Witness Name: Jane Oldham
Statement WITN7300001
Exhibits: WITN7300002-041
Dated: 30th November 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF JANE OLDHAM

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

I, Jane Oldham, will say as follows: -

Section 1: Introduction

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

1. My name is Jane Catherine Oldham. My date of birth is GRO-C 1972. My address is GRO-C

2. I am registered with the Nursing and Midwifery Council as a Registered Nurse (Adult) and have maintained this professional qualification since 25th September 1995. I have BSc (Hons) degrees in Nursing Studies (University of Edinburgh, 1995) and Nursing Practice: Developing Nursing Autonomy (University of East Anglia, 2000) and a MSc in Advancing Healthcare Practice (Open University, 2013).

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

responsibilities within that role.

3. I am currently employed by NHS National Services Scotland (Scottish National Blood Transfusion Service (SNBTS)) as a transfusion practitioner, based in NHS Lothian.

4. The hospitals I routinely cover are the Western General Hospital (WGH) in Edinburgh and St John's Hospital (SJH) in Livingston. There are two transfusion practitioners based in NHS Lothian, so I also provide annual leave/absence cover for all NHS Lothian sites. Whilst we have named transfusion practitioner cover for each site, my work routinely brings me into contact with individuals and teams in all parts of NHS Lothian.

5. Whilst I am an employee of SNBTS, my role is embedded within NHS Lothian. The transfusion practitioner is a core member of the Hospital Transfusion Team (HTT). Each main hospital site has a HTT, which consists of a core membership of the transfusion laboratory manager, transfusion lead haematologist and transfusion practitioner and can also include other key transfusion stakeholders. One of the core roles of the HTT is to implement the objectives of the Hospital Transfusion Committee (HTC). I am a member of the WGH and SJH HTTs and the overarching NHS Lothian Transfusion Committee (LTC). The LTC covers all hospitals in NHS Lothian. I work closely with clinical, managerial and support staff within NHS Lothian and provide subject matter expertise in the promotion and facilitation of the safe and appropriate use of blood components.

6. I am one of a national team of 16 transfusion practitioners. Between us we provide transfusion practitioner cover for all hospitals in Scotland. We are supported in our work by a central team based nominally in Edinburgh, consisting of our clinical lead, senior nurse, office manager, programme administrator, transfusion researcher, transfusion education specialist and head of nursing (SNBTS Patient Services). Collectively we are the SNBTS Transfusion Team (SNBTS TT).

7. Alongside my collaborative work with NHS Lothian colleagues, I also work

closely with the rest of the SNBTS TT across Scotland. This aspect of my work involves national project work designed to achieve key goals aligned to the SNBTS TT strategic priorities. The current SNBTS TT 5-year Strategy is described in Appendix 5 of the attached SNBTS Information for Hospital Transfusion Committee Chairs and Consultant Transfusion Leads (WITN7300016).

8. The role of the transfusion practitioner in Scotland has evolved since 2003, when it was introduced as part of the Better Blood Transfusion (BBT) Programme. The BBT service underwent review several years ago (a process that concluded in 2019). The service review and resultant revised role of the transfusion practitioner is outlined in the SNBTS Information for Hospital Transfusion Committee Chairs and Consultant Transfusion Leads (WITN7300016).

9. Since the conclusion of this review, the transfusion practitioners are organised into four regional teams, to provide mutual support and resilience. I work alongside colleagues in NHS Borders and NHS Fife as part of the East Regional Team, and as such provide leave/absence cover for the hospitals in these Scottish Territorial Health Boards also. We are supported in our role by a transfusion support assistant. The regional model is described in Appendix 3 of the attached SNBTS Information for Hospital Transfusion Committee Chairs and Consultant Transfusion Leads (WITN7300016).

10. My role and responsibilities include:

- Promotion of the safe and appropriate use of blood and blood components through the development of national (Scottish and United Kingdom (UK)) programmes of education, quality improvement and clinical effectiveness initiatives, in collaboration with clinical, laboratory and management colleagues (these may be NHS Lothian employees, SNBTS employees or stakeholders from other organisations (for example, other Scottish Territorial Health Boards or Higher Education Institutions).

- Active membership of the LTC in terms of its contribution to NHS Lothian's clinical governance framework and maintenance of strategic oversight of clinical transfusion practice in NHS Lothian
- Monitoring of transfusion-related key performance indicators (KPIs) and associated improvement activity, where necessary, alongside NHS Lothian and SNBTS colleagues. Transfusion-related KPIs are used to monitor clinical and laboratory transfusion practice and may be those set by NHS Lothian or by SNBTS and applied locally and related to local services. Examples of KPIs include blood component traceability and proportion of O negative red cells being taken into laboratory stock. All KPIs are routinely monitored by the HTT and LTC. SNBTS KPIs are also routinely monitored and reported at SNBTS TT meetings, which occur every two months. I am responsible for working alongside NHS Lothian and SNBTS colleagues to review performance against KPIs (using the interactive SNBTS Blood Bank Dashboard for relevant measures) and for influencing local action where required. National SNBTS TT meetings are used to share and discuss associated good practice and challenges across Scotland
- Contribution to SNBTS TT national programmes of work aligned to patient safety and best practice. An example of a national programme of work that I have led is the development and rollout of a new national 'Once for Scotland' transfusion education programme for undergraduate midwifery students
- Provision of subject matter expertise in blood transfusion to owners of incidents (the appropriate manager or senior clinical staff member in the responsible area) and local teams, in response to transfusion-related adverse events, reactions and near-miss events, including oversight of the same alongside other members of the HTTs
- Submission of reportable serious adverse event, serious adverse reaction and near miss event reports to the Serious Hazards of Transfusion (SHOT) UK haemovigilance scheme and the Medicines and Healthcare products Regulatory Agency (MHRA) via the Serious Adverse Blood Reactions and Events (SABRE) reporting system, as a member of the reporting team. For the hospitals that I cover, this

reporting team also includes the transfusion laboratory manager and the transfusion lead haematologist. All reports submitted to SHOT and MHRA are anonymised, such that no patient or staff identifying information is submitted.

11. I attach a copy of my job description to supplement my response (WITN7300002).

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

12. Having completed a three-year development post as a palliative care nurse practitioner in December 2003, I relocated to Scotland where my partner's work base had moved. The role of the transfusion practitioner was new to me, but I recognised that my experiences of clinical transfusion practice, clinical education, new role development and familiarity with transfusion governance activity (having represented the palliative care department at the HTC in my previous role) would be of value in the post.

13. I responded to a national advertisement for the role of transfusion practitioner with SNBTS in early 2004. Following submission of my application, I was shortlisted for the post and interviewed by a panel. I was successful in securing the post and was appointed in April 2004. I was initially employed under a one-year fixed term contract to cover a maternity leave absence in NHS Fife and subsequently covered sickness leave absence in NHS Forth Valley before commencing work in NHS Lothian in late 2004.

14. In 2005 my contract was extended until August 2006. In 2006 my contract was extended until March 2009. This was subsequently made into a permanent appointment.

15. I have been employed on a full-time basis since my appointment in 2004.

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

dates.

16. My career history is as follows:

- **October 1995 – April 1997 Staff Nurse D Grade** (East and Midlothian NHS Trust) – I was a member of a multidisciplinary team in general surgery, high dependency and gynaecology ward settings. I provided nursing care and support for patients undergoing surgery, miscarriage and termination of pregnancy, with a requirement to respond rapidly to changing clinical circumstances and emergencies, manage pain and mentor and support student nurses
- **May 1997 – December 2000 Staff Nurse / Team Leader E Grade** (Norwich Primary Care NHS Trust) – I led a team of nurses and clinical support staff and provided nursing care as part of a multidisciplinary team caring for individuals with chronic disease and related complex needs in a specialist palliative care inpatient unit; I mentored and supported student nurses and represented the department on the Trust's HTC
- **December 2000 – December 2003 Palliative Care Nurse Practitioner H Grade** (Norwich Primary Care NHS Trust) – I designed and established an outreach service from a specialist palliative care facility into community hospitals; I provided specialist palliative care for patients and their families in a variety of inpatient, community and home settings; I created and led a new outpatient intravenous therapy service; I introduced an educational programme for community staff to support individuals to provide high quality and effective palliative care and I provided clinical supervision of nursing colleagues
- **April 2004 – present - Transfusion Practitioner Band 7** (NHS National Services Scotland) – role as described in answer to Question 2

Section 2: Hospital Transfusion Committee history, structure & relationships

13. 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 was established;**

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

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

RLIT0001079 may also assist.

17. I started work as a transfusion practitioner in NHS Lothian in late 2004. At this time the LTC was already established. I am unable to assist in answering questions relating to the establishment of the LTC or how the NHS Lothian hospitals monitored transfusion practice before this date.

14. **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?**

18. As stated in response to Question 5, I started working as a transfusion practitioner in NHS Lothian in late 2004. At this time the LTC was already established. I am unable to answer questions relating to any influence that a recommendation of the Working Group on Transfusion Practice and HIV Infection in Scotland had on the establishment of HTCs at the hospitals.

15. **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.**

19. The LTC had been established in April 2000 in response to the NHS circular "Better Blood Transfusion" (HSC 1998/224) and replaced the previously separate WGH and Royal Infirmary of Edinburgh (RIE) Committees. The circular (HSC 1998/224) does not define membership but states that the Committee must be multi-disciplinary (WITN7300003).

20. The LTC membership has been defined in its constitution and remit which have been revised over time. I have included the earliest and most recent versions of the constitution and remit that I have in my records (WITN7300004, WITN7300005). I only hold a draft version of the latter document.

21. I cannot state which source was used by NHS Lothian, regarding recommended membership, in the development of the LTC constitution, as I was not a member of the Committee at the time this was developed.

22. The LTC has a membership of around 24. This number naturally fluctuates with staff changes and moves. Meetings are generally attended by approximately 12 members on each occasion. The Committee meets on the RIE site (via MS Teams since 2020 and to date) on a quarterly basis.

23. The first LTC meeting that I have a record of attending was in June 2005. I am unable to state whether there was another LTC meeting between the time I started in post in NHS Lothian (late 2004) and June 2005. As stated in my response to Question 3, I was responsible for covering the transfusion practitioner role across three Scottish Territorial Health Boards for various periods when I was first appointed. There may have been another LTC meeting between the time I joined NHS Lothian and June 2005 that I was unable to attend, because of a requirement to be present in another Board at the time, or it may be that I attended an earlier meeting but do not have a record of the minutes of that meeting.

24. When I first joined the LTC the Committee was chaired by a NHS Lothian employed consultant anaesthetist, who held the position of Chair until 2011. A

further NHS Lothian employed consultant anaesthetist served as Chair of the Committee between 2012 and 2020. Since 2020 the Committee has been chaired by a NHS Lothian employed consultant haematologist. The change from anaesthetic to haematology Chair relates to staff moves (the previous Chair was retiring from post) and the capacity of suitably experienced representatives being in a position to accommodate this role - rather than a deliberate change.

25. Since I joined the LTC it has maintained a core composition of representatives of blood-using clinical teams from the following areas:
    - anaesthetics (theatre and critical care)
    - medicine (gastrointestinal, transplant, general, acute and emergency)
    - surgery (cardiothoracic, vascular, transplant)
    - obstetrics and gynaecology
    - haem-oncology
    - paediatrics
    - palliative care

26. The LTC has also maintained a core composition of members of the HTTs representing all key sites:
    - transfusion laboratory managers
    - haematology and transfusion medicine consultants
    - transfusion practitioners

27. Medical professionals provide the majority of clinical area representation (consultant level with occasional attendance by haematology specialist trainee doctors). Nursing representation has fluctuated over the years (members have included associate nurse directors, clinical nurse managers, practice education facilitators and staff nurses) including some periods without nursing representation. There has been consistent laboratory quality manager representation. Other roles have been represented for shorter time periods or at individual meetings, to offer subject matter expertise (e.g. SNBTS

compliance officers, operating department practitioners, blood conservationist, transfusion specialist midwife, SNBTS directors).

28. Organisational changes to the structure of NHS Lothian were in progress around the time that I became a transfusion practitioner.

29. When I commenced in post in 2004 there were three HTCs in existence in NHS Lothian. At that time, the LTC served as the overarching Committee for NHS Lothian. It also dealt with transfusion-related activity on the RIE site along with all other Lothian sites served by the same transfusion laboratory. HTCs were also in existence on the WGH site and the SJH site. Representatives from the WGH and the SJH HTCs were also members of the LTC.

30. As part of a NHS Quality Improvement Scotland (QIS) (now Healthcare Improvement Scotland (HIS)) peer review of clinical standards for blood transfusion in NHS Lothian in 2007, it was agreed that the governance structure would be made clearer with the introduction of different arrangements. This resulted in the WGH HTC and the SJH HTC being renamed as Hospital Transfusion Groups (HTGs), along with the formation of a separate RIE HTG. It was agreed that the Quality Improvement Team (QIT) for the Royal Hospital for Sick Children (RHSC) (as it was named at the time – now called the Royal Hospital for Children and Young People (RHCYP)) would act in lieu of a HTG for that site. The LTC membership consistently included representatives from each of the site HTGs (including a member who attended the RHSC QIT).

31. More recently, the structure has been streamlined further, such that each site simply has a HTT, which is an amalgamation of the previous HTT and HTG membership. LTC membership continues to include representation from each hospital site's HTT.

32. The RHCYP (previously RHSC) representation at the LTC has remained unchanged following that hospital's move to the Little France, Edinburgh site (2021) where it now shares the same site as the RIE. The RIE HTT has now expanded to accommodate RHCYP representation.

16. 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.

33. Since I joined the LTC in 2005, it has carried out the roles, functions and responsibilities I have listed below. The list is not exhaustive, but I have tried to reflect all core activities. I understand that the Inquiry has access to the minutes of the LTC from 2005 to date.

34. The Committee reports to the NHS Lothian Acute Clinical Management Group, which reports to the NHS Lothian Healthcare Governance Committee and, through this route, is accountable to the chief executive of NHS Lothian.

35. An agenda is prepared by the Chair prior to each meeting. The minutes taken at each meeting record the topics covered as well as agreed decisions and actions.

36. I have indicated in my response the way in which each role, function or responsibility relates to the examples listed in the question. I have done this by ending each point with the associated letter/s in brackets. The roles, functions or responsibilities that I have included at the end of the list do not readily correspond with the examples listed in the question.

37. It might be helpful to mention at this point that there are three hospital transfusion laboratories in NHS Lothian. Those on the WGH and SJH sites are owned and managed by NHS Lothian. The transfusion laboratory on the RIE site is owned and managed by SNBTS. All transfusion laboratories are represented at the LTC. Therefore, when my answer refers to LTC activity relating to NHS Lothian, where this includes laboratory activity, this may involve SNBTS as well as NHS Lothian teams.

    a. Maintenance of awareness of any relevant new or revised national guidance (e.g. British Society for Haematology (BSH); National Institute for Health and Care Excellence (NICE); Serious Hazards of Transfusion (SHOT); Safety of Blood Tissues and Organs (SaBTO)) or standards, and associated translation into information/guidance/policy for staff in NHS Lothian *(this response is relevant to question 8a)*

    b. Maintenance of awareness of any relevant new research or study findings and associated translation into information/guidance/policy for staff in NHS Lothian *(this response is relevant to question 8e)*

c. Authorship, review and maintenance of transfusion-related policies and related procedures and guidance. Core documents include the NHS Lothian Blood Transfusion Clinical Policy and Procedures (NB this is a single document containing the NHS Lothian Transfusion Policy along with the accompanying NHS Lothian Transfusion Procedures), NHS Lothian Major Haemorrhage Protocol, NHS Lothian Satellite Blood Fridge Policy, NHS Lothian Procedure for Managing Red Blood Cell or Platelet Shortages and NHS Lothian Resources for Managing Patients who Refuse Blood (including Jehovah's Witnesses). This list may change over time depending on clinical requirements *(this response is relevant to questions 8b and 8d)*

d. Monitoring of SNBTS and NHS Lothian KPIs and other aspects of clinical and laboratory transfusion practice *(this response is relevant to questions 8d and 8i).* Such measures have included:
    i. traceability of blood components
    ii. blood component usage
    iii. blood component non-usage
    iv. rates of transfusion sample rejection: these are transfusion samples that do not meet defined sample acceptance criteria in the laboratory because of errors or omissions relating to the patient's minimum identification dataset (on sample tube or accompanying request form) and / or problems with the quality of the sample. The transfusion laboratories have very exacting sample acceptance criteria as an important patient safety measure
    v. staff transfusion training
    vi. staff collection competency assessment completion: the UK Blood Safety and Quality Regulations (2005) (BSQR) require all members of staff who are involved in collecting blood components from a laboratory or a satellite blood fridge to have been assessed as competent to undertake this procedure – this is a face to face practical competency assessment undertaken by an individual who has completed recognised SNBTS Blood Collection

Competency Assessor Programme (BCCAP) preparation, which is coordinated by the transfusion practitioners

e. Review and analysis of all SHOT and MHRA reportable serious adverse events, reactions and near misses, with onward escalation of any issues of concern to the NHS Lothian Acute Clinical Management Group. It should be noted that, separate to the LTC, the transfusion practitioners also report the same SHOT and MHRA reportable serious adverse events, reactions and near misses onto an online portal (ServiceNow) where this anonymised data (all patient and staff identifiable information removed) is collated centrally from across NHS Scotland (NHSS) by the SNBTS TT central team *(this response is relevant to question 8h)*

f. Coordination of transfusion-related audit activity in NHS Lothian *(this response is relevant to question 8d and 8i)*. The Committee coordinates NHS Lothian participation in all SNBTS TT national audits: a Scottish National Transfusion Audit Programme has been in existence since 2014, managed by the SNBTS TT. It looks at the use and administration of blood components and it is expected that all Scottish Territorial Health Boards take part in this audit programme. The LTC also considers all invitations for involvement in UK National Comparative Audit of Blood Transfusion (NHS Blood and Transplant) (NCABT) audits, makes decisions as to which are of relevance and value to NHS Lothian and coordinates associated activity for those that are undertaken. The NCABT is a programme of clinical audits which looks at the use and administration of blood and blood components in NHS and independent hospitals in England. NHSS hospitals are also invited to take part. The SNBTS TT actively promote at least one NCABT audit per year, but Scottish Territorial Health Boards can decide which to take part in.

