Witness Name: Prof Marc Turner
Statement No.: WITN3530007
Exhibits: WITN3530008-84
Dated: 07/10/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF MARC TURNER

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 and dated 1 March 2021 addressed to Craig Spalding.

I, Marc Turner, will say as follows:

Section 1: Organisation history & structure

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

1. Name: Marc Leighton Turner
   Address: Scottish National Blood Transfusion Service, The Jack Copland Centre, 52 Research Avenue North, Heriot-Watt Research Park, Edinburgh EH14 4BE.
   Date of Birth: GRO-C 1959.
   Qualifications:
   Bachelor of Medicine, Bachelor of Surgery, University of Manchester
   Doctor of Philosophy, University of Edinburgh
   Master in Business Administration (Life Sciences), Open University
   Fellow of the Royal College of Physicians of Edinburgh
   Fellow of the Royal College of Physicians of London
   Fellow of the Royal College of Pathologists

2. Please set out your current role at SNBTS and your responsibilities in that role.

2. I am the current Medical Director of the Scottish National Blood Transfusion Service (SNBTS), a position which I have held since 1st April 2011. My principal responsibilities relate to medical and scientific professional leadership of the organisation and oversight of clinical governance including compliance with SNBTS's legal and regulatory responsibilities under SNBTS's Blood Establishment Authorisation (BEA), Human Tissue Authority (HTA) licence and Advanced Therapy Medicinal Product (ATMP) manufacturing licences. I provide line management to the Medical and Clinical Scientist staff, the Tissues, Cells and Advanced Therapies Directorate, the Patient Services Directorate and the National Microbiological Reference Unit.

3. Please note that although I have been a member of the organisation since 1994, during the earlier parts of my career I held relatively junior positions and only started to take on Consultant responsibilities in 1997 and managerial responsibilities in 2001. Due to the passage of time there is no longer anyone currently working in the organisation who was involved at a senior medical, scientific or managerial level prior to around 1997. Therefore, the testimony of the current senior management of SNBTS is based on, and constrained by, current knowledge of the organisation and field, the documentary evidence available to us and input from current SNBTS colleagues. Where former SNBTS colleagues have been consulted, this has been agreed with the IBI legal team. Former SNBTS colleagues who have contributed to the text are identified as having done so below and within the relevant sections of this response namely:
    - Dr Moira Carter, former Associate Director for Donors and Transport and current COVID-19 Convalescent Plasma Programme Lead: Sections 2, 4 and 8.
    - Dr Peter Foster, former Head of R&D at PFC: Section 6 Question 26, Section 7 Questions 29, 30 and 31.

- Dr Bob Perry, former Director Protein Fractionation Centre (PFC): Section 7 Questions 29 and 30: Section 11 Question 50b.
- Dr Brian McClelland, former Regional Director Edinburgh and SE Scotland Regional Transfusion Centre: Section 11 Question 50b.

4. We have provided exhibits when referencing internal SNBTS documents or those documents that may not be otherwise easily accessible such as specialist medical or scientific publications. We have not provided exhibits for documentation readily accessible in the public domain but have provided hyperlinks where we felt that they may be helpful to the Inquiry or the general reader. SNBTS is happy to provide documents that the Inquiry has any difficulty accessing.

3. Please outline the purpose, functions and responsibilities of SNBTS, both currently and historically.

5. The purpose of SNBTS is to ensure that Scotland has a safe, effective and sustainable supply of blood, tissue and cellular products for human application. SNBTS also provides a number of clinical and laboratory services in support of the delivery of these products. The various functions and responsibilities of SNBTS can be categorised into three main themes:
   - Blood Products
   - Tissues, Cells and Advanced Therapies
   - Clinical Laboratory and Patient Services

Blood Products

6. Blood Products are classified as either 'Blood Components' or 'Plasma Products '.

7. Blood Components include red cell concentrates, platelets, fresh frozen plasma (FFP) and cryoprecipitate. SNBTS is the sole provider of blood components to NHS Scotland and was formally established for this purpose in 1974. Between 1940 and 1974 this function was provided by the Scottish

National Blood Transfusion Association (SNBTA). SNBTS undertakes (and SNBTA undertook) all voluntary non-remunerated blood donations within Scotland. SNBTS currently provides all blood processing and donation testing at the Jack Copland Centre in Edinburgh (opened in 2017). Between approximately 1998 and 2017 blood processing and testing was carried out at the SNBTS Edinburgh and Glasgow Regional Blood Transfusion Centres and prior to 1998 at all 5 Regional Blood Transfusion Services (Glasgow & West of Scotland Blood Transfusion Service, Edinburgh & South-East Scotland Blood Transfusion Service, Dundee & East of Scotland Blood Transfusion Service, Aberdeen & North East Scotland Blood Transfusion Service and Inverness & North of Scotland Blood Transfusion Service). Blood components are distributed to 32 hospital blood banks in Scotland, 4 of which are operated by SNBTS (at the Royal Infirmary of Edinburgh, Ninewells Hospital Dundee, Aberdeen Royal Infirmary and Raigmore Hospital Inverness), while the remaining 28 are operated by the territorial health boards. These activities are regulated under the Blood Safety and Quality Regulations 2005 as amended (BSQR) by the Medicines and Healthcare products Regulatory Agency (MHRA).

8. Plasma Products include albumin, immunoglobulin, a range of hyperimmune immunoglobulins (such as anti-D, anti-hepatitis A, anti-tetanus, anti-varicella zoster and anti-cytomegalovirus), and a range of coagulation factors including Factor VIII concentrate, Factor IX concentrate, Prothrombin Complex Concentrate, Fibrinogen, Thrombin and Fibrin Sealant.

9. Plasma products are Medicinal Products manufactured in pharmaceutical manufacturing facilities which, in the UK, must comply with the Human Medicines Regulations 2012 (formerly the Medicines Act 1968) as regulated by the MHRA (formerly the Medicines Control Agency MCA)

10. SNBTS manufactured plasma products from Scottish plasma from the 1950s, first on a relatively small scale within the Edinburgh and SE Scotland Blood Transfusion Service at the Royal Infirmary of Edinburgh and later on

a larger scale in a purpose built manufacturing facility, the Protein Fractionation Centre (PFC) which opened in 1975 at Liberton in Edinburgh. In 1998 it switched to the use of imported plasma as a variant Creutzfeldt-Jakob (vCJD) disease precautionary measure. PFC stopped manufacturing in 2006 and closed in 2008 and since that time SNBTS has acted as the wholesale distributor for commercial plasma products for NHS Scotland. These plasma products are procured through NHS National Services Scotland's (NSS) National Procurement (NP) Function, but are physically stored and distributed to hospitals by SNBTS.

Tissues, Cells and Advanced Therapies

11. SNBTS provides tissue retrieval, processing, storage and distribution services. This includes donations from both living and deceased donors and includes bone, tendon, heart valves, corneas and ovarian and testicular tissue. In addition, SNBTS provides haematopoietic stem cell procurement, processing and storage and pancreatic islet cell processing. These functions are regulated under the Human Tissue (Scotland) Act 2006 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) by the Human Tissue Authority (HTA). SNBTS has also manufactured ATMPs including, virus-specific T lymphocytes, corneal epithelial stem cells and macrophages under the Human Medicines Regulations 2012 regulated by the MHRA.

Clinical Laboratories and Patient Services

12. SNBTS provides a number of clinical and laboratory services directly to clinicians and patients. These include hospital blood banks in the 4 hospitals listed above which carry our patient blood grouping, red cell antibody testing, cross-matching and issue of blood components, specialist antenatal and reference immunohaematology laboratories to detect complex mixtures of red cell antibodies in patients, and histocompatibility and immunogenetics laboratories to ensure matching of solid organ and haematopoietic stem cell transplants to patients. SNBTS also provides clinical apheresis services in

Aberdeen, Edinburgh and Glasgow which undertake therapeutic plasma and red cell exchange and procurement of peripheral blood haematopoietic stem cells and starting materials for ATMP manufacture. Clinical transfusion practice across Scotland is supported by the SNBTS Transfusion Practitioner Team and specialist SNBTS Consultant Haematologists in each region.

13. Historically, SNBTS also manufactured blood testing reagents for NHS Scotland. This function was privatised as Alba Bioscience in 2007 and subsequently became part of Quotient.

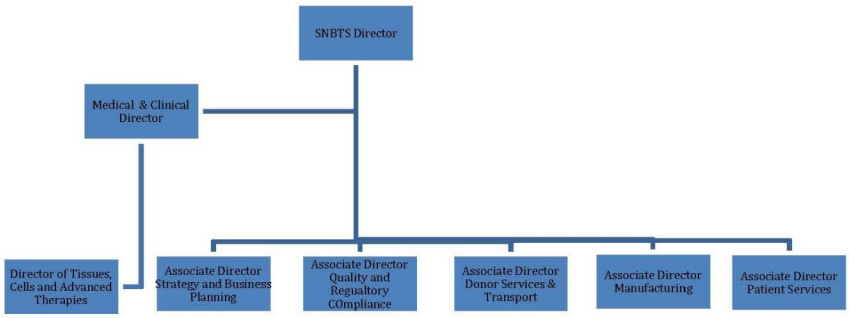
4. Please explain the current structure of SNBTS, including:

a. its staffing, in particular the roles and responsibilities of key decision-makers (for example the Director, the Medical Director, the Scientific Advisor etc.);

14. SNBTS currently has 920 staff of whom the majority are nurses (341), biomedical scientists (363) and office services staff (128) with smaller numbers of medical and clinical scientist (35), transport (34), support services (18) and senior management staff(1).

15. The two key decision making roles within SNBTS are those of the Director and the Medical Director. The Director has overall responsibility for the functioning of SNBTS. However, as a non-clinical employee, the Director relies on the Medical Director to ensure that appropriate clinical governance is in place and operational across the organisation. This requires close collaboration between the two roles. Although the Medical Director reports into the Director, he/she has the right to veto decisions on the basis of clinical governance concerns. This is further supported by professional links between the Medical Director of SNBTS and the Medical Director of NHS NSS, the parent body to which SNBTS belongs.

16. The Director of SNBTS has a team of senior managers who each have delegated responsibilities for key areas, as per the following organisational chart.



b. how, and by whom, key strategic decisions are made;

17. Responsibility for the key strategic decisions in SNBTS lies ultimately with the SNBTS Director, who is accountable to the NSS Chief Executive Officer (CEO). The overall strategic plan for SNBTS is approved by the NSS CEO and NSS Board and resource allocation (budgetary process) is carried out according to NSS planning, financial and performance management processes. This involves preparing budgets and workforce plans, which are scrutinised by the NSS CEO and Chief Financial Officer before being approved.

18. Once these plans have been approved, the Director takes responsibility for strategic decision making within SNBTS. Such decision making is conducted in close collaboration with the Medical Director to ensure that administrative and clinical considerations are always evaluated in tandem. Input into these decisions is sought from the SNBTS Senior Management Team.

c. how it is funded;

19. SNBTS is funded by the Scottish Government through NSS. SNBTS does not charge hospitals for supply of blood components, tissue or cell products but is required to operate within its revenue and capital allocations and to meet its annual Cash Releasing Efficiency Savings targets (currently 5% of NSS baseline revenue). SNBTS does also partially cross-charge some of its clinical and laboratory services to NHS Scotland Territorial Boards. Income from NHS Boards and 3rd Party income sources constitutes around 15% of total SNBTS revenue.

20. Special requests or directions to undertake additional work, such as the request from the Scottish Government in 2020 to collect SARS-CoV-2 convalescent plasma, are generally funded by the Scottish Government in addition to the annual operating budget.

d. the structure, composition and role of its various committees or working groups;

21. The main decision making and governance fora within SNBTS are:

22. Strategic Management Group: is Chaired by the SNBTS Director and has the collective responsibility and accountability for strategic decision making, overall governance, leadership, management and service delivery within SNBTS. It has the following sub groups/committees:

23. Clinical Governance and Safety Group: is Chaired by the SNBTS Medical Director and has the collective responsibility and accountability for clinical governance, blood and tissue safety within SNBTS and for raising issues of concern with the SNBTS Senior Management Group and /or the NSS Clinical Governance Committee.

24. Operational Management Group: is Chaired by the Associate Director of Strategy, Planning and Performance and has the collective responsibility and accountability for overseeing corporate governance within SNBTS. The Group exists to allow appropriate scrutiny and review of performance and risk management to a level of depth and detail not desired in SMG meetings. The purpose of the Group is to oversee the day-to-day management and direction of SNBTS, review its performance against objectives and provide assurance as to the efficacy of risk management.

25. Health & Safety Committee: is Chaired by the SNBTS Director and established to assist him/her in discharging his/her responsibilities in respect of health and safety, seeking advice where necessary from members of the NSS Healthy Working Lives Team and the other nominated 'Competent' persons within NSS as identified in the NSS Health, Safety & Wellbeing Policy.

26. Partnership Forum: is Jointly Chaired by the SNBTS Director and Lead Trades Union Representative and is the formal mechanism for Partnership working involving SNBTS Management and the recognised Trade Unions and has the collective responsibility for assurance of partnership working and staff governance within SNBTS.

27. Separate Terms of Reference for each group/committee are provided [**WITN3530008, WITN3530009, WITN3530010, WITN3530011 and WITN3530012**].

28. In addition to these key decision making and governance committees each of the SNBTS Directorates (Blood Donation and Transport; Blood Component Testing and Processing; Tissues, Cells and Advanced Therapies; Patient Services; Quality and Regulatory Compliance; Strategy, Planning and Performance) have operational management groups chaired by the relevant Associate Director.

e. its remit, including the geographical area it covered and the transfusion centres within this area; and

29. SNBTS is responsible for blood, tissue and cell collection, processing and testing for the whole of Scotland. Blood is collected in 5 fixed donor centres in Aberdeen, Dundee, Edinburgh, Glasgow and Inverness, as well as community sessions which take place across Scotland. SNBTS currently operates a centralised model for blood, tissue and cell processing and testing. Blood and tissue donations are transported to the Jack Copland Centre in Edinburgh after collection, where they are processed, tested and stored before being distributed either directly to hospital blood banks, or to a secondary storage and distribution facility in Glasgow.

30. In addition, SNBTS operates 4 hospital blood banks (out of 32 blood banks operational in Scotland). These are situated at the Raigmore Hospital in Inverness, Aberdeen Royal Infirmary in Aberdeen, Ninewells Hospital in Dundee and the Royal Infirmary of Edinburgh. All other hospital blood banks are operated by the Scottish territorial health boards.

f. the legislative and regulatory framework under which SNBTS operates.

31. SNBTS operates as one of the Strategic Business Units of NSS. NSS is the common name of NHS Scotland's Common Services Agency which is a statutory Non Departmental Public Body constituted pursuant to the National Health Service (Scotland) Act 1978 (as amended) and having its headquarters at Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB.

32. In supplying blood, tissue and cell products to the people of Scotland, SNBTS is regulated by the following regulatory agencies. SNBTS holds a Blood Establishment Authorisation (BEA) from the Medicines and Healthcare products Regulatory Agency (MHRA) which governs blood and blood component collection, testing, processing, storage and distribution under the Blood Safety and Quality Regulations 2005 as amended (BSQR). The distribution of plasma derived medicinal products is licensed by the

MHRA under a Wholesale Distributors Authorisation. SNBTS also holds a Human Tissue Authority (HTA) licence for its Tissue and Cell products under the Human Tissue (Scotland) Act 2006 (as amended) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). Finally, SNBTS holds a set of licences from the MHRA for the manufacture of ATMPs including a Manufacturers' and Importers' Authorisation (MIA), an MIA for Investigational Medicinal Products (MIA-IMP) and a Manufacturers' Specials Licence (MS). SNBTS also holds a licence from the Human Fertilisation and Embryology Authority (HFEA) for storage of gametes.

5. Please explain how the structure of SNBTS has changed over time in light of questions 4(a) to (f).

33. The best description of the early history of Blood Transfusion Services in Scotland was provided by Dr Ronald Girdwood in a paper published by the Scottish Medical Journal in 1990 **[PRSE0003986]**. Originally, a walking blood donor panel was established in Edinburgh by Mr Jack Copland. With the advent of World War 2 the Scottish National Blood Transfusion Association (SNBTA) was formed as a charitable body responsible for blood donation and processing and 5 relatively autonomous Regional Blood Transfusion Services were established, each led by a medically qualified Regional Transfusion Director. When the National Health Service was created the SNBTA continued as a charitable body but the Secretary of State for Scotland took over all its premises, equipment and staff. In 1950 a unit for the preparation of products from plasma was created in the Edinburgh and SE Scotland Blood Transfusion Service led by a Scientific Director.

34. In April 1974, the Service was reorganised and placed administratively within the newly formed Common Services Agency (CSA) of the Scottish Health Service as the Scottish National Blood Transfusion Service (SNBTS). A summary of the governance and financial arrangements in SNBTS between 1974 and 2009 was written in 2011 for the Penrose Inquiry

and this is provided as an exhibit (Governance and financing of the blood supply in Scotland 1974 - 2009 J Francis and N Billing 2011/00141) **[WITN3530013]**. The SNBTA continued as a charitable body to represent blood donors. An SNBTS Head Quarters unit was established at Ellen's Glen Road in Liberton, Edinburgh adjacent to the newly constructed facility for the manufacture of plasma products to which the Protein Fractionation Centre (PFC) relocated in 1974. The positions of National Medical Director and National Administrator were created at this time. SNBTS and the CSA continued to be funded and overseen by the Scottish Home & Health Department (SHHD) accountable to the Department of the Secretary of State for Scotland. With the advent of devolution in 1999 the SHHD was succeeded by the Scottish Executive Health Department and the Scottish Government Health Department accountable to the Scottish Parliament.

35. SNBTS was initially managed through Directors' meetings chaired by the National Medical Director and supported by a National Administrator with the remaining membership including

- Regional Medical Directors of the
    - Glasgow & West of Scotland Blood Transfusion Service
    - Edinburgh & South-East Scotland Blood Transfusion Service
    - Dundee & East of Scotland Blood Transfusion Service
    - Aberdeen & North East Scotland Blood Transfusion Service
    - Inverness & North of Scotland Blood Transfusion Service
- The Scientific Director of Protein Fractionation Centre

36. The SNBTS Directors were independently accountable to the Blood Transfusion Service Sub-committee of the CSA. The National Medical Director was considered primus inter pares and not the head of the Service.

37. This structure remained largely unchanged following the appointment of Professor JD Cash in 1978 but the role of National Administrator was gradually replaced with more formal support services. A high degree of autonomy was retained by the Regional Services throughout this period in

relation to management authority and clinical policy, though SNBTS staff were encouraged to participate in national and international working parties that focussed on establishing industry standards. A National Headquarters Research Laboratory, National Reagents Units and National Quality Unit were also created around this time.

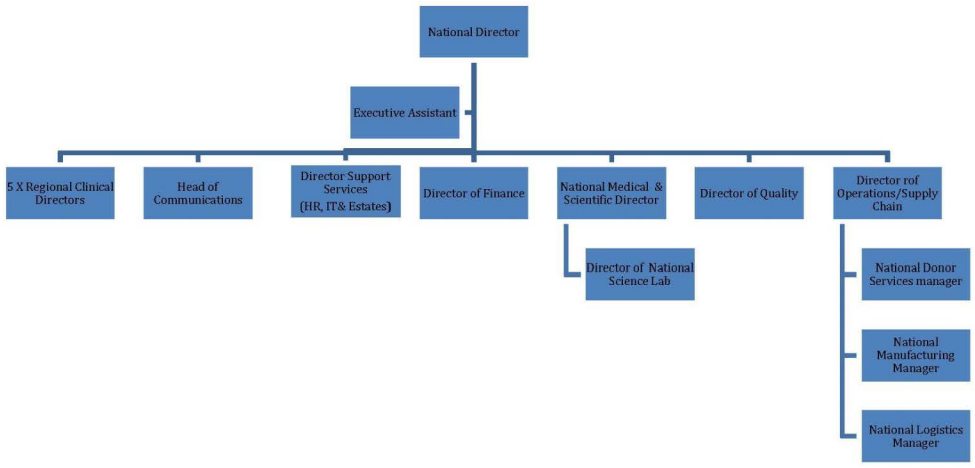
38. In 1990, a General Manager position was created (renamed National Director in 1996) and the National Medical Director became the National Medical and Scientific Director. The Regional Directors and PFC Director became managerially accountable to the General Manager / National Director and professionally accountable to the National Medical and Scientific Director. There was a greater focus on national strategic direction and the Service was rebranded across all regions as SNBTS with the current logo replacing the regionalised versions of the original SNBTA Logo. This was symbolic of a broader cultural shift in management and accountability during this period when the NHS in Scotland was experiencing radical redesign. Each of the Regional Blood Transfusion Services were renamed Regional Transfusion Centres. The service strategy aimed to harness best practice and to ensure service viability for the Regional Transfusion Centres and the PFC. At this time the Service was primarily driven by the need to collect sufficient plasma for the production of Factor VIII and the other coagulation factor concentrates.

39. The so called SNBTS Management Board at this stage comprised

- National Director (General Manager)
- National Medical and Scientific Director
- 5 Regional Transfusion Centre Directors
- Director of National Science Laboratory
- Director of PFC
- National Donor Services Manager
- Director of Human Resources
- Director of Finance

- Director of Quality (excluding PFC)

40. Following the strategic review in 1998/99 **[WITN3530014]**, SNBTS was restructured to reflect a move away from a regional structure and towards a national functional structure. A Director of Operations was created to manage Donor Services, Manufacturing and Logistics and the number of blood processing and testing units was reduced to two. A National Quality Directorate was formed along with other national support services. Hospital blood banking and related clinical and laboratory functions remained distributed within the Regional Transfusion Centres and the Regional Transfusion Directors became Clinical Directors:



41. In 2002/2003 the CSA underwent a strategic review, following which governance arrangements were strengthened, the SNBTS National Director became an Executive Director of the CSA Board and the CSA Board adopted the governance structure of other Health Boards including a Clinical Governance Committee and the centralisation of some support services.

