with the Senior Management of NHS Lothian. Transfusion was always well supported in NHS Lothian by Management and Transfusion Annual Update Reports were sent by the LTC Chair to the NHS Lothian Management Group.

Haemoglobin level

28. 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?

48. I am unable to remember the discussions in detail, but transfusion triggers and thresholds were discussed at the LTC, along with reference to SHOT annual reports and any published papers. From memory, between 2008 and 2021, the guidance was as published above by SHOT, with recognition that some specialities areas would have their own local policies, such as cardiac and orthopaedic surgery. Information and guidance was available for staff on the NHS Lothian Intranet under the transfusion section.

29. 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.

49. I am unable to remember details about this.

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.

50. Yes, the LTC would have been aware of excessive or unnecessary transfusions, as these would have been reported as incidents, so would have been investigated with clinical staff involved. Root cause and outcomes would have to be completed on the incident report before it could be closed. These were then tabled at the LTC for discussion and learning outcomes, and also reported to SHOT.

30. 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

51. Yes, published papers, circulars and SHOT reports were discussed at the LTC. When the annual SHOT reports were published each year they were tabled at the LTC and recommendations benchmarked

Fresh Frozen Plasma ("FFP")

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

52. I remember there being guidance. There were also discussions at the LTC with clinicians and transfusion laboratory representation, but I am unable to remember exactly when this would have been and I don't now have access to previous minutes or emails to get the full details about this.

53. The Chair of the LTC will be able to assist with this.

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

54. I am unable to answer this in detail, but during my employment as a TP there were patient information leaflets available informing patients of the risks and benefits of transfusion. The consent section on the 'NHS Lothian documentation for transfusion of blood components' (WITN7104008) 'Administering a Transfusion Document', required to be completed by the clinician consenting the patient for transfusion. This had a prompt to discuss risks and benefits with the patient. WITN7104008 is a version from 2011, this was updated every 2 years or so when it was going for reprint.

33. 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.

55. From memory, this information would have been available to staff in NHS Lothian. Transfusion policy and procedures could be accessed by staff on the Lothian intranet. The Chair of the LTC will be able to provide further information if required.

34. Was 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?

56. The LTC would have been provided with national guidance, either directly or via SNBTS, I am unable to remember what this guidance was or when it would have been given.

Platelets

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

57. There were discussions at the HTG and the LTC about platelet transfusions, however I am unable to remember exactly what these discussions were.

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

58. I am unable to remember details about this, but all staff were prompted in the 'NHS Lothian documentation of blood components'', in the consent section, about highlighting the risks and benefits with patients. This document may have been updated since I left the organisation.

37. 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.

59. Guidance was available for clinicians and hospital staff in the NHS Lothian transfusion policy and procedures but I am unable to remember the detail around this.

38. 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?

60. The LTC would usually have received national guidance and/ or recommendations when issued, either directly or via SNBTS but unable to remember details or dates.

Single-unit transfusion

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

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

61. There were numerous discussions at the LTC about single unit transfusions, but I am unable to recall the detail of these conversations.

62. Information and guidance work involved with rolling out single unit transfusions would be available in the LTC minutes, as well as in various education materials, policies and guidelines.

63. The LTC and current TPs will be able to help with this.

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

64. From memory, one of the main reasons for introducing single unit transfusion was to reduce the potential risks to patients by receiving unnecessary transfusions.

65. Please also see my response to Question 39

41. 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.

66. When single unit transfusions were introduced, guidance was given to staff and still is during education sessions. There may also be an awareness alert on the NHS Lothian intranet, but unfortunately I am unable to remember the full detail around this as it was quite a few years ago.

67. Please see my response to Question 39.

42. 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?

68. I remember that if an unnecessary transfusion had occurred they were reported on the local incident reporting system and followed up by TP and clinical staff but unable to remember details or access the incident management system to obtain further details around this.

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

69. I only remember single unit transfusions being discussed at the HTG or LTC in a positive way. I don't remember potential waste being discussed in relation to this.