38. The LTC also maintains an overview of local transfusion related audit activity. Examples include audit of notification of irradiated blood requirements for patients in haematology and medical blood use audit.

39. Ensuring role appropriate transfusion education (induction and regular revalidation) is in place for all relevant staff groups and monitoring of same *(this response is relevant to question 8c)*

40. Ensuring a fit for purpose transfusion document is in place. Between 2004 (when I commenced work in NHS Lothian) and 2011, as I recall, the practice in NHS Lothian was that blood components were prescribed on the patient's intravenous fluid infusion prescription chart or anaesthetic chart and any associated clinical documentation was written in the patient's healthcare record. There is also reference to blood components requiring to be prescribed on a dedicated 'blood and blood component / product prescription form' in the 2006 version of the NHS Lothian Blood Transfusion Clinical Policy and Procedures. Since 2011, a dedicated transfusion document 'NHS Lothian Documentation for Transfusion of Blood Components' has been used. This document was initially based on a NHS QIS (2008) risk-assessed record template. It has subsequently undergone several revisions, overseen by the LTC, reflecting developments in national transfusion guidance over the years. This document is used to capture the pre-transfusion discussion, information provision and informed consent process, the written authorisation for blood components, the administration of those components (and associated pre-transfusion safety checklist) and the record of the specific component/s transfused to the patient (part of the UK BSQR traceability requirement). It also includes helpful practical and patient safety advice for clinicians at the bedside and guidance on initial management if a transfusion reaction is suspected.

41. Since 2020 the NHS Lothian Documentation for Transfusion of Blood Components has also included a transfusion associated circulatory overload (TACO) risk assessment tool to be completed by the individual responsible for making the decision to transfuse prior to any components being authorised. TACO is a recognised hazard of transfusion defined by SHOT as 'acute or worsening respiratory compromise and/or acute or worsening pulmonary oedema during or up to 12 hours of transfusion, with additional features including cardiovascular system changes not explained by the patient's underlying medical condition, evidence of fluid overload and a relevant

biomarker'. Some patient groups or those with certain medical conditions are at greater risk. All relevant staff receive education in the assessment of patients to identify this risk, risk reduction methods, swift identification and management of TACO events.

42. In late 2022 NHS Lothian will transition to using a new SNBTS National Transfusion Record (WITN7300015) which performs the same functions as the NHS Lothian Documentation for Transfusion of Blood Components with the advantage that it will be a standardised document being introduced in the majority of Scottish Territorial Health Boards. This is an example of a 'Once for Scotland' approach promoted by SNBTS and designed to improve patient safety via reduction in variation (recognising that staff and patients can move between different organisations) *(this response is relevant to question 8g, 8f and 8j)*

43. Oversight of systems to provide up-to-date transfusion information resources for patients (including parents and carers) and relatives. A core SNBTS patient information leaflet 'Receiving a blood transfusion' is designed for patients for whom transfusion is a proposed treatment and, where applicable, their relatives/parents/carers. The content is revised regularly. The current version of this leaflet is attached (WITN7300006). I do not know when the first version of the SNBTS 'Receiving a blood transfusion' leaflet was introduced: it was already an established resource when I became a transfusion practitioner. The 'Receiving a blood transfusion' patient information leaflet used in NHSS was, until recently, prepared by SNBTS. Since 2021 this leaflet has become a standardised resource prepared by the UK and Ireland Blood Transfusion Network on behalf of the 4 UK Blood Services. A range of other leaflets are available for patients (and parents/carers where appliable) who may have more specialist transfusion requirements (for example those who require irradiated blood components) *(this response is relevant to question 8f and 8j)*

44. Development of guidance for staff when looking after individuals who may refuse to receive blood components *(this response is relevant to question 8j)*

45. Promotion of appropriate transfusion practice and oversight of developments relating to restrictive transfusion practice for appropriate patient groups, including single unit transfusion and promotion of same: the single unit transfusion approach is a patient safety measure designed to tailor a transfusion more closely to the patient's clinical requirement, reduce donor exposure and reduce TACO risk *(this response is relevant to question 8i)*

46. Maintenance of awareness of the work of the SNBTS TT: this ensures the LTC stays abreast of relevant national transfusion developments and related quality improvement initiatives. In addition to providing an overview of national activity for the LTC at each meeting, the transfusion practitioners, along with their colleagues in the central SNBTS TT, compile an annual report outlining SNBTS TT activity nationally, as well as in NHS Lothian specifically: this report is shared with LTC members as well as other key stakeholders in NHS Lothian *(this response is relevant to question 8e)*

47. Maintenance of awareness of relevant clinical effectiveness or quality improvement initiatives being undertaken locally or nationally that have impact on transfusion practice in NHS Lothian, e.g. introduction of standardised SNBTS transfusion education programmes for all undergraduate nurses and undergraduate midwives (using a Once for Scotland approach) *(this response is relevant to question 8e)*

48. Blood saving initiatives and overview of systems supporting alternatives to transfusion e.g. cell salvage *(this response is relevant to question 8f)*

49. Promotion of the principles of patient blood management to clinical users of blood via education, departmental presentations and policy inclusion *(this response is relevant to questions 8f and 8j)*

50. Ensuring clinical staff are aware of changes to blood product guidance e.g. anti D, prothrombin complex concentrate (a blood product containing human prothrombin complex used most commonly for the treatment or prevention of bleeding where there is an acquired deficiency of the prothrombin complex

coagulation factors and rapid correction of the deficiency is required (e.g. emergency warfarin reversal)) and review of / response to any associated clinical practice issues. For example, prothrombin complex concentrate awareness sessions, designed to familiarise staff with product reconstitution technique, led to the development of new guidelines for staff *(this response is relevant to question 8e)*

51. Review of relevant national safety alerts, ensuring communication with clinical teams and development of action plans where applicable *(this response is relevant to question 8i)*

52. Blood component and product availability *(this response is relevant to question 8i),* including, for example:
    a. licensing arrangements (e.g. ensuring representatives remained abreast of changes to licensing arrangements for the use of fibrinogen concentrate over time)
    b. changes to donor testing which can impact on local policy (e.g. hepatitis E virus (HEV) testing of blood components commenced in 2015/16 when there was associated new guidance in place to ensure HEV negative components were ordered for relevant patient groups. The LTC was involved in ensuring policy was updated to reflect this new transfusion 'special requirement' and for ensuring that associated laboratory systems were established. When subsequent standard issue of HEV negative components from SNBTS was introduced (2017) this required the LTC to ensure discontinuation of the systems thus rendered obsolete

53. Review of any issues raised by clinical or laboratory teams regarding emergency protocols (e.g. Major Haemorrhage Protocol, Code Red Protocol) and identification of any required improvement activity *(this response is relevant to question 8e)*

54. Review of issues raised by clinical or laboratory teams or changes to or new guidance relating to any aspect of the blood transfusion procedure, and identification of any required action e.g.

    c. sample acceptance criteria (e.g. patient safety improvements such as increases in stringency of sample acceptance criteria over the years; the transition from 'hospital number' to use of the CHI (Community Health Index) number as the standard unique patient identifier for patients in Scotland)
    d. sample tube design (e.g. local quality improvement initiative involving collaborative work with manufacturer to introduce a more effective paediatric sample tube which had greater surface area, thus enabling clearer patient identification detail documentation)
    e. revised SaBTO guidance on consent in transfusion
    f. revised request forms
    g. patient identification systems
    h. hospital site changes
    i. new service developments

55. Maintenance of awareness of key changes in laboratory practice (e.g. transition to electronic issue of blood); the interface between laboratory information management systems and patient administration systems; electronic blood management systems.

56. Ensuring effective systems are in place to enable NHS Lothian to meet the requirements of the UK BSQR (2005)

57. Maintenance of awareness of local and national blood use via the Scottish Transfusion Epidemiology Database (STED) and, more recently, the SNBTS Blood Bank Dashboard. This enables monitoring of NHS Lothian and SNBTS KPIs and allows the LTC to retain a real time understanding of levels of blood component use (and other pertinent measures) in NHS Lothian

17. 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.

58. In my experience in NHS Lothian, I would suggest that there have been beneficial changes since this document was published. The LTC does fulfil the functions of providing an ongoing assessment of the use of blood components and introducing guidance and policy designed to promote the highest standards of patient care. Additionally, it plays an important, central and active role in all other aspects of the clinical governance structure of NHS Lothian relating to blood transfusion and has a focal role regarding strategic decision making in terms of safe and appropriate blood transfusion practice.

59. I do not agree that the responsibilities of the Committee and to whom it reports are unclear. The responsibilities and reporting arrangements have been laid out in the LTC's written constitution and remit and I cannot recall any occasion where there has been expression of dubiety regarding either lines of accountability or responsibility.

18. 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. DHSC0038527_092 may also assist.

60. My experience of the work of the LTC is that it achieves far more than providing an interface between the laboratory as a provider and clinicians as users of blood components. Whilst this is undoubtedly an important aspect of the Committee's work, its role extends to the full remit of clinical governance activity relating to transfusion. The Committee plays an important strategic decision-making role regarding safe and appropriate transfusion practice in NHS Lothian, ensuring that practice remains abreast of current guidance and standards and promoting a strong learning culture in terms of response to adverse events and near misses experienced in NHS Lothian, as well as those experienced elsewhere in the UK (as informed by the work of SHOT).

61. Via promotion and support of NHS Lothian's active involvement in SHOT reporting, as well as promotion in NHS Lothian of the recommendations that come from SHOT, the LTC remains actively engaged with the wider UK haemovigilance community.

62. The Committee remains in touch with contemporary transfusion practice and the broader clinical environment via the active engagement of representatives from a broad range of blood using areas. The Committee has been well and consistently attended by representatives from a broad range of clinical blood-using areas throughout my experience. The transfusion laboratories are also consistently and well represented, and the Committee has been and remains an effective avenue for communication and information exchange between the laboratories and users of blood.

19. 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].

63. The LTC aims to meet quarterly. Since 2005 when I joined the Committee, this has been achieved in 8 of the intervening 17 calendar years. On average, the Committee has met 3.3 times per annum since I joined. The table below shows meeting dates from 2005 to the time of writing:

Calendar Year	Meetings
2005	June, Oct
2006	Jan, Apr, June
2007	Jan, Apr, Aug, Oct
2008	Feb, May, Sept
2009	Jan, Apr, Sept
2010	Jan, Apr, Aug, Dec
2011	Mar, Jun, Sept, Dec
2012	Mar, Jun, Oct, Dec
2013	Mar, Jun, Sept, Dec
2014	Mar, Jul, Oct
2015	Jan, May, Aug, Nov
2016	Feb, May, Aug, Nov
2017	Apr, Aug, Nov
2018	May, Sept
2019	Mar, Jul
2020	Feb, May, Aug, Dec
2021	Jun, Oct
2022	Feb, June

64. When quarterly meeting achievement has not been possible this is generally due to the need to arrange suitable meeting dates to ensure appropriate and adequate representation.

20. 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.

65. I am able to respond to Question 12 in relation to the period from 2005 onwards.

66. Transfusion education is highly valued, supported, promoted and championed in NHS Lothian at all organisational levels and amongst all professional, and support, groups involved in transfusion practice. Systems of mandatory transfusion education are well established and embedded in the workings of NHS Lothian.

67. It is also the SNBTS TT education strategy to embed an education culture, which is learner-centred and adopts a 'Once for Scotland' approach to transfusion education across all staff groups.

68. I was initially employed as a transfusion practitioner, as part of the BBT Programme in NHS Scotland. This Programme had launched in 2003 and a key component of its remit was to undertake a training needs analysis of all relevant staff in the Scottish Territorial Health Boards and develop associated programmes of safe transfusion practice education. Whilst the training needs analysis had been completed by the time I joined NHS Lothian, I was, and have remained, involved with the subsequent development and maintenance of safe transfusion practice education systems for all relevant staff groups.

69. I have outlined below the mandatory transfusion educational programmes in NHS Lothian that are established for the core staff groups involved in the blood transfusion process. I have shared original training agreements in places to illustrate how such programmes originated. Please note that, whilst systems of transfusion education for all appropriate staff groups remain in place, practical arrangements will have changed over the years. Where educational content has changed, I have alluded to this in the text.

70. Additional tailored education sessions for departments, key staff groups, teams and individuals are provided. Such teaching may be provided in response to a range of circumstances e.g. as an element of learning and improvement following an adverse event or near miss; upon invitation to take part in study days for speciality groups (e.g. major haemorrhage management for nurses attending a Critical Care Liver Study Day); discussion of key updates in blood transfusion practice at departmental meetings.

71. The core suite of learning materials used for induction and regular update for all staff groups is Learnbloodtransfusion (LBT). LBT materials became available in eLearning format in late 2004, prior to which a standard set of materials designed for in-person teaching was used.

72. LBT is an interactive digital education programme available throughout the UK and Republic of Ireland (ROI). The programme aims to provide an evidence based educational resource for practitioners working in transfusion to improve transfusion safety for patients receiving blood components. Originally developed by the BBT Continuing Education Programme (BBTCEP), this programme is now overseen by a LBT Editorial Board of which I am a member. The LBT Editorial Board oversees the LBT workplan with members from the four UK and Irish blood transfusion services contributing to the LBT education agenda. This group reports to the UK and ROI Blood Transfusion Services (BTS) Transfusion Team Network group. The materials cover a wide range of transfusion related topics, including safe transfusion practice, consent for transfusion, blood components and reaction management. LBT is

recommended by SHOT, NHS Quality Improvement Scotland (now NHS Healthcare Improvement Scotland), the Scottish National Blood Transfusion Committee (SNBTC) and is supported by the UK Blood Services.

73. The BBTCEP was established by the SNBTS Effective Use of Blood (EUB) Group, which pre-dated the BBT Programme (subsequently SNBTS TT) in Scotland. I believe the EUB Group formed in 1998.

74. The suite of LBT modules and contents features in Learnbloodtransfusion – The Essential Guide (WITN7300007) (NB since this document was published the clinical and laboratory anti D module contents have been amalgamated, and there have also been important changes to LBT access arrangements in some parts of the UK, but the document still provides a broad overview of LBT module content used in NHSS).

75. The core LBT module that is completed as a mandatory requirement by any member of staff involved in any aspect of the blood transfusion process is LBT *Safe Transfusion Practice.* LBT *Safe Transfusion Practice* material covers haemovigilance; ABO and D serology; the decision to transfuse/discussion with patient/informed consent requirement; taking transfusion samples and requesting blood components; collection of blood components; administration of blood components; monitoring patients receiving blood components and management of transfusion reactions.

76. The agreed frequency of LBT module refresher education in NHSS is two-yearly.

Doctors in Training

77. LBT *Safe Transfusion Practice* education has been a mandatory requirement for all junior doctors in NHS Lothian since 2005. The attached joint training agreements (between NHS Lothian and BBT) from 2005 (WITN7300008) and 2008 (WITN7300036) describe the establishment and early evolution of transfusion educational arrangements for this group in NHS Lothian. An

established programme of transfusion training for pre-registration house officers (as previously called, now foundation year one (FY1) doctors) and some groups of senior house officers (as previous called, now foundation year two (FY2) doctors), coordinated by the post – graduate education centre / educational supervisors, was in existence prior to February 2005. I am unable to state when this prior teaching arrangement had commenced.

78. The letter provided for FY1 doctors at induction into NHS Lothian in 2022 (WITN7300037) describes the most up to date mandatory transfusion eLearning arrangements for this group.

79. Over time, mandatory education content for doctors in training has expanded. LBT *Blood Components and Indications for Use* (covering blood components, their uses and indications; adverse events; blood component use in major haemorrhage) has been incorporated since 2007.

80. In line with the SNBTS Training Matrix (WITN7300013) mandatory education content for doctors in training now also includes LBT *Consent for Transfusion*, LBT *Acute Transfusion Reactions* and LBT *Safe Blood Sampling for Transfusion*. These three important aspects of transfusion practice have always been included in the LBT *Safe Transfusion Practice* module but these additional modules provide a much greater depth of learning.