42. Following the review of CSA/NSS in 2011, there was a period of wider organisational structural change in 2012/2013 which resulted in the consolidation of a number of NSS Divisions into Strategic Business Units (SBUs) and the centralisation of support services such as HR, finance and IT with business partners being appointed to SNBTS Senior Management

Team. SNBTS was considered of sufficient size and speciality to retain its own identity and dimensions. In 2013, the SNBTS 'Board' was renamed the Senior Management Group chaired by the SNBTS National Director and the Medical and Scientific Committee was renamed the Clinical Governance and Safety Group chaired by the SNBTS Medical Director. The posts of Clinical Directors were removed and SNBTS was organised into a number of national Directorates led by Associate Directors: Donor & Transport Services; Blood Manufacturing and Testing; Tissues, Cells and Advanced Therapeutics; Patient Services; Quality Assurance & Regulatory Compliance; Strategy, Planning and Performance. The Operational Management Group was established and chaired by the Associate Director of Strategy, Planning & Performance. There has been no significant further change to structure since this time.

6. **Please provide a list of individuals who held decision-making roles in SNBTS from 1970 to today.**

43. The key historical decision-making roles in the organisation between 1970 and July 2009 are described in the document 'Legal and Administrative Structure of SNBTS since 1970' provided as an exhibit **[WITN3530015].**

44. An update of post-holders from July 2009 to date is provided in the table below.

Post	Post-holder	Dates
NSS Chair	Mr Bill Matthews	2008 - 2012
	Prof Elizabeth Ireland	2013 - 2019
	Mr Keith Redpath	2019 - date
NSS CEO	Mr Ian Crichton	2007 - 2015
	Dr Marion Bain (acting)	2015 - 2016
	Mr Colin Sinclair	2016 - 2021
	Mrs Mary Morgan	2021 - date
NSS Director of Finance	Mr Simon Belfer	2009 - 2014
	Mrs Carolyn Low	2014 - date
SNBTS National Director	Mr Keith Thompson	2004 - 2011

	Mrs Mary Morgan	2011 - 2018
	Mrs Hazel Thomson (acting)	2018 - 2019
	Mr Craig Spalding	2019 - date
SNBTS Medical Director	Prof Ian M Franklin	1996 - 2010
	Prof Marc L Turner	2011 - date
Associate Medical Director	Prof Marc L Turner	2009- 2011
	Dr Rachel Green	2011 - 2019
	Dr Megan Rowley	2021 - date
Operations Director	Mr Martin Bruce	2001 - 2012
National Manufacturing Manager	Mr Willie Hughes	1998 - 2013
Associate Director Manufacturing	Mr Willie Hughes	2013 - 2018
	Mr Anthony Docherty	2018 - date
National Donor Services Manager	Mrs Mairi Thornton	1991 - 1996
	Dr Moira Carter	1997 - 2013
Associate Director Donors and Transport	Dr Moira Carter	2013 - 2018
	Mrs Lynne Willdigg	2018 - 2021
	Mrs Debbie McNaughton	2021 - date
Finance Director	Mrs Hazel Thompson	2005 - 2013
Associate Director for Strategy, Planning and Performance	Mrs Hazel Thompson	2013 - date
Associate Director for Patient Services	Mrs Susan Buchanan	2013 - 2020
	Prof Marc L Turner (acting)	2020 - date
Quality Director	Dr Bruce Cuthbertson	2003 - 2012
	Dr Jacqueline Barry	2012
	Mr Ian Stewart	2013

Associate Director for Quality and Regulatory Compliance	Mr Anthony Docherty	2013 - 2018
	Mrs Evelyn MacLennan	2018 - date
Tissue Director	Dr George Galea	1996 - 2013
R&D Director	Dr Chris Prowse	1990 - 2011
	Prof Robin Fraser	2011 - 2012
	Prof John Campbell	2013 - 2018
Associate Director for Tissues, Cells and Advanced Therapies	Prof John Campbell	2018 - date
NMRU Director	Dr Brian Dow	1995 - 2010
	Dr Lisa Jarvis	2010 - date

7. **Please describe SNBTS's involvement in any other inquiries, investigations or criminal/civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.**

45. As an organisation, SNBTS has contributed to a large number of inquiries and investigations in relation to infections in blood components and/or plasma products. These inquiries and investigations have taken place both within and outwith the UK. They have involved senior medical and scientific SNBTS personnel in their capacity as employees of SNBTS and experts in their specialist areas.

46. The following list sets out the inquiries and investigations in which SNBTS and its senior medical and scientific personnel have been involved and, where known, the identity of the SNBTS personnel involved:

- Krever Commission (Canada) 1997 [Professor John Cash and Mr Martin Bruce]
- Finlay Tribunal (Ireland) 1997 [Dr Peter Foster and Dr Robert Perry]

- USA Multi-District Litigation, MDL-986, 1997 [Dr Peter Foster and Dr Robert Perry]
- Scottish Executive Investigation – Hepatitis C and the Heat Treatment of Blood Products in the mid-1980s - 2000
- Health & Community Care Committee Investigation 2001
- A & Others v National Blood Authority 2001 [Dr Peter Foster]
- Lindsay Tribunal (Ireland) 2002 [Dr Peter Foster and Dr Robert Perry]
- Archer Inquiry 2009 [Dr Peter Foster and Professor Ian Franklin]
- House of Commons Science and Technology Committee – UK Blood Safety and the Risk of variant Creutzfeldt-Jakob Disease 2014 [Professor Marc Turner]
- Penrose Inquiry (Scotland) 2015 [SNBTS as Core Participant]

47. SNBTS was involved in an investigation by the Crown Office and Procurator Fiscal Service in 2005, concerning a potential Fatal Accident Inquiry into the deaths of GRO-A & Others. This investigation related to HCV transmission by blood and/or plasma products.

48. SNBTS has been involved as a defender in civil litigation in relation to HIV, HBV and HCV transmission by blood components and/or plasma products.

Section 2: Record keeping arrangements

49. Following discussion with the IBI legal team, we have interpreted record keeping arrangements to concern how information on blood donors and their donations is stored and used in the management of the blood supply in Scotland.

50. The following Section has been contributed by Dr Moira Carter.

51. In responding to the questions in this section, information is provided on:

- Donor Consent
- Hard copy and electronic storage systems

- The Donor Session Record and its use
- MAK Progesa functionality (primary electronic storage of donor records)
- The Account for Donation Data Warehouse and its use
- Paper based files for
    - Donors who donate specific blood components using a collection machine (Apheresis)
    - Donor medical files
- Retention of records

52. The responses where appropriate consider the changes across the following time periods:
    - Pre 1987 - where records were held regionally and were paper based
    - Between 1987-1997/8 - when electronic storage and donor management systems were implemented
    - Post Progesa implementation in 1997/98

53. Additionally, where relevant information is provided on the impact on the operations of the BSQR.

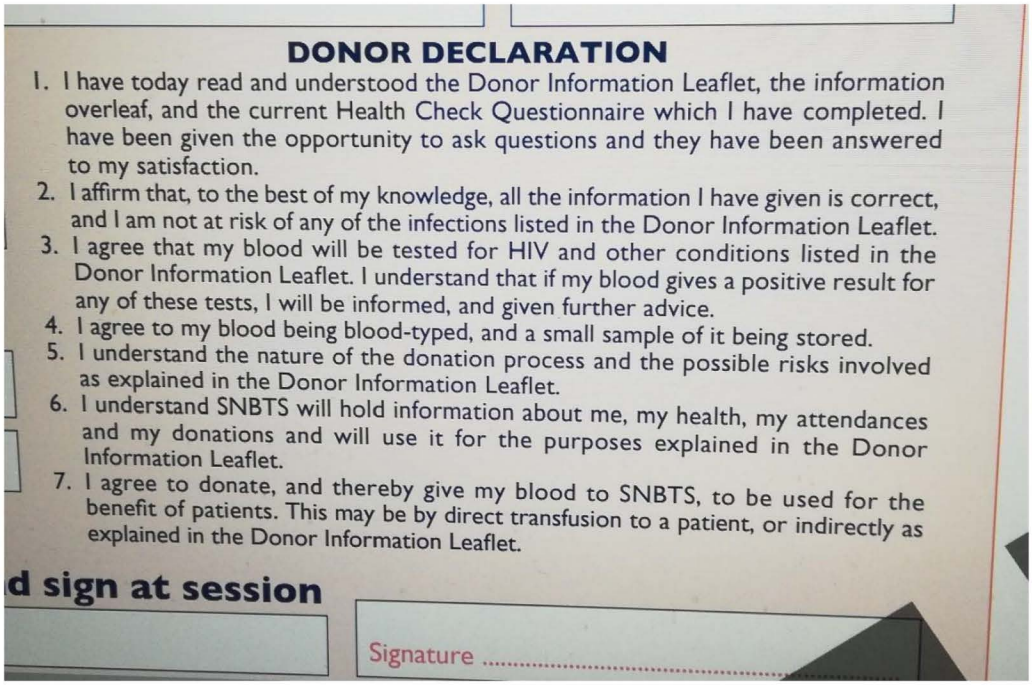
Donor Consent

54. A crucial element of the donation process is ensuring that appropriate verbal and written informed consent is obtained for the donation process and the future management of the donor and their gift to SNBTS. Donors are required to sign a donor declaration at the time of donation. The declaration asks the donors to sign:
    - That they have read and understood the Health Check Questionnaire and have been given the opportunity to ask questions
    - That the information they have provided is correct
    - That they agree to their donation being tested and to being contacted if positive for any of the microbiological markers
    - That they agree to their donation being typed and allowing storage of an archive sample that would allow the donations to be retested, if required, at a later date.

- That they understand the donation process and risks such as bruising, fainting or rarer complications such as nerve injury as outlined in the Donor Information Leaflet.
- That they understand the information that will be stored and how it might be used as explained in the Donor Information Leaflet
- That they agree to donate and thereby give their blood to SNBTS and consent to it being used as described in the Donor Information Leaflet, either directly or indirectly for patient benefit.

55. The Donor Declaration referred to in the Donor Information Leaflet **[WITN3530016]** is provided in the Figure below and a copy of the current version of the Donor Session record and Donor Health Check Questionnaire is provided for reference **[WITN3530017]**. Consent for the retention of donor information is taken from the donor at each occasion of donation and is recorded on the paper copy Donor Session Record. At each donation, donors are asked to confirm that they have read and understood the Donor Information Leaflet (DIL) and if they have any further questions prior to donation. If the donor has no further questions and is happy to proceed, they are then asked to sign the declaration. The donor declaration is signed by the donor on each occasion.

Donor Declaration Statement



DONOR DECLARATION

1. I have today read and understood the Donor Information Leaflet, the information overleaf, and the current Health Check Questionnaire which I have completed. I have been given the opportunity to ask questions and they have been answered to my satisfaction.
2. I affirm that, to the best of my knowledge, all the information I have given is correct, and I am not at risk of any of the infections listed in the Donor Information Leaflet.
3. I agree that my blood will be tested for HIV and other conditions listed in the Donor Information Leaflet. I understand that if my blood gives a positive result for any of these tests, I will be informed, and given further advice.
4. I agree to my blood being blood-typed, and a small sample of it being stored.
5. I understand the nature of the donation process and the possible risks involved as explained in the Donor Information Leaflet.
6. I understand SNBTS will hold information about me, my health, my attendances and my donations and will use it for the purposes explained in the Donor Information Leaflet.
7. I agree to donate, and thereby give my blood to SNBTS, to be used for the benefit of patients. This may be by direct transfusion to a patient, or indirectly as explained in the Donor Information Leaflet.

d sign at session

Signature .....

56. The requirement for donors to sign a donor declaration is believed to have been introduced around the time of introduction of HIV testing during the 1980s and the issue of consent to testing is discussed in a paper on the impact of AIDS prior to the identification of the causative agent in 1983 **[WITN3530018]**.

57. The wording of the donor declaration has been revised at various points following key events.

- Following the Inquiry into the unauthorised storage of tissues at Alder Hey Hospital in 2001, the donor declaration was specifically modified to strengthen the consent to retain an archive sample from each donation and provide information to donors about how their information is stored and used.

- At the time of implementation of the BSQR revisions included that:

- Donors confirm that they had read and understood the Donor Information Leaflet (see below) and had the opportunity to ask questions
- Donors understood the risks of donation and how their blood would be used

58. The BSQR also introduced the requirement for the Donor Information leaflet (DIL) (Scotblood | Giving blood: Donor information leaflet) **[WITN3530016]** which is version controlled to ensure that it is updated to align with current donor selection, screening and regulatory requirements. The BSQR requires that the DIL be provided to blood donors at each visit. This leaflet is comprehensive and provides information on:
    - Blood safety and tests performed
    - Donor selection criteria (summary)
    - Donation process (outline)
    - Complications of donation
    - Tests performed
    - How donations are used
    - What data is stored, how it can be used and refers to the Data Protection Leaflet (Scotblood | How we're protecting your data).

59. All current publications, referred to in this response are available on the www.Scotblood.co.uk website.

8. Please describe the record keeping system in place for donor information at SNBTS, both currently and historically.

60. The response to this question will provide information on:
    - Electronic storage of information outlining current practice, historical development and use of electronic storage
    - Hard Copy/Paper based records - reflecting current and historical practice

61. Regarding the period prior to 1997- answers provided will be to the best of the organisation's knowledge - following a review of available information

Current Electronic Record Storage

62. Information on donors and their donations are stored in three electronic systems

- eProgesa - the primary record - implemented in 1997 as Progesa and subsequently upgraded to eProgesa in 2011
- Donor Web Portal - links to eProgesa –implemented 2018
- Account for Donation

MAK System eProgesa (Primary Electronic Records Storage)

63. The primary record storage systems for all donor information is the core blood establishment systems entitled MAK System eProgesa.

64. MAK eProgesa is defined as a Medical Device and as such it must comply with the In Vitro Medical Devices Regulations. It is also CE marked and FDA approved (Ref: L_2017117EN.01000101.xml (europa.eu) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/640404/MDR_IVDR_guidance).

65. Progesa was implemented in SNBTS between August 1997- April 1998 and upgraded to eProgesa in 2011. The upgrade to eProgesa primarily served to transfer the system to a more digitally enabled software platform that improved its ability to interface and utilise modern technology and software.

66. The eProgesa system is a powerful database system that provides extensive functionality. It enables and controls the complete management of donations from donors to the point of issue to hospital blood banks including donor recruitment, collection, testing, processing, labelling and dispatch to hospitals (Blood Centers - MAK-SYSTEM ePROGESA software). This functionality is pivotal to the safety of the blood supply by ensuring that only eligible donors can donate and that only blood that has

been tested and screened can be issued to hospital blood banks. The system is capable of configuration to meet the changing needs of a modern Blood Service. It is highly flexible and able to control product release using robust test algorithms. The system is configured to meet the SNBTS User Requirement specifications and all developments or modifications are conducted in compliance with Good Automated Manufacturing Practice Guidelines (What is GAMP®? | ISPE | International Society for Pharmaceutical Engineering) and the requirements of the BEA as enshrined in the BSQR (2005) (see Section 1, Q4f. above). The MAK system software is the most widely used blood establishment system internationally.

67. All donors are registered in eProgesa and records include:
    - Donor demographics (e.g. age, sex, address, telephone numbers, e-mail etc.)
    - Donation history
    - Blood group and extended phenotype information
    - Tissue typing results for some donors
    - Deferral information
    - Medical remarks & comments
    - Test result history
    - Donor invitation history
    - Donor communications information
    - Donor Appointments

68. The system allocates a unique identification number to each donor, which is linked to all donation events. The system does not use or record the donor's NHS Scotland Community Health Index Number (CHI) and does not link to other NHS systems or records (e.g. GP or other healthcare records). This policy recognises the unique status and relationship that SNBTS has with its donors and aims to ensure their confidentiality. Where there is a requirement for donors to be referred to other medical specialities or for the service to communicate with the donor's GP this would be undertaken separately with the additional and specific consent of the donor.

MAK System: Donor Web Portal

69. The Donor Web Portal (DWP) is a module of the MAK Systems Donor Relationship Management system. This is a separate software system designed to integrate with eProgesa and provides additional functionality in donor relationship management, communications and facilitation of online registration and appointment booking. New donors can register in the web portal. This creates a provisional record in eProgesa which is confirmed manually by specialist donor services staff. Should the prospective donor not proceed to donation, the record can be deleted on request by the donor. Only donors who are currently eligible to donate can book an appointment online.

70. For existing donors who create a DWP account, the system automatically links new accounts created to the eProgesa account where the 5 critical identifiers (name, date of birth, sex, postcode, phone number) match to the donor's eProgesa account. Only those not matching and/or new donors would be manually connected to eProgesa.

Account for Donation

71. Account for Donation is a business intelligence platform/ data warehouse that is used to allow analysis of information from different systems including eProgesa and the DWP. It holds a copy of the data held within eProgesa and is used to inform business decision making and performance management. This system is not used to manage the relationship with donors but provides high level donation and manufacturing information that supports effective operational management.

Historical Electronic Record Storage

Electronic Records 1980-1997

72. Prior to the current electronic databases being put in place in 1997/98, SNBTS undertook some in-house development of electronic databases during the 1980s, allowing increased use of technology to improve process

control and data security. These initial databases were used for storage of donor and testing information, including test results and processing outcomes. They incorporated controls on the eligibility of donors and the release of products. The national donor database, DOBBIN, was implemented across each of the five Scottish Regional Blood Transfusion Services by 1987. DOBBIN replaced the need to retain paper records of donor demographics and captured limited donor deferral information and donor management information. This provided a national but regionally segregated donor base, where each region maintained the register of local donors but shared key deferral information with other regions. If a donor tested positive in a microbiological test in any region or had a permanent deferral, the donor was registered in all areas with the appropriate result and excluded from future donation.

73. DOBBIN introduced the concept of unique Donor Registration numbers. Additionally, it supported the use of unique barcodes for donation using the CODABAR system, linking the donor electronically with the donation prior to processing. This provided secure indexing and traceability of the donation to the donor and vice versa.

74. Information from a Price Waterhouse **[WITN3530019]** audit of the organisation's IT infrastructure in 1992 provides the following information about DOBBIN:
    - DOBBIN was used as the primary donor management tool in all regions
    - Laptops with an extract of DOBBIN were in use in collection sessions, to support donor management and donor selection and ensure that donors with deferrals would not be accepted
    - Regional variations in practice required five discrete versions of DOBBIN to be maintained
    - There was regional variation in the practice in linking the donor to the donation electronically in terms of where this was undertaken (i.e. at the collection session or in the laboratory).
    - DOBBIN was used as the database for management of the processing and testing of donations in the Scottish Regional Transfusion Centres

(excluding the (then) Glasgow and West of Scotland Regional Transfusion Centre) and analysers were interfaced with this system.

- In the (then) Glasgow and West of Scotland Regional Transfusion Centre, DOBBIN was used for Donor Management but a locally developed system was used to manage processing and testing, called LABLAN, from which information was uploaded to DOBBIN.

75. The Price Waterhouse Audit recommended the development of a comprehensive IT strategy across SNBTS to promote standardisation and consistency. The development of the strategy identified the need for an integrated blood donor management system. This led to the procurement and implementation of MAK Systems Progesa in a phased implementation between August 1997 and April 1998.

Paper Record Storage

Current Practice: Donor Session Records

76. For each donor's attendance the donor is issued with a Donor Session Record/Donor Health Check (DSR/DHC) **[WITN3530017]**. This form is important in ensuring blood safety and serves multiple functions in the donation and processing process. It is a version controlled document that complies with the requirements of BSQR. It may be issued to the donor prior to the collection session, by post, or printed at the collection session on the day of donation. The donor demographic information and contact details are pre-populated by eProgesa. The form contains the following information:

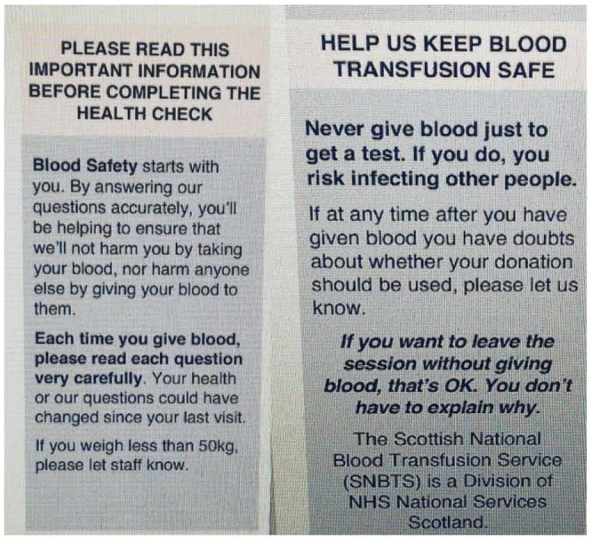
- It asks new donors about previous donations with SNBTS or other Blood Services and checks for any name change – to avoid duplication of records
- It records the date of last donation
- It records blood group and extended blood typing information for laboratory use
- It records any current deferral from donation or comments that are relevant to the eligibility or management of the donor (donors who are deferred would not be sent a DSR/DHC by post)

- It sets out the Donor Declaration and has a signature box.
- Audit information regarding the donation process, a signature section and laboratory slip section - used by staff to record results (e.g. Haemoglobin) and for them to initial each stage in the process and additional relevant information - a full audit trail is recorded for each donation
- Recording of additional donor testing and information (e.g. for Malaria or West Nile Virus (WNV) due to recent travel)
- A tear off laboratory slip section is returned with the donation to the manufacturing site - which is used during processing to assist in selecting appropriate donations for each product (e.g. Female Group A donors for platelets, Male blood group A for Fresh frozen plasma)

The reverse of the form contains:

- The Donor Health Check (tick box) questionnaire, which is completed by donors at each donation event
- Information about blood safety and keeping blood safe (see Figure below for more information)
    - Information about the importance of donors answering the questions accurately and reading the questions carefully each time they donate
    - A reminder to donors that they should never give blood to receive a test
- Date of completion of the form
- Space for donor initials on completion of the health check
- Space for clinical notes or decisions made by collection staff

Extract from the reverse of the Donor Session Record:



PLEASE READ THIS IMPORTANT INFORMATION BEFORE COMPLETING THE HEALTH CHECK

Blood Safety starts with you. By answering our questions accurately, you'll be helping to ensure that we'll not harm you by taking your blood, nor harm anyone else by giving your blood to them.