44. 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?

70. The LTC would usually receive national guidance and or recommendations when issued either directly or via SNBTS but unable to remember details or dates.

45. 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. DHSC0038527_093 may assist.

71. I can't recall carrying out a single unit transfusion audit, however this doesn't mean it wasn't done, as it may have been audited by clinical staff or transfusion laboratory staff.

Red blood cell concentrates

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

72. I am unable to remember discussions to be able to answer this question. The LTC Chair has access to the relevant documents, policies and minutes.

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

73. I am unable to remember discussions to be able to answer this question. The LTC Chair has access to the relevant documents, policies and minutes. Also unable to remember details about this, but all staff were prompted in the 'NHS

Lothian documentation of blood components', in the consent section, about highlighting the risks and benefits with the patients. This document may have been updated since I left the organisation.

48. 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.

74. Guidance was available in the NHS Lothian transfusion policy and procedures' but unable to remember the detail around this.

49. 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?

75. The LTC would have received national guidance and or recommendations when red cell concentrates were issued, either directly or via SNBTS, but I am unable to remember details or dates.

50. 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.

76. I am unable to remember definite details about this, however any adverse reactions would have been reported directly to the transfusion laboratory, who would then report on their local SNBTS incident/even management system. If reported by the clinical area it would have been reported on the Lothian incident/event management system (as Lothian didn't have access to any of SNBTS IT systems and vice versa). An investigation would have been carried out and advice given by the SNBTS on call haematologist or consultant within the clinical area, depending on the severity of the reaction. All SHOT/MHRA reportable incidents and reactions were also tabled at the LTC for discussion and any further action taken if required.

51. In relation to red blood cell concentrates:

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

77. Unfortunately I am not able to answer Questions 50 a. to c. from the 1970s and 1980s.

Section 4: Knowledge of risk

52. 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?

78. Unfortunately I don't recall details or discussions about this.

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

79. I do not have access to documents or minutes to be able to look back at this.

54. 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.

80. I do not have access to documents or minutes to be able to look back at this.

55. 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.

81. While working as a TP in Lothian, the HTG and the LTC meetings always tabled SHOT and or MHRA near miss incidents, full incidents and reactions. Usually, by this point the investigation/follow up was complete, but if not, or if further investigation was required the HTGs and/ or LTC would provide support and guidance, if required.

56. 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?

82. I am unable to recall any discussions about this.

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

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

a. What procedure did the Hospitals have in place?

83. I am only aware of clinical nursing and medical staff and /, or laboratory staff reporting adverse reactions or symptoms following a blood transfusion, which would be reported via their own local incident reporting system. When blood

components were being administered, it would be usual practice for staff to inform the patient that if they felt unwell they should alert the staff immediately.

b. Did this procedure extend to a time after a patient had been discharged from hospital?

84. I wasn't involved with patients after discharge, however, from experience it would be normal practice for staff to advise a patient to call their GP or the NHS helpline if they felt unwell after being discharged.

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?

85. During the time I was employed as a TP it was the clinical staff involved with looking after the patient who reported if there were any adverse reactions , via the local incident system. They were also able to contact the transfusion laboratory or the SNBTS 'on call' haematology medical staff via the Lothian switchboard, if further advice or guidance was required.

e. Was there any mechanism for the Hospitals to report any adverse reactions or symptoms to the Regional Transfusion Centre?

86. Yes, either via the hospital transfusion laboratory, the on call SNBTS transfusion consultant/registrar, or the TP.

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.

87. I wasn't aware of a death following a blood transfusion during my time as a TP, and not sure what this process would have been.

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

88. The LTC wouldn't usually report directly to the supplying blood centre or SHOT, as this would usually have already been done by the transfusion laboratory, the SNBTS Consultant/ registrar based in the hospital or the TP.

59. 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?