81. The SNBTS Training Matrix is one element of a Once for Scotland approach to transfusion education for all staff involved in transfusion which recommends mandatory LBT module content aligned to staff roles. This approach is endorsed by the SNBTC (previously Scottish Clinical Transfusion Advisory Committee (SCTAC)) and the LTC.

82. Induction education for FY1 doctors entering NHS Lothian has also included an additional practical clinical skills workshop since 2013, which covers safe transfusion sampling technique, information provision about risks and benefits of transfusion, discussion with the patient prior to transfusion, the gaining of

informed and valid consent regarding transfusion, and correct documentation of transfusion.

83. The responsibility for monitoring compliance with mandatory transfusion education for doctors rests with the medical education directorate in NHS Lothian.

Consultants and Speciality and Associated Staff (SAS) Grade Doctors

84. LBT *Safe Transfusion Practice* education has been a mandatory element of the appraisal process for consultants and speciality and associated staff (SAS) grade doctors working in applicable clinical areas since 2008. I attach a letter sent to all consultants and SAS grade doctors in 2008 from the director of medical education at the time describing this inclusion (WITN7300009). LBT *Blood Components and Indications for Use* has subsequently been included for this group. This is predominantly achieved via eLearning (with some in-person teaching for some departments in previous years).

85. I am unable to describe the transfusion-related education that may have been in place for these groups prior to this date.

Registered Nurses, Midwives and Operating Department Practitioners (ODPs)

86. LBT *Safe Transfusion Practice* education has been a mandatory requirement for all nurses, midwives and operating department practitioners (ODPs) working in applicable clinical areas since 2005. An established programme of induction transfusion education for this group was in existence when I joined NHS Lothian. In 2005 a joint training agreement (between NHS Lothian and BBT) established a 'train the trainer' system to develop a team of local transfusion trainers to provide regular LBT transfusion education for nurses, midwives and ODPs, as well as clinical support workers and phlebotomists, in NHS Lothian (WITN7300038) A subsequent training agreement reflecting the evolution of arrangements for transfusion education of these groups followed in 2008 (WITN7300010). Induction sessions were delivered face to face until early

2020, when the COVID-19 pandemic prompted a move to eLearning for induction. eLearning is used for two-yearly updates. The responsibility for monitoring compliance with mandatory training for these groups rests with an individual's line manager and is monitored as part of the annual appraisal process. The attached letter for registered nurses, registered midwives, operating department practitioners - Virtual Induction April 2020 (WITN7300039) describes the most up to date mandatory transfusion educational arrangements for these groups.

87. Nurses, midwives and operating department practitioners working in some settings or in some roles may be required to undertake additional mandatory transfusion education (for example, advanced nurse practitioners who have undertaken the required programme to be able to authorise blood components). Midwives complete the LBT *Anti D* module as part of their mandatory programme of transfusion learning.

Healthcare Support Workers

88. Please see reference in section above 'Registered Nurses, Midwives and ODPs' regarding training agreement in place for this group, which also includes phlebotomists. Please note healthcare support workers were previously known as clinical support workers.

Porters

89. Whilst I have evidence of transfusion education being provided for porters in NHS Lothian dating back to 2007, LBT *Safe Transfusion Practice* education (role-specific elements) has been a formal mandatory requirement for porters involved in the transport and delivery of blood components since 2010 when joint (NHS Lothian and BBT) site training agreements for each applicable site were established. I have included one such example as part of my response (WITN7300011). Education for this group has predominantly been achieved via in-person teaching with updates required every two years.

90. I am unable to describe the transfusion-related education that may have been in place for this group prior to this date.

Biomedical Scientists (BMS) and Biomedical Support Workers

91. A joint (NHS Lothian and BBT) training agreement covering mandatory LBT *Safe Transfusion Practice* education for biomedical scientists involved in blood transfusion was established on the SJH and WGH sites in 2006. A subsequent overarching training agreement covering both laboratory services in NHS Lothian (the WGH and SJH transfusion laboratory service is managed by NHS Lothian; the RIE transfusion laboratory service is managed by SNBTS) was established in 2011 (WITN7300012). This group also undertakes LBT *Good Manufacturing Practice for Blood Banks*.

92. This learning is designed as an addition to the transfusion science education that is a fundamental aspect of preparation for the BMS role. I am unable to describe any other additional transfusion-related education that may have been in place for this group prior to 2006.

Undergraduate medical, nursing and midwifery students

93. Transfusion education is an important, valued and well-established component of undergraduate medical, nursing and midwifery education in the East of Scotland region, supported by all associated Higher Education Institute partners.

94. LBT module content for medical students in the region aligns with the SNBTS Training Matrix. Education for medical students in South-East Scotland was revised in 2016, when a clinical skills simulation education model was adopted. This incorporates several scenarios including a conversation with a patient prior to transfusion and discussion of risks, benefits, and alternatives to transfusion; recognition and response to a transfusion reaction and safe transfusion sampling technique.

95. As part of its 'Once for Scotland' approach to education, the SNBTS TT have recently developed and launched national transfusion education programmes for undergraduate nurses and undergraduate midwives which align with the SNBTS Training Matrix and provide resources for both transfusion theory and practical skills development.

96. Transfusion education developments, changes, challenges and issues are brought to the attention of the LTC, where they are discussed and any required actions identified and overseen. Actions might involve, for example, approaching the relevant education team (e.g. medical education team, clinical education team) to work collaboratively to resolve issues of concern or, if there are repeated or unresolved issues of concern, this might result in escalation to the NHS Lothian Acute Clinical Management Team.

21. 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?

97. In my experience, the relationship between the LTC and blood-using hospital departments has been very effective, and this has remained consistent throughout my employment as transfusion practitioner. Meetings are well attended and allow opportunity for healthy discussion and debate. Membership remains dynamic and opportunities are made available for non-members to attend one-off meetings to discuss a specific clinical issue, where appropriate.

98. Relevant clinical transfusion issues have been brought to the Committee's attention via a variety of routes, e.g. directly by department representatives in attendance, via direct communication by clinical or non-clinical staff with the Chair or members of the Committee and through adverse incident reports. In

my experience, any guidance or instruction issued from the LTC is given due credence and acted upon.

99. In addition to the above-mentioned methods that have allowed the Committee awareness of transfusion-related decisions being made in departments, the Committee also requests that any locally developed blood transfusion *procedures* or *guidance* be submitted to the Committee for review and agreement. The aim of this oversight has been to monitor compliance with existing policies and to ensure that all appropriate governance arrangements associated with new transfusion developments have been addressed and that proposals are in line with evidence and best practice in terms of safe and effective transfusion practice.

100. I would suggest the greatest challenge in this regard, particularly in a very large organisation with significant numbers of staff, teams and clinical settings, is remaining assured of timely communication of plans for the development of new local procedures to the Committee. The broad representation on the Committee does help to achieve this. If a new local procedure relating to transfusion is identified as being in development, this will be brought to the attention of the Committee, with associated communication with the author.

101. Any new *policy* in the organisation (including any new transfusion policy) must also be submitted to the NHS Lothian Policy Approval Group, as part of its formal ratification process.

102. As part of the 'Once for Scotland' approach, the SNBTS TT has developed a Scotland-wide National Transfusion Policy which is available for Scottish Territorial Health Boards to adopt. The LTC has decided to incorporate this policy (WITN7300014), which will be supplemented with detail regarding NHS Lothian transfusion procedures. The resulting amalgamated document will be submitted, as for all other new policies, to the NHS Lothian Policy Approval Group for ratification.

103. As the transfusion laboratory at RIE is managed by SNBTS, their standard operating procedures are developed and agreed by SNBTS nationally. The LTC serves an important function in that it allows an opportunity for discussion around the differences that might arise between SNBTS and NHS Lothian laboratory procedures, particularly those which may change how clinical staff on different sites have to act. Wherever possible, the LTC works to minimise cross site differences: this is done through discussion, collaboration and exploring the best way forward. There is SNBTS and NHS Lothian laboratory representation at the LTC and the relationship between these parties is positive. A standard approach is not always feasible but changes have been made by both NHS Lothian and SNBTS in the past, to achieve this aim whenever possible.

22. 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].

104. The Information for Hospital Transfusion Committee Chairs and Consultant Transfusion Leads (WITN7300016) is a document created by SNBTS and updated annually. SNBTS disseminates this document to relevant stakeholders in the Scottish Territorial Health Boards. It describes the role of the Scottish National Blood Transfusion Committee (SNBTC) and its relationship with the HTCs.

105. The SNBTC is a multidisciplinary committee accountable to Scottish Government as well as being represented on a number of transfusion-related UK bodies.

106. SNBTC is a forum for HTC chairs or their alternates to discuss and agree matters of organisational and strategic importance to clinical transfusion practice within Scotland. SNBTC is supported by SNBTS who provide administrative support and subject matter expertise. SNBTC also provides oversight of the daily work and national outputs of the SNBTS TT.

107. The precursor to the SNBTC was SCTAC. The change of this Committee's name occurred in 2021. I am unable to state when SCTAC was formed, but I have documentation relating to its existence and activity at least back to April 2009.

108. There is a note in the LTC minutes from a meeting in 2007 about the SNBTS Clinical Users Group being wound up and emerging under a new name. At that time one of our BBT lead clinicians in Lothian (also a member of the LTC) was a member of that group. It is likely that this is when this group was renamed as SCTAC, but I cannot confirm this.

109. LTC minutes describe SCTAC minutes and newsletters being circulated to LTC members and feedback to SCTAC from the LTC.

110. The SNBTC (/SCTAC) issues requests, advice or guidance to the Scottish Territorial Health Boards and HTCs that is of a collective national nature. Examples have included:

- Recommendations from the National Patient Safety Agency (NPSA) (now NHS Improvement) Rapid Response Report 2010 (regarding the transfusion of blood and blood components in an emergency (NPSA/2010/RRR017), (WITN730017) were addressed via the development of a NHSS Major Haemorrhage Template (WITN7300018), which was developed by, and disseminated via, SCTAC to NHSS HTCs
- 2015 SCTAC position statement on the introduction of a blood group check policy across Scotland and recommendation for Scottish Territorial Health Boards to consider its introduction communicated to NHSS HTCs

111. Guidance issued by SNBTC (/SCTAC) has been brought to the attention of the LTC by the LTC Chair or by the SNBTS transfusion practitioners. Relevant SNBTC (/SCTAC) communications are issued to key members of local transfusion teams, including the Chair and transfusion practitioners, as well as key stakeholders in the Scottish Territorial Health Boards (e.g. chief executives, medical director, nurse director, clinical governance lead).

112. There have been opportunities for contribution to SCTAC / SNBTC via direct attendance by a LTC representative or via communication with SCTAC / SNBTC members.

113. From memory, there has been reasonably consistent representation of the LTC at SCTAC / SNBTC, usually via attendance by one of our (previously titled) BBT lead clinicians or the Chair of the LTC.

114. A representative of the SCTAC / SNBTC, for example the SNBTS transfusion medicine consultant, has been a consistent member of the LTC.

115. In 2012 SCTAC commenced a programme of national annual education meetings which has since allowed opportunity for interaction between SCTAC/SNBTC, Scottish Territorial Health Board transfusion teams, clinical and laboratory staff and SNBTS TT to meet and share ideas and developments both from a SNBTC and Board perspective.

23. 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?

116. There has always been a close working relationship between the LTC and the SNBTS.

117. In NHS Lothian, one transfusion laboratory (based at RIE) is owned and run by SNBTS and two transfusion laboratories (based at WGH and SJH) are owned and run by NHS Lothian. LTC membership therefore reflects both SNBTS and NHS Lothian in terms of laboratory and senior haematology / transfusion medicine staff.

118. The two transfusion practitioners based in NHS Lothian are SNBTS employees. They are responsible for maintaining an up-to-date list of key stakeholders in NHS Lothian (e.g. chief executive, LTC Chair, medical and nursing directors, clinical governance lead, transfusion team members etc) and this is used by the SNBTS TT (central team) to issue important communications.

119. The positive relationship between the LTC and SNBTS has remained consistent throughout my employment as transfusion practitioner. I would suggest one relevant change that occurred during this time was associated with the review of the SNBTS TT that concluded in 2019 (as described in my response to Question 2). The role of the transfusion practitioner was revised as

part of this process and this involved the required transfer of some role responsibilities from the SNBTS transfusion practitioner to NHS Lothian colleagues. This therefore resulted in some transition of responsibilities amongst LTC members.

24. 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.

120. Transfusion laboratory managers (both SNBTS and NHS Lothian) are core members of the LTC and the relationship is a positive and constructive one. Committee matters are equally concerned with both clinical and laboratory issues, illustrating a beneficial multidisciplinary approach to the work of the Committee.

25. 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?

121. I am unable to answer this question as I only have experience of the LTC from 2005 onwards.

Section 3: Policy and Standard Practice

18. 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.

122. I am only able to answer this question in relation to the period 2005-2010 (i.e. from the date I joined the LTC to the end of the period in question).

123. The nature of the meeting means that the majority of LTC discussions during this period would have been directly or indirectly related to the four main blood components that are used (red cell concentrate, fresh frozen plasma, platelets and cryoprecipitate) and, where necessary, blood products (such as anti D).

124. I have reviewed the LTC minutes covering this period to identify the sources that informed the LTC's knowledge regarding blood component (red cells, platelets, plasma, cryoprecipitate) and product (manufactured from human blood or plasma) use, the circumstances in which they were used and how this may have changed over time, and summarise this information below. Please note, this is in addition to LTC members bringing clinical transfusion experience from their own speciality, which is an equally important way that the LTC uses to remain informed of how blood components and products are being used by clinical teams in NHS Lothian.

- discussions relating to audit data (e.g. 2009 discussion of red cell use in post-partum setting conducted to support introduction of an obstetric transfusion pathway designed in part to reduce exposure to red cells)
- policy development and review (e.g. Surgical Blood Ordering Schedule (SBOS) revision, involving discussion regarding surgical blood use, with relevant clinical groups e.g. orthopaedics, obstetrics, urology, colorectal, vascular, trauma)
- examination of incident and reaction reports relating to red cells, platelets, FFP, cryoprecipitate (rare, due to the low volume of cryoprecipitate used in relation to other blood components) and blood products, such as anti D
- review of component wastage events
- preparation for NHS QIS standards peer review
- reviews of Major Haemorrhage Protocol (MHP) activations
- examination of availability and patterns of use of specific blood products
- examination of transfusion activity in specific settings (e.g. community and outlying areas)

- discussion regarding blood conservation strategies: at a meeting in 2008 it was noted that the majority of blood conservation activity to date had been carried out in theatre/surgical settings but that it was recognised that medical blood use remained higher (in relation to surgical blood use). It is worth noting here that, in the early days of BBT, most blood conservation strategies were directed at surgical blood use. Transfusion in a surgical setting is generally associated with bleeding so techniques to minimise bleeding (e.g. surgical techniques) or to provide an alternative to allogeneic blood transfusion (e.g. intraoperative cell salvage) can be effective at reducing exposure to donated blood. Following significant advances in blood conservation in this setting, attention was turning to the issue of medical blood use. The majority of blood conservation strategies used in the surgical setting do not readily translate to the medical setting and, whilst some important alternatives to component transfusion in the medical setting were available and advised at this time (e.g. iron replacement therapy for iron deficiency), options for reducing blood use or alternatives to transfusion were more limited. Decisions regarding transfusion in a medical setting require consideration of a range of factors which at times can be complex and nuanced. Therefore I suggest that the LTC's recognition that blood use in the medical setting remained 'high' (in comparison with surgical blood use) reflected a situation that was apparent in other healthcare organisations at that time (and was not exclusive to NHS Lothian). As evidenced by a discussion at the same meeting about work that was being done at the time in the gastrointestinal unit regarding transfusion indications for non-life-threatening bleeding, it is apparent that the LTC was working to support and identify ways in which the challenge of reducing blood use in a medical setting might be addressed.

125. It is also important to note that, since this time, much has been achieved in terms of reductions in red cell use in medical settings, where this is safe and appropriate for patients. A significant driver for this has been the evolution of a more restrictive approach to transfusion which has been guided by an emerging clinical evidence base.

- review of Scottish Transfusion Epidemiology Database (STED) reports and discussion regarding a recognised reduction in red cell use in NHS Lothian between 2002 and 2007.

126. STED is managed by the SNBTS central TT. In Scotland up-to-date national information on the stocking and clinical use of blood components is provided by the SNBTS data marts Account for Blood (AfB) and the STED. A data mart is a subject-orientated database which is a subset of a data warehouse. AfB securely collects systematic, validated data from hospital blood bank laboratory information systems (LIMS) on a daily basis. The data is linked and stored in a SNBTS corporate data warehouse. Healthcare data for individual patients in Scotland is collected as a series of Scottish Morbidity Records (SMR). SMR01 records relate to general/acute inpatient and day-case hospital activity. AfB data is linked with inpatient SMR01 episode records to form STED. Initially STED covered only major blood-using surgical procedures, but was expanded in 2021 to include all medical indications. Data is used to produce information dashboards for hospital blood banks and clinical teams that set out local and national blood use. Information is also provided in response to data requests by SNBTS and NHSS colleagues, in support of audit and quality improvement initiatives. SNBTS apply the NHS National Services Scotland Information Service Division (ISD) Statistical Disclosure Control Protocol when generating and releasing data.