Each time you give blood, please read each question very carefully. Your health or our questions could have changed since your last visit.

If you weigh less than 50kg, please let staff know.

HELP US KEEP BLOOD TRANSFUSION SAFE

Never give blood just to get a test. If you do, you risk infecting other people.

If at any time after you have given blood you have doubts about whether your donation should be used, please let us know.

If you want to leave the session without giving blood, that's OK. You don't have to explain why.

The Scottish National Blood Transfusion Service (SNBTS) is a Division of NHS National Services Scotland.

77. Since May 2018, the Donor Session Record forms are scanned and stored electronically in PDF format in an access controlled directory which can only be accessed by authorised staff. The transfer of paper copy to electronic PDF format is undertaken by NHS NSS, Practitioner and Counter Fraud Services (PCFS) and the service is fully defined and described in a Service Level Agreement between SNBTS and NSS PCFS. The policy, procedures and management of this electronic storage system are described in the Standard Operating Procedure NATS DAD 066 **[WITN3530020]**. The records for each collection session are identified by the date and eProgesa venue code in the file name. This naming convention acts as the search index for the archived storage. Only authorised and fully trained staff can access the electronic file system. The activities undertaken using these forms include initial preparation for scanning, the scanning process, quality checks and transfer to repository storage and amendments in eProgesa, which are tracked using a version controlled form that is retained in the archive alongside the batch of records.

78. Once scanning is completed, the electronic records are placed in the repository area on the secure Donor Session Record file system by PCFS.

A restricted number of authorised SNBTS staff (Donor Operations and Resourcing Managers and Assistant Office Managers) transfer the files to the 'active workload' area - into subfolders identified by date and territory. The electronic files are reviewed and used to update the eProgesa records within the donor offices in Glasgow (Gartnavel) and Edinburgh (the Jack Copland Centre - JCC) and ensure that all relevant information relating to donor management is appropriately recorded in line with the SOP NATS DAD 050 **[WITN3530021]**. On completion, each file is transferred into the 'completed workload' area, pending the six-week review of the process for each session. The six-week review process is conducted to ensure full reconciliation of all donations and test results. This is timed to ensure that any donation requiring additional investigation or additional testing (e.g. Malaria or WNV) is included. A limited number of authorised staff can give instruction for the paper copy files to be destroyed. Destruction is confirmed by PCFS by email. The electronic records are stored for at least 30 years, as mandated by the BSQR.

79. Once all actions are completed, the electronic files are transferred to the archive storage area. Access to this electronic records archive is permitted only to authorised staff and on a "read only" basis. These records may be required to respond to donor complaints or as part of a review of the donor history if the donor later becomes positive for any microbiological marker.

Current Practice: Donor Apheresis Files

80. Donors who donate platelets or plasma by apheresis require additional tests and evaluations, such as total protein, full blood count and biochemistry testing. These are not supported by eProgesa. To manage this each apheresis donor has an additional confidential local apheresis file maintained, which is paper based. These files are stored as individual files for each donor and are retained in the Donor Centre in which the donor donates. They are stored in secure, locked filing systems that are only accessed by staff in the Donor Apheresis units. These files contain the donor's consent to donate by apheresis, relevant additional test results and

records of the annual medical evaluation of each apheresis donor. Once a donor decides to stop donating by apheresis, the file will be archived and stored in line with the NSS Document retention policy and BSQR requirements (see answer to Question 11).

Historical Practice: 1997-2018 Paper Records

81. During the period Aug 1997 - May 2018, the Donor Session Record forms were used to update eProgesa and stored regionally for 3 months. Following this the paper copy forms were stored in indexed archive storage with agreed contracted suppliers. These records can be retrieved from storage if required for lookback. Prior to the implementation of the BSQR, the only guidance on retention of records was in the first edition of the Guidelines for Blood Transfusion Services in the UK (known as the 'Red Book') **[PRSE0002989]** which advised storage of records associated with donation for 15 years. Subsequent editions did not advise on the length of retention prior to the introduction of the BSQR in 2005, which specified 30 years. In practice, SNBTS has retained all donor records from this period. Prior to May 2018 this was in hard copy.

Historical Practice: 1970-1997 Paper Records

82. Blood collection programmes operated on a Regional Blood Transfusion Service model, designed to meet local demand for fresh blood components and to meet their agreed plasma targets for PFC. As a result, the operating practices and record keeping varied in format and content between regions. This is reflected in the paper on SNBTS Donor Selection Policies and Procedure Sept 2010, 2010/00056 App2 **[WITN3530022]**, which also provides a comprehensive review of the development of donor selection criteria within the UK and in SNBTS.

83. The format of donor files retained at each of the Regional Blood Transfusion Services also changed over the relevant period. It is understood that donor information was retained on index cards and ledgers for each collection

venue and that these were taken to collection venues and updated manually.

84. The documentation associated with each donation also varied across each region in terms of format, content and information recorded. This remained the case until the appointment of the first National Donor Services Manager (M Thornton) in 1991. Under the direction of the SNBTS General Manager, there was increased focus on standardisation of practice which led to the first national Donor Selection Guidelines in 1992/3 and standardisation of the Donor Session Record.

85. The storage and retention policies also varied regionally across this time period. Between 2000-08 all available historical paper records relating to donation were placed in a centralised archive storage and remain available. In the Glasgow and West of Scotland Regional Transfusion Centre information from donor records was transferred to microfilm/fiche. They also remain available in addition to the paper archive.

9. Does SNBTS maintain a central database of blood donors?

86. Yes - as outlined in our response to Question 8.

a. How long has this database been in operation?

87. There is no formal documentation on the date of implementation of the first national database but the Price Waterhouse Audit referred to in Question 8 indicated that:

- SNBTS has had a National Donor Database system since the 1987 DOBBIN implementation
- This was replaced by MAK systems Progesa during a phased implementation between August 1997 and April 1998, to transfer all information to a licensed CE marked medical device

- Progesa was upgraded to eProgesa in 2011 and is updated regularly to maintain currency and compliance with the most recent versions of the MAK software
- Data on all donors registered in DOBBIN were transferred to Progesa alongside the results from the most recent donation recorded. Donor deferral data was also transferred, with any donor recorded as having seropositive results in DOBBIN being permanently deferred on migration. All donors who had not donated in the previous two years had a deferral code applied to ensure that a full assessment of eligibility would be undertaken when they next attended to donate

b. What donor details does it record?

88. The Progesa (both Progesa and eProgesa) system provides an integrated blood management system that is capable of importing data from other platforms to populate test results into the donor record. The configuration of the system has been modified to reflect the operating requirements of SNBTS, enabling centralisation of manufacturing and introduction of new tests and processes. This system controls and manages:
    - Donor call up and invitation
    - Collection planning
    - Donor eligibility to donate
    - Donor deferrals
    - Manufacturing
        - Processing
        - Testing
        - Confirmatory testing
        - Dispatch & Issues

89. As outlined in Question 8, the following donor details are recorded:
    - Donor demographics (e.g. age. sex, address, telephone numbers, e-mail etc.)
    - Donation history
    - Blood group and extended phenotype information
    - Tissue typing results for some donors

- Deferral information
- Medical remarks & comments
- Test result history
- Donor invitation history
- Donor communications information
- Donor Appointments

90. Between August 1997 and April 1998 the following data was migrated from the two previous databases DOBBIN and LABLAN (West of Scotland only):
    - Donor demographics
    - Details of last donation and associated test results
    - Deferral information
    - Details of donors held on a central record of microbiological positive donors

c. How is the information stored?

Mainframe:

91. The database information is stored on two mirrored servers to ensure timely and secure disaster recovery. Information is in a proprietary Oracle relational database owned by MAK systems that enables search capability on multiple criteria to link information stored in different tables within the database. Further information on the SNBTS IT System can be found in the SNBTS IT Systems Description document (NATS ITD 009 02) **[WITN3530023]**

Laptops:

92. An extract from the main database is available on remote local area network (LAN) Mobile Server Laptops (MSL). These are used to support remote community sessions and are updated each morning prior to use to upload appointment bookings and ensure that all donor information is accurate and up to date. These MSLs communicate wirelessly with other Client Laptops (CL) in use at the Donor Registration station and the Donation Linking station on session. The CL does not store any data themselves. Whilst in

operation they are not linked to the mainframe, instead data from each collection event is downloaded from the MSL devices to encrypted USB storage devices. They are returned with the blood collected to the SNBTS National Centre and uploaded to the Mainframe in the Manufacturing hall. Each session has two MSL to provide back up if required, although only one of these devices is in operation at any one time on a session.

Back Up

93. The mainframe system is fully backed up to remote server storage each day. In addition, transactional logs are updated to the disaster recovery site every fifteen minutes using Oracle Streams, which is a proprietary system designed to manage the flow of information within and between databases.

d. Who is able to access this information?

94. The systems are fully access controlled and are restricted by predefined user protocols. Each user requires:
    - Unique username
    - Password
    - Badge number to access specific programs

95. The user profiles ensure that staff can only access programs that they are authorised to use. This can also be used to define what actions within specific programmes can be undertaken by the user.

e. Is SNBTS required to report to other organisations in respect of any of the donor information it stores?

96. No

f. How long does SNBTS store this information for?

97. SNBTS stores all information associated with donors and donations for a minimum of 30 years, in compliance with the requirements of the BSQR and

its subsequent amendments and in full compliance with the GDPR and NSS Information Governance standards **[WITN3530024].**

g. What is SNBTS's policy in relation to the destruction of these records?

98. SNBTS policy is to maintain all donor records for at least 30 years in compliance with the BSQR. No donation records have been deleted or removed from Progesa or eProgesa.

99. Only donor records for individuals with no associated donations and results can be deleted as they have not become blood donors.

100. Key historical information from DOBBIN has been extracted and stored in Oracle Views to facilitate the look back of historical cases. The original server that supported DOBBIN was fragile and the IT system became obsolete, which resulted in some data corruption. The data was therefore transferred to a more stable and fully supported database to secure future access to this information.

101. As indicated in Question 8, all available paper records relating to donations have been archived. There are some limited records stored on microfilm/fiche from the former Glasgow and West of Scotland Regional Transfusion Service. There are also limited national records stored in electronic storage in a legacy system provided by a previous supplier - ERM. These records are retrievable and continue to be utilised for lookback if required. Variability in the condition of older records and indexing and grouping of records means that they require to be searched manually.

10. Does SNBTS contribute donor information to databases maintained by other organisations? If so, please provide details.

102. No

11. What are the retention policies of SNBTS regarding medical records of individuals? Have these policies changed since the 1960s? If so, please provide details.

103. Following discussion with the IBI legal team, SNBTS interpret this question as referring to donor records.

104. In responding to this question, we have summarised:

- Current policy
- Historical Background
- Historical Practice

Current Policy

105. The NSS Document Storage, Retention and Disposal Policy V7 **[WITN3530024]** states the retention period for Donor Session Records, Session and Reconciliation Paperwork, and Donor Testing Records to be 30 years.

106. This is in compliance with BSQR, which came into effect in the UK in November 2005 and implemented EU Directive 2002/98/EC "setting standards of quality and safety for the collection, testing, processing and storage and distribution of human blood and blood components" in the UK.

Historical Practice and Policy

107. Prior to 2005 the "Guidelines for Blood Transfusion Services" in the UK (the "Red Book") were first published in 1990 as compiled by experts from all the UK Blood Transfusion Services.

108. The 1989 edition (published in 1990) states that "The records or references shall be maintained in a product history file for at least fifteen years". The second edition (1993) and subsequent editions make no reference to a retention time **[PRSE0002989]**.

109. The Red Book superseded the NBTS, "Memorandum on the Selection, Medical Examination and Care of Blood Donors". This Memorandum was prepared by the National Blood Transfusion Service for England and Wales, and versions were produced in 1977, 1983, 1985 and 1987 **[PRSE0004358, WITN3530025** and **PRSE0004115]**.

110. No version of the Memorandum makes any reference to retention times and therefore it cannot be established what retention time periods were in place for blood donor records prior to 1990.

111. Prior to 2003, when the NSS Document Storage, Retention and Disposal Policy was implemented, NSS complied with Scottish Governance guidance to Health Boards and NHS Trusts on the minimum periods for which certain categories of health records were retained.

112. While there was no national policy for record retention or destruction prior to 1983, we believe that in practice, SNBTS have largely retained the majority of donor records since 1974 unless accidentally damaged or lost.

12. Is SNBTS subject to any legislative or regulatory requirements in respect of record keeping? If so, please provide details.

113. The legislative and specific regulatory requirements are detailed in "SNBTS Policy on Records Management" (NATP QUAL 030 01) **[WITN3530026]** and are in compliance with BSQR.

13. Does SNBTS have a policy on recording information on death certificates when a patient has been infected with blood borne infections relevant to the Inquiry's terms of reference? Has this policy changed since the 1960s? If so, please provide details.

114. The following section has been contributed by Professor Marc Turner

115. In Scotland a Medical Certificate of the Cause of Death is completed by the attending Medical Practitioner when somebody has died. If the death is

unexplained, sudden or suspicious then it is reported to the Procurator Fiscal under the Act of Westlaw 'Inquiries into Fatal Accidents and Sudden Deaths etc (Scotland) Act 2016. SNBTS has no involvement in, or access to, the death certification process and therefore has no policy in this regard.

Section 3: Relationship of SNBTS to other UK blood services

14. Please explain SNBTS's relationship to the other three blood services in the UK and how this has changed over time, particularly from the 1970s to date.

116. The four UK Blood Services are operationally independent of each other and accountable to their relevant health boards and administrations (Section 5 pertains). However, the Services cooperate formally through the medium of the UK Forum as described in our answer to Question 15. On a professional level there are also many informal links between colleagues in different Services due to the relatively small size of Blood Transfusion as a speciality. It's very difficult for the current senior management of SNBTS to comment on relationships between the Blood Services in the past when, as we understand it, there were semi-independent Regional Blood Services throughout all four nations.

15. Please outline the arrangements in place to enable cooperation between the four blood services, including any forums or reporting lines established to aid this cooperation.

117. The four UK Blood Services participate in both formal and informal collaboration. The main vehicle for formal collaboration between the Services is the UK Forum which was established in 1999 at the instruction of the UK Department of Health with the objective of providing a means by which UK Blood Services could work together on matters of common interest **[WITN3530027]**. The UK Forum provides a means by which joint professional advice, standards, reports and programmes can be commissioned which the UK Blood Services can rely upon in the

development and implementation of policy. The UK Forum also provides a means to represent the UK Blood Services to Government and other bodies.

118. The UK Forum is comprised of the Chief Executives / Directors and Medical Directors of the four UK Blood Services, with other professionals invited as required. The Forum itself meets four times a year, mainly now virtually. It is not a legal entity in its own right but is hosted by NHS Blood and Transplant. A number of professional groups are funded by and accountable to UK Forum including:

- UK Blood Services Joint Professional Advisory Committee (JPAC). JPAC provides expert advice on blood quality and safety matters. More details on JPAC are contained in the response to Question 16 below and on the JPAC website: (Welcome to JPAC (transfusionguidelines.org).
- Serious Hazards of Transfusion (SHOT). SHOT is an overarching UK haemovigilance scheme that allows oversight of reported adverse events linked to blood transfusion: (Home - Serious Hazards of Transfusion (shotuk.org)).
- Systematic Reviews Initiative (SRI) is a clinical research group set up to develop the evidence base for the practice of transfusion medicine through systematic reviews and other evidence-based medicine research projects: Welcome to the Systematic Review Initiative (SRI) (transfusionguidelines.org)

119. In addition to these formal channels of collaboration, numerous informal collaborations exist at many levels between the UK Blood Services ranging from professional advice to joint research projects.

16. Is there a UK-wide approach to policy development and implementation in respect of blood and/or transfusion safety, or is an approach agreed on a case by case basis? Has this changed over time? If so, please provide details.

120. There is a UK-wide approach to blood transfusion quality and safety policy development mediated through two structures: The UK Blood

Services Joint Professional Advisory Committee (JPAC) and the Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO)

121. Our understanding is that a UK Blood Transfusion Services (BTS) / National Institute for Biological Standards and Controls (NIBSC) Joint Liaison Group with 3 Working Groups was formed in March 1987 to develop scientific guidelines and standards for the quality and safety of blood and plasma products.

122. In April 1991 the Liaison Group became an Executive Committee and the Working Groups became Standing Advisory Committees. The Executive Committee provided advice to the UK Blood Service Medical Directors but was not responsible for operational implementation.

123. In June 2001 the UK Forum changed the name of the Executive Committee to the Joint UKBTS / NIBSC Joint Advisory Committee with the following terms of reference **[WITN3530028]:**

- To prepare detailed service guidelines for the United Kingdom Blood Transfusion Services. These will constitute the professional advice to the Services. They should be reviewed regularly, at present annually.

- To be an advisory committee to the United Kingdom Transfusion Services, normally by reporting to the Medical Directors of the individual Services, who are themselves individually accountable to the Chief Executives.

124. In 2013 the name was again changed to Joint UKBTS Professional Advisory Committee (JPAC) to reflect the inclusion of the MHRA and HTA and that only the four UK Blood Services contribute financially to JPAC.

125. JPAC now consists of seven Specialist Advisory Committees (SAC): Care and Selection of Donors; Blood Components; Immunohaematology; Transfusion Transmitted Infections; Clinical Transfusion Medicine; Tissues

and Cellular Therapy Products; Information Technology. Some of the SACs form subcommittees to deal with specialist issues, for example the SAC on Transfusion Transmitted Infections (SACTTI) has a standing subcommittee on parasites as Malaria, Chagas disease (American Trypanosomiasis), Toxoplasmosis, Leishmaniasis and Babesiosis.

126. Professional advice on the risk of transmission of vCJD by blood and tissues was initially provided through a subcommittee of SACTTI (November 2000 – March 2010), but thereafter 2 specialist Working Groups were formed which were directly accountable to the UK Forum: the Prion Reduction Working Group (Nov 2005 – March 2010) and the Prion Assay Working Group (August 2006 – March 2010). These 3 groups were amalgamated into a single group, the Prion Working Group, in March 2010.

127. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) was created in January 2008 to advise Health Ministers in England, Wales, Scotland and Northern Ireland; the UK Health Departments; the UK Blood Services and Transplant Service, and the NHS more widely on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation **[WITN3530029]**. The Chair and Members are independently appointed by the Department of Health.

128. Prior to the formation of SaBTO advice was provided at UK Government level by the Committee for the Microbiological Safety of Blood, Tissues and Organs (MSBTO) and its predecessor, the Committee for the Microbiological Safety of Blood and Tissues (MSBT) (1993 – 2007). Prior to that we understand that advice was provided on a national level by a body called the Advisory Committee on the Virological Safety of Blood (ACVSB). The current senior management of SNBTS have little understanding of how MSBTO and its predecessors were constituted and appointed and understand that their deliberations were regarded as confidential. SNBTS suggests that the UK Government may be able to advise in this regard.

17. Does SNBTS share information with other UK blood services about excluded donors, donors that pose a risk to the safety of the blood supply, or infected blood donations? If yes, is this on a formal or informal basis? Please describe the mechanisms in place to share information (if any) including how these have changed over time.

129. SNBTS does not routinely share personal details of donors (either people who have donated or those who have been deferred) with any other organisations. However, if a donor with an infection reports donating previously in another Blood Service and the infection time period is relevant then, with their consent, we notify the other Blood Service so that they can review the previous donation. This is a very rare event – current Donor Medical Staff can only recall one such notification over the past several years. SNBTS does share anonymised data monthly with the other three UK Blood Services regarding the number and type of infections in blood donors for epidemiological monitoring purposes. The data on microbiology testing for all four UK Blood Services is collated by NHS Blood and Transplant (NHSBT) / Public Health England (PHE) and published as an annual report on the PHE (GOV.UK) website (Safe Supplies 2019: data in context - GOV.UK (www.gov.uk).

Section 4: Relationship of SNBTS to transfusion centres

130. Following discussion with the IBI legal team, SNBTS interpret this Section as referring to its relationship with its donor centres.

131. The following section has been contributed by Dr Moira Carter

18. Please explain the relationship between SNBTS and the transfusion centres within its remit, including but not limited to the following issues:

132. In responding to the questions in this section information will be provided on:

- Relevant background and history

- The blood collection infrastructure in Scotland
- The organisational management structure for Donor Services

Background

133. All blood collection activities for the production of blood components, such as red cells, platelets and fresh frozen plasma (FFP) are managed by SNBTS. This has been the case since the formation of SNBTS in 1974. Prior to 1974 such activities were managed under the aegis of the Scottish National Blood Transfusion Association (SNBTA).