89. SHOT was already launched and fully established when I commenced in post in 2008. There were key people responsible for reporting to SHOT, the TP, the transfusion laboratory senior staff member, the compliance manager and the SNBTS consultant. Reports were compiled by the TP for clinical incidents/events/reactions and the SNBTS laboratory completed reports for any laboratory incidents, all SHOT/MHRA near misses, events and reaction reports were submitted to the LTC meetings.

60. 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?

90. Reporting was fully established when I commenced in post and staff were very aware of the importance of reporting.

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

91. Part of my role as the TP was to monitor local blood component wastage (blood components ordered but not used, avoidable and unavoidable wastage). The transfusion laboratory recorded all unused units that were returned to the laboratory with date, time and clinical area in which it occurred. I then completed a monthly report to track and trend this. The report was tabled at the local HTG and action taken if required with individual clinical areas to address any unavoidable wastage issues. Blood component use and wastage of blood components were a standing agenda item at the HTG and LTC meetings.

92. The LTC also had access to the SNBTS electronic dashboard that provided information on blood component use, stock levels and wastage for each of the blood components for hospitals and individual clinical areas

62. 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?

93. I am unable to remember the circumstances of the internal and external audits. The Chair of the LTC and current TPs will be able to help with this. this.

63. 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.

94. From memory, yes, there was information available regarding this from the transfusion laboratory database, and the SNBTS blood banks dashboard was able to provide this information instantly if required, as it was a 'live' database. This information could be obtained by the TP, transfusion laboratory or a member of SNBTS staff.

64. 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.

95. I am not aware that the LTC recorded this information. It would tend to request this information from the transfusion laboratory or SNBTS if required.

65. 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.

96. Yes, audits were conducted at various times on all components / treatments mentioned in Question 65 a. to e.

66. 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.

97. I am unable to recall information around the process of the action that would have been taken, but, during my time of involvement, the LTC would definitely have taken corrective action, if required.

Section 6: Treatment of patients

Provision of information to patients

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

98. I can't remember discussions about this and I do not now have access to previous minutes or emails as a reminder.

68. 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?

99. From memory, I would expect this to have been included during the consent process for transfusion.

Consent

69. 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?

100. While working as a TP during 2008-2021, informed consent was included in education sessions for clinical staff, scenario based learning for medical students as well as included in the mandatory elearning for all staff involved in transfusion 'Safe Transfusion Practice'

101. There was a 'consent for transfusion' section in the NHS Lothian documentation for transfusion of blood components (WITN7104008). This was developed around 2010 (from memory) although I can't remember which

version the consent, risks and benefits section was extended to include more around risks and benefits after a QIS recommendation. They recommended that all documentation from a 'transfusion episode' should all be within one document as oppose to in various parts of the medical notes. A national document was developed after this but adapted to suit each local health board's specific requirement. It was a four page document that clinical staff could access that had all the information (consent, prescription, administration, guidance/advice re reactions in one place). The first page had the consent section with tick box prompts to be completed after discussion, such as risks and benefits. Page two was the prescription section, and where the traceability tag could be inserted. Page three was a pre-administration checklist and page four was some general transfusion information and guidance. The clinician consenting the patient for an elective transfusion signed this section after the discussion had taken place.

102. This may have been updated since I retired.

70. 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.

103. I am unable to remember any details of discussions around consent at the LTC, but consent guidance was included at education sessions during induction and is included in the mandatory two yearly 'Safe Transfusion Practice' elearning module. From memory, there was also a Consent Module online for staff to access.

Section 7: vCJD

71. 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].

104. I am unable to answer this as I didn't start in post as a TP until 2008.

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

105. I am unable to answer this as I didn't start in post as TP until 2008.

Section 8: Look back

73. 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?

106. I am unable to answer this as I didn't start in post as a TP until 2008.

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

107. I am unable to answer this as I didn't start in post as a TP until 2008.

Section 9: Other

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

108. I don't have any further comments, thank you.

76. 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.

109. I don't have any access to documents to include, but the LTC Chair or the current TPs could assist with this, if required.

Statement of Truth

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

Signed GRO-C

Dated 11th October 2022