127. A traceability system, involving procedures in both the transfusion laboratory and wards/clinical areas designed to obtain and maintain, for 30 years, a record of "unambiguous traceability" of all blood and blood components from donor to patient and vice versa or final fate if not transfused was introduced across NHS Lothian between late 2005 and early 2006, as required by the launch of the UK BSQR (2005). Traceability compliance is routinely monitored by the LTC and this also provides accurate monthly data on the number of red cells, platelets, fresh frozen plasma and cryoprecipitate that are being transfused in NHS Lothian. WITN7300034 shows the blood component transfusion data that the transfusion practitioners collate, drawing data from LIMS traceability data and the SNBTS Blood Bank Dashboard. The report

shows how many red cell, platelet, FFP and cryoprecipitate components have been transfused in NHS Lothian each month. This information is reviewed at each LTC meeting and allows the Committee to monitor monthly blood component use as well as annual trends.

19. 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.

128. Multiple maximum surgical blood ordering schedules (MSBOS) have been used by NHS Lothian hospitals in the past but, in terms of its original function, this is now a largely outdated resource. Initially these were designed for use primarily in elective surgery. The only exception to this was the 2008 Lothian-wide version which added a section regarding emergency/trauma events.

129. I have copies of a WGH MSBOS dated August 2005, a RIE MSBOS dated June 2006 and a MSBOS for the Department of Clinical Neurosciences (DCN) dated August 2005.

a. I cannot state whether these were the first versions.
b. A new amalgamated Lothian-wide MSBOS was published on the NHS Lothian intranet in February 2008 (this covered pre-operative arrangements in RIE, WGH and SJH). This schedule was revised in

2013 (at this time it was renamed the Surgical Blood Ordering Schedule (SBOS)) and in 2016.

c. A paediatric MSBOS was developed later and was launched in the 2014/15 financial year.

d. I attach copies of all (M)SBOS documents referred to above exhibits: WITN7300020, WITN7300021, WITN7300022, WITN7300023, WITN7300024. WITN7300025 and WITN7300026.

130. The purpose of the MSBOS was to guide medical staff and pre-assessment clinic teams in pre-operative preparations, to ensure suitable blood availability for a patient if they required transfusion intra-operatively. It was originally designed to feature the suggested number of red cell units that should be crossmatched in preparation for a certain surgical procedure (a clinician could always adapt a request for a patient considered more likely to bleed, for example).

131. When I first joined NHS Lothian, these documents were generally available in hard copy in doctors' offices in appropriate clinical areas. In 2008 the document was made available via the NHS Lothian intranet.

132. The introduction of more automated methods of blood issue from the laboratories (e.g. electronic issue, designed to enhance patient safety as well as efficiency of blood issue) gradually diminished the value of the MSBOS. If a patient is suitable for an electronic issue of blood, there is no requirement for components to be 'put aside' prior to surgery, as these can be made available swiftly as and when required by the theatre/surgical team. The volume of transfusion is tailored to the patient's clinical requirement at the time. Individualised plans for patients not suitable for electronic issue are communicated between laboratory and clinical areas. Electronic issue of blood components is now practiced in all transfusion laboratories across NHS Lothian. Over the years the (M)SBOS has been increasingly used purely as a guide as to which surgical procedures prompt the requirement to take a pre-operative transfusion sample. The LTC decided in May 2020 that the current

SBOS will therefore be discontinued and replaced with specific guidance regarding appropriate pre-operative group and screen sampling practice.

20. 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:

How did the HTCs at the Hospitals operate to standardise or enable the above practices? If the HTCs did not, why not?

a. The nature and frequency of patient observations

133. Instructions to staff on observing patients, which vital signs to measure (e.g. blood pressure, temperature, respiratory rate, heart rate) and the frequency with which this should be done before, during and following a blood component transfusion have been detailed in the NHS Lothian Blood Transfusion Clinical Policy and Procedures since I have been in post. This instruction is reinforced in mandatory LBT *Safe Transfusion Practice* education for all relevant staff. A dedicated transfusion document (the NHS Lothian Documentation for Transfusion of Blood Components) also provides guidance for staff regarding the nature and frequency of observations before, during and after a transfusion episode.

134. This document is also used by the clinician who makes the decision, alongside the patient, to transfuse, in order to document their discussion with the patient and his / her provision of informed consent prior to transfusion; by the clinician who authorises the blood component/s to document their instruction to transfuse and by the clinicians who administer the blood component to complete the pre-transfusion safety checklist and to document the confirmed transfusion. The safety checklist incorporates a check to confirm completion of appropriate patient observations associated with each component.

135. This paper document is stored in the patient's healthcare record. At the end of the care episode it is scanned to become part of the patient's electronic healthcare record.

b. Who wrote local policies

136. Since I have been in post, transfusion policies have been written by LTC members, in collaboration with clinical and laboratory teams.

c. The need for two signatures to confirm adequacy of the checking procedure

137. Upon review of the document being referred to in this question, my understanding is that this point relates to obtaining two signatures from those individuals involved in the pre-administration checks (rather than two signatures at the point of collecting blood from a transfusion laboratory or satellite blood fridge). It has been, and remains, NHS Lothian policy for two individuals to be involved in the pre-administration checks prior to the transfusion of every blood component, thus two signatures are obtained as part of this procedure. This requirement is reinforced in mandatory LBT *Safe Transfusion Practice* education for all relevant staff.

d. The use of wristbands for patient identification

138. Since I have been in post it has been NHS Lothian policy that the patient's identification band has been used as the source of patient identification for inpatients and day-case patients.

139. Accurate patient identification is fundamental to safe transfusion practice. I have therefore, along with HTT colleagues, been involved in discussions regarding patient identification band use over the years. The LTC has coordinated audits in NHS Lothian that have looked at patient identification

band use and the transfusion practitioners have contributed to reviews of NHS Lothian patient identification policies.

140. At an LTC meeting in 2013 the Chair reported a meeting that he and the two transfusion practitioners had had with the associate medical and nursing directors for the acute division (now 'service') regarding patient wristband identification. Routine audit arrangements for the correct use of identification bands were discussed at this meeting. A system of self-audit by clinical areas had been established and the transfusion practitioners had arranged access to the resultant data. It was agreed that this data would be shared with the LTC.

141. The quality of patient identification bands was improved in 2013 when electronic printed identification bands replaced hand-written identification bands, a development supported and welcomed by the LTC.

142. A check to make sure that the patient's identification band is present, correct and legible is built into the transfusion procedure at all stages where patient identification checks are of central importance (taking transfusion samples, collecting blood and administering blood components). This check involves the clinician (or two clinicians, as required at the point of administration) performing positive patient identification i.e. asking the patient to state their name and date of birth and matching this information against the patient's identification band and any other associated paperwork. Staff are instructed to stop at this point and resolve any apparent discrepancy or problem with the patient's identification band before progressing.

143. Additional procedures are defined in the NHS Lothian Blood Transfusion Clinical Policy and Procedures for those occasions when a patient may not be able to state their own name and date of birth (i.e. confused, unconscious, babies and young children). Additional procedures include, for example, confirmation of patient identity with a second member of staff or attending parent or carer.

144. The NHS Lothian Blood Transfusion Clinical Policy and Procedures describe the agreed method for identifying outpatients and clinic patients who will not be wearing an identification band (for the purposes of pre-transfusion sampling). This involves asking the patient to state their name and date of birth, confirming this matches the full identification dataset on the patient's healthcare record and using this source to label the patient's blood sample before leaving the patient's side. The policy states that the sampler must not have any other patient's healthcare record with them at the time of taking a transfusion sample.

e. The need for a doctor to be present during transfusion

145. Since I have been in post it has never been a policy requirement that a doctor remains present during a transfusion. Registered nursing/midwifery/operating department practitioner staff remain present during a transfusion and are educated to be able to administer and monitor transfusions and respond in the event of a transfusion reaction. An important part of responding in the event of a suspected transfusion reaction is to alert a medical member of staff. Therefore there is a requirement for suitable medical cover to be in place, with a clinician available, in any setting where transfusions may take place. The LTC has been involved in discussions with service managers and senior medical staff regarding this aspect of governance in the past (for example, when new transfusion services in non-acute settings have been developed).

f. The action to be taken in the event of a transfusion reaction.

146. Since I have been in post, the action to be taken in the event of a transfusion reaction has been defined in the NHS Lothian Blood Transfusion Clinical Policy and Procedures This is reinforced in mandatory LBT *Safe Transfusion Practice* education for all relevant staff.

21. 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.

147. Broad generic guidance has been provided for all clinical staff via the NHS Lothian Blood Transfusion Clinical Policy and Procedures, which are authored by the LTC. Clinicians are routinely referred to the transfusion guidance available from the British Society for Haematology (BSH), SHOT and the Handbook of Transfusion Medicine (a publication of the UK Blood Services). Since 2016 the NHS Lothian Blood Transfusion Clinical Policy and Procedures have referred all clinicians to the NICE Blood Transfusion Guideline (NG24) and specifically incorporate NG24 recommendations for red cell transfusions (supporting a restrictive transfusion approach for patients who are not actively bleeding).

148. Transfusion guidance for clinical staff caring for specific patient groups is also issued by relevant professional bodies, for example the Royal College of Obstetricians and Gynaecologists (RCOG), the Association of Anaesthetists (AAGBI), the Royal College of Surgeons (RCS)), the Royal College of Physicians (RCP) as well as the BSH.

149. Examples of additional specific guidance that has been provided are detailed below.

a. Obstetrics;

150. The LTC contributed to discussion regarding a transition to a more restrictive transfusion approach in post-partum care, a piece of work led by the LTC obstetric representatives (2009).

b. Trauma and emergency care;

151. The LTC contributed to discussion regarding the development of the Code Red Protocol (rapid provision of blood components activated before or upon arrival at hospital for trauma patients experiencing major haemorrhage), a piece of work led by the LTC emergency medicine representative (2014).

152. The LTC coordinated NHS Lothian's involvement in national Scottish and UK audits of major haemorrhage protocol activations and management of major haemorrhage (2014 and 2018 respectively): the recommendations were shared with emergency and haematology department stakeholders, site HTTs and incorporated into educational sessions with relevant clinicians.

c. Surgery;

153. The maintenance of a (M)SBOS by the LTC involved liaison with all blood-using surgical teams and resulted in guidance (issued/revised in 2005/06, 2008, 2013 and 2016) regarding anticipated blood requirements in the event of bleeding.

154. STED surgical blood use reports have been shared with surgical teams which has allowed overview of local blood use practice and opportunity to benchmark against other comparable organisations (for example other Scottish Territorial Health Boards undertaking comparable type and complexity of surgical procedures), to stimulate discussion and review of local practice.

155. The LTC coordinated NHS Lothian's involvement in a national UK audit of patient blood management in scheduled surgery which was led by a LTC anaesthetic representative: the recommendations were shared with anaesthetic stakeholders and site HTTs.

d. Haematological malignancies;

156. The LTC coordinated NHS Lothian's involvement in the national UK audit of platelet use in haematology: the recommendations were shared with haematology stakeholders.

157. Detailed transfusion guidance is available for clinicians caring for patients with haematological malignancy in the NHS Lothian intranet haematology department pages.

e. Thalassaemia; and

158. Management guidelines for adult patients with thalassaemia (Scottish Paediatric and Adult Haemoglobinopathy Managed Clinical Network) are available for all staff via the NHS Lothian intranet. A link to the Scottish Paediatric and Adult Haemoglobinopathy Network paediatric protocols and guidance is provided in the child health policy page on the NHS Lothian intranet.

159. Clinical staff are also routinely directed to BSH guidance and the guidance contained within the Handbook of Transfusion Medicine (this is reinforced at all transfusion induction and two-yearly updates for appropriate staff groups) – both of which provide guidance on the transfusion of patients with thalassaemia.

f. Sickle Cell Anaemia.

160. On behalf of the LTC, the new SNBTS patient information leaflet 'Information for patients with sickle cell disease who may need a transfusion' (WITN7300027) has recently been disseminated to appropriate teams.

161. Management guidelines for adult patients with sickle cell disease (Scottish Paediatric and Adult Haemoglobinopathy Managed Clinical Network) are available for all staff via the NHS Lothian intranet. A link to the Scottish Paediatric and Adult Haemoglobinopathy Network paediatric protocols and guidance is provided in the child health policy page on the NHS Lothian intranet.

162. Clinical staff are also routinely directed to BSH guidance and the guidance contained within the Handbook of Transfusion Medicine (this is reinforced at all transfusion induction and two-yearly updates for appropriate staff groups) – both of which provide guidance on the transfusion of patients with sickle cell disease.

22. 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?

163. Review of all serious adverse events, near misses and serious transfusion reactions that occur in NHS Lothian has remained a standing agenda item at each LTC, at least since I have been a member. Any incident involving a failure to comply with policy is managed within the relevant clinical team, often with the involvement of the transfusion practitioner in their capacity as subject matter expert, but the senior clinical team remains responsible for the event and any required corrective and preventive action.

164. Preventive and corrective actions are shared with the LTC. If the LTC decides that further action is required, it will be agreed by the Committee how this is to be undertaken and who in the organisation should be involved/informed. Any unresolved issues or trends of concern are escalated to the NHS Lothian Acute Clinical Management Group. This group is co-chaired

by the acute nurse director and the acute medical director and feeds into the NHS Lothian Healthcare Governance Committee.

165. The LTC actively promotes a safety culture. Staff are encouraged and supported to report any transfusion-related near miss event or actual adverse event to allow learning and improvement to occur. This approach is supported and championed at all levels in NHS Lothian.

166. Transfusion incident investigation aims to focus on all contributory factors that may have resulted in a near miss or actual adverse event. A human factors approach is taken, as promoted by SHOT. The term 'human factors' relates to how a human interacts with processes, systems, equipment and the environment. The SNBTS TT provide a suite of investigation tools that are available for clinical teams and HTTs across NHSS, to guide appropriate and thorough investigation of all serious transfusion events and near misses. These resources are designed around human factor principles to allow a full understanding of incidents and thus greater opportunities for improvement.

23. 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.

167. At least since I have been in post, unnecessary transfusion has been a SHOT reportable event and, as such, clinical and laboratory teams have been guided to complete an incident report if such an event is identified. This event would be followed up with the relevant clinical team as required, with associated review by the relevant site HTT, review by the LTC and reported to SHOT.

168. In my experience, unnecessary transfusion events may also come to light through other routes, for example through discussion with clinical teams, audit findings and feedback from laboratory staff. The transfusion practitioner and their HTT colleagues are well placed to use this as a prompt to discuss appropriate transfusion with relevant clinical teams and incorporate feedback into appropriate educational opportunities. Events that meet SHOT reporting criteria will be reported as such and reviewed at the LTC. Such events are also discussed at site HTT meetings. Important learning points are shared at LTC meetings and disseminated as appropriate.

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

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

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

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

iii. Autologous transfusion

iv. Single-unit transfusion

v. Fresh-warm blood transfusion

vi. Knowledge of risk of transfusion related infections

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

169. I am unable to respond to this question as I was not in post at the time of the issue of this health service circular and subsequent discussions and actions identified by the LTC.

170. This circular was for the attention of Health Trusts in England (I do not know if this was also for the attention of Health Trusts in Wales and Northern Ireland). In Scotland, the corresponding document was NHS MEL (1999) 9 (WITN7300028).

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

171. In my experience, and from memory, occasions where recommendations of the LTC have not resulted in action are rare.

Haemoglobin level

26. A Scottish Working Group on Blood and Blood Products in 1992 [SCGV0000004_007] noted that patients with a haemoglobin count of <10 g/d would require a blood transfusion. However, in the SHOT annual report 2005 [SHOT0000013] it states that, '*In general, the published data indicates that in adults, red cell transfusions will usually be required when the haemoglobin level is <6 g/dl, and will rarely be required when it is >10 g/dl. Comparative studies in adults with haemoglobin levels within the range of 6 - 10 g/dl have not shown red cell transfusions to improve outcome in surgical and intensive-care-unit (ICU) patients*'. What did the HTCs understand to be the level at which a patient required transfusion and how did this change over time? Was guidance provided to clinicians at the time, and updated guidance once the HTCs became aware of any clinical change?

172. Since I have been in post, the LTC has always recommended use of the blood component use guidance provided by the BSH (www.b-s-h.org.uk) and The Handbook of Transfusion Medicine (www.transfusionguidelines.org.uk).

173. BSH guidance is available for different patient groups and has been revised over the years. To provide one example, the BSH guidelines on the management of anaemia and red cell transfusion in adult critically ill patients (2012) recommends that 'a transfusion threshold of 70 g/L or below, with a target Hb range of 70–90 g/L, should be the default for all critically ill patients, unless specific co-morbidities or acute illness-related factors modify clinical decision-making (evidence Grade 1B)' and 'Transfusion triggers should not exceed 90 g/L in most critically ill patients (evidence Grade 1B)'. Archived BSH guidelines are accessible on the BSH website.