134. Before 1998, Scottish donor centres were managed locally by the relevant Regional Blood Transfusion Services. Since the strategic review of SNBTS in 1998/99 **[WITN3530014]**, all blood donor services have been managed nationally.

135. Since 2016, Donor Services have also managed the Transport Function within SNBTS.

Blood Collection Infrastructure

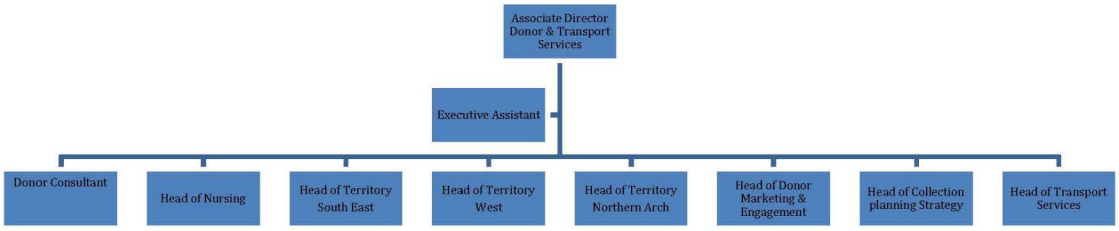
136. The relationship between SNBTS and the Donors Centres is one of direct management as all blood collection activity is managed nationally as part of SNBTS Donor & Transport Services (DS&T), which is responsible for:

- The recruitment, retention and management of blood donors
- Collection planning and ensuring the collection plan is aligned to meet patient requirements for the full product range
- Ensuring that donor invitations align to patient requirements by blood group and product
- Ensuring that processes for donor selection comply with appropriate legislation to ensure donor and blood safety
- Ensuring that all collection activities and processes are delivered to the agreed standard of service delivery for blood donors and thereby ensuring safety and sufficiency for patients

- Ensuring that there is an evidence based workforce model designed to ensure that all sessions are appropriately staffed and skilled to manage the clinical workload.

Donor Services Management Structure

137. The Organisational chart below outlines the management structure of Donor Services.



138. As shown, SNBTS blood collection activities are undertaken by three territories, each led by a Head of Territory (HOT). Each Territory has collection and administrative staff based locally as follows:

- West - 98 whole time equivalent (WTE) staff
- South East - 65 WTE
- Northern Arch -72 WTE

139. The whole blood collection teams are led by registered nurses and are multidisciplinary, with clinical support workers fully trained in blood collection processes.

140. These territorial functions are supported by a number of national activities:

- Clinical Management of Blood Donors – led by Consultants in Donor Medicine with a trained medical team
- Donor Marketing & Engagement: responsible for donor communications, marketing and donor relationship management (17 WTE)

- Collection Planning: review and plan the collection session (7 WTE)
- Service & Quality Improvement: multidisciplinary team of 17 WTE
- Clinical Support Team - 17 WTE, comprised of registered nurses and trained clinical support workers who deliver excellence in care and communications via the 03459090999 helpline. These staff undertake initial donor health-screening and eligibility checks prior to appointment booking
- Transport Services - manage the transfer of blood collected across Scotland to the SNBTS National Centre (JCC) in Edinburgh.

SNBTS currently have 5 fixed site collection centres:

- Glasgow: Whole blood, Platelet and Plasma collection
- Edinburgh: Whole blood, Platelet and Plasma collection
- Aberdeen: Whole blood, Platelet and Plasma collection
- Dundee: Whole blood, Platelet and Plasma collection
- Inverness: Whole blood

141. In August 2021, SNBTS opened a further fixed site centre in Livingston, which will collect whole blood in the first instance. In addition to the fixed site collection venues, SNBTS collects blood in community, educational and workplace venues across Scotland. Each of the three territories and venues have agreed collection targets and the collection plan for each territory is designed to ensure delivery against these targets. This is further supported by Donor Marketing and Engagement which ensures that delivery to target is supported by a comprehensive and responsive donor recruitment and retention plan designed to optimise the reliability of collection and ensure sufficiency of supply.

a. the authority SNBTS has over the day to day activities of transfusion centres;

142. SNBTS controls and directly manages all of the day-to-day activities of its donor centres and ensures consistency of policy, practice, procedures and service level provided for blood donors in Scotland. This is central to

ensuring safety and sufficiency of supply of blood for Scotland's patients. All activities are covered by the SNBTS Quality Management System (QMS see Question 44) as a core requirement of the BEA (see Section 1, Question 4f.) and all activities are regularly audited by the MHRA against the BSQR and all relevant legislation.

b. the role, if any, SNBTS plays in setting plasma targets for transfusion centres;

143. SNBTS has not collected plasma for fractionation since the exclusion of UK plasma in 1999. There has therefore been no requirement to set specific plasma targets as the current requirements for plasma based blood components can be adequately supplied from the planned whole blood collections. Plasma collected from whole blood collections is currently used clinically in two ways:

- For the manufacture of Fresh Frozen Plasma (FFP) using donations derived from male donors.
- Plasma from male donors can also be used to make pooled cryoprecipitate. This requires five doses of plasma to make one dose of pooled cryoprecipitate

Future Plasma Requirements

144. In March 2021, Ministers approved a recommendation from the Commission on Human Medicines that plasma derived from UK donors could be used for the manufacture of Immunoglobulin products. SNBTS is currently exploring the options and clinical requirements for increased self-reliance in respect of domestically sourced plasma for this purpose.

Setting Targets

145. In terms of other blood components, including red cells (manufactured from whole blood), platelets and fresh frozen plasma, SNBTS sets all collection targets for donor centres to meet the anticipated demand. This is conducted as part of the Demand and Operational Supply Process which is used to plan collection (see Section 8 Question 40 for further information)

which considers demand trends by each component, any emerging trends or issues and clinical intelligence provided by the health boards on planned activity that may influence the requirement for:

- Red cell collection as whole blood (note: blood can be split into its component parts to make up to three life saving products – red cells, pooled platelets and FFP) by blood group
- Single Donor Platelets by Apheresis (these products are required for some clinical indications in preference to pooled platelets that are recovered from 4 whole blood donations) by blood group
- Since April 2021 FFP by plasmapheresis by blood group

146. These targets are set at several levels:

- Annually and Regionally
- Daily and at the individual centre and collection venue level
    - In response to the level of each blood component held within the SNBTS inventory (SNBTS aims to maintain a minimum of three days' supply for red cells of all blood groups)
    - To meet anticipated patient requirement for recovered platelets by blood group (from whole blood donations) based on current demand trends
    - FFP by sex and blood group (SNBTS only make FFP from male donors as safety measure to prevent Transfusion Related Acute Lung Injury (TRALI)

147. Targets are set in close collaboration and with guidance from the SNBTS Manufacturing Laboratories. The target for donations from each collection event is set based on the number of available donors and past performance at the venue. The targets for donor attendances are designed to achieve a planned number of blood donations that can be processed into blood components – so planning must incorporate losses from donor deferrals on session into their planning assumptions.

c. the role, if any, SNBTS plays in setting funding levels for transfusion centres; and

148. All funding and budgets for SNBTS Donor & Transport Services activities are set, agreed, managed and monitored by SNBTS. Where there are any changes in practice or service requirement, SNBTS Donor & Transport Services review and assess the resources required to support these new activities and require to submit robust business cases to secure additional funding from NHS NSS or the Scottish Government Department of Health and Social Care. SNBTS Donor Services uses a robust workforce planning tool to ensure that the planned clinical and operational workload in collection is appropriately skilled, staffed and resourced to ensure both donor and patient safety.

d. the level of accountability of transfusion centres to SNBTS.

149. The Management of all Donor Centre and Blood Collection activities are directly accountable to the Associate Director of Donor and Transport Services and through her leadership to the SNBTS Senior Management Team and on to the NSS Board. All these activities are conducted in compliance with relevant legislation and the BEA (Section 1, Q4f). Performance of collection activities is monitored daily within Donor Services and reviewed monthly by the SNBTS Operational Management Group.

19. Does SNBTS issue organisational guidelines or directives relating to transfusion safety/best practice, or blood safety more generally, to its transfusion centres? If so, please provide copies of such guidelines that SNBTS deems to be relevant to the Inquiry's terms of reference.

150. All Donor & Transport Services activities at all collection and donor administration sites in relation to blood collection and donor management use:

- National Standard Operating Procedures that define process and practice based on agreed best practice and are controlled by the SNBTS Quality Management System (QMS) and policies. This represents a comprehensive suite of documents, a list of which is supplied **[WITN3530030]**.
- Donor Selection Guidance that is service wide and fully compliant with the BSQR and the UK Transfusion Guidelines and are robustly version controlled within the QMS as the Donor Selection Toolkit, that is a searchable, indexed, digital version of the materials required to undertake donor selection and is designed for ease of use with links to all relevant information. It is tightly version controlled by the QMS and is used in all settings where donor selection is undertaken. It includes:
    - Donor Selection Guidelines
    - Geographical Disease Risk Index
    - Supplementary guidance to support effective donor selection

- The collection processes are part of a process that is designed to ensure continuous improvement based on best practice. All changes to procedure are fully risk assessed as part of the QMS Change Control process to ensure donor and patient safety.

152. All collection venues are assessed by staff who are trained specialists in this process - for suitability for vehicular access, collection activities and to meet all requirements for infection control, fire safety and health & safety regulations. This uses a multidisciplinary approach and a holistic view of all regulations that apply within the workplace. The assessment is updated as required after each visit to the venue.

153. Each venue has a defined collection venue layout plan that is aligned to agreed best practice and is adhered to on each occasion. All layouts are risk assessed. SNBTS uses computer-aided design software to provide guidance and optimise space utilisation at each venue to ensure confidentiality, optimise donor flow and support Good Manufacturing Practice. The Charge Nurse on session is responsible for ensuring that the

session is laid out in compliance with the agreed layout. The consistency of the collection and donor administration function is audited by the MHRA as part of the biannual inspection cycle.

20. What record keeping requirements does SNBTS place on its transfusion centres? Is record keeping centrally managed by SNBTS or is it delegated to individual transfusion centres? Have these practices changed over time?

154. All records are centrally managed by SNBTS.

155. As previously described, the primary record (Section 2 Question 8) for all activities is eProgesa, which provides comprehensive management of donors, venues, donations and components derived from each donation.

156. Following the collection sessions, the Donor Session Records are returned to the SNBTS National Centre then scanned as outlined in Section 2 Question 8. Once this is complete, these scanned records are reviewed and trained SNBTS staff update all donor records in eProgesa as required.

157. The collection planning activities are undertaken by the National Collection Planning Department for all collection sessions and centres. This is managed by the Head of Collection Planning Strategy who is accountable to the Associate Director of Donor and Transport Services (D&TS). The National Collection Planning department was formed as part of the Transforming the Donation Experience Review in 2014/5 **[WITN3530031]**. This led to standardisation in practice and procedures to achieve best practice, following a review and redesign process that was informed by an international review of other services to identify best practice. Prior to this, the planning function reported to the Regional Donor Services Manager but was still accountable to the Associate Director for D&TS.

Electronic venue and planning Details & Data:

158. Details of each venue are stored within eProgesa.

159. Each venue has a unique code within eProgesa which is used in all planning documentation

160. All donations recorded in eProgesa are linked to the venue at which they were collected

161. This has been in place since Progesa implementation in 1997/98 - prior to this the planning information was largely paper-based and stored in files for each venue.

Hard Copy Planning Files:

162. SNBTS National Collection Planning department maintains a paper file for each collection venue that is stored in the territory/region in which the collection lies. These are retained in the SNBTS Donor Operational Support hubs in Glasgow, Edinburgh, Aberdeen and Dundee. The files for previous venues and historic files for current venues are stored in the paper archive.

Documentation and Records from each collection event

163. All paperwork and documentation associated with each collection is standardised and controlled as part of the requirements of the SNBTS QMS. The documentation is version controlled within the QMS IT system, Q-Pulse. There are a number of forms associated with this that are designed to ensure that activity is recorded appropriately:

- Donation barcode number range used
- Number of successful donations
- Donation outcomes
    - Donor deferrals
    - Failed venepunctures
    - Donation volumes
    - Adverse events
    - Complaints
    - Quality event and incidents
- Equipment used
- Quality Control tests

21. What information sharing requirements, if any, exist between SNBTS and its transfusion centres? Have these requirements changed over time?

164. Since 1998, all Donor Centres and venues have used eProgesa and the national reporting systems.

165. The national blood collection plan is widely shared across all departments including transport services, blood components manufacturing and testing. The plan is accessible on the shared national file system. Also shared are clear performance criteria and management and business intelligence reports that support effective decision making, troubleshooting, monitoring and performance management. This has been the case since the 1998/99 Strategic Review **[WITN3530014]**. Prior to this the information was more regionally held and shared as part of more informal Donor Services professional fora / management groups, rather than centrally managed or mandated. Prior to 1998, the activities and processes in blood collection would have been similar but would have used local standard operating procedures and practices. The information generated would largely have been shared within the Regional Transfusion Centre, with only high-level reporting to SNBTS Senior Management.

22. Does SNBTS impose information sharing requirements between transfusion centres? For example, regarding donors who had been excluded from donating at one centre because they posed a risk to the safety of the blood supply, or otherwise infected donations received by a transfusion centre?

166. All information relating to donor eligibility and deferrals/exclusion is stored in eProgesa as part of the national database and is accessed at all collection sessions.

167. Donor exclusion is managed by deferral codes within eProgesa that prevent an ineligible donor being accepted by any donor centre. Donors with temporary deferrals can be reassessed and accepted, and there is a well regulated process to assess eligibility using the Donor Selection Toolkit that

enables this. The deferral code cannot be deleted at the collection event and any donation with an active deferral generates a 'Donation Hold' flag that prevents the donation being labelled and released for issue to hospitals.

168. Additionally, the Clinical Support Team who support the donor helpline for Donor Health Queries and appointment booking also uses the communications file in eProgesa to record any relevant additional information on donor eligibility or donor requirements or preference. This is access controlled by the system to ensure security and provides a clear audit trail of actions and decisions that relate to donor management or eligibility identifying the operator who recorded the information with the date and timestamp available in the eProgesa action log. Donors who are permanently deferred or excluded from donating are placed off service and are not invited to donate. The deferral codes ensure that donors who are permanently deferred cannot book appointments online or donate without a full medical review, should they attend a collection session. As stated, the deferral code would also prevent any product being issued.

169. All donors who test positive in the mandatory microbiology tests for Hepatitis B or C, HIV, HTLV or Syphilis, are deferred from donation. This is controlled by eProgesa using fully validated and tested algorithms. If a donor tests positive for any of the mandatory microbiology markers or discretionary tests (e.g. Malaria or West Nile Virus - as a result of travel-associated risk of infection) this also prevents the blood and any components derived from the donation being labelled or released for issue to hospitals. A reactive test status in any mandatory test triggers a 'Donation Hold' flag that prevents any future donation being processed and would result in a discarded component. This is controlled by eProgesa and would have an associated discard code. In short, the system is designed to fail safe at several stages in the process to ensure that:

- Excluded donors are not permitted to donate unless fully reassessed and accepted on session, as authorised by appropriate staff who are fully trained and assessed by SNBTS in donor selection. This would require additional assessment and approval from a registered nurse.

- If, in error, a donation was accepted, the manufacturing protocols would identify and discard any unsuitable donations
- eProgesa would block the component being labelled and prevent it being released for issue.
- Any donation accepted in error would be fully investigated and managed through the QMS to ensure all appropriate corrective action had been taken. This can include identifying retraining requirements or additional process controls being introduced. This would also ensure that the donation was appropriately managed and that the donor was informed and updated on the outcome.
- There are robust procedures in place to manage and ensure continuous process improvement as part of the QMS.

Section 5: Relationship of SNBTS to government

23. Please explain SNBTS's relationship to government departments, in particular the Department of Health. Has this relationship changed over time? If so, please provide details.

170. The following section has been contributed by Professor Marc Turner

171. Health is devolved responsibility, and as such SNBTS' primary relationship with the Government is the Scottish Department of Health and Social Care. The Department of Health and Social Care is under the responsibility of the Cabinet Secretary for Health and Sport, who has a number of Ministers supporting that role. The relevant Minister that oversees SNBTS is the Minister for Public Health and Sport.

172. The Chief Executive of NHS Scotland and Director-General of the Scottish Government's Health and Social Care Directorates provides overall management responsibility for all NHS activities in Scotland, which are organised into 14 Territorial Health Boards and 8 National Health Boards. SNBTS is part of NHS National Services Scotland (NSS), which is one of the 8 national Health Boards. NSS has a Chief Executive Officer (CEO) and

a Board. The Director of SNBTS reports directly to the CEO of NSS. Therefore, SNBTS deals with the Scottish Government formally through the line of accountability thus described.

173. In addition, SNBTS has a 'sponsor branch' within the Department of Health and Social Care which provides a direct link into policy development and implementation. The responsible person in Scottish Government for managing the relationship between the sponsor branch and SNBTS is the Donation and Abortion Branch Lead.

174. The history of SNBTS's relationship to UK Government is difficult for the current senior management of SNBTS to comment on due to a lack of direct knowledge, but we note that this is documented to some extent in Lord Penrose's Preliminary Report (Chapter 5).

24. To what extent is SNBTS accountable to government departments? To what extent is SNBTS's decision-making authority affected by government oversight?

175. SNBTS is directly accountable to the CEO and the Board of NSS. The CEO and Board are accountable directly to the Scottish Government Department of Health and Social Care.

176. The Scottish Government may direct SNBTS to undertake new activities or adopt or amend blood safety measures. Recent examples include the procurement of convalescent plasma from donors recovered from SARS-CoV-2 infection for clinical trials in patients with COVID-19 and the direction to change the blood donor eligibility guidelines whereby men who have had sex with men were automatically excluded from donating blood for 3 months after the most recent sexual contact. Following an extensive scientific review by SaBTO, the Scottish Government (and other UK Governments) agreed to change this to an individualised risk based approach. The Scottish Government instructed SNBTS to implement this change on 14th June 2021.

177. The other aspect in which SNBTS' decision making may be impacted by the Scottish Government is through the funding arrangements, whereby SNBTS is fully funded by the Scottish Government. SNBTS does not charge individual hospitals for blood products, but rather is expected to operate within a set budget. However, the manner in which SNBTS uses the money allocated is not decided by the Scottish Government, but rather SNBTS follows the processes that exist within NHS National Services Scotland to determine how to utilise the allocated budget.

178. Therefore, it can be said that the decision making role of the Scottish Government extends to overall budgetary approval and decisions on implementation of new products or services and blood safety measures.

25. Does SNBTS report to or advise government departments in respect of its responsibilities or functions? If so, please provide details. Are such reports and/or advice provided on a regular basis or are they provided on request? What form do these reports and/or advice take?

179. There is no formal reporting system in place directly between SNBTS and either the Scottish or UK Governments. However, the Director and Medical Director meet regularly with the Scottish Government sponsor, who is the Donation and Abortion Policy Lead for the Scottish Government. These meetings do not contain a formal report, rather an update and discussion on key initiatives and issues.

180. In addition to regular meetings, there are numerous ad hoc communications between SNBTS and the Donation and Abortion policy team. These may take many forms, from regular emails, phone calls or meetings in response to emergent or evolving issues to preparation of business cases for new developments such as the implementation of SARS-CoV-2 Convalescent Plasma in April 2020.

181. From time to time SNBTS is also asked to assist the Scottish Government in responding to Parliamentary questions from individual MSPs or Committees.

182. This ongoing dialogue between the Scottish Government sponsors and SNBTS is important in ensuring that the Government and Ministers are aware of strategic and operational considerations that affect SNBTS's ability to continue to ensure the quality, safety and sufficiency of blood, tissue and cell products in Scotland and in supporting appropriate and timely responses to new and emergent issues.

Section 6: Relationship of SNBTS to laboratories

183. Following discussion with the IBI legal team, SNBTS have interpreted this question as referring to its relationship with blood component and plasma product manufacturing and testing facilities.

26. Please outline the laboratories currently engaged in manufacturing blood products for Scotland from plasma procured by SNBTS.

184. As outlined in our response to Question 3 the term 'blood products' encompasses blood components and plasma products.

185. SNBTS tests and manufactures blood components at the Jack Copland Centre (JCC) in Edinburgh. SNBTS operates under a BEA issued by the MHRA and JCC is the only facility in Scotland licensed for these purposes (see response to Question 4f). Blood components include red cell concentrates for the management of anaemia or blood loss, platelets for treatment of disorders of primary haemostasis, and clinical fresh frozen plasma and cryoprecipitate for the treatment of patients with acquired coagulation disorders who are bleeding or at risk of bleeding and where specific coagulation factor concentrates are clinically not appropriate or not available (for example in the context of major haemorrhage, cardiac surgery, liver disease or disseminated intravascular coagulation).

186. UK plasma has not been able to be used for the manufacture of plasma products (coagulation factors, immunoglobulins and albumin) since 1999 as a precautionary vCJD risk reduction measure. This measure was rescinded by Ministers with regard to immunoglobulin on the advice of the Commission on Human Medicines on 25th February 2021 and new arrangements for the manufacture of plasma products from Scottish plasma are now being put in place.

27. How have SNBTS's relationships with the various laboratories manufacturing blood products for Scotland changed over time? Specifically, please describe as far as you are able how SNBTS's relationships, if any, with the Bio Products Laboratory (formerly Blood Products Laboratory), Plasma Fractionation Laboratory (Oxford), Central Blood Laboratories Authority, Plasma Fractionation Centre (Scotland) have evolved.