174. The Handbook of Transfusion Medicine has been revised over the years. The 5th edition (2013) provides guidance for transfusion in surgery, critical illness, major haemorrhage, medicine, haemoncology, obstetrics, paediatrics and for a number of specialist groups. This makes it difficult to provide a concise response regarding transfusion trigger advice in this source as it will vary depending on patient group and clinical circumstance. To provide an example, for red cell transfusion in surgery it states that 'most experts now agree that transfusion should be considered if Hb below 80 g/L; if the Hb is below 70 g/L transfusion is usually indicated; the decision to transfuse should be based on the clinical condition of the patient (higher thresholds may be appropriate in individual cases)'. For transfusion in medical patients, it suggests that 'there is no universal transfusion trigger – the decision to transfuse should be based on clinical assessment of the patient, supported by the results of laboratory tests and informed by evidence-based guidelines.'

175. These resources have been conveyed to clinicians largely via the NHS Lothian Blood Transfusion Clinical Policy and Procedures and mandatory transfusion education (the LBT *Safe Transfusion Practice* and LBT *Blood Components and Indications for Use* modules both signpost clinicians to these, and other, resources).

176. Guidance contained in a NHS Lothian 'Blood Component Summary' approved by the LTC in October 2005 stated: *'Always check haemoglobin before transfusion. Consider transfusion threshold carefully for each patient. As a rule maintain Hb 70 - 90 g/L. With ischaemic heart disease 90 - 100g/L'.*

177. The NHS Lothian Blood Transfusion Clinical Policy and Procedures (2011 version, covering all hospitals in NHS Lothian) provided the following guidance:

'*Clinical judgement and haemoglobin thresholds for transfusion should take into account the patient's age, BMI, underlying medical condition(s) and current physiological status'.*

'There is no universal "trigger" for transfusion but this is usually indicated if the haemoglobin is below 70 g/L and rarely if above 100 g/L (please note that some clinical specialities have local guidelines in place which incorporate suggested transfusion triggers for specific patient groups e.g. stable post-partum women, orthopaedics, abdominal aortic surgery).

For symptomatic anaemia it is good practice to transfuse one unit at a time, rechecking the haemoglobin and reassessing the patient's condition before further units are transfused'.

178. At an LTC meeting in 2012 there was discussion around a more restrictive approach to transfusion: the Chair had discussed this with the NHS Lothian medical director who agreed with this approach and agreed to the LTC incorporating this into guidance for clinical teams.

179. The LTC updated the NHS Lothian Blood Transfusion Clinical Policy and Procedures further, in line with emerging evidence which supported a restrictive transfusion approach, primarily in critical care, but subsequently in other settings. The Committee incorporated restrictive red cell transfusion guidance, including a single unit transfusion approach for patients who are not actively bleeding, from NICE (NG24) 2015, into the NHS Lothian Blood Transfusion Clinical Policy and Procedures (version 2016). This provided the following advice: *'When using a restrictive red blood cell transfusion threshold, consider*

a threshold of 70 g/Litre and a haemoglobin concentration target of 70–90 g/Litre after transfusion' and *'consider a red blood cell transfusion threshold of 80 g/Litre and a haemoglobin concentration target of 80–100 g/Litre after transfusion for patients with acute coronary syndrome*' *The higher transfusion threshold of 80 g/Litre may also be appropriate in other patients with coronary artery disease'.*

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

a. Did the HTCs hold any discussions about the frequency of monitoring haemoglobin levels? If so, please provide details and outcomes of any discussions.

180. The LTC supported NHS Lothian taking part in the NCABT Audit of Medical Blood Use in 2011, which involved measuring practice against the audit standards of taking a pre-transfusion haemoglobin level within 3 days of a transfusion, and preferably on the same day as the transfusion, and of taking a post-transfusion haemoglobin level within 3 days after the transfusion, and preferably on the same day as the transfusion. The results of the report were discussed by the LTC in March 2013, which concluded that practice in Lothian was favourable in this regard (please note the audit report was not issued from NCABT until February 2013). The NHS Lothian Documentation for Transfusion of Blood Components (the development of which is overseen by the LTC) guides clinical staff to reassess patients clinically after the transfusion of each blood component, before progressing to authorising further components (where

appropriate for circumstances). The NHS Lothian Blood Transfusion Clinical Policy and Procedures contains guidance about the timing of post-transfusion haemoglobin measurement. It states: '*An indication of the post-transfusion haemoglobin level can be obtained as early as 2 – 4 hours following completion of transfusion in stable patients. Timing of post-transfusion haemoglobin measurement should be tailored according to the clinical circumstance'*.

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.

181. I would refer to the answer that I provided for question 23.

182. Recognition of a patient being transfused inappropriately or excessively would act as a trigger for a transfusion incident report, with subsequent investigation and identification of preventive and corrective action. The HTT might also respond to recognised trends (for example, following feedback regarding component request patterns identified by transfusion laboratory teams), prompting feedback to clinical teams via educational opportunities or presentation at team meetings, etc. Any identified events demonstrating inappropriate transfusion would be reported by HTT members to SHOT and the LTC.

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

183. In 2010 SCTAC, in its response to a National Patient Safety Agency (NPSA) Rapid Response Report ('The transfusion of blood and blood components in an emergency' (NPSA/2010/RRR017)), (WITN7300017) produced a NHSS Major Haemorrhage Template (WITN7300018) which was shared with all Scottish Territorial Health Boards. The template was designed

to be an aid to Boards when updating major haemorrhage policies. This template contained reference to haemoglobin measures and target ranges to be used to guide component use during a major haemorrhage event. The guidance stated that, once blood results were available, blood component support should be tailored to maintain the patient's haemoglobin above 8 g/dL (target range 9-10 g/dL).

184. Guidance regarding detailed clinical transfusion practice, such as haemoglobin levels in relation to transfusion, tends to come from professional bodies, such as BSH. There may have been other guidance that was issued from NHS Scotland or from SCTAC/SNBTC concerning haemoglobin levels that I am unable to recollect or have not retained a record of. Others in those organisations would be better placed than I am to provide a confirmed record.

Fresh Frozen Plasma ("FFP")

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

185. I have reviewed the LTC meeting minutes and provide an outline of the subject of discussions that the LTC have had relating to FFP below:

- Monitoring of monthly FFP use in NHS Lothian
- Number of FFP transfusions administered in specific settings e.g. non-acute and community settings
- Introduction and arrangements for use of pre-thawed FFP on RIE site to support timely major trauma response
- Fibrinogen concentrate, including a local study being conducted to compare the use of fibrinogen concentrate with FFP in bleeding patients
- Introduction of a blood group check policy in relation to FFP issue
- FFP provision for Code Red Protocol, associated audit and review
- Anticipated rise in demand for methylene-blue treated imported FFP (MB-FFP) with the increase in number of patients potentially requiring transfusion falling into the age group recommended to receive this component (i.e.

individuals born since 01/01/1996) and an increased demand from other services relevant to this age group (e.g. Teenage Cancer Trust) *NB UK SaBTO guidance regarding MB-FFP provision has subsequently changed*

- New BSH guidance regarding red cell : FFP : platelet component ratio guidance in transfusion of bleeding patients following trauma
- Evidence from England suggesting an increased use of FFP and resultant agreement to start monitoring monthly NHS Lothian FFP usage (this commenced in 2016)
- Proposal (received from SCTAC) to introduce Octaplas LG® (a pooled plasma (human), solvent/detergent treated solution for intravenous infusion) for clinical indications previously in place for MB-FFP (the Committee raised no concerns and this was fed back to SCTAC)
- Participation in national audit of FFP use in Scotland (2017)
- Recognition of work done in NHS Lothian associated with appropriate use of FFP in non-bleeding patients
- Review of SHOT Annual Report (2018) highlighting TACO risk associated with FFP use in non-bleeding patients: discussion regarding plan to introduce TACO risk assessment tool in NHS Lothian (a TACO risk assessment tool was subsequently incorporated into the NHS Lothian Documentation for Transfusion of Blood Components)
- SNBTS KPIs associated with FFP utilisation
- Revised SaBTO recommendations (2020) for plasma and platelet components for those born since January 1996
- Convalescent plasma trials (REMAP-CAP and RECOVERY trials). Convalescent plasma is the antibody-rich plasma of someone who has recovered from a virus: these clinical trials aimed to identify treatments for specific groups of patients being hospitalised with COVID-19 at the time (WITN7300029)
- Component demand and supply changes during COVID-19 pandemic

186. It is a standing LTC agenda item that the transfusion practitioners report all serious adverse events, near miss events and serious reactions relating to any blood components or products that have been reported to SHOT and/or

MHRA since the preceding meeting. Each event/reaction is described and corrective and preventive action discussed. The Committee identifies if there is any outstanding preventive action required or whether further awareness raising of an issue is required. If so, an action plan is agreed and will be reported at the subsequent meeting. Any persistent issues or trends of concern are escalated to the NHS Lothian Acute Clinical Management Group.

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

187. Since I have been involved with the LTC, it has remained up to date in terms of awareness of the annual evidence issued from SHOT regarding the hazards of transfusion relating to FFP.

188. Risks associated with potential reactions are considered by the Committee in terms of routine analysis of all serious transfusion reactions that occur in NHS Lothian.

189. Consideration of the benefits of FFP use, for example in terms of management of major haemorrhage, are apparent from discussions relating to ensuring timely provision following trauma and major haemorrhage.

190. The cost of MB-FFP in comparison with Octaplas LG® formed part of the discussion at the LTC meeting in 2016, in response to communication from SCTAC regarding potential transition to using Octaplas LG® in lieu of MB-FFP.

31. 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.

191. The NHS Lothian Transfusion Blood Transfusion Clinical Policy and Procedures routinely refer clinicians to the most up to date BSH and Handbook of Transfusion Medicine guidance on all blood components and, since 2016, also refers clinicians to NICE blood transfusion guidance (NG24). The LTC's

promotion of mandatory transfusion education for all appropriate staff groups includes completion of the LBT *Blood Components and Indications for Use* eLearning module for medical staff, which provides guidance on FFP transfusion. Recommended rates of FFP transfusion are contained in the NHS Lothian Documentation for Transfusion of Blood Components (WITN7300030) to guide clinicians at the point of authorising FFP transfusions.

32. 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?

192. The LTC was provided with the NHSS Major Haemorrhage Template by SCTAC in 2010, in its response to the NPSA Rapid Response Report ('The transfusion of blood and blood components in an emergency' (NPSA/2010/RRR017)). This document provided guidance on use of FFP in major haemorrhage events. For trauma patients it recommended that 4 units FFP be ordered in the first instance, and repeated if bleeding persisted and no coagulation screen results were available yet. Once results were available, it guided to transfuse 4 units FFP if APTT (activated partial thromboplastin time) or PT (prothrombin time) ratio > 1.5 x normal with a view to normalising APTT and PT. For patients experiencing major haemorrhage but with no immediate risk of coagulopathy, the guidance was to anticipate requirement for FFP (allowing for thaw time) in the event of continued bleeding and risk of coagulopathy and, once results were available, to transfuse 4 units FFP if APTT or PT ratio > 1.5 x normal with a view to normalising APTT and PT.

193. In 2016 the LTC received a communication from SCTAC regarding the proposal to switch from MB-FFP to Octaplas LG®. This was discussed at the meeting in August 2016.

194. In 2019/2020 the Committee received the revised SaBTO recommendations 'Paediatric Components Working Group – Report: Importation of plasma and use of apheresis platelets as risk reduction

measures for variant Creutzfeldt-Jakob Disease for plasma and platelet components for those born since Jan 1996'.

Platelets

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

195. I have reviewed the LTC meeting minutes and provide an outline of the subject of discussions that the LTC have had relating to platelets below.

- Monitoring of monthly platelet use in NHS Lothian
- Number of platelet transfusions administered in specific settings e.g. non-acute and community settings
- National platelet wastage audits
- KPI monitoring including those associated with platelet utilisation
- Platelet stockholding arrangements
- Appropriate ordering and dosage of platelets
- Introduction of STED reports and recognition of value in informing local practice
- Introduction of a blood group check policy in relation to platelet issue
- Platelet provision plans for Code Red Protocol
- Anticipated new BSH guidance regarding red cell : FFP : platelet component ratio guidance in transfusion of bleeding patients following trauma
- Evidence from England suggesting an increased use of platelets and associated agreement to start monitoring monthly NHS Lothian platelet usage
- Commencement of 7-day expiry for platelets (2016)
- Transition to SNBTS issuing a new pooled platelet component (in platelet additive solution) (2016)
- Introduction of SNBTS Blood Bank Dashboard data (including platelet utilisation data)

- National and local audits looking at platelet use
- Annual trends in platelet use in NHS Lothian (a 20% reduction noted in 2018 – reason unknown at the time and monitoring continued)
- Recognition of decline in platelet use (2020) with discussion around increased use of rotational thromboelastometry (ROTEM) (a point-of-care blood test showing clotting capacity by measuring the viscoelastic properties of clot formation and dissolution) and the possibility this might have contributed to change in usage (by reassuring staff when platelets may not be required)
- Revised SaBTO recommendations (2020) for plasma and platelet components for those born since January 1996
- Revision of the NHS Lothian Procedure for Managing Red Cell Shortages with new inclusion of Procedure for Managing Platelet Shortages (in line with SNBTS Integrated Shortage Plan for SNBTS and NHSS Hospitals (Interim Draft Guidance in Response to COVID-19 Contingency Planning))
- Component demand and supply changes during COVID-19 pandemic

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

196. Since I have been a member of the LTC, it has remained up to date in terms of awareness of the annual evidence that is issued from SHOT regarding the hazards of transfusion relating to platelets.

197. Risks associated with potential reactions (particularly significant febrile events that are acted on and investigated swiftly and thoroughly, out of recognition of the greater risk (albeit rare) of bacterial contamination of components stored at room temperature) are considered by the LTC in terms of routine analysis of all serious reactions and associated investigations that occur in the organisation.

198. Recognition of benefits of transfusion are apparent via conversations associated with, for example, provision for haematology patients (for example,

platelet use in haematology audit showing appropriate use to prevent bleeding in patients with low platelet counts), inclusion of contingency for platelet shortage in the event of national stock shortage (i.e. recognition that provision for key groups needs to be planned for in potential times of shortage) and in terms of provision during major haemorrhage events (i.e. recognising life-saving value of platelets if/when platelet counts fall during haemorrhage).

199. Whilst financial costs are not discussed per se, the LTC maintains a keen interest in platelet wastage/outdating and improvement activity to minimise this.

35. 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.

200. The NHS Lothian Blood Transfusion Clinical Policy and Procedures routinely refer clinicians to the most up to date BSH and Handbook of Transfusion Medicine guidance regarding all blood components and, since 2016, also refers clinicians to NICE blood transfusion guidance (NG24). The LTC's promotion of mandatory transfusion education for all appropriate staff groups includes completion of the LBT *Blood Components and Indications for Use* eLearning module by medical staff, which provides guidance on platelet transfusion.

36. 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?

201. The LTC was provided with the NHSS Major Haemorrhage Template by SCTAC in 2010, in its response to the NPSA Rapid Response Report ('The transfusion of blood and blood components in an emergency' (NPSA/2010/RRR017)). This document provided guidance on use of platelets during major haemorrhage events. Following trauma, it advised that, after initial transfusion of RCC/FFP, if bleeding had persisted and results were not yet available, to order a unit of platelets - transfuse one unit of platelets (2 units if

platelet count < 30) with the aim of maintaining the patient's platelet count > 75 $x10^9$/L. For patients experiencing major haemorrhage but with no immediate risk of coagulopathy, the guidance was to anticipate the requirement for platelets and, once results available, to transfuse one unit of platelets (2 units if platelet count < 30) with the aim to maintain the patient's platelet count > 75 $x10^9$/L. The guidance also alerted clinicians to the fact that platelets might not be available locally on site and may need to be transported from the regional transfusion centre (and to allow transport time for this).

202. In 2019/2020 the Committee received the revised SaBTO recommendations 'Paediatric Components Working Group – Report: Importation of plasma and use of apheresis platelets as risk reduction measures for variant Creutzfeldt-Jakob Disease'.

Single-unit transfusion

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

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

203. Expert opinion now *recommends* the use of single unit transfusions (in patients who are not actively bleeding) e.g. NICE guidance NG24 (2015). The documents referenced in this question are from previous years when single unit transfusion was considered *undesirable*. I would like to make it clear that my responses to questions 37-43 are made from the perspective of current thinking. Since I have been in post, any discussions regarding single-unit transfusions have been in the context of this being *desirable* practice.

204. I have reviewed the LTC meeting minutes and provide an outline of the subject of discussions that the LTC have had relating to single unit transfusions below.

- NHS Lothian results of NCABT Audit of Medical Blood Use 2011/12, which revealed that single unit red cell transfusions at that time continued to be uncommon

- The revised version of the NHS Lothian Transfusion Blood Transfusion Clinical Policy and Procedures (2016) which had been published on the intranet for all staff. The new version contained an expanded section regarding appropriate transfusion, which included reference to the NICE 2015 recommendations (NG24). These recommendations include using a restrictive transfusion approach and single unit transfusions unless indicated otherwise. At this meeting there was extensive discussion regarding the promotion of single unit transfusion (for appropriate patients) as an important element of appropriate transfusion practice, in line with SHOT recommendations and the desire to reduce the risk of TACO

- Contributory factors to observed reduced red cell use in the organisation, including the embracing of single unit transfusion in many clinical settings (2018)

- Recognised advances in appropriate transfusion in NHS Lothian including the adoption of single unit transfusion (2018)

- A proposed standard operating procedure for a new service offering transfusion in a step-down unit (providing an intermediate level of care between hospital and home) in a community hospital: the Committee requested inclusion of advice to consider a single unit transfusion approach (2019)

- Review of an event where there was subsequent requirement to discuss TACO risk assessment and single unit transfusion approach *('both of which are supported by this Committee')* with the clinical team involved (2020)

- Post-partum transfusion document and the desire to continue to have such a document which supports an established single unit transfusion approach (2020)

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

205. Consideration regarding risk has been given by the LTC, to ensure that single unit transfusion (and restrictive transfusion practice in general) is guided by the available evidence and expert opinion. Guidance issued by the LTC, in the form of the NHS Lothian Blood Transfusion Clinical Policy and Procedures and the NHS Lothian Documentation for Transfusion of Blood Components, makes clear that this approach is only suitable for patients who do not have active bleeding.

206. Considerations regarding benefits of single unit transfusions discussed by the LTC have related to the reduction of risk of TACO and the reduction of patient exposure to donor blood.

207. Whilst I do not recall discussions relating to financial cost reductions in terms of a single unit transfusion approach, the LTC is aware of the financial cost of blood donation, processing and testing, as well as the time given by the donor as part of the donor's gift.

39. 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.

208. In 2016 the LTC oversaw a revision of the NHS Lothian Blood Transfusion Clinical Policy and Procedures which subsequently contained an expanded section regarding appropriate transfusion, including reference to the NICE NG24 recommendations. These recommendations include using a restrictive transfusion approach and single unit transfusions, unless indicated otherwise.

40. 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?

209. As indicated in my answer to question 37, the concept of excessive use of single unit transfusions being a negative concept does not reflect contemporary practice. In my experience, the growth of a single unit transfusion approach, for suitable patients, has been welcomed as a positive development.

210. Any transfusion identified as being unnecessary is reviewed, investigated with the clinical team and reported to SHOT (by a member of the HTT). All SHOT reportable adverse events of this nature are reviewed by the LTC. A single unit transfusion would not be considered an unnecessary transfusion. An example of an unnecessary transfusion might be a transfusion given without referral to the patient's most recent haemoglobin results (which may since have risen, such that transfusion is no longer deemed necessary).

41. 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.

211. From the time I joined the LTC, I do not recall single unit transfusions being referred to by the Committee in a negative way. The emergence of evidence supporting a more restrictive transfusion approach for suitable patients, and the associated recognition of the single unit transfusion approach becoming recommended practice for patients without active bleeding, led to a formal inclusion of the recommendation of this approach in the revised NHS Lothian Blood Transfusion Blood Transfusion Clinical Policy and Procedures issued in 2016 from the LTC to clinicians in NHS Lothian.

42. 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?

212. Guidance regarding detailed clinical transfusion practice, such as recommended transfusion volumes, tends to come from professional bodies, such as BSH. There may have been other guidance that was issued from NHS Scotland or from SCTAC/SNBTC concerning single-unit or two-unit transfusions that I am unable to recollect or have not retained a record of. Others in those organisations would be better placed than I am to provide a confirmed record.

43. 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.

213. I cannot comment about audits conducted regarding single unit transfusions in the context of the audit report referred to as this occurred prior to the time I was in post.

214. A local audit of blood use in medical patients was conducted in 2016 which included collection of data regarding single unit transfusions across one acute hospital site in NHS Lothian. This audit was designed in response to national guidance (NICE Guideline 24) promoting a restrictive approach to transfusion as well as an increasing awareness of the benefits of single unit red cell transfusion. Results were presented locally and discussed at the LTC, with

local guidance updated to reflect best practice. A re-audit conducted in 2018 demonstrated a marked increase in the adoption of a single unit transfusion approach. I am unable to share this report as it is owned by the member of clinical staff who undertook the audit with whom I no longer have contact.

Red blood cell concentrates

44. 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?

215. Since joining the LTC, red cell concentrate has been the standard red cell component used. I have not been aware of any discussions relating to the use of red cell concentrate in place of whole blood or other components.

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

216. Since joining the Committee, it has remained up to date in terms of awareness of the annual evidence that comes from SHOT regarding the hazards of transfusion relating to red cells.

217. Consideration of the benefits of red cell transfusion are implicit in LTC discussions, in terms of returning or maintaining safe oxygen carrying potential in individuals who have lost blood or have anaemia that threatens life, function or quality of life, where an alternative treatment is not possible.

218. The financial costs of red cell transfusion are not commonly discussed at LTC meetings. I have known clinicians approach the LTC to clarify current costs of red cells, so that cost calculations can be considered as part of an audit, for example. The Committee is aware of the financial costs of donating, processing and testing red cell concentrate as well as the time given by the donor as part of the donor's gift.

219. I am not acquainted with the detail of the financial arrangements of blood transfusion in NHSS, but my understanding is that the cost of producing blood components for use in Scotland is largely borne by SNBTS. Scottish Territorial Health Boards also have associated costs, for example in terms of the transfusion laboratories that they operate within hospitals, but they do not pay SNBTS for the blood components that they use.

46. 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.

220. The Lothian Blood Transfusion Clinical Policy and Procedures routinely refer clinicians to the most up to date BSH and Handbook of Transfusion Medicine guidance on all blood components and, since 2016, also refers clinicians to NICE guidance (NG24). The LTC's promotion of mandatory transfusion education for all appropriate staff groups includes completion of LBT *Blood Components and Indications for Use* eLearning for medical staff which provides guidance on red cell transfusion. The NHS Lothian Documentation for Transfusion of Blood Components provides guidance on suitable rates for red cell transfusion.

47. 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?

221. The LTC was provided with the NHSS Major Haemorrhage Template by SCTAC in 2010, in its response to the NPSA Rapid Response Report ('The transfusion of blood and blood components in an emergency' (NPSA/2010/RRR017)). This document provided guidance on use of red cells during major haemorrhage events. It outlined suitable timescales for provision of red cells in the initial response to a major haemorrhage (uncrossmatched O blood, group-specific, fully crossmatched).

222. For trauma patients it advised that 6 units of red cells be ordered in the first instance then, if bleeding persisted and blood results were not yet available, a further 4 units red cells should be ordered. Once results became available, the guidance was to maintain haemoglobin > 8 g/dL (target range 9 – 10 g/dL). For patients experiencing major haemorrhage who were not at immediate risk of coagulopathy, the advice was to access the nearest O negative red cell stock. Then, once results became available the guidance was to maintain haemoglobin > 8 g/dL (target range 9 – 10 g/dL).

223. Guidance regarding detailed clinical transfusion practice, such as the use of specific blood components, tends to come from professional bodies, such as BSH. There may have been other guidance that was issued from NHS Scotland or from SCTAC/SNBTC concerning red cell concentrate specifically that I am unable to recollect or have not retained a record of. Others in those organisations would be better placed than I am to provide a confirmed record.

48. 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.

224. I do not understand the reference in this question to “specialty uses” of red cell concentrate, platelets and/or FFP. It is not a term of which I am aware.

225. I can confirm that there have been patient reactions associated with red cell concentrate, platelets and FFP over the years that I have been in post, that have required investigation. All those that met SHOT/MHRA reporting criteria were reported to those bodies and reported and discussed at the LTC, with appropriate follow-on action, if required.

49. 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?**

226. I am unable to answer this question as I was not in post during the period concerned. Since I have been in post, red cell concentrate has been the standard red cell component in use.

Section 4: Knowledge of risk

50. 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?

227. The annual report issued by SHOT comes to the attention of the LTC each year and provides information regarding any viral transmission that has occurred in the UK within the reference year.

228. During the time I have been in post, the LTC has remained acutely aware of the potential viral risk associated with transfusion. Key sources of related information have been received from SHOT, SaBTO and SNBTS. National communications from SNBTS are sent to key stakeholders in NHS Lothian, including the LTC Chair and transfusion practitioners. The Committee has been

aware of the changing levels of relative risk with the progression of years, as outlined, for example, in the SNBTS 'Receiving a blood transfusion' information leaflet provided for patients and relatives (WITN7300006). The Committee has also remained abreast of specific changes in risk (e.g. the reduction in CMV risk as reflected in revised guidance from SaBTO (2012) and emergent risks associated with HEV (2015/16), with accompanying changes in component provision and special requirement arrangements.

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

229. Since being in post, the LTC has championed appropriate transfusion practice, including exploration and promotion of alternatives to transfusion of allogeneic blood (for example supporting the development of cell salvage activity) and, as the evidence base has developed, this has transitioned to a championing of a restrictive approach to transfusion for suitable patients. This approach is evident in the policies (e.g. NHS Lothian Blood Transfusion Clinical Policy and Procedures) and documents (e.g. NHS Lothian Documentation for Transfusion of Blood Components) that have been developed by the LTC.

230. Appropriate transfusion practice and restrictive transfusion practice are aimed at tailoring transfusion appropriately to a patient's clinical requirements and avoiding unnecessary exposure to donor blood. Active promotion of alternatives to transfusion is also aimed at reducing donor exposure.

52. 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.

231. Since I have been in post, the NHS Lothian Transfusion Blood Transfusion Clinical Policy and Procedures have always informed clinicians that

blood transfusion carries a variety of potential risks, including risk of viral transmission, and refers clinicians to SHOT data, which includes annual updates on transfusion-transmitted infections. The policy provides instruction and guidance for clinicians regarding the following pertinent issues:

- Provision of information to patients for whom blood component transfusion is indicated, regarding risks of transfusion, including viral risk, and associated patient information sources (SNBTS 'Receiving a blood transfusion' information leaflet)
- The associated process of discussion with a patient prior to gaining and documenting informed and valid consent
- Methods to reduce exposure to donated blood (e.g. single unit transfusion, consideration of alternatives to transfusion)
- Possible serious sequelae of blood transfusion, including viral infection and the associated reporting requirements
- Indications for cytomegalovirus (CMV) negative blood components and how these are ordered for relevant patients

232. The LTC also supports the system of mandatory LBT *Safe Transfusion Practice* education for all staff groups and this includes information about viral risk of transfusion. Medical staff also complete the LBT *Blood Component and Indications for Use* module, which provides greater detail in terms of viral risks associated with transfusion. Guidance for clinical staff has reflected key changes (for example the NHS Lothian Blood Transfusion Clinical Policy and Procedures were revised with respect to HEV special requirement arrangements when these were introduced in 2016 (subsequently made obsolete in 2017 by the introduction of standard issue of HEV negative components). Mandatory education for medical staff in NHS Lothian now also includes LBT *Consent for Transfusion* which provides a greater depth of guidance regarding the discussion of transfusion related risk with patients than is already covered in the established *LBT Safe Transfusion Practice* module.

53. 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.

233. Known and suspected risk of infection associated with transfusion are taken very seriously by the LTC. Any reaction that may be indicative of a potential infection is swiftly reported and investigated, and appropriate and timely action taken to test implicated components (and potentially quarantine components from the same donor via liaison with SNBTS), where indicated. Whilst rates of actual contamination are exceedingly low (the vast majority of such events are ultimately found not to be associated with infection/contamination) the trigger for suspicion and investigation/action is maintained at a low level and all such events are reviewed by the LTC and reported to SHOT/MHRA.

234. Systems to ensure special requirements (e.g. CMV negative component provision for specific patient groups) are designed with great care. Challenges can arise, particularly when patients may be moving between different clinical teams, departments or even Territorial Health Boards for their care. Any associated adverse event or near miss is taken very seriously, reported as a serious adverse event, investigated and corrective and preventive activity instigated (such an event will be reported to MHRA/SHOT as well as being brought to the attention of the LTC).

235. Powerful risk-reduction methods have included universal screening, testing and provision of negative components as default (e.g. a swift transition to the provision of universal HEV negative components, as introduced by SNBTS in 2017), (see exhibit WITN7300031).

54. 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?

236. Whilst the risk of viral transmission is acknowledged to be low, it is known to exist and, as such, the risk of transmission increases with the number of components a patient is exposed to, hence the championing of appropriate, and increasingly restrictive, transfusion practice by the LTC, and its encouragement of alternatives to transfusion wherever possible. Such approaches are equally promoted out of recognition of the potential for emergent infectious risks that are yet unknown.

237. Risk is greater in those circumstances when only certain groups of patients require components that are negative for a named virus (e.g. CMV). In other words, the majority of components issued are not screened for this virus as it is known not to cause harm in most recipients. Virus negative components need to be identified, ordered and issued specifically for certain groups recognised to be at potential risk if they come into contact with the virus. The risk is greater due to potential system failures or human error, an issue recognised across the UK, which has prompted a recent SHOT Safety Notice: Ensuring patient specific transfusion requirements are met (WITN7300032). As described in previous questions, the LTC monitors related adverse events or near misses closely: a focus on associated preventive action with revision of systems and processes, as necessary, forms an important part of the LTC's response.

238. I am not aware of any transfusion methods that carry higher risk of viral infection. I interpret 'methods' in this question as being practical ways to transfuse e.g. via intravenous route (short-term intravenous catheter or indwelling central venous catheter) or intraosseous route; cell salvage; etc.

Section 5: Reporting and audits

55. 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:

239. Yes, the Hospitals have procedures in place to ensure patients are aware to report adverse reactions or symptoms following a blood transfusion.

a. What procedure did the Hospitals have in place?

240. As part of mandatory transfusion education for all relevant staff groups, clinical staff are educated to monitor patients during and following transfusion and recognise signs and symptoms indicative of transfusion reactions: this includes advising patients to alert staff if any indicative symptoms are experienced. If a transfusion reaction is identified or suspected (this may or may not include a patient reporting symptoms), in addition to the appropriate procedure being instigated to care for the patient, the clinical team is required to complete an incident report (via the Datix reporting system) if the nature of the suspected reaction has resulted in discontinuing the transfusion (i.e. a moderate or serious reaction). Datix is the NHS Lothian Safety & Learning System, a web-based tool used by staff across the organisation to report and learn from safety concerns, such as actual adverse events and near misses. Reporting via Datix ensures that the relevant individuals and managers in the team are aware of the event, to capture subsequent investigation and outcomes. A local incident reference number is also required in order for the HTT to report on to SHOT/MHRA.

241. A separate transfusion reaction form is also completed and returned to the transfusion laboratory immediately following the recognition of the reaction or potential reaction. This is used to capture the patient's signs and symptoms and details of the associated transfusion, and is used to guide immediate investigation or further action as may be required by laboratory staff and the HTT.

242. All reactions are investigated and reviewed by the HTT in conjunction with the relevant clinical team. Those that meet SHOT/MHRA reporting criteria are reported to those bodies and tabled at the next LTC meeting.

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

243. Staff are guided accordingly in the NHS Lothian Blood Transfusion Clinical Policy and Procedures *'In-patients should be observed for late reactions during the subsequent 24 hours. Day-case and short stay transfused patients should be advised about the possibility of late adverse reactions and should be given contact details so that they can access immediate clinical advice if this occurs'.*

c. Were patients asked to report any adverse reactions or symptoms within a certain timeframe?

244. I am not privy to all discussions that take place with patients relating to adverse reactions or symptoms.

245. Staff are guided in relation to adverse reactions or symptoms by the NHS Lothian Blood Transfusion Clinical Policy and Procedures (see answer for section b). Staff are also requested to provide the SNBTS patient information leaflet 'Receiving a blood transfusion' (WITN7300006) to any patient receiving a transfusion. This advises patients to get in touch with clinical staff in the event of developing symptoms of a reaction after going home, but this does not specify timescale. The SNBTS 'Receiving a blood transfusion' leaflet was already available when I commenced in post. Its use was reinforced upon the publication of the NHS QIS Clinical Standards for Blood Transfusion (2006) (WITN7300019). Further reinforcement of its use was brought about by the introduction of the NHS Lothian Documentation for Transfusion of Blood Components, which provided a checklist to be completed by the individual making the decision to transfuse. The checklist includes a prompt to provide the potential recipient with the SNBTS 'Receiving a blood transfusion' information leaflet.

246. A significant proportion of patients who receive transfusion in an outpatient setting in NHS Lothian are under the care of the haematology team.

These individuals are provided with a 24-hour emergency number to get in touch with the clinical team at any time if they develop complications once at home.

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?

247. If a clinician becomes aware of a patient showing signs or symptoms indicative of a reaction (that is moderate or serious in nature), they are required to report this to the practitioner in charge of the clinical area, the transfusion laboratory staff, the on-call haematology specialist trainee doctor and to complete a transfusion reaction report. Additionally, an incident report (Datix reporting system) is generated, which brings the reaction (or potential reaction) to the attention of the appropriate clinical management team and the HTT. Via this route the reaction is then reported by the HTT to SHOT/MHRA and the LTC.