Blood Component manufacture

187. Historically, blood component testing and manufacturing was carried out in each of the five Regional Blood Transfusion Services / Centres. Following the strategic review of 1998/1999 these were reduced to two Centres in Glasgow and Edinburgh. In 2017 all of SNBTS testing and manufacturing was brought together in a single site at the Jack Copland Centre in Edinburgh.

Plasma Product manufacture

188. The following section has been contributed by Dr Peter Foster

189. Detailed information on this was provided by SNBTS to the Penrose Inquiry **[PRSE0002556]**.

190. The manufacture of plasma products from blood donated in Scotland was undertaken by SNBTA/SNBTS, from 1952 – 1998. First at its Blood Products Unit, BPU (renamed Protein Fractionation Centre, PFC, in 1970),

which was situated within the Edinburgh Regional Blood Transfusion Centre and subsequently (from 1974/75) at a new purpose-built manufacturing centre situated in Liberton, Edinburgh. PFC received plasma from whole blood or plasmapheresis donation in the five SNBTS Regional Blood Transfusion Services / Centres. Plasma from Northern Ireland was also processed at PFC from 1983 - 1998 and products supplied back to Northern Ireland (for further information see Foster PR. The manufacture of blood plasma products in Scotland: a brief history, Scot Med J 2016, 61, 34-41) **[WITN3530032]**.

191. Elsewhere in the UK, plasma was collected by Regional Transfusion Services / Centres and sent to the Bio Products Laboratory (BPL) or Plasma Fractionation Laboratory (PFL) for the manufacture of plasma products. Unlike Scotland, the fractionation centres (BPL/PFL) were organisationally separate from the Regional Blood Transfusion Services / Centres, but were funded centrally by the Department of Health. PFL was closed in the early 1990s. BPL was part-privatised in 2013 and fully privatised in 2016.

192. As plasma products are Medicinal Products, they must be authorised for use in the UK by the Commission on Human Medicines (CHM) (formerly the Committee on the Safety of Medicines (CSM)) according to the Human Medicines Regulations 2012 (formerly the Medicines Act 1968). Imported commercial plasma products were approved for use by CSM from the early 1970s. Authority to purchase commercial plasma products for the treatment of patients with haemophilia was assigned by the Department of Health to Haemophilia Directors or their nominees.

193. In January 1975 the UK Government decided that the UK should aim to become self-sufficient in the provision of plasma products. The role of SNBTS was to achieve this for Scotland using only blood or plasma donated voluntarily from non-remunerated donors in Scotland. This objective required plasma to be obtained by replacing whole blood transfusions with transfusion of red cell concentrates. The yield and output of Factor VIII concentrate from PFC also had to be increased substantially.

194. An unpredicted growth in demand for Factor VIII concentrate, combined with a desire for people with haemophilia to receive their therapy at home, led some Haemophilia Doctors in Scotland to purchase commercial Factor VIII concentrate before SNBTS/PFC supplies could be increased to the level required.

195. In 1998, the UK Government banned the preparation of plasma products from UK-donor plasma as a precaution against the risk that vCJD might be transmitted (and spread) via them. SNBTS/PFC was authorised to import plasma to be able to continue to meet the needs of the Scottish Health Service for plasma products. All plasma imports had to be approved by CSM/MHRA and were funded centrally by the Scottish Health Department. PFC did its utmost to continue to obtain plasma from non-remunerated volunteer donors in accordance with WHO policy, but this was not possible for hyper-immune plasma (such as required for the preparation of anti-D immunoglobulin) for which plasma from paid donors was imported. Sufficient unpaid donor plasma from normal donors was not always available to SNBTS/PFC and had sometimes to be supplemented with plasma from USA paid donors.

196. In January 2006, PFC underwent its bi-annual inspection by MHRA. Despite having passed an inspection in 2004, a different inspector indicated that he wanted a large number of measurements to be repeated, even though equivalent data had been accepted by the previous inspector. On receipt of his verbal report, the acting PFC Director decided to stop production in order to expedite this large volume of work. Consequently, SNBTS therefore obtained alternative supplies of plasma products. These alternative products were obtained under the Wholesale Dealers Authorisation that had been held by PFC since 1991 **[PRSE0002556]**

197. The issues that had been raised by the Medicines Inspector were resolved, ensuring that PFC continued to hold its Manufacturer's Licence and was awarded a Good Manufacturing Practice (GMP) Certificate.

However, by this time a decision had been taken by the Scottish Minister of Health & Community Care to sell or close PFC; therefore no further production of human plasma products was undertaken at PFC.

The SNBTS's Relationships with the Protein Fractionation Centre.

198. As indicated above, the Scottish Protein Fractionation Centre (PFC) was an operational unit within SNBTS. The unit was created by SNBTS (formerly SNBTA) as part of the Edinburgh and South East Scotland Blood Transfusion Service in an extension to the Royal Infirmary of Edinburgh that was opened in 1950. The PFC was subsequently relocated to a new purpose-built centre in 1974. (For further information see Girdwood RH. Fifty years of an organized blood transfusion service in Scotland, Scot Med J 1990, 35, 24-28 **[PRSE0003986].**

199. The Director of PFC was a member of the SNBTS Management Team which was responsible for SNBTS planning to meet the needs of NHS Scotland, making annual budget submissions and allocating the funding awarded as well as general operational management of the service.

200. The PFC Director attended the annual planning meetings of SNBTS Directors and Scotland's Haemophilia Directors with officials of the Scottish Health Department. The Head of R&D at PFC also attended these meetings from 1981 onwards.

201. PFC staff interacted operationally with SNBTS Regional Blood Transfusion Services / Centres in Edinburgh, Glasgow, Dundee, Inverness and Aberdeen (and with the Belfast Regional Blood Transfusion Service from about 1983). For example:

- Products from PFC were allocated to Regional Blood Transfusion Services / Centres and transported to them by PFC staff for onward distribution by each Regional Blood Transfusion Service / Centre.

- On the return journey, PFC staff collected frozen plasma from each Regional Blood Transfusion Service / Centre and delivered it to PFC for frozen storage and subsequent processing.
- Specialist testing of PFC products was undertaken at Regional Blood Transfusion Services / Centres in Edinburgh and Glasgow.
- Staff of the PFC Quality Department were in regular contact with Regional Blood Transfusion Services / Centres, especially where there might be issues concerning the quality of a plasma donation or when notified of any adverse reaction in a recipient of a PFC product.
- R&D collaborations were undertaken between PFC and Regional Blood Transfusion Services / Centres, especially Edinburgh and SE Scotland Regional Blood Transfusion Service / Centre and staff of the SNBTS Headquarters Laboratory (subsequently named the SNBTS National Science Laboratory), which was established in 1980.

The SNBTS's Relationships with the Bio-Products Laboratory (formerly Blood Products Laboratory) and with The Plasma Fractionation Laboratory Oxford.

202. The SNBTS always regarded its relationships with BPL/PFL as being very important. Although most communications were relatively informal, formal meetings were held jointly with the Department of Health and the Scottish Home & Health Department for the purposes of planning, sharing information and establishing best utilisation of the available facilities. These included joint meetings held in February 1965 **, May 1968 [WITN3530076], November 1968 [WITN3530077], March 1969 [WITN3530078], June 1969 [PRSE0000210], November 1969 [WITN3530079], July 1971 [WITN3530080], March 1973 [PRSE0003839], March 1977 [WITN3530081] and August 1977 [WITN3530082]**

203. BPL/PFL routinely supplied SNBTS/PFC with a number of plasma products for use in Scotland. These were primarily products for which demand was not sufficient to justify duplication of manufacture at PFC and included anti-Rabies immunoglobulin, anti-thrombin III, Factor VII

concentrate, Factor XI concentrate, Factor XII concentrate and Factor XIII concentrate.

204. In 1979/1980 a formal review of fractionation technology was led by Professor Peter Dunhill of University College London to assist BPL in their design of a new centre that was being planned. A number of staff from PFC were invited to participate, as was the architect from the CSA building division who had designed the PFC building at Liberton.

205. In 1981/82 the option of processing English plasma at PFC was considered in a series of meetings. This option was eventually rejected by the Department of Health & Social Security on grounds of cost, despite being informed by the Scottish Home & Health Department that incorrect cost estimates had been used (Blood Transfusion Service: Protein Fractionation Centre, Liberton. Letter from SHHD to DHSS, 15 September 1982) **[DHSC0002333_018]**.

206. In 1990, a European Plasma Fractionation Association (EPFA) was established to enhance communications between organisations engaged in not-for-profit plasma fractionation in Europe. This body now operates on an international basis and is known as the International Plasma Fractionation Association (IPFA). From the outset SNBTS/PFC strongly supported this initiative, which BPL also joined.

207. In the mid-1990s, the Department of Health engaged management consultants Bain & Company to determine if the operation of the UK plasma fractionation facilities at BPL and PFC could be better integrated. Experienced staff from PFC and BPL were nominated to participate. The SNBTS does not appear to have received a formal report of the exercise and none of the proposals were implemented.

208. In 1997, SNBTS/PFC obtained a temporary supply of high-purity Factor IX concentrate from BPL to provide Scotland with this type of product

pending the completion of the development of a comparable product by SNBTS.

209. Plasma fractionation is a complex and highly specialised bio-pharmaceutical process industry. The SNBTS PFC (Edinburgh), BPL (Elstree) and PFL (Oxford) were the only facilities in the UK engaged in processing human plasma. These facilities were all within the NHS and were therefore considered by their staff as being within the same organisation. It was for this reason that PFC staff were encouraged to communicate with their counterparts at BPL/PFL. This approach was reciprocated by staff of BPL/PFL. Therefore, informal communications involving information exchange took place at a professional level. Staff also participated in reciprocal visits to meet their counterparts and view their facilities.

210. Examples of 'ad hoc' collaborations between SNBTS/PFC and BPL/PFL include:

- The sharing of information by PFC on the preparation of coagulation factor concentrates that had been provided personally by world authority Dr Alan Johnson (New York University Medical Center) circa 1970. It is believed that this exchange of information enabled the UK to be first in the world to be able to supply intermediate-purity factor concentrates for the treatment of haemophilia A and haemophilia B using plasma from unpaid donors.

- BPL assisted PFC to increase its output of Factor VIII concentrate in the late-1970s by providing a specialist glass vial from its own stock. This enabled more vials to be loaded into the freeze drier at PFC, pending the installation of a larger freeze drier. Thereafter BPL continued to supply PFC with these vials from its own stock until the early 1990s.

- The joint development of a heat treated Factor IX concentrate in 1984/85 and the on-going provision of anti-thrombin III by BPL/PFL for this purpose, as this had been found to be a necessary ingredient to prevent a risk of

potential thrombogenicity (i.e. increased risk of blood clots) in recipients of heated treated Factor IX concentrate.

- The virus validation of BPL/PFL dry heat treatment by PFC, which possessed the facilities and equipment necessary (1986-89).

- A joint study to identify new depth filters for the preparation of albumin and immunoglobulin to replace a traditional type of filter which had been discontinued (1989-1990).

211. The highly specialised nature of plasma fractionation meant that staff had little opportunity to develop their careers elsewhere and many of them spent their whole working life at either PFC, BPL or PFL. Consequently, communication with their counterparts was not temporary, but often lasted decades.

212. Relationships between SNBTS staff and those of BPL/PFL were enhanced by attendance at conferences and symposia, such as those held by the International Society of Thrombosis & Haemostasis (ISTH), the International Society of Blood Transfusion (ISBT), the World Federation of Hemophilia (WFH), the British Blood Transfusion Society (BBTS), the Institute of Medical Laboratory Science (IMLS) and the annual SNBTS Scotblood Conference. SNBTS staff also met their counterparts from BPL/PFL at specialist meetings such as those organised by the National Institute for Biological Standards &Control (NIBSC), the Medicines Control Agency (MCA/MHRA) and the European Medicines Evaluation Agency (EMEA/EMA).

28. Please outline the arrangements in place, if any, to enable cooperation between SNBTS and the various laboratories involved in manufacturing blood products for Scotland, including any reporting lines or forums established to aid this cooperation.

213. The following section has been contributed by Professor Marc Turner

214. SNBTS has interpreted this question as relating to plasma products since, as described previously, SNBTS manufactures its own blood components at the Jack Copland Centre in Edinburgh.

215. Since 2006 NHS Scotland has imported plasma products from commercial manufacturers. National Services Scotland National Procurement (NP) (Home :: NHS National Procurement (scot.nhs.uk)) is responsible for the procurement of plasma products with advice from the National Plasma Products Expert Advisory Group (NPPEAG): (nppeag.scot.nhs.uk). From the 1st July 2021 NPPEAG and NP will work in collaboration with the Commercial Medicines Unit (England) to secure contracts with commercial manufacturers of plasma products. Further details of the procurement processes are provided by NP in the response to Question 30. Orders from manufacturers are directly managed from the Jack Copland Centre (JCC). These activities are conducted within the control of the SNBTS Quality Management System under the Wholesale Dealers Authorisation (Human) regulatory licence (referenced in SNBTS response to Question 4f). Service Level Agreements are in place between NSS and Health Boards to manage the supply of products to them from the JCC. These agreements manage order quantities, transport responsibilities and recall arrangements and are reviewed on a periodic basis. Thus there is no co-operation between SNBTS and commercial plasma product manufacturers beyond that which is standard between a commercial pharmaceutical supplier and an NHS storage facility or pharmacy.

Section 7: Relationship of SNBTS to pharmaceutical companies

216. Following discussion with the IBI legal team, SNBTS have interpreted this question as referring to its relationship with commercial manufacturers of plasma products.

29. Please explain SNBTS's relationship with any pharmaceutical companies involved in the production, manufacture, sale and/or importation of blood products. Has this changed over time? If so, please provide details.

217. Since the SNBTS Protein Fractionation Centre ceased manufacturing in 2006 all plasma products in Scotland have been supplied by commercial manufacturers. Procurement of these products is managed by NSS National Procurement (NP) under the advice of the National Plasma Procurement Expert Advisory Group (NPPEAG) (please refer to the responses to Questions 28 and 30 for more detail). SNBTS provides a warehousing and distribution function only under its Wholesale Dealer's Authorisation as discussed in the SNBTS response to Questions 4f and 28.

218. The following section has been contributed by Dr Robert Perry and Dr Peter Foster

219. Whilst it was operational, SNBTS/PFC had an extensive network of contacts with both commercial and not for profit organisations involved in plasma fractionation primarily for the purpose of scientific knowledge exchange. None of these informal relationships were the subject of formal agreement or contract apart from occasional confidentiality agreements.

220. There were a small number of specific scientific collaborations and product supply arrangements including:

221. Relationships were established by Mr John Watt (PFC Director, 1967-1983) with scientific staff at a number of commercial companies concerned with the production of plasma products. The purpose of this was to exchange limited scientific and technical information on an informal basis. These relationships largely ceased after Mr Watt left SNBTS/PFC in December 1983.

222. The companies concerned were primarily Alpha Therapeutics, Cutter/Bayer, CSL and Speywood. Examples of informal information exchange included:

- In 1976 PFC provided Alpha Therapeutics with information to assist them in the development of their first Factor IX concentrate (Profilnine) which was prepared using PFC's published method (Middleton SM, et al. A therapeutic concentrate of coagulation factors II,IX &X from citrated, factor VIII-depleted plasma, Vox Sang 1973, 24, 441-456) **[PRSE0003648]**. This method was chosen by Alpha Therapeutics as the PFC product concerned (DEFIX) had been found to have a low potential thrombogenicity (and therefore a lower risk of causing blood clots in recipients) in comparison to other Factor IX concentrates ((Kingdon HS, et al. Potentially thrombogenic materials in factor IX concentrates. Thromb Diath Haemorrh 1975, 33, 617-631)**[WITN3433033]**.

- In 1983 Cutter/Bayer provided technical information to PFC to assist in its development of Intravenous Immunoglobulin.

- At this time, CSL (The Commonwealth Serum Laboratory) was the not-for - profit Australian state manufacturer of Plasma Products and operated in a manner similar to that of PFC and BPL/PFL in the UK. SNBTS/PFC engaged in considerable exchanges of information with CSL over many years, including the provision of assistance to CSL in the development of a heat treated Factor VIII concentrate based on PFC's 8Y method. The relationship between PFC and CSL ceased when CSL was privatised. CSL is currently the largest manufacturer/supplier of commercial Plasma Products in the world.

- Speywood manufactured a porcine (pig) Factor VIII concentrate in the UK for the treatment of haemophilia patients who had developed inhibitors (antibodies) to human factor VIII. SNBTS/PFC provided Speywood with informal advice on establishing their fractionation facility.

- In the early 1990s SNBTS/PFC established a scientific collaboration, product supply and manufacturing agreement with the not for profit Centre Regional Transfusion Sanguine (CRTS) in Lille France as part of its development and supply of a high purity FVIII product for Scottish haemophilia patients.

- Importation and supply of very small quantities of C-1-Esterase inhibitor product from the not for profit CLB (now Sanquin), the Netherlands.

- Following a disruption in supply of Albumin by Baxter to English Health Authorities, PFC sold/supplied albumin to Baxter for onward supply to Health authorities.

- Collaboration with Pharmaceutical Proteins Ltd (PPL) - a biotech company based in Roslin, Scotland and formed out of the Roslin Institute. This collaboration concerned the potential development of transgenic human proteins. The company was closed following the BSE outbreak and the collaboration ceased

30. Does SNBTS contract directly with pharmaceutical companies involved in the production, manufacture, sale and/or importation of blood products? Has this changed over time? If so, please provide details.

223. No - all contracts for the purchase of commercial plasma products in Scotland have been managed by National Procurement (NP) since PFC stopped manufacturing in January 2006.

The following section has been contributed by colleagues from National Procurement

224. National Procurement (NP), part of National Services Scotland (NSS) have managed the tendering and award process directly for the following 3 framework areas, as listed below:

- NP31518 Albumin Products since 2009 **[WITN3530034]**

- NP32617 Human Normal Immunoglobulin (Ig), since 2003 **[WITN3530035]**
- NP34917 Specific Immunoglobulins (Anti-D Immunoglobulin, Hyper Immune Globulin and Prothrombin Complex Concentrate (PCC) since 2009 **[WITN3530036].**

225. All procurement activity has been undertaken in accordance with the relevant procurement regulations, mostly recently "Procurement Reform (Scotland) Act 2014" and "Public Procurement Regulations (Scotland) 2015" with opportunities and awards all available publically, historically within the EU and UK.

226. Products awarded to these frameworks are all delivered to SNBTS, who then manage the ordering, storage and distribution of products on behalf of NHS Scotland Health Boards.

227. The above areas within scope of individual framework agreements are currently overseen by the National Plasma Product Expert Advisory Group (NPPEAG). Further details of the role of NPPEAG can be found at nppeag.scot.nhs.uk, including a list of group members. Membership of NPPEAG consists of Consultant Haematologists, Immunologists, Neurologists, Obstetricians, Pharmacists and SNBTS representing NHS Scotland health boards. The group is also supported by representation from the Scottish Government and 2 patient groups.

228. Plasma is currently sourced from donors in a handful of countries internationally, predominantly the US. For the last few years global demand for plasma products has exceeded available supply. Demand is driven by an increase in the potential clinical applications for the product, patients surviving longer and increased demand from emerging markets. The SARS-CoV-2 pandemic has exacerbated the strain on supplies, as demand for plasma has increased while global plasma donations have reduced to around 80% of normal levels seen in 2019. As a result of increased global demand for plasma products exceeding available supply, agreement was

received to collaborate with NHS England and Northern Ireland in a joint procurement in an attempt to mitigate future supply risks for Human Normal Immunoglobulin. The new framework commenced on 1 July 2021. This procurement was undertaken by NHSE&I Commercial Medicines Unit (CMU) in accordance with the Public Contracts Regulations (PCR) 2015 and their internal governance procedures including the approach to market, tender evaluation and approval to award.

229. National Procurement are still responsible for the tendering activity for the remaining areas, with the exception of Prothrombin Complex Concentrate (PCC). Effective from 1 May 2021, SNBTS call-off directly (i.e. place an order to purchase an agreed product at an agreed price) from an established NHSE&I CMU framework agreement: - NHS Framework Agreement for the supply of products for the treatment of bleeding disorders. See attached documents:

- NP32617 Strategy V1.1 **[WITN3530037]**
- 2017-OJS039-070527-en (Contract Notice that outlines Technical and Professional requirements) **[WITN3530038]**
- NP32617 Important Introductory Information V01.0 (Final) **[WITN3530039]**
- ITT_ itt_16583 - NP32617 **[WITN3530040]**
- NP32617 Tender Specification v01.0 (Final) **[WITN3530041]**
- NP32617 Tender Specification Appendix A V01.0 (Final) **[WITN3530042]**
- NP32617 Scoring Illustration V01.0 (Final) **[WITN3530043]**
- Plasma Products Strategy V1 (includes general commodity area and market overview) **[WITN3530044]**
- Appendix B NP32621 Strategy V1 **[WITN3530045]**
- Bleeding Disorders Framework Briefing Document v11 extended until 300622 **[WITN3530046]**

230. The first 7 documents are related to the current Immunoglobulin framework as this is the largest area of spend.

231. The 8th document is the Briefing Paper issued by NHS&I CMU that includes some plasma-derived products that SNBTS and NHS Scotland Health Boards can call off against. NHS Scotland now purchases Prothrombin Complex Concentrate (PCC) from this agreement.

232. The 9th and 10th documents were developed to support the new collaborative Ig agreement that commenced on 1 July 2021.

233. NHS Scotland Health Boards also have access to call off products from the following national framework agreements (mainly recombinant products, however there are some plasma derived products). These agreements are managed, and led by the CMU.