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

248. Yes, the HTT is responsible for reporting relevant symptoms/reactions to the SNBTS regional transfusion centre. For example, if symptoms indicate the potential for a contaminated component, reporting to the regional transfusion centre enables rapid quarantine of associated donor components when appropriate. Reporting also occurs if a suspected transfusion related acute lung injury (TRALI) event is identified. TRALI is a very rare, serious respiratory complication of transfusion, and any suspected TRALI reaction investigation is coordinated by appropriate specialists in SNBTS.

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.

249. If a serious reaction or potential reaction has been reported from the clinical team, the relevant HTT are responsible for reporting this to SHOT/MHRA. This report includes information about the patient outcome (including death), along with information regarding whether the outcome was considered to have been associated with the transfusion, or otherwise.

250. As to the position in relation to the registration of the death and consideration of what is recorded on the death certificate, I am unable to respond to this question as my role does not include involvement in the direct provision of patient care or responsibility for this procedure.

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

251. I am unable to answer this question as SHOT was established before I started in post.

57. 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?

252. I am unable to comment about events at the time of the launch of SHOT as I was not in post at the time.

253. In relation to the system that has been used during the time I have been a transfusion practitioner based in NHS Lothian, each HTT reviews all transfusion events and reactions reported from clinical and laboratory areas via the incident reporting system (Datix). Any reactions reported directly to the transfusion laboratory would be added to the reporting system, if not already added. The HTT is responsible for identifying any reactions or events (including near misses) that are reportable to SHOT/MHRA and reporting via SABRE as required. SABRE is the secure online system used by registered reporters to submit haemovigilance reports to the MHRA and to SHOT. The

transfusion practitioners in NHS Lothian are responsible for collating all SHOT/MHRA reportable reactions and events (including near misses) and presenting these at each LTC meeting.

58. 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?

254. A change that occurred soon after I commenced in post relates to the introduction of reporting serious adverse reactions and relevant serious adverse events to the MHRA and the associated launch of the SABRE reporting system, which commenced with the introduction of the UK BSQR (2005). This change meant that hospital transfusion laboratories became responsible for reporting all serious adverse transfusion reactions and applicable serious adverse transfusion events to the MHRA via SABRE as well as to SHOT (in line with reporting criteria for both organisations). In NHS Lothian the responsibility for this reporting arrangement is held by the HTT.

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

Transfusion practice:

255. Following my commencement in post, transfusion practice in NHS Lothian has been audited via a combination of local audits and participation in national Scotland and UK audits.

256. Local audits are typically conducted by members of clinical teams, with or without the direct involvement of members of the LTC, but the LTC retains an overview of transfusion related audits that are being undertaken and receives outcome reports.

257. NHS Lothian takes part in all SNBTS TT national audits, with involvement being coordinated by the LTC.

258. Scottish hospitals may also be invited to take part in NCABT UK audits and the LTC decides which of these the Hospitals will take part in. The LTC coordinates involvement with appropriate NCABT audit activity when this is undertaken.

259. As time has progressed, there has been more emphasis on taking part in national audits and less emphasis on local audits (although these remain important and do still take place).

260. Another change over time has been that aspects of national audit activity, such as data collection, were often conducted by members of the LTC (e.g. the transfusion practitioners) in the early years of my role. The responsibility for data collection for some years now has been delegated to a member of the clinical team in the appropriate clinical setting (e.g. a trainee doctor). This is regarded as an effective way to engage clinical teams in such improvement activity and ensures that resultant learning points become embedded naturally in clinical practice. Clinicians involved in such audits also help to spread such learning to other departments and hospitals (and potentially Territorial Health Boards) when their position rotates (for example in the case of trainee doctors), thus enhancing opportunities for the sharing of good practice.

Blood usage:

261. Blood usage has been the subject of many local, national Scottish and national UK audits that the LTC has overseen. Audit activity has covered the use of all blood components as well as transfusion in a variety of settings (use in medical and surgical settings, critical care, haematology, oncology, obstetrics and emergency department). Planned, elective transfusion as well as transfusion in response to major haemorrhage has been audited. Audits have

included those focussed on specific components e.g. irradiated components or particular blood groups e.g. O negative red cell components.

Blood wastage:

262. Wastage of blood components has been the focus of a number of local and national audits overseen by the LTC.

263. NHS Lothian annual BBT (now SNBTS TT) reports show that routine monitoring of red cell wastage has taken place in NHS Lothian since at least March 2006. For the hospitals that I cover, blood component wastage data is now obtained from the SNBTS Blood Bank Dashboard. Prior to the introduction of this dashboard (in 2019), this data was obtained directly from the LIMS and from Datix reports. The Datix system is used to record and feedback component wastage events to clinical teams, to prompt local investigation and corrective and preventive activity. Component wastage data is tabled at each LTC meeting by the transfusion practitioners.

264. National KPIs have included those associated with reducing component losses since at least 2010/11. Clinical wastage events are monitored and reviewed closely. Such events can arise, for example, during a major haemorrhage where it is recognised that challenges exist in terms of ensuring adequate and timely provision of blood components in the face of rapidly changing clinical circumstances and uncertainty of approaching component requirement. The HTT works closely with clinical teams to address associated issues with a view to minimising wastage occurrence.

60. 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?

265. Since being a member of the LTC, it has coordinated audit activity for all Scottish National Transfusion Audit Programme audits and many NCABT UK

audits. All invitations to take part in NCABT audits are reviewed by the LTC and a decision taken as to which are appropriate and of value to NHS Lothian.

266. Local audit activity is initiated by individual practitioners or teams in NHS Lothian to establish whether a specific clinical standard is being met. LTC members may or may not be directly involved, but the LTC would maintain an overview and review results.

267. A review of LTC minutes indicates that the LTC has been involved in or had overview of at least 30 local audits since 2005, and has coordinated involvement in at least 15 national (UK or Scottish) audits over the same period, as listed below:

Year	**Audit subject**	**Local/Scotland/UK**
2005	Colorectal blood use and MSBOS compliance	Local
2005	Satellite blood fridge use	Local
2005	SIGN (Scottish Intercollegiate Guideline Network) 54	I am unsure whether this was a local or national audit
2006	Albumin use	Local
2007	Management of acute upper GI bleeding	UK (NCABT)
2007	Patient identification	Local
2007	QIS blood transfusion standards	Local
2008	Patient identification bands and use of CHI number	Local
2008	Bedside transfusion practice (reaudit)	UK (NCABT)
2008	O negative red cell use	UK (NCABT)
2009	Pre-operative transfusion sampling in breast surgery	Local
2009	Obstetric transfusion pathway	Local

2010	O negative red cell use (reaudit)	UK (NCABT)
2010	Use of platelets in haematology (reaudit)	UK (NCABT)
2010	Platelet wastage	Local
2011	Bedside transfusion practice (reaudit)	UK (NCABT)
2011	Cord blood sampling	Local
2011	Major haemorrhage protocol activations	Local
2011	Use of blood in adult medical patients (parts one and two)	UK (NCABT)
2012	Special requirement requesting	Local
2012	Platelet use in ICU	Local
2012	O negative red cell clinical use and stock management	Scotland (SNBTS BBT)
2012	Transfusion document completion (orthopaedics)	Local
2012	Transfusion document completion (care of the elderly)	Local
2012	Patient information leaflet availability	Local
2013	Historical pre-transfusion sample availability for pre-operative patients	Local
2014	Patient information	Local
2014	Pre-transfusion sampling in trauma patients (A&E)	Local
2014	Rejected samples and blood requests (Acute Receiving and Assessment Area)	Local
2014	Cryoprecipitate use in liver transplant patients	Local
2014	Major haemorrhage protocols and review of major haemorrhage activations in Scotland	Scottish (SNBTS BBT Audit Group)
2015	Pre-transfusion samples and historical blood group data	Local
2015	Code Red activations	Local
2015	Patient Blood Management in adults undergoing elective, scheduled surgery	UK (NCABT)

2015	Pre-transfusion sample rejection in Scotland	Scotland (SNBTS BBT Audit Group)
2016	MB-FFP provision	Local
2016	Perioperative transfusion in colorectal surgery	Local
2016	Medical blood use (SJH)	Local
2017	Platelet use in haematology	Local
2017	Plasma components	Scotland (SNBTS BBT Audit Group)
2018	Management of major haemorrhage	UK (NCABT)
2018	Management of anaemia in oncology patients	Local
2019	Transfusion in iron deficiency anaemia	Scotland (SNBTS TT)
2020	Induction eLearning completion (nurses/HCSWs)	Local
2021	Blood collection	Local
2022	Acute upper gastrointestinal bleeding: clinical management and the use of blood *(in progress)*	UK (NCABT)

61. 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.

268. NHS Lothian red cell transfusion data has been collated throughout my employment as a transfusion practitioner, and has been monitored consistently by the LTC. When I first commenced in post a national 10% reduction in red cell use over a 3-year period (2003-2006) was a SNBTS BBT Programme target in Scotland. From memory, this data was collated centrally (by the SNBTS BBT Programme central team) to enable measurement and monitoring against this target.

269. Following this period, a national BBT KPI of the number of red cells transfused for every 1000 head of population was introduced. NHS Lothian red cell use continued to be monitored for this purpose.

270. Following significant achievements in the reduction of red cell use across NHSS, a new series of national KPIs was introduced in the 2012/13 financial year which continued to include measures associated with optimising blood usage but no longer measured the number of red cells transfused for every 1000 head of population. My understanding is that SCTAC were the authorising body for national KPIs at this time, having taken over BBT governance responsibilities in 2011. A letter from SCTAC to Scottish Territorial Health Board chief executives, nursing and medical directors in May 2011 describes these transition arrangements (WITN7300033). The LTC decided to continue routine and regular measurement and reporting of red cell use within NHS Lothian.

271. Data regarding component use for the NHS Lothian transfusion laboratories (at WGH and SJH) is obtained from the LIMS. Data regarding component use for the SNBTS transfusion laboratory (at RIE) is obtained from the SNBTS Blood Bank Dashboard. The Blood Bank Dashboard is an interactive dashboard designed by SNBTS to support local hospital blood banks with management of blood component inventory, logistics service and other features. I have described the data sources that SNBTS uses to develop its dashboards in my response to question 18.

272. Monthly transfusion data is collated on a MS Excel spreadsheet ('NHS Lothian Blood Component Transfusion Rates') which shows monthly red cell transfusion data in NHS Lothian from 2011/12 to the present day (WITN7300034). This data is presented to the LTC by the transfusion practitioners at each meeting. Within this document there is reference to 'unconfirmed' components. This only accounts for a very small number of components and is a feature of a 'working' document such as this. A small number of component transfusions may not have been confirmed at the time this data is collated (for example at the end of a calendar month) as transfusion

confirmation requires the return of paperwork from the clinical area and this may still be in transit.

273. At an LTC meeting in May 2016 the LTC Chair informed the Committee about evidence from England indicating that platelet and FFP use was increasing there (I cannot recollect the original source of this information): as a result the Committee decided to commence monitoring of monthly platelet, FFP and cryoprecipitate transfusion data and this has also been collated and presented at each LTC meeting since. The data sources used are the same as those described for red cells above.

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

274. Annual NHS Lothian blood component transfusion data is shared by HTT members with MHRA via:

- The Hospital Blood Bank Compliance report: hospital blood banks must send a blood compliance report to MHRA every year. This provides details about the activities they carry out, together with specific information relating to processes, procedures, equipment and personnel. The compliance report is used to assess the responsible organisation for risk
- Annual Summary of SABRE Reports: hospital blood banks are legally required to submit an Annual Summary of all Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) reported to the MHRA during the reporting year

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

a. FFP;

275. Yes, audits of FFP use have been conducted, including a Scottish national audit of plasma components as well as looking at FFP use in major haemorrhage events.

b. red blood cell concentrate

276. Yes, audits of red blood cell concentrate use have been conducted including national audits of blood use in medical settings and a national Scottish audit of transfusion of patients with iron deficiency anaemia.

c. platelets

277. Yes, audits of platelet use have been conducted, including national and local audits of the use of platelets for haematology patients as well as looking at platelet use in major haemorrhage events.

d. massive transfusions;

278. Yes, audits of massive transfusion have been conducted, including national UK and Scottish audits of the management of major haemorrhage and activation of the major haemorrhage protocol.

e. autologous transfusion

279. Yes, audits of autologous transfusion have been conducted, including a national UK audit of patient blood management which included measurement of intraoperative cell salvage activity.

64. 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.

280. Yes, the LTC has taken corrective action as a result of an audit relating to blood transfusion practice, for example:

281. Relating to the NCABT Audit of the Management of Major Haemorrhage 2018, NHS Lothian results were presented at a haematology departmental meeting. It was noted that the use of tranexamic acid in non-trauma and non-post-partum haemorrhage patients in NHS Lothian was lower than the national rate. The audit report suggested that *'you should satisfy yourself that there are adequate clinical reasons for not using tranexamic acid in your non-trauma patients'.* Following discussion it was agreed that a prompt to consider the use of tranexamic acid in any major haemorrhage event be added to NHS Lothian's major haemorrhage protocol (MHP). This proposal was submitted for discussion at the LTC where it was agreed and the required change was made to the MHP.

Section 6: Treatment of patients

Provision of information to patients

65. 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?

282. I have reviewed the LTC minutes and outline below the topics of discussion related to provision of information to patients in NHS Lothian about the risks of infection in consequence of treatment with blood.

- Transfusion information leaflets for patients, topics including:
    - Availability
    - Distribution arrangements
    - Introduction of NHS QIS Clinical Standards for Blood Transfusion (2006) (including standard requiring that leaflets explaining the risks

and benefits of, and alternatives to, transfusion are readily available for patients who may require to be, or have been transfused)

- Rollout of NHS Lothian Documentation for Transfusion of Blood Components which introduced a checklist for the individual making the decision to transfuse, incorporating a specific check to ensure the patient had received the SNBTS patient transfusion information leaflet 'Receiving a blood transfusion'

- Updated SaBTO guidance on patient consent (2011) including provision of information regarding risks to patients prior to transfusion (or retrospectively, where applicable), the use of patient information leaflets and associated staff education, supportive documentation (prompts provided in new NHS Lothian Documentation for Transfusion of Blood Components and new NHS Lothian standard elective consent form at the time) and requirement to meet related NHS QIS standard

- NCABT Audit of Patient Information and Consent

,

- Transition from SNBTS to UK joint Blood Services standardised patient information leaflets

66. 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?

283. Since being in post, the LTC has provided oversight of the provision of the SNBTS transfusion information leaflet 'Receiving a blood transfusion' for patients (which includes information regarding viral risk of transfusion).

284. The LTC oversaw the introduction of a dedicated transfusion document, the NHS Lothian Documentation for Transfusion of Blood Components, which contains a checklist to guide the individual making the decision to transfuse (or the individual authorising the blood component) to discuss the risks associated

with transfusion with the patient prior to a transfusion (and a prompt to discuss in retrospect, where appropriate) – this also includes a specific prompt to provide the SNBTS patient information leaflet 'Receiving a blood transfusion'.

285. The LTC coordinated NHS Lothian involvement in the NCABT Audit of Patient Information and Consent, including review of findings and associated action planning.

286. The LTC has overseen the introduction of systems for mandatory transfusion education for all relevant staff groups. All staff involved in transfusion are required to undertake the LBT *Safe Transfusion Practice* learning module (eLearning or face to face) which provides a basic overview of the importance of informed consent in transfusion. Education for medical students in South-East Scotland was revised in 2016, when a clinical skills simulation education model was adopted. This incorporates a scenario regarding a conversation with a patient prior to transfusion, involving discussion of risks, benefits, and alternatives to transfusion. Induction education for FY1 doctors entering NHS Lothian has also included an additional practical workshop since 2013, which covers informed consent regarding transfusion, information provision about risks and benefits of transfusion, discussion with the patient prior to transfusion and appropriate documentation of transfusion.

Consent

67. 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?

287. I am unable to comment about the response to this audit in 1998, as this occurred some years before I came into post.

288. Provision of patient information and discussion regarding risks and benefits of transfusion has been a recognised requirement of transfusion practice since I have been in post, and has been reflected in LTC discussions. I do not recall any discussions at LTC regarding patients who had been transfused without their express or informed consent.

289. It is an established requirement that patients who receive a blood transfusion in a life-saving emergency, who may not be able to provide prior consent (with the exception of patients who hold an advanced directive document stating they do not wish to receive donated blood), are provided with information regarding risks of transfusion in retrospect. This requirement was made explicit in the NHS QIS Clinical Standards for Blood Transfusion published in 2006.

68. 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.

290. Since being in post, the NHS Lothian Blood Transfusion Clinical Policy and Procedures have provided guidance regarding informed consent for blood transfusion.

291. The 2006 version of the policy stated:

'Although the task of gaining written informed consent for a blood transfusion is not a legal requirement within the UK, there is a responsibility to ensure that the patient/guardian receives adequate information regarding their transfusion. This should include information pertaining to the risks and benefits of transfusion as well as information relating to available alternatives, for example, iron supplementation. Clinical practitioners therefore, have a professional duty to ensure that they have adequate knowledge of transfusion related issues or that they can access the information and support required by patients

undergoing transfusion therapy. Patient information leaflets published by SNBTS are available'.