- NP350/18 CMU Recombinant Factor IX (rFIX) products for the treatment of Haemophilia B **[WITN3530047]**
- NP43420 NHS National Framework Agreement for the supply of products for the treatment of Haemophilia A **[WITN3530048]**
- NP489/18 Icatibant and C1 Esterase Inhibitor **[WITN3530049]**

234. The following section has been contributed by Dr Robert Perry and Dr Peter Foster

235. Prior to 2006 the underlying principle was that non-SNBTS PFC plasma products such as commercially manufactured Factor Eight Inhibitor Bypass Activity (FEIBA) were procured, funded and supplied by the Territorial Health Boards.

236. A small number of products were obtained from not for profit plasma fractionators that we are aware of:

- SNBTS/PFC obtained small supplies of the C1-Esterase Inhibitor from the Netherland Red Cross (NRC). This product was not manufactured at either PFC or BPL/PFL. The NRC functioned on a non-commercial basis with its plasma being obtained from unpaid donors.
- In the early 1990s SNBTS/PFC obtained a small supply of high-purity Factor VIII concentrate that had been prepared at the plasma

fractionation facility of the Regional Transfusion Centre at Lille, France to be able to supply Scotland's Haemophilia Doctors with a product of this type, pending completion of the development of an equivalent product at PFC (Liberate).

- BPL/PFL routinely supplied SNBTS/PFC with a number of Plasma Products for use in Scotland for which demand was not sufficient to justify duplication of manufacture at PFC and included anti-Rabies immunoglobulin, anti-thrombin III, Factor VII concentrate, Factor XI concentrate, Factor XII concentrate and Factor XIII concentrate.

31. Has SNBTS ever received any financial or non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

The following section has been contributed by Professor Marc Turner

237. Not to the best of our knowledge. Purchase of commercial plasma products was historically carried out by Territorial Health Boards prior to 2006 and subsequently by NP under NPPEAG advice as discussed above. Prescription of plasma products (as medicinal products) is the responsibility of individual clinicians and therefore the choice of which blood products to use does not lie with SNBTS.

32. Has SNBTS ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.

238. In 2003/2004 MSBTO recommended the importation of clinical plasma for patients born after 1st January 1996 and those with Thrombotic Thrombocytopenic Purpura requiring high volume plasma exchange. Solvent Detergent treated plasma is the preferred treatment for the latter group of patients and because SNBTS provides the Clinical Apheresis Service which carries out plasma exchange procedures the Scottish

Government funded SNBTS to purchase Octaplas on behalf of NHS Scotland.

33. What regulations, requirements or guidelines are in place at SNBTS concerning declaratory procedures for involvement with a pharmaceutical company?

239. SNBTS operates under the governance of NHS National Services Scotland (NSS) Standing Financial Instructions (SFIs) **[WITN3530050]** which is a scheme of control detailing the financial responsibilities adopted by NSS. Their purpose is to effect sound control of NSS' financial and related activities and ensure these are carried out in accordance with the law and Scottish Government policy.

240. The incorporated Code of Conduct **[WITN3530050],** applicable to all staff, sets out the rules governing the giving or receipt of gifts and hospitality by employees. This instructs that all employees should:

- Not put themselves in a position where their official and private interests may conflict
- Be aware of the presumption of influence on a potential purchasing decision or strategic decision relating to the business objectives of NSS;
- Not make use of their official positions to further their private interests.
- Be committed to the prevention of bribery and consider the guidelines in relation to the Bribery Act 2010

241. There is a general presumption against the acceptance of gifts and hospitality. The guiding principle is that hospitality, taken to mean an offer of food, drink, invitations to events, travel and/or accommodation should always be refused except where it is modest in nature. Similarly, SFIs instruct that employees should not accept gifts, except if the gift is of minimal or nominal value.

242. If acceptance of a gift or hospitality from suppliers or others is being contemplated, then approval from a senior executive has to be given prior to acceptance. All details of any gifts and hospitality offered and received are recorded in a NSS Gifts and Hospitality Register.

243. The SFIs also set out that all NSS staff must declare any financial interests or relationships with any manufacturer, supplier or contractor, with whom the NSS has, or is likely to enter into a contractual relationship, or any financial or other interests which may affect NSS's decisions.

34. Does SNBTS provide any pharmaceutical companies with results from medical research studies undertaken? If so, please provide details.

244. Not at present and not to the best of our knowledge in the past.

Section 8: Sufficiency of modern blood supply

The following section has been contributed by Dr Moira Carter.

245. In responding to the questions in this section it would be useful to consider aspects of how the blood supply is managed in Scotland and how this relates to ensuring sufficiency of supply. To this end, information will be provided on:

- Relevant background to the management of the blood supply in Scotland and how this has changed over time and in response to key events in the history of the service
- The factors that influence the sufficiency of the blood supply
- Operation of the modern SNBTS blood service
- Integrated supply chain management and how this operates within SNBTS
- The impact of Scottish Government guidance to NHS Scotland and SNBTS
- The transition to SNBTS National Centre in 2017/18

Background

246. The modern blood service in Scotland, including the structures, governance, resources and collective responsibility for ensuring sufficiency in supply, was shaped at the turn of the 21st century by a number of important developments.

- The SNBTS Strategic Review in 1998/99 which transformed the service into a national, functionally led service, introduced the concept of supply chain management as set out below **[WITN3530014].**
- The Management Executive Letter (NHS MEL 1999/9) which identified the need to further develop clinical practice, training, collaboration and governance of the blood supply **[WITN3530051]**

247. These developments were then followed by two Health Department Letters (HDLs), each strengthening both the shared responsibilities and enabling a more integrated approach to the management of the blood supply chain.

- NHS HDL (2003/19) - encompassing the establishment of the Better Blood Transfusion Programme, with a network of transfusion specialists and lead clinicians, the need for better intelligence and information on practice and variations in use of components **[WITN3530052]**.
- NHS HDL (2005/25) - encompassing advice in relation to BSQR, the establishment of an integrated plan for managing blood shortages and a project focused on minimising waste and increasing alignment between supply and demand **[WITN3530053].**

248. The above MEL and HDLs were informed by constructive discussion between SNBTS and Government sponsors in response to operational pressures experienced by SNBTS in maintaining a safe and sufficient supply and to support safe transfusion practice across NHS Scotland.

249. The implementation of the BSQR in 2005 also had far-reaching implications for how SNBTS and the other UK Blood Services operated. In particular, hospital blood banks were precluded from further processing of blood components, such as washed red cells or pooled cryoprecipitate.

SNBTS is required to develop new processes and products (e.g. pooled cryoprecipitate) to support blood banks and meet patient requirements. In addition, the added regulatory requirements placed on NHS Scotland Hospital Blood Banks within the Territorial Health Boards to comply with the BSQR required additional support and advice from SNBTS

The Impact of the Guidance to NHS Scotland and SNBTS

250. As discussed above, the Scottish Government and NHS Scotland guidance for SNBTS that were important in shaping the modern blood service and these are discussed in greater detail here.

251. The Management Executive Letter **[WITN3530051]** dated 14 Jan 1999, identified the need for improved clinical transfusion practice in the NHS in Scotland. Note that this MEL was issued prior to the devolution of the responsibility for Health in Scotland so NHSiS is now known as NHS Scotland (NHSS).

252. The reasons identified for this were stated as:

- The greatly increased demand for blood resulting from increased clinical activity and increased requirement for non-surgical uses of blood
- The demand for blood associated with the waiting list initiative (which was recognised by a special allocation to SNBTS)
- The introduction of new, more stringent donor deferrals had increased by ~5% which further impacted the availability of blood
- The impact on the NHSiS of leucodepletion and nucleic acid testing of blood
- The recommendations from the Serious Hazards of Transfusion (SHOT) haemovigilance system on how the safety of patients receiving blood could be improved
- The risk of vCJD
- The implications of clinical governance for blood transfusion practice

253. The MEL required that from March 1999, the 'NHS Trusts' (as they were at that time, now NHSS Health Boards)

- Form Hospital Transfusion Committees (HTC) to oversee all aspects of blood transfusion
- Participate in the SHOT reporting system

254. The MEL also required, by March 2000, all 'NHS Trusts' where blood is transfused:
   - Agree and disseminate local protocols for blood transfusion, based on guidelines and best national practice, and supported by in-house training;
   - Explore the feasibility of autologous blood transfusion and ensure that where appropriate, patients are aware of this option; in particular, they should have considered the introduction of perioperative cell salvage.

255. The MEL was the equivalent of the Health Service Circular for England and Wales (1998/224 Better Blood Transfusion) **[WITN3530054]** and a number of the recommendations contained in both documents were taken forward by the UK as a whole. These initiatives were further strengthened by the later HDL (2003/19) **[WITN3530052]** following which SNBTS responded by supporting the development of the Better Blood Transfusion Programme (BBTP). This introduced Transfusion Practitioners to each Health Board to support improvements in transfusion practice across Scotland. By 2006 demand for red cells had reduced by 10%.

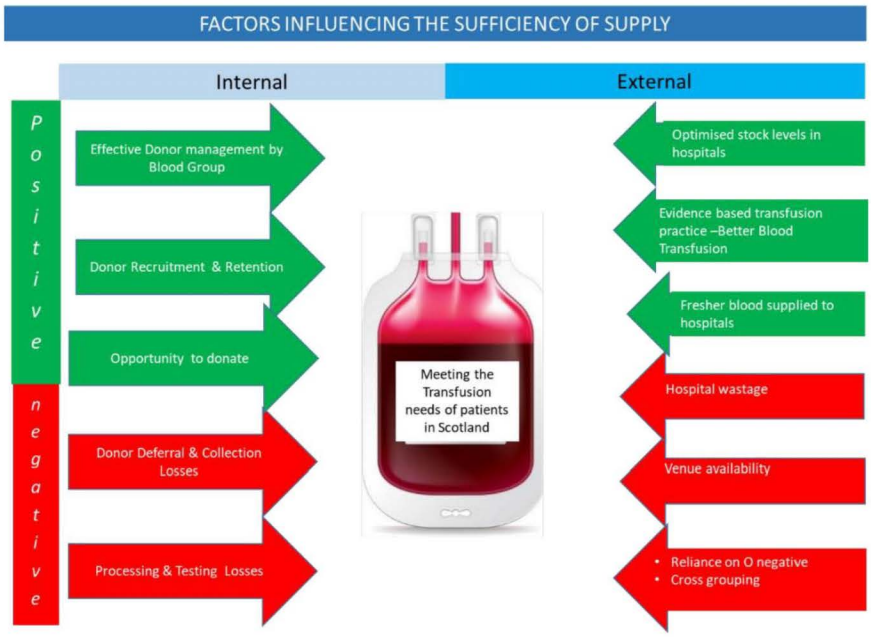
Factors Influencing Sufficiency of the Blood Supply

256. There are factors that influence the sufficiency of the blood supply in Scotland and these are outlined in the diagram below.

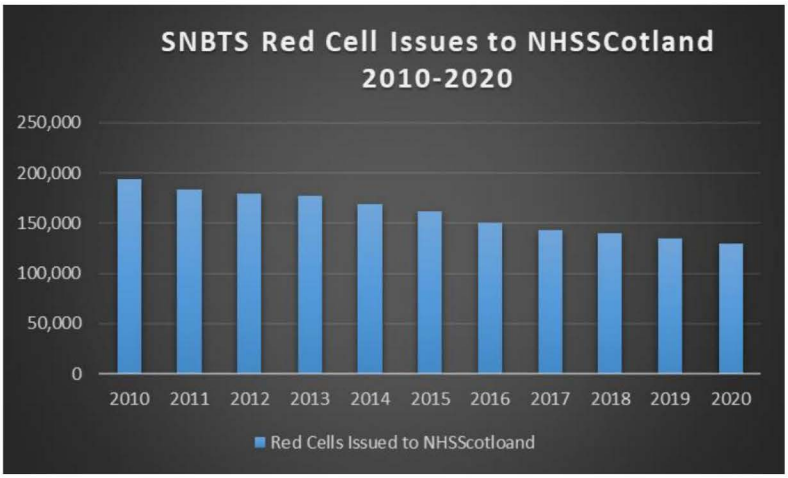
257. Since the mid-1990s SNBTS has made concerted efforts to make more effective use of the blood supply as an additional strategy to further ensure sufficiency, improve efficiency and maximise the benefit / risk ratio of a blood transfusion. This aimed to ensure consistency and avoid unnecessary transfusion by promoting best practice. This was initiated with the formation

of the Effective Use of Blood Team in the early 1990s and the later establishment of the Better Blood Transfusion Programme in 2003. SNBTS have taken a holistic approach to addressing and managing these factors by:

- Improving donor relationships and donor management
- Promoting effective use of blood
- Supporting best clinical practice.



258. This multidisciplinary, collaborative approach to the management of supply has been highly effective in ensuring that SNBTS meets the transfusion needs of patients in Scotland. The demand for red cells in Scotland has reduced year on year since 2010 and has reduced by 33% overall during this period. The detailed responses to this question will provide more information on how this has been achieved.



Impact of SNBTS Strategic Review 1998/99

259. The SNBTS Strategic review in 1998/99 **[WITN3530014]** transformed the management of the supply from a regional to a national model. It introduced the concept of supply chain management, with a revised organisation structure designed to meet the transfusion needs of patients in Scotland and using a functional model based on activity rather than geographical location. This review recognised the need to improve the national planning and management of the blood supply and the need to promote effective use across Scotland. The work to improve clinical practice was led initially by the Effective Use of Blood initiative and from 2003 by its successor the Better Blood Transfusion Programme. These initiatives were key in developing the strategic direction for SNBTS at that time.

260. This change was pivotally important in ensuring the sufficiency of supply by enabling:

- Standardisation to best practice across the supply chain
- National management of Donor Services and standardisation of collection processes and procedures to best practice
- Improved standardisation, training control and monitoring of Donor Selection and deferral rates

- Centralized processing, testing and management of the blood supply from 5 sites to 2
- More rapid implementation of changes and improvements (e.g. Universal Leucodepletion, NAT testing for HIV & HCV)
- Avoiding duplication
- Optimising the productivity of the available donor base
- Improved organisational efficiency

261. This strategy was designed to address supply issues and concerns by optimising
    - Donor recruitment and retention
    - Improving collection efficiency and practice
    - Increasing manufacturing yields
    - Reducing loss rates across the supply chain
    - Supporting effective use of blood and better blood transfusion practice

262. The national functional management of Donor Services promoted more effective cooperation across all disciplines and regions in Scotland and promoted rapid improvements in donor recruitment and retention, collection planning and avoiding shortages. The Donor Communications strategy was reviewed and repositioned to support increased recruitment, clear motivation and consistency of messages across all communication channels. The 'Give Blood' campaign is an award winning and internationally recognised exemplar of a social marketing campaign that promotes donation while ensuring donors understand blood safety issues. (Carter et al (2011) Transfusion & Apheresis Science 45 (2011)31-43) **[WITN3530055].**

263. The blood collection process was redesigned and standardised to deliver a truly national service as part of the first Donor Services Review in 2002 **[WITN3530056]** and supported consistent clinical practice and medical policy for the care and selection of blood donors. There have been a number of further national reviews that have modernised and strengthened

the national management and effectiveness of the Donor Services function, as part of the Transforming the Donation Experience Strategic review **[WITN3530031]**.

264. The change in approach to managing the blood supply rapidly delivered tangible benefits and SNBTS has not needed to launch an emergency appeal for blood donors since 14th October 2003.

Prior to the 1998/1999 Strategic Review

265. Prior to the implementation of the 1998/99 Strategic Review, the service model for SNBTS was regionally managed by Directors in each of the 5 Scottish regions. The collection programmes were planned to meet local rather than national demand. The target setting for each region was agreed internally to that region and the collection plan designed to meet the requirement. From the early 1990s there was a recognition that there were regional differences in blood sufficiency. In January 1990 there was evidence of blood shortages in Glasgow that could have been avoided if blood had been imported from another region. This is recorded in the witness statement from Mr Martin Bruce supplied to the Penrose Inquiry **[WITN3530057].**

266. Until the late 1990s SNBTS was primarily driven by the need to collect sufficient plasma to meet the need for fractionated products and in particular Factor VIII. This meant that most regions generated a surplus of red cells until the mid-1990s, when demand for red cell components increased and there were frequent localised and occasional national blood shortages, particularly for O negative blood.

267. In 1996/7 SNBTS initiated a pilot project to explore the benefits of a more national approach to the management of Donor Services that included centralised management of three of the five Scottish regions. This was a pilot program, designed to explore the benefits of greater regional cooperation by:

- Establishing key common blood collection processes to agreed quality standards
- Integrating donor records, donor panel management and programme planning
- Fully integrating donor publicity and PR
- Provision of consistently high standards of donor medical management policies and procedures
- Provision of key performance data monitoring

268. This project rapidly demonstrated tangible benefits within the first year of the planned two-year programme. The recommendations were accelerated and incorporated into the plans for the strategic review that was initiated in 1997/98 and delivered in 1998/99. (SNBTS Strategic Review Donor Project Report) **[WITN3530058]**. This work was important in informing the future strategy for Donor Services that was delivered following the 98/99 strategic review.

The Integrated Supply Chain

269. As discussed above, the Strategic review of SNBTS in 1998/99 **[WITN3530014]** introduced the concept of supply chain management to SNBTS. Since then the service has worked strategically to deliver the benefits that can be achieved by taking a whole system approach to managing the blood supply.

270. As part of this development, SNBTS have collaborated with Herriot Watt University in a Knowledge Transfer Partnership on Supply Chain Management (SCM) as part of the UK wide programme managed by Innovate UK (ktp.innovateuk.org/). This was jointly funded by Innovate UK and SNBTS. This project sought to further strengthen the SNBTS approach to supply chain management. In their published work Rutherford et al (2016) **[WITN3530059]** described the SNBTS as a four-stage supply chain stretching from blood donors to final consumers, i.e. patients. They described this as a vertically integrated supply chain from procurement (donation) to administration (transfusion). This encompasses the SNBTS

elements (comprising Donor Services and Production (processing & testing), and NHS Hospital customers throughout, as illustrated in the diagram below, provided from this paper.

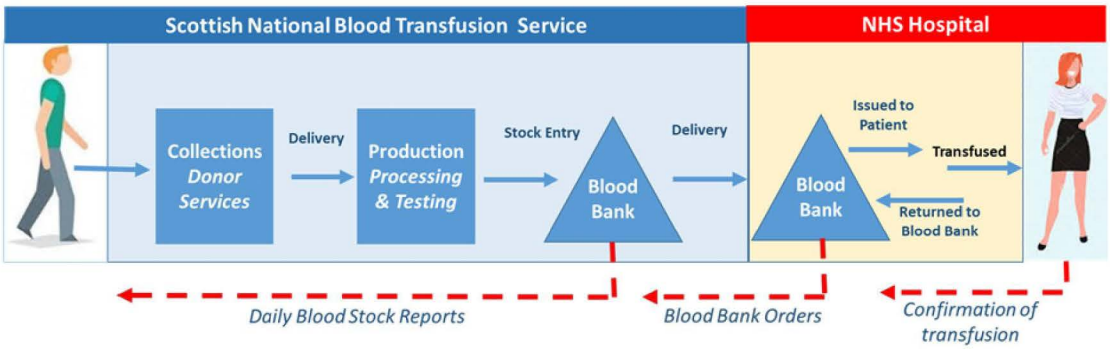


Figure 1: Schematic of the end to end blood supply chain in Scotland.

Extract from the published paper: *Evidence of Bullwhip in the Blood Supply Chain Citation for published version: Rutherford, C, Cheng, SY & Bailie, K 2016, 'Evidence of Bullwhip in the Blood Supply Chain', Paper presented at 23rd Annual EurOMA Conference 2016, Trondheim, Norway, 17/06/16 - 22/06/16.*

271. The aims of an integrated supply chain are:

- To meet demand with the most efficient use of resource
- To match supply to demand and to do so with minimum inventory, this requires visibility of true demand in real time
- To reduce the lead time to manufacture products in response to demand signals
- To optimise manufacturing flow to support the right mix and location of supplies to meet customer requirements
- To optimise stock management to eliminate wastage at every step of the supply chain process
- To optimise the logistics to support effective distribution in meeting customer needs

272. Since 1998/99, SNBTS have worked towards translating these principles to the blood supply chain. The blood supply chain is potentially unique in that our source of starting materials (blood donors) choose whether to donate. Therefore, in order for SNBTS to ensure that there is enough blood for patients there is a need for excellent relations with our suppliers (our valued blood donors) to ensure sufficient blood donations of the right type at the right time to meet the transfusion needs of patients in Scotland for the

full range of blood components. So, while our ultimate customers are the patients who receive blood, we must also maintain a customer service relationship with blood donors.

273. SNBTS has almost complete (97%) visibility of the blood supply chain due to data integration that enables shared information on blood stocks between NHS Scotland hospital blood bank Laboratory Information Management (LIM) systems and SNBTS. This improved visibility of the blood supply from donor to patient has been pivotally important in the management of the supply chain and in driving forward improvements, increasing efficiency and effectiveness in delivering patient care and ensuring sufficiency of supply.

Demand and Operational Planning (DOP)

274. A key element of effective supply chain management is dynamic forecasting and accurate data on demand. Where products have short shelf life and demand is unpredictable this process needs to be tightly managed and reviewed frequently. This is highly relevant in the management of the blood supply as there is an extensive product range with varying shelf lives and over time SNBTS has developed a Demand and Operational Planning (DOP) process that is robust and effective.

275. To support the integrated supply chain model and effective DOP planning SNBTS has developed a comprehensive set of management tools and dashboards to ensure effective management of the blood supply and avoid shortages. These tools enable the service to visualise complex data and undertake detailed analysis of issues to optimise collection activity by targeting the right donors and to maximise the product yield from planned collections by optimising the manufacturing schedules.

276. Further information and historical background can be found in the witness statement of Mr Martin Bruce, former SNBTS Director of Operations (2001-2012) **[WITN3530057].**

The Blood Supply Chain

277. The blood supply chain is complex and requires timely management of a product range that requires secure temperature control and where the products are perishable and, in some cases, have a very short shelf life (e.g. platelets).

278. In effect, SNBTS has multiple supply chains for different products:

- Platelets - highly volatile demand – short shelf life (7 days) and require 22°C storage
- Red Cells - differ by blood group in terms of volatility of demand with a shelf life of 35 days and require 4°C storage
- Fresh Frozen Plasma and Pooled Cryoprecipitate - less volatile – 3-year shelf life at –25°C storage
- Niche – just in time products:
    - irradiated blood
    - washed red cells
    - granulocytes

The Impact of Data Integration and Improved Supply Chain Visibility

279. HDL 2003/19 **[WITN3530052]** set out the need for improved data integration and for tailored information systems to understand the clinical context of the use of blood. This resulted in the development of a data driven approach to the oversight and management of the blood supply chain "from vein to vein". From the early 2000s SNBTS developed an approach to collection and maintenance of data sources on blood supply and demand to improve visibility on use of blood in Scotland.

280. This data is obtained from the business intelligence databases that are described in greater detail below:

- Account for Blood (AfB)
- Account for Donations (AfD)
- Account for Patients (AfP)

281. Data integration, data analytics and data visualisation are now well established within SNBTS, using a mixture of structured data warehousing, logical data warehousing and analytical/presentation software. The development of the business intelligence platform has progressed over the last decade and is now capable of delivering rapid development of dashboards presenting key indicators across the supply chain.

282. The first data integration project brought together data from the majority of hospital LIMS systems in Scotland and is known as Account for Blood (AfB). AfB was implemented in 2010 and continues to the present, with daily updates on hospital activity and use of stock.

283. In addition, AfB allowed the Scottish Transfusion Epidemiology Database (STED) to be developed. It links together the data on patient blood use with hospital inpatient records, providing insight into the clinical context of blood use. The clinical use of blood components has also been important to the Transfusion Medicine dialogue with the clinical community, as variations in practice are explored and audits, research and historical analyses are undertaken.

284. The Account for Donation (AfD) data warehouse development in 2014 provided intelligence in relation to donor management, collection methods and performance, and the manufacture, testing and distribution of blood components.

285. The Account for Patient (AfP) data warehouse development in 2016 provided intelligence about the laboratory activities of blood banks using the Traceline database. Traceline is the SNBTS hospital LIMS system and is used in 11 NHS Board run laboratories.

Working in Partnership with NHS Scotland's Health Boards

286. The business intelligence platform SNBTS is now operating on enables performance management across the entire supply chain, improving visibility and responsibility for all stakeholders including Hospital Transfusions Committees, Blood Bank Managers and Health Board Management. This has facilitated increased collaboration with NHS Boards regarding the configuration of their local LIMS system, the ongoing operations of the data transfer and the activity/performance data available to NHS Boards. It has enabled key performance indicators to be set and monitored, ensuring accountability and responsibility across the entire supply chain. This has been further supported by the development of interactive dashboards that enable visualisation of the data using Tableau software that allows customer hospitals to drill into the data and compare themselves with other hospitals. This has fostered continuous improvement and encouraged users to learn from each other **[WITN3530060]**. As a result of these collaborations NHS Scotland has reduced its stockholding overall and has reduced time expiry and wastage.

287. The platform also enables SNBTS to use other sources of information collected in Scotland, such as emergency and routine hospital admissions by NHS Health Board by speciality, from NHS Scotland (NHSS) System Watch, as surrogate indicators to support the understanding and forecasting of demand.

Transition to the SNBTS National Centre in 2017

288. The transition to the new SNBTS National Headquarters at the Jack Copland Centre in Edinburgh in 2017 centralised SNBTS manufacturing activities to a single site and resulted in substantial redesign of:

- Inbound and outbound logistics to promote a 'Full Out, Full In" model that improved efficiency and reduced carbon footprint while enabling more frequent delivery to customer hospitals. This uses the same journey to distribute blood components to our customer hospitals on the outward journey and collects donations for processing on the inbound journey to the SNBTS National Centre This has delivered a number of benefits:
    - Improved ability to supply 'niche' specialist products such as washed red cells and irradiated products for individual patient requirements
    - Reduced age of stock at time of issue to hospitals allowing greater opportunity for each donation to be transfused before expiry
    - Reduced wastage
    - Reduced cross grouping and more controlled use of O negative (the universal donor)
    - Increased supplies available for NHS Scotland

- Revised stockholding for SNBTS distribution hubs based on average issues and development of target stock levels based on actual demand for components and the frequency of delivery
- Co-location of key personnel and functional departments to this site further fostered the integrated supply chain model and promoted streamlined collaboration and further improved the DOP process

35. **How does SNBTS understand its responsibility to ensure a sufficient supply of blood in Scotland? Has this responsibility changed over time in nature and / or extent? If so, please provide details.**

289. SNBTS is responsible for the delivery of a sufficient blood supply to meet the transfusion needs of patients in Scotland. This includes the provision of red cell concentrates, platelets, fresh frozen plasma, cryoprecipitate and other highly specialised blood components. SNBTS is accountable to the NSS Board and the Scottish Government Department of Health and Social

Care. The Service is funded by NSS as outlined in Section 1, Question 3. SNBTS is the only licensed Blood Establishment in Scotland (see Section 1 Question 4f).

290. This responsibility has largely remained unchanged with the exception that:

- SNBTS is no longer responsible for the provision of plasma products following the closure of PFC in 2007
- The BSQR changed the requirements for blood components due to restrictions placed on Hospital Blood Banks on their ability to modify products (e.g. wash red cells or irradiation of components) or to pool products (e.g. Cryoprecipitate). As a result, SNBTS now supplies these products direct to Hospital Blood Banks

36. Does SNBTS share its responsibility to ensure the sufficiency of the blood supply in Scotland with other stakeholders (for example, government departments or other medical/public health organisations)? If so, please provide details.

291. SNBTS shares the responsibility for securing support and funding for developments and policies that support the quality, safety and sufficiency of the blood supply with the NSS Board and the Scottish Government Department of Health and Social Care.

292. The two HDLs discussed above **[WITN3530052]** and **[WITN3530053]** mandate a shared responsibility for the management and governance of blood stocks, clinical transfusion practice and the effective use of blood with the Scottish Territorial Health Boards and their Hospital and Overarching Transfusion Committees.

293. As mandated by BSQR, to maintain product quality and safety, SNBTS are subject to regular inspections by the MHRA, to ensure that the Quality Management System is in compliance with the terms of SNBTS's BEA (Section 1 Q 4f).

294. SNBTS is also heavily reliant on Local Government bodies for access to suitable collection venues in their ownership. These are critical in maintaining an adequate supply of blood for Scotland. This has been particularly challenging throughout the SARS-CoV-2 pandemic and SNBTS sought Scottish Government support to secure access to these facilities during lockdown.

295. There is a Memorandum of Understanding between the four UK Blood Services on providing mutual aid in times of blood shortage or in response to major incidents **[WITN3530061].**

37. To what extent does SNBTS ensure the sufficiency of the blood supply through its management and oversight of its transfusion centres?

296. The SNBTS blood collection model includes the use of five fixed site donation centres and mobile community collection venues. The annual collection plan is designed to meet forecast demand for each blood group and to address seasonal factors. Historically, SNBTS collected around 80% of whole blood from peripatetic collection in communities, workplaces and educational venues. However, the reduction in demand has required reduction in collection activity, and has increased the proportion of collection from fixed site donor centres to 40%.

297. The fixed site collection centres offer optimised opportunities to donate and access to large donor panels that are vitally important in addressing blood shortages rapidly. Recent experience during the SARS-CoV-2 pandemic where the availability of collection venues was restricted due to loss of access to workplace and educational venues and the need to ensure social distancing for the protection of donors and staff, has led to a reassessment of the risks associated with reliance on venues owned by third parties. As a result, SNBTS is evaluating the benefits and viability of increasing the number of fixed site collection centres to improve resilience, and aim to collect around 50% from these sites in future.

298. As outlined in the response to Section 4, Question 18, all collection activity is managed nationally as part of SNBTS Donor & Transport Services. More recently the implementation of national appointment only sessions via the Donor Web Portal or the donor helpline/call centre support has:

- Improved forecasting of intake for whole blood, platelets and plasma
- Enabled improved and dynamic monitoring of collection performance
- Improved the ability to take corrective action in response to demand signals
- Helped to address anticipated shortfalls

38. To what extent does SNBTS ensure the sufficiency of the blood supply through its engagement with laboratories?

299. In responding to this question we have interpreted 'laboratories' to include:

- The 4 hospital blood banks directly operated by SNBTS
- The 28 Hospital Blood banks operated by the NHS Scotland Territorial Health Boards

300. SNBTS directly manages four of the largest hospital blood bank laboratories in Scotland and these are integrated within the SNBTS governance system. These hospital blood bank laboratories participate in the SNBTS Blood Bank Working Group, reporting to the Patient Services Operational Management Group and feeding into the SNBTS Operational Management Group. There is laboratory and clinical participation in the Demand and Operational Planning (DOP) group, so there is both laboratory and clinical participation and leadership in the operational groups across SNBTS with responsibility for ensuring sufficient supply.

Working in Partnership with Hospital Blood Banks

301. As set out in the response to Question 35, the developments arising from the HDLs **[WITN3530052]** and **[WITN3530053]** led to a more collaborative approach between SNBTS and NHS Scotland Boards. This collaboration was established and enhanced through:

- Data Integration developments
- The network of Transfusion Specialists
- The integrated plans for blood shortages with the initial plan established in 2005 and updated in March 2020 **[WITN3530062]**

302. Data integration projects have permitted discussion, engagement and review of the availability and use of stock. SNBTS has made significant contributions to both the safety and sufficiency of the blood supply through the Better Blood Transfusion Programme (HDL 2003/19) **[WITN3530052]** and HDL the Blood Express programmes (May 2005) **[WITN3530053]** that supported appropriate use of blood and promoted best practice.

303. As previously discussed, since the early 2000s SNBTS has developed a series of linked business intelligence databases recording the vein-to-vein fate of blood donations in Scotland. These systems are: Account for Blood (AfB); Account for Donation (AfD) and Account for Patient (AfP)i. They provide a comprehensive picture of clinical blood transfusion throughout Scotland, covering 97% of the blood supply. Data from Laboratory Information Management Systems is obtained daily from the majority of Hospital Blood Banks (HBBs) on all blood components, including final fate coding and patient blood group information.

304. This information was initially provided to Hospital Blood Banks, SNBTS Transfusion Teams (Transfusion Practitioners who are based within customer hospitals and were formerly known as the SNBTS Better Blood Transfusion Team) and Hospital Transfusion Committees as monthly PDF

reports. It enabled Hospital Blood Banks to monitor their blood stock management against nationally agreed targets. From 2018 SNBTS started to provide this information through an interactive Tableau dashboard (SNBTS Blood Bank Dashboard) available to members of the Hospital Transfusion Team. This enables comparison against similar hospitals across Scotland within and out-with NHS Health Boards and also enables trending of usage and wastage to allow tracking of the impact of continuous quality improvement initiatives. For example, a recent initiative to review the excess demand on O negative red cells in 2019 was addressed by the SNBTS Transfusion Team of Transfusion Practitioners using quality improvement methodology and supported by regular review at a local level of the SNBTS Blood Bank Dashboard and sharing of best practice. Significant improvement in O negative red cell issues was achieved but the SARS-CoV-2 pandemic has resulted in further pressure on this limited resource, leading to short-term shortages, so the project was re-launched in early 2021.

Managing Blood Shortages

305. In addition to the Integrated Blood Shortage Plan (2005, updated 2020) **[WITN3530062],** SNBTS has developed a partnership working with Hospital Blood Banks. The SNBTS Transfusion Team has always provided a conduit for sharing best practice in clinical blood transfusion. For example, at the start of the SARS-CoV-2 pandemic when demand for blood and blood components was unknown and non-COVID-19 clinical services were severely disrupted, the SNBTS Transfusion Team developed a COVID-19 Situation Report (C-19 SitRep) and a dedicated email to return regular updates from Hospital Transfusion Teams which was in turn used to support demand and operational planning (DOP).

306. The SNBTS Medical Team and the SNBTS Transfusion Team worked with Hospital Blood Bank Managers through the Managed Diagnostic Network of Haematology and Transfusion Scotland (HaTS), which has a Transfusion Subgroup. These relationships allow the development of two-

way communication pathways and clinically appropriate responses when impending shortages (Pre-Amber Alerts) are notified for O and A red cells or platelets. These groups also provide the opportunity for benchmarking key indicators with other blood banks in Scotland.

Scottish National Blood Transfusion Committee

307. SNBTS also works through the Scottish National Blood Transfusion Committee (SNBTC) (previously the Scottish Clinical Transfusion Advisory Committee (SCTAC) and was renamed in 2021), which is the national transfusion committee for Scotland, to review national performance against blood stock management targets and to promote guidance and initiatives to promote evidence-based, and therefore appropriate use of blood components. Each NHS Scotland Health Board is a member of SNBTC through the chair of the Hospital Transfusion Committees. SNBTC reports to the Deputy Chief Medical Officer for Scotland. SNBTS is represented on SNBTC by its Director and/or Medical Director, as well as the Clinical and Operational Leads for the SNBTS Transfusion Team.

Customer Engagement

308. In recent years SNBTS has also hosted customer engagement events bringing together laboratory, clinical and SNBTS staff to review and discuss performance and benchmarking results and to focus on particular initiatives or important developments affecting the blood supply chain.

39. Please explain how SNBTS's functions and practices contribute to maintaining the sufficiency of the blood supply in Scotland. For example, you may wish to comment on the SNBTS's policies, guidance or practices that relate to:

a. public information campaigns to recruit donors;

309. SNBTS uses the well-established, multi-channel 'Give Blood' communications strategy to recruit and retain blood donors. This strategy is managed by the Donor Marketing and Engagement department within Donor & Transport Services. The publications and promotional materials can be found on www.Scotblood.co.uk. In addition, examples of the creative materials such as TV adverts and promotional videos can be found on the SNBTS YouTube channel. As indicated earlier, the Give Blood Campaign is award winning and recognised as an exemplar **[WITN3530063]**. It utilises: Positive proactive Public Relations

- Paid advertising
    - Television, Radio
    - Online
- Social and digital media
    - Scotblood Website
    - Donor Web portal for registration and appointment booking
    - Facebook
    - Twitter
    - YouTube
- Direct marketing
    - E-mail
    - SMS
    - Letters
    - Direct Marketing campaigns:
        - Blood Donor 24 designed to get donors to donate within 24 hours in response to increased demand
        - Winback strategies designed to reactivate donors who have not donated in the last 12 months

310. SNBTS have had a well-funded media strategy since 2001. This has been essential in raising public awareness of the ongoing need for blood and blood donors. This is primarily funded through the NHS NSS annual business planning and resource allocation process. The level of funding required is supported by specific business cases, as required (e.g. to

conduct research or develop new adverts and other creative executions required to support the campaign). The Give Blood campaign encompasses a communication strategy that is based on qualitative and quantitative research and which has evolved to meet the changing strategic goals and the changing media environment over time. Further information on the effectiveness of the marketing strategy can be found in a review article - Carter et al (2011) Transfusion & Apheresis Science 45 (2011) 31-43 **[WITN3530055].**

311. The transition to integrated supply chain management has significantly changed the campaign requirements since 1997 and as a result the marketing strategy has evolved alongside this to reflect this. The campaign messaging has changed from "Any Donor -All the Time "to "Right Donor-Right Time-Right Patient". This campaign strategy evolution is underpinned by appropriate research to:

- Probe and understand donor attitudes and barriers to donation and provide insight on how to address issues
- To test creative solutions and advert scripts
- Evaluate advertising effectiveness
- Evaluate the impact of service change

312. This work is usually undertaken by specialist research organisations procured via tender exercises

313. Similarly, the changes in the media landscape and the impact of social and digital media have been transformative in developing the Give Blood Campaign from a "mass marketing" advertising campaign to a much more nuanced communication strategy that enables more effective relationships and supports donor education and engagement. This has reduced SNBTS' reliance on paid media channels and improved overall cost effectiveness. It also ensures donors are more aware of donor selection criteria and how to seek advice on donation.

314. At key times the level of activity and recruitment has been increased as a result of anticipated additional donor losses or increased demand. For example:

- Increased Demand: NHS Waiting Time Initiative 2000 resulted in increased demand for blood and an increased frequency of shortfall in supply that needed to be addressed. To support this the Scottish Health Department funded new advertising materials and media to support increased recruitment
- Increased Deferrals and Losses
- The permanent exclusion of previously transfused donors in 2004 as a vCJD risk reduction resulted in the loss of many of SNBTS's most loyal and motivated donors and resulted in reduced donor availability
- Implementation of BSQR resulted in increased donor deferrals as a result of changes in donor selection criteria and required haemoglobin levels, leading to additional pressure on the supply for blood

315. As previously set out, the transition to integrated supply chain management has fostered a Right Donor-Right Time approach that has reduced SNBTS's reliance on traditional mass media advertising. There is now a greater reliance on specific and timely interventions such as e-mail or SMS that are more targeted and which consider the current requirements by blood group and individual donor characteristics.

316. Key messages are closely managed and consistent across all channels of communication. This ensures increased responsiveness and a synergistic effect that promotes donor loyalty and responsiveness, both of which are vitally important in maintaining sufficiency of supply. This relies on effective and clear adverts that motivate new and existing donors to donate.

b. maintaining adequate infrastructure, including ensuring appropriate geographical coverage of transfusion centres and/or increasing the number of transfusion centres;

317. A detailed description of the infrastructure of Donor & Transport Services has been provided in Section 4 Question 18, SNBTS uses a combination of collections from multiple session types and a planning approach that is designed to optimise the opportunity to donate and maintain adequate supplies of blood components at all times. The collection targets for each of the 3 Donor and Transport Services territories (see Section 4 Question 18) are based on regional populations, donor availability and logistics in collecting from each community. The frequency of donation opportunities for each also vary depending on donor availability and yield.

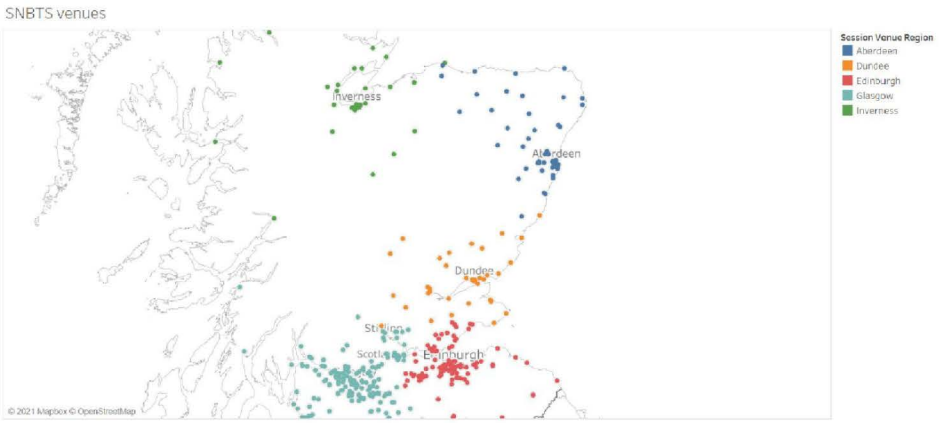
318. The demand for red cells has reduced by around 33% since 2010 and this has led to the review and reduction of the collection footprint to balance the need for efficiency, by retaining the most productive collection venues with the need to maintain a resilient donor base across Scotland. This has largely been achieved by reducing the frequency of collection from each venue to retain the footprint, but some logistically difficult venues have been discontinued (e.g. Stornoway). The collection plan is also designed to manage the risk of adverse weather at key times of the year.

319. The collection programme is designed to meet all product requirements including short shelf life products, such as platelets, and scheduling must consider manufacturing constraints alongside patient requirements. For example:

- Platelets have a nominal shelf life of seven days but require testing to reduce the risk of bacterial contamination, which takes around 48 hours, resulting in an effective shelf life of five days
- Peak demand for platelets each week is Tuesday and Wednesday which reflects operational activity levels in hospital blood banks, clinics and theatres

- Collection takes place on Saturdays and Sundays to meet the demand for platelets on these peak days
- This optimises the availability of the product and reduces wastage by avoiding time expiry, which contributes significantly to our ability to maintain adequate supplies at all times

320. In addition to the 5 fixed-site Donor Centres, SNBTS collects blood from around 420 venues across Scotland, including community, educational and workplace venues. The map below is provided to outline the geographical location and spread of collection venues in use in Scotland. The collection profile for the last 12-18 months has been affected by the SARS-CoV-2 pandemic, which resulted in the loss of most educational and workplace venues and the loss of a large number of community venues. This increased SNBTS' reliance on fixed site centres when almost 50% of all donations were collected in one of the 5 fixed site donor centres.



c. maintaining adequate logistical arrangements to ensure the appropriate storage and distribution of blood and blood products;

321. The SNBTS Transport Department reports to Donor Services and delivers a comprehensive inbound and outbound logistics function for blood components. In addition, the department supports the distribution of plasma

products such as Immunoglobulin, Prothrombin Complex (Factor II, VII, IX &X) and Albumin as discussed elsewhere.