292. The 2011 version of the policy stated the following (the underlined sections indicate the changes/additions):

'*The decision to transfuse should be made following consideration of the potential risks and benefits of, and the alternatives to, transfusion. Patient information leaflets (SNBTS) are available and should be offered to patients who may require transfusion (see page … for information about how to obtain leaflets and formats available)*'.

'The reason for transfusion should be discussed with the patient, including valid alternatives and the option to refuse. Details should be recorded in the patient's healthcare record / transfusion documentation, including the patient's agreement (or from their legal guardian if not capable of informed consent) - see page … for detail. Where pre transfusion discussion is not possible e.g. in an emergency, clinicians should act in the patient's best interests, taking into account any advance decision documents. The reason for transfusion should be discussed retrospectively, a patient information leaflet offered and the discussion documented in the healthcare record'.

'Patients who do not accept blood component or product transfusion: refer to NHS Lothian Policy and Guidance for Obtaining Consent (….), particularly the sections relating to treatments acceptable/unacceptable to Jehovah's Witnesses and withholding of consent'.

'Although the task of gaining written informed consent for a blood transfusion is not currently a legal requirement within the UK, there is a responsibility to ensure that the patient/guardian receives adequate information regarding their transfusion and that this is clearly documented in their healthcare record. This should include information pertaining to the risks and benefits of transfusion as well as information relating to available alternatives, for example, iron supplementation. Clinical practitioners therefore have a professional duty to

ensure that they have adequate knowledge of transfusion related issues or that they can access the information and support required by patients undergoing transfusion therapy.

Staff should consider whether any additional support is required to ensure that the patient/guardian can understand the information being provided. There may be situations where information needs to be provided in a different way to ensure full understanding e.g. delivering information at a slower rate or repeating important points.

The NHS Lothian Policy for Meeting the Needs of People with Limited English Proficiency provides guidance on interpretation and translation support and can be accessed via the NHS Lothian Intranet > Healthcare > Clinical Guidance. Patient information leaflets published by SNBTS are available and currently contain a peel off label that can be placed in the patient's record by way of recording that a pretransfusion discussion and leaflet provision have been undertaken'.

293. The 2013 and 2016 versions of the policy state the following (the underlined sections indicate further changes/additions):

'The decision to transfuse should be made following consideration of the potential risks and benefits of, and the alternatives to, transfusion. Patient information leaflets are available and should be offered to patients who may require transfusion (see page … for information about how to obtain leaflets and formats available)'.

'The reason for transfusion should be discussed with the patient, including valid alternatives and the option to refuse. Details should be recorded in the patient's transfusion document, including the patient's agreement (or from their legal guardian if not capable of informed consent) - see page … for detail'.
'Where pre-transfusion discussion is not possible, clinicians should act in the patient's best interests, taking into account any advance directives where appropriate. The reason for transfusion should be discussed retrospectively, a

patient information leaflet offered and the discussion recorded in the transfusion document. If the patient has a current advance directive, this should be indicated clearly on the transfusion document and/or the patient's healthcare record'

'NHS Lothian guidance is available for staff who work in maternity services that may care for women who decline blood components. This is found at NHS Lothian intranet > ….'

'Patients who do not accept blood component or product transfusion: refer to NHS Lothian Consent Policy (….), particularly the sections relating to treatments that may be acceptable/unacceptable to Jehovah's Witnesses and withholding of consent'. (NB new NHS Lothian Resources for Managing Patients who Refuse Blood (including Jehovah's Witnesses) have since been introduced).

'Although the task of gaining written consent for a blood transfusion is not a legal requirement within the UK, there is a responsibility to ensure that the patient/guardian receives adequate information regarding their transfusion and that this is clearly documented in their transfusion document. This should include information pertaining to the risks and benefits of transfusion and the risks and benefits of not having a transfusion. Information relating to available alternatives to transfusion should be considered (e.g. iron supplementation). Verbal informed consent should be obtained and recorded in the patient's transfusion document by the person making the decision to transfuse or the person prescribing/authorising the transfusion.

For long term multi-transfused patients it is unnecessary to re-document the individual's consent at each transfusion episode. However this should be revisited with the patient as dictated by clinical circumstances e.g. if there has been a significant time lapse in between transfusions or if the indication for transfusion has changed.

Patients who have received a transfusion are no longer eligible to donate blood. This information is also included in the patient information leaflet (see below).

Clinical practitioners have a professional duty to ensure that they have adequate knowledge of, or access to information on, transfusion-related issues.

Staff should ensure that the patient/guardian can understand the information being provided. Information sometimes needs to be provided in a different way to ensure full understanding e.g. delivering information at a slower rate or repeating important points.

The NHS Lothian Interpreting and Translation Policy provides guidance on interpretation and translation support and can be accessed via the NHS Lothian Intranet > Healthcare > Clinical Guidance > Interpreting & Translation Policy. Patient information leaflets published by SNBTS are available. They can be found in all transfusing wards and departments throughout NHS Lothian. Leaflets are also available for children and parents/guardians'.

294. The 2006 NHS QIS Clinical Standards for Blood Transfusion and associated peer review outcomes (2007) were widely discussed in NHS Lothian at the time (the standards included those relating to informed consent).

295. The NHS QIS Clinical Standards for Blood Transfusion (2006) were introduced to provide a series of quality statements describing the care, relating to blood transfusion, that patients should expect to receive across NHSS. NHS QIS set standards for clinical services as part of their remit to run a national system of quality assurance of clinical services, and performance was assessed by QIS across NHSS against these standards. Following achievement of the standards, these are now embedded as part of day-to-day practice. NHS QIS evolved to become NHS HIS in 2011.

296. The NHS Lothian Documentation for Transfusion of Blood Components (in place since 2011) includes a checklist to guide the clinician making the decision to transfuse (or the individual authorising the blood component) to

discuss the risks of, benefits of, and alternatives to blood transfusion with the patient, provide a patient information leaflet and document the patient's verbal informed consent prior to transfusion. It also includes prompts to state if the patient has an advanced directive document stating they do not wish to receive blood components and also a prompt to provide retrospective information for those patients who were unable to provide consent prior to an emergency transfusion.

297. In 2022 completion of the LBT *Consent for Transfusion* eLearning module has been incorporated into mandatory transfusion education for medical staff, building on the established content regarding informed consent in LBT *Safe Transfusion Practice.*

298. In 2022 a dedicated statement, issued by the SNBTS TT (WITN7300035) regarding informed consent in blood transfusion, reflecting the updated 2020 SaBTO guidance on informed consent in transfusion, was added to the NHS Lothian Consent Policy.

299. The LTC has overseen appropriate systems for mandatory transfusion education for all relevant staff groups. All staff involved in transfusion are required to undertake LBT *Safe Transfusion Practice* education which provides a basic overview of the importance of informed consent in transfusion.

300. Education for medical students in South-East Scotland was revised in 2016, when a clinical skills simulation model was adopted. This incorporates a scenario involving conversation with a patient prior to transfusion and discussion of the risks of, benefits of and alternatives to transfusion. Induction education for FY1 doctors entering the organisation has also included an additional practical workshop since 2013, which covers informed consent in transfusion, information provision about risks and benefits of transfusion and discussion with the patient prior to transfusion.

301. SaBTO guidance on consent in transfusion has also been circulated to representatives of blood-using clinical groups.

Section 7: vCJD

69. 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].

302. I am unable to state when and in what circumstances the LTC became aware of the risks of transmission of vCJD via transfusion, as I recall this was established knowledge when I became a transfusion practitioner in NHS Lothian. The 2006 version of the Lothian Blood Transfusion Clinical Policy and Procedures referred clinical staff to the SHOT 2004 Annual Report which contained the first reported case of possible prion transfusion transmission, as reported by the National CJD Surveillance Unit that year.

303. LTC members maintained an awareness of identified cases of suspected transmission via the sharing of annual SHOT reports.

304. LTC members were recipients of communications in 2009 regarding the revision to Annex J of the Transmissible Spongiform Encephalopathy (TSE) Infection Control guidance, which advised that patients who are due to have high risk surgery or neuro-endoscopy should be asked whether they have received transfusions of blood or blood components from 80 or more donors since 1980. This same information had also been shared directly with the chief executive, medical directors, heads of surgery, infection control managers and health protection teams in NHS Lothian.

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

305. The LTC's involvement in management of this risk aligns with information already provided regarding the promotion of appropriate and ultimately restrictive transfusion practice, championing and support for alternative treatments to blood transfusion, oversight of provision of patient information (including in leaflet form) and maintenance of mandatory LBT *Safe Transfusion Practice* education for all staff involved in the transfusion process (covering the importance of obtaining informed consent and provision of information pertaining to risks of transfusion).

306. The transfusion practitioners have used all appropriate in-person transfusion educational opportunities to raise staff awareness of the vCJD precautionary measure, that those who have received, or think they may have received, a blood transfusion since 1980, are no longer eligible to donate blood. This information is contained within the SNBTS patient information leaflet but staff are encouraged to proactively bring this to patients' attention.

Section 8: Look back

71. 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?

307. I am unable to answer this question as it relates to a time period before I started in post.

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

308. I am unable to answer this question as it relates to a time period before I started in post.

Section 9: Other

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

309. Thank you for the opportunity to contribute. I hope my responses are helpful to the Inquiry.

74. 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.

Statement of Truth

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

Signed GRO-C

Dated 30th November 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
November 2020	SG023Band 7 Job Description Transfusion Practitioner FINAL	WITN7300002
11 December 1998	NHS circular "Better Blood Transfusion" (HSC 1998/224)	WITN7300003
23 August 2007	LTC Updated Constitution 2007 (V4)	WITN7300004
26 January 2015	LTC structure and remit DRAFT 2015	WITN7300005
01 July 2021	Receiving a blood transfusion	WITN7300006

	SNBTS patient and relatives information leaflet 2021	
September 2017	Learnbloodtransfusion-The-Essential-Guide-v6_Sept.-2017 (1)	WITN7300007
09 February 2005	Training agreement (NHS Lothian and BBT) Junior Doctors 2005	WITN7300008
09 August 2008	Appraisal Letter from Director Medical Education - To All Consultants and SAS grades - 09 08 08	WITN7300009
18 July 2008	Training agreement (NHS Lothian and BBT) Registered Nurses, Enrolled Nurses, ODPs, Clinical Support Workers, Bank Staff 2008	WITN7300010
24 September 2010	Training agreement (NHS Lothian and BBT) Porters SJH 2010	WITN7300011
25 February 2011	Training agreement (NHS Lothian, SEBTS, BBT) BMS and BMSW 2011	WITN7300012
24 April 2020	2020-05_SNBTSTT_LBTTrainingMatrix_Version1.2	WITN7300013
22 April 2021	SNBTS National Transfusion Policy Version 2 Final	WITN7300014
February 2020	458263_SCT0220167574-001_SNBTS National Transfusion Record_P2	WITN7300015

October 2021	SNBTS Scottish HTC chair and CTL Information Sheet October 2021	WITN7300016
21 October 2010	2010 10 21_NPSA Rapid Response Report_Access_to_blood NPSA/2010/RRR017	WITN7300017
28 July 2010	SNBTS Scottish_Major_Haemorrhage_Template-Final11	WITN7300018
September 2006	NHS QIS Clinical Standards for Blood Transfusion 2006	WITN7300019
August 2005	WGH MSBOS 2005	WITN7300020
June 2006	RIE MSBOS 2006	WITN7300021
July 2005	MSBOS for DCN 2005	WITN7300022
February 2008	NHS Lothian University Hospitals Division MSBOS 2008	WITN7300023
June 2013	NHS Lothian University Hospitals Services SBOS 2013	WITN7300024
June 2016	NHS Lothian University Hospitals Services SBOS (Adults) 2016	WITN7300025
May 2015	NHS Lothian Royal Hospital for Sick Children SBOS 2015	WITN7300026
16 May 2022	SNBTS Sickle cell patient information leaflet FINAL	WITN7300027
14 January 1999	MEL 1999 no 9 Better Blood Transfusion	WITN7300028

July 2020	SNBTS COVID 19 Convalescent Plasma Fact Sheet	WITN7300029
May 2020	NHS Lothian Documentation for transfusion of Blood Components V5	WITN7300030
17 October 2017	HEV labelling letter to hospitals 20171017	WITN7300031
June 2022	SHOT Safety Notice SRNM June 2022	WITN7300032
12 May 2011	SCTAC letter to NHSS_Board_BBT_Objectives and KPIs_v2[2]	WITN7300033
April 2022	Lothian Blood Component Transfusion Rates to Apr 2022+	WITN7300034
10 May 2021	2021-05-10_SNBTS TT HB Informed consent for blood transfusion proposed wording for Board consent policy (003)	WITN7300035
23 April 2008	Training agreement (NHS Lothian and BBT) FY and ST 1&2 2008	WITN7300036
August 2022	Letter for FY1s INDUCTION August 2022	WITN7300037
14 March 2005	Training agreement (NHS Lothian and BBT) for transfusion trainers 2005	WITN7300038
April 2020	Letter for RN RM OPD VIRTUAL INDUCTION April 2020	WITN7300039
22nd June 2005	Meeting minutes of the Lothian HTC	WITN7104041

5th October 2005	Meeting Minutes of the Lothian HTC	WITN7104042
11 January 2006	Meeting minutes of the Lothian HTC	WITN7104043
19 April 2006	Meeting minutes of the Lothian HTC	WITN7104045
28 June 2006	Meeting minutes of the Lothian HTC	WITN7104047
10 January 2007	Meeting minutes of the Lothian HTC	WITN7104048
18 April 2007	Meeting minutes of the Lothian HTC	WITN7104050
22 August 2007	Meeting minutes of the Lothian HTC	WITN7104052
31 October 2007	Meeting minutes of the Lothian HTC	WITN7104055
20 February 2008	Meeting minutes of the Lothian HTC	WITN7104057
28th May 2008	Meeting minutes of the Lothian HTC	WITN7104060
3 September 2008	Meeting minutes of the Lothian HTC	WITN7104064
8 January 2009	Meeting minutes of the Lothian HTC	WITN7104067
29 April 2009	Meeting minutes of the Lothian HTC	WITN7104068
2 September 2009	Meeting minutes of the Lothian HTC	WITN7104070
8 January 2010	Meeting minutes of the Lothian HTC	WITN7104072
30 April 2010	Meeting minutes of the Lothian HTC	WITN7104075
19 August 2010	Meeting minutes of the Lothian HTC	WITN7104077
8 December 2010	Meeting minutes of the Lothian HTC	WITN7104078
30 March 2011	Meeting minutes of the Lothian HTC	WITN7104081
22 June 2011	Meeting minutes of the Lothian HTC	WITN7104084
28 September 2011	Meeting minutes of the Lothian HTC	WITN7104086

14 December 2011	Meeting minutes of the Lothian HTC	WITN7104084
14 March 2012	Meeting minutes of the Lothian HTC	WITN7104088
6 June 2012	Meeting minutes of the Lothian HTC	WITN7104089
10 October 2012	Meeting minutes of the Lothian HTC	WITN7104090
5 December 2012	Meeting minutes of the Lothian HTC	WITN7104091
13 March 2013	Meeting minutes of the Lothian HTC	WITN7104092
28 June 2013	Meeting minutes of the Lothian HTC	WITN7104093
25 September 2013	Meeting minutes of the Lothian HTC	WITN7104094
18 December 2013	Meeting minutes of the Lothian HTC	WITN7104095
26 March 2014	Meeting minutes of the Lothian HTC	WITN7104096
2 July 2014	Meeting minutes of the Lothian HTC	WITN7104097
8 October 2014	Meeting minutes of the Lothian HTC	WITN7104098
28 January 2015	Meeting minutes of the Lothian HTC	WITN7104099
6 May 2015	Meeting minutes of the Lothian HTC	WITN7104100
12 August 2015	Meeting minutes of the Lothian HTC	WITN7104101
4 November 2015	Meeting minutes of the Lothian HTC	WITN7104102
10 February 2016	Meeting minutes of the Lothian HTC	WITN7104103
4 May 2016	Meeting minutes of the Lothian HTC	WITN7104104
10 August 2016	Meeting minutes of the Lothian HTC	WITN7104105
16 November	Meeting minutes of the Lothian HTC	WITN7104106

2016		
5 April 2017	Meeting minutes of the Lothian HTC	WITN7104107
9th August 2017	Meeting minutes of the Lothian HTC	WITN7104108
22nd November 2017	Meeting minutes of the Lothian HTC	WITN7104109
25 September 2018	Meeting minutes of the Lothian HTC	WITN7104111
6 March 2019	Meeting minutes of the Lothian HTC	WITN7104112
3 July 2019	Meeting minutes of the Lothian HTC	WITN7104113
19 February 2020	Meeting minutes of the Lothian HTC	WITN7104114
13 May 2020	Meeting minutes of the Lothian HTC	WITN7104115
5 August 2020	Meeting minutes of the Lothian HTC	WITN7104116
2 December 2020	Meeting minutes of the Lothian HTC	WITN7104117
2 June 2021	Meeting minutes of the Lothian HTC	WITN7104118
6 October 2021	Meeting minutes of the Lothian HTC	WITN7104119
23 February 2022	Meeting minutes of the Lothian HTC	WITN7300040
8 June 2022	Meeting minutes of the Lothian HTC	WITN7300041