322. As indicated above the model was substantially reviewed in 2017/18 to support the transition to Jack Copland Centre - to deliver a "Full out –Full in" model for scheduling that uses the same journey to deliver products to our blood banks on the outward journey and then collect donations for return to the Manufacturing site in Edinburgh in the inbound trip. This has had a number of benefits:

- Releasing delivery capacity in the schedule to deliver to SNBTS Hospital Blood Banks 7 days a week
- Releasing capacity to increase frequency to other external blood banks
- Greater consistency in the delivery schedule and increased capacity to maintain sufficiency in each blood bank
- Reducing SNBTS's carbon footprint and environmental impact and improving affordability of the service to NHS Scotland that improves sustainability of the solution which is a requirement of our core function.
- These changes make a significant contribution to effective SCM by smoothing demand and reducing delivery intervals that can reduce overall stock holding of short shelf life products such as platelets and avoid wastage

SNBTS Fleet

323. The SNBTS fleet is fully liveried and is supported by a rolling replacement programme. SNBTS have maintenance and breakdown arrangements that are managed via national contracts. SNBTS utilises a range of vehicles:

- Pool cars
- Refrigerated delivery vans (2-7°C)
- Blue light response vehicles (all-wheel drive)
- Equipment trucks
- Staff transport vehicles (minibuses)

- Dual Temperature vehicles used to supply the Gartnavel site by delivering consumables (21°C) and blood components at (2-7°C) in the same vehicle. These vehicles have flexible format to allow increased volumes in either compartment
- Mobile Donor Centre (6 donation beds)
- Collection Pod vehicles (2-6 donation beds)

Vehicles

324. All refrigerated vehicles including the dual temperature trucks are fully validated to MHRA regulations and all other required regulatory standards for the distribution of blood components and products. They are fitted with temperature alarms and monitored and maintained by the SNBTS Transport department as part of the QMS in a compliant state to meet regulatory requirements. In vehicles that are not temperature controlled, monitoring is by data loggers and temperature probes, whose data is reviewed by blood bank staff on receipt, to ensure compliance.

Consignment packaging

325. All packaging and transport boxes are validated for their ability to maintain the desired transportation temperature and temperature data loggers are used to measure temperature in transit and thus ensure the integrity of the supply chain conditions.

Emergency Response

326. SNBTS maintain and operate the capability for emergency response deliveries using Blue Light response vehicles on a 24/7/365 basis with the ability to cover the full geographic area. All staff are fully trained in emergency response driving, to the same standards as the other emergency services. This capability ensures that the service is able to respond with respect to:

- Emergency provision for individual patient needs (e.g. HLA matched platelets or specialist product)
- Emergency restock of blood banks

- Major incidents with multiple casualties

Delivery Schedules to Customers

327. The delivery schedule to each blood bank is designed to reflect the hospital size and type, the average use of components and product range held in stock (e.g. platelets, red cells, frozen components). The stock levels and delivery frequency form part of the Service Level Agreement discussions with each hospital blood bank.

SNBTS Hospital Blood Banks & Distribution Hubs

328. SNBTS Hospital Blood Banks in Glasgow, Aberdeen, Dundee and Inverness also function as regional distribution hubs for their own geographical area. The JCC acts as the distributor hub for the Edinburgh and South East Scotland area.

329. The SNBTS Hospital Blood Banks also undertake specialist transfusion support such as antibody screening and extended blood grouping to find compatible units with rarer blood groups systems for the hospital blood banks that each supply and providing specialist products to these hospitals on an ad hoc basis.

Contracted Couriers & Taxis

330. To augment the core fleet, SNBTS has contractual arrangements with approved couriers and taxi companies to deal with exceptional/ad hoc deliveries. All drivers employed by these companies are fully trained to SNBTS requirements.

Stock Movements

331. Once blood components have been issued to Blood Banks out of SNBTS, this stock cannot be returned to SNBTS as the Blood Establishment. SNBTS can rotate stock around its own blood banks but this is not routinely done between the hospital-based blood banks in Aberdeen, Dundee, Edinburgh or Inverness, as this would require importing the blood

back into eProgesa from the SNBTS hospital blood banking system, eTraceline. Only blood that has remained within SNBTS temperature control can be returned to SNBTS. Stock is regularly rotated and moved between the SNBTS HQ at JCC and the Glasgow stock holding hub (GHUB), which supplies the West of Scotland. This is to balance inventory and optimise the age profile between the two sites.

d. methods to maximise the yield of blood products from donated blood; and

332. SNBTS continues to make concerted efforts to improve productivity and efficiency across the supply chain by:

- Reducing outdated and discard internally with SNBTS
- Reducing outdated and discard within NHS Scotland by
    - reducing the age of blood issued to hospitals
    - sharing performance data using interactive dashboard as discussed above
- Aligning collection activities with supply requirements at the blood group and product level.

333. Additionally, SNBTS works in partnership with Health Boards and Hospital Blood Banks to make the best use of each donation and its resultant components.

334. The methods used to maximise yield of blood components from donated blood to ensure sufficiency, include:

Blood Donor Management.

- Refining donor invitations to reflect the demand profile by blood group.
- This optimises the yield from the available donors by aiming to only collect donations that are required to maintain target stock levels of each blood group
- This means that donors are immediately available when their donation is in demand

- Managing donor deferrals out-with the collection environment increases the number of donation that can be collected from the appointment booked
- Monitoring of recurring donor discards, adverse events, deferrals and yield from donors to improve donor care and maximise the component yield from each donor attendance

Inventory algorithms and dedicated processing streams

335. As outlined in the introduction to Section 8, SNBTS have multiple supply chains with multiple product types. Each product type has a separate workflow and process and can be made from the same starting material. However, different products require collection in different collection pack formats to optimise and streamline production and avoid additional processing steps. The product range includes:

- From Whole Blood Donations (~155,000 per annum)
    - Whole blood used in specific patient groups and used to manufacture paediatric doses
    - Red Cell Concentrates in additive solutions that optimise red cell storage and condition
    - Pooled platelets separated from red cells and plasma by centrifugation using the platelets from 4 donations of the same blood group to make one adult dose stored in platelet additive solution to extend shelf life and optimise condition during storage
    - Fresh frozen plasma (FFP)
    - Cryoprecipitate which is made from the fresh plasma derived from five donations and is used in the treatment of low fibrinogen levels.
- From Apheresis Donations
    - Single donor platelets that can be split to make up to three adult doses (7500 donations ⇔ 15,000 adult doses)
    - These are used to provide platelets that match specific patients tissue type (HLA) and are often collected specifically for that patient

- COVID-19 Convalescent Plasma to support clinical trials in response to the SARS CoV-2 pandemic
- FFP by plasmapheresis –since April 2021

336. Planning the manufacture of the full range from planned intake is highly complex and dependent on current inventory levels across the product range, the day of the week, anticipated demand as well as orders for bespoke / individualised components/products. In order to optimise this, SNBTS have put in place systems that:

- Set target stock levels for every product type to provide sufficient stock to cope with volatile demand (resilience) whilst avoiding surplus supply (efficiency)
- Optimising the pack type allocation profile at collection to meet product requirements
- Manufacturing processes allocated according to pack type/ product / blood group target / stock levels
- Algorithms for platelet manufacture by pooling platelets from 4 donations to make a single dose. This is based on forecast of demand for platelets, target stock levels and platelet apheresis collection plans
- Dedicated plasma filtration manufacturing process to maximise multi-component yield from key donations to make red cells, platelets and Fresh Frozen Plasma from a single donation
- Performance management of waste/yield at all points along the supply chain
    - Waste indicators used for each stage of supply chain both internal and external to SNBTS
    - Quality improvement and system redesign methodologies, such as Lean and Six Sigma, that are widely used in industry for process improvement and reduction of waste
    - The impact of quality improvement assessed using agreed success criteria or KPIs
    - Specific performance indicators to monitor collection or manufacturing yield

- Daily monitoring reports to ensure product yield is maximised - designed to highlight issues to each department head and support the DOP process
- Daily reports to highlight where intervention is required in the manufacturing process to minimise product waste

e. the setting and reviewing of targets for the amount of plasma required to be collected by each transfusion centre under SNBTS's remit.

337. SNBTS have not collected plasma for fractionation since the exclusion of UK plasma in 1999.

338. The clinical plasma currently used in NHS Scotland is largely derived from whole blood as described in Question 39e and as a result there is no requirement to set collection targets specifically for plasma as this can be adequately met by whole blood donations. This is managed through the manufacturing processes described above to maintain target stock levels for FFP and Cryoprecipitate.

339. In February 2021, the Commission on Human Medicines approved reinstatement for plasma sourced from UK blood donors for the manufacture of immunoglobulin products. SNBTS is currently in discussion with the Scottish Government Department of Health and Social care to establish future requirements.

340. The targets for each blood component (Red Cells & Platelets) are set annually for each collection territory. Central planning information is cascaded using the AFD Database, to inform manufacturing schedules and products from each collection session. Further details are provided in the response to Question 18b.

341. Since 2013, SNBTS has used Time Series Forecasting of red cells for transfusion, to project future demand. This is used as a basis for target setting. The planning information is cascaded using dashboards to review

collections against target and to inform manufacturing schedules and products from each collection session. Red cells, platelets and plasma collection targets are reviewed, refined and amended by the DOP process (see Section 8 Background) on a rolling review. Unfortunately, the impact of the COVID-19 pandemic has resulted in the data from last year distorting this model, as a result we are using revised planning assumptions based on pre-COVID trends and using more detailed and frequent analysis of demand as NHS Scotland remobilises.

40. How effective are SNBTS's current functions, policies and practices in ensuring the sufficiency of the blood supply in Scotland? Please compare the current approach with the historical approach, highlighting significant differences and developments.

342. Transition to a nationally managed blood donation programme has resulted in more effective forward planning. This together with greater integration across the supply chain and the Better Blood Transfusion initiatives across NHS Scotland have been highly effective in ensuring that there is reliable collection and supply available and that demand is well understood. Also that the use of blood components in Scotland is according to evidence-based practice. These critical factors have ensured that SNBTS continues to meet the transfusion needs of patients in Scotland and have avoided the need for an emergency appeal for blood donors since October 14th 2003.

343. As indicated above, SNBTS increasingly utilises an integrated approach to supply chain management to ensure:

Effective Forecasting

- Since April 2013 SNBTS has used a Time Series Forecasting model for red cells that incorporates seasonal factors and other variables. Prior to the SARS-CoV-2 pandemic, this methodology had a mean absolute % error (MAPE) of under 3%.

- This is an enormous improvement on previous methodology that simply used arithmetic trend analysis and market intelligence to predict future demand
- The accuracy of the forecast enables improved business planning assumptions and confidence levels, that have facilitated efficiency gains while ensuring enough blood for patients in Scotland
- The effectiveness could therefore be that we have fully met the demand for blood and its components in Scotland from a fewer number of donations but with the same clinical benefit to patients

Effective and timely Demand and Operational Planning (DOP)

344. The Demand and Operational planning process for whole blood needs to be initiated well in advance of the financial year being planned in order to secure access to third party venues and in practice is initiated in September of the previous financial year for collections starting in March. This is then reviewed at the end of December and initial targets set for each collection territory and the target finalised following a review of predicted demand in March. These high-level targets for the collection plan are designed to ensure that the whole blood collection plan has sufficient capacity and opportunity to donate to ensure sufficiency with a key goal to be able to nimbly flex the number of donors attending up or down in response to demand.

345. Targets for platelets by apheresis are set annually.

346. The DOP reviews the plans in a number of appropriate time frames:
- **Longer Term:** to support the outline planning for whole blood collection, venues booked and timing of collection
- **Mid Term:** to review and refine the alignment of forecast demand and intake for each product over the forthcoming 3 months to anticipate and avoid shortfalls in supply

- **Shorter Term:** DOP undertaken weekly and daily- considers the forthcoming 4 weeks and gives closer scrutiny to a range of indicators at blood group and product level
- **Exceptional:** in exceptional circumstances, such as periods of adverse weather when supply may be constrained, and more recently during the global SARS-CoV-2 pandemic. In these circumstances there would be additional daily situation reporting and planning meetings to manage supply across the product range

347. Effective and efficient use of the available donor base to match supply to demand by blood group and product
    - Targeted recruitment of O Negative blood donations, to meet the requirement to issue 13.5% of issues from a population base where 9.5% are O negative.
    - Current level of O Negative collection is 14.2% year to date - a 150% increase in collection compared to population profile
    - Changed blood group profile for platelet collection to increase blood group A collection from around 40% to 50-60% to provide optimal product profile and support British Society for Haematology transfusion guidance that increases the use of cross-grouped group A HT negative platelets when own group is not available or unknown
    - Diverting blood group AB donors to donate plasma or serum for use in cellular therapy products to avoid shelving excess red cells in this blood group

Improvements in the optimisation of stock volume and age profile

348. It is a key objective of SNBTS that we should issue products at the earliest point in their shelf-life where possible. This maximises the likelihood of transfusion for each donation as each donation can be cross matched for up to six patients in its lifespan. This together with evidence-based stock holding targets based on the hospital demand helps smooth demand and reduce the age of the blood at the time of issue. In 2014 SNBTS set a target that we should increase the proportion of blood issued below 10 days ⇔ 25

days of remaining shelf life and have made significant progress in this in the intervening period as indicated below:

- In 2014, 37% of all red cell issues were <10 days old at the time issue to the Hospital Blood Banks
- In 2019, 80% of issues were <10 days old when issued to Hospital Blood Banks

Reducing the number of donations lost from Donor Attendance: red cells banked

- This includes: on session donor deferrals, collection associated losses due to failed venepuncture, below volume donation, lab losses during processing and testing
- In 2007 this was around 24% due to increased deferrals and BSQR changes in relation to haemoglobin specification being increased
- SNBTS introduced the Clinical Support Team in 2014 to assess donors before attending collection sessions and this has reduced donor deferrals on session, meaning more donors who attend can successfully donate
- Due to focus on reducing losses the overall loss rate rated reduced to 15.8% of red cell donations
- This releases the equivalent of an extra 13,500 donations available for transfusion compared to 2007 when the losses from donor attendance to the red cells being banked peaked.

Time expiry of products

- Time expiry (TE) reduced from 1.6% in 2014 to 0.6% in 2021
- O Negative (TE) from 1% in 2014 to 0.7% in 2021

Supporting optimum transfusion practice

349. The SNBTS Transfusion Team works closely within hospitals to promote safe transfusion and appropriate clinical transfusion practice. One measure of best practice is the level of homologous transfusions undertaken –

meaning the recipient receives red cells of their own group rather than a compatible but non-homologous group. There are circumstances where this is not possible – either where the own group is not available within the timescale required or where the blood group has not been safely established. For example, in an emergency the patient might be transfused with the universal donor blood group O negative.

350. The ability of the Hospital Blood Bank to match the patient's blood group relies on them having access to the product required by the correct group at the time required. SNBTS supports this by reviewing stock holding to ensure that the hospitals have sufficient supplies of all blood groups at all times. This is done in partnership with the Hospital Blood Banks and ensures that blood stock is replenished at the required frequency. In an emergency SNBTS will make exceptional deliveries and if required under 'blue light' transportation.

351. Additionally, SNBTS have encouraged Hospital Blood Banks to stock blood group AB red cells for transfusion as many hospitals did not stock these as they were in low demand and likely to expire and contribute to their wastage figures. SNBTS promoted this by discounting Group AB from the wastage figures reported in the Hospital Blood Bank dashboards.

352. Currently 93% of all transfusions in Scotland are the same blood group as the patient despite the requirement for 13.5% O negative to support emergency use although 31.2% of O negative red cells are transfused to non-O-negative patients

353. Perhaps the most persuasive measure of the effectiveness of this approach is the fact that SNBTS have not had to issue an emergency appeal for donors since the 14th of October 2003. Certainly, the management of the exceptional fluctuations in supply and demand over the past 18 months of the SARS-CoV-2 pandemic would have been much more problematic in the absence of integrated supply chain management.

Section 9: Safety of modern blood supply

41. How does SNBTS understand its responsibility to ensure the safety of the blood supply in Scotland? Has this responsibility changed over time in nature and / or extent? If so, please provide details.

The following section has been contributed by Professor Marc Turner

354. SNBTS accepts primary responsibility for the quality, safety and sufficiency of the blood supply in Scotland. So far as we are aware, this responsibility has not changed substantively with regard to blood components since the organisation was created, though up until around 1991 SNBTS consisted of Regional Blood Transfusion Services and the responsibility would have been more distributed than it is currently as discussed in our response to Question 5. SNBTS held the responsibility for the quality and safety of its plasma products until it ceased manufacture of these in 2006 as discussed in our response to Question 27.

42. Does SNBTS share its responsibility to ensure the safety of the blood supply in Scotland with other stakeholders (for example, government departments or other medical/public health organisations)? If so, please provide details.

355. SNBTS is a Strategic Business Unit of NSS (formally known as the Common Services Agency). The Executive Management Team and Board of NSS therefore also have a duty to ensure that SNBTS transacts its responsibility to ensure the safety of the blood supply in Scotland.

356. NSS is itself accountable through NHS Scotland to the Scottish Government who therefore also have a duty to ensure that SNBTS is resourced and governed in such a way as to ensure the safety of the blood supply in Scotland. The Scottish Government may direct SNBTS to adopt specific blood safety measures in response to advice from UK advisory committees such as SaBTO.

357. Finally, SNBTS holds a BEA issued by the MHRA under which it is inspected for compliance against the BSQR.

43. To what extent does SNBTS ensure the safety of the blood supply through its management and oversight of its transfusion centres?

358. As previously, following discussion with the IBI legal team, SNBTS interprets this question to refer to its donor centres.

359. SNBTS no longer operates on a Regional Blood Transfusion Service model. As described in our response to Section 1 Questions 4 and 5 above there is a national functional management structure in place, one Directorate of which is (Blood) Donor and Transport Services. SNBTS has five permanent Donor Centres based in Edinburgh, Glasgow, Dundee, Aberdeen and Inverness with the recent addition of a small proof of concept Donor Centre based in Livingston. Management and oversight of these Donor Centres is discussed in our responses in Section 4. The SARS-CoV-2 pandemic has accelerated a change in the balance between Centre-based and community sessions due to the reduced availability of venues and the removal of small sessions and workplaces from our collection programme due to the need to ensure the safety of donors and staff by complying with all social distancing guidance. Donor selection policies are set at a national level as described in our response to Question 44 and all operational management of staff and standard operating procedures flow down through the national functional management structure.

44. Please explain how SNBTS's functions and practices contribute to maintaining the safety of the blood supply in Scotland. For example, you may wish to comment on the SNBTS's policies, guidance or practices that relate to:

360. The safety of the blood supply is based on a complex set of donor selection criteria and microbiological screening tests. SNBTS policy in this regard is set through the SNBTS Clinical Governance and Safety Group and

is compliant with the requirements of the BSQR and all relevant guidance from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and the UK Blood Services Joint Professional Advisory Committee (JPAC). Policy is implemented through the SNBTS Quality Management System (QMS).

361. A pharmaceutical quality management system (QMS) is defined as a formalized management system that enables the delivery of products with quality attributes which meet the needs of patients, healthcare professionals, regulatory authorities and other stakeholders (ICH Q 10; Eudralex Volume 4; EDQM Good Practice Guidelines for Blood Establishments required to comply with Directive 2005/62/EC). It documents the processes, procedures and responsibilities for maintaining product quality standards.

362. In the case of SNBTS, the QMS facilitates the delivery of blood products to the quality standards required for patient care. It covers quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, external and internal auditing, contract management, incident management, corrective and preventative actions, risk management and regulatory compliance.

363. All SNBTS sites and its QMS are inspected on a bi-annual basis by the MHRA under the terms of the SNBTS BEA.

a. identifying risks of infection associated with the use of blood and / or blood products;

364. There are a large number of potential transfusion transmitted infections, many of which are known, but some of which are new and emergent due to genetic change, zoonotic transmission or geographic spread due to the effects of climate change, globalisation and international travel (*Busch MP*

et al. Prevention of transfusion transmitted infections. Blood 2019; 133 (17): 1854-1864, Stramer SL et al. Emerging infectious disease agents and their potential threat to transfusion safety. Transfusion 2009; 49: 1S – 29S) **[WITN3530064]** and **[WITN3530065].** Moreover, established infectious agents are subject to continuous genetic evolution as one can see from the continuing emergence of SARS-CoV-2 variants during the current ongoing pandemic.

365. Horizon scanning (i.e. surveillance for new and emergent infections) is carried out by the NHSBT/PHE Epidemiology Unit (NPEU) and the JPAC Specialist Advisory Committee on Transfusion Transmitted Infections (SACTTI) (JPAC Horizon Scanning Management Process Description January 2021 **[WITN3530066]** & JPAC Position Statement on Emerging Infections May 2020 **[WITN3530067].**

366. The SACTTI Chair, secretary of SACTTI and an Organ Donation and Transplant representative review an Emerging Infections Report (EIR) prepared by NPEU monthly. Information from the European Centre for Disease Prevention and Control (ECDC) and the European Blood Alliance (EBA) Emerging Infectious Disease Monitor Group feeds into the EIR, however SACTTI also receives these alerts as they arise and will assess them and take action if necessary.

367. Each EIR within the monthly report is reviewed to determine if any action is required. Actions can include:

- The requirement for SACTTI to perform a risk assessment
- Changes to the Geographical Disease Risk Index (GDRI) based on spread of a microbiological agent (JPAC Position Statement GDRI - addition and removal of specific country risk May 2020 **[WITN3530068].**
- Additional information to be sourced for SACTTI discussion/action
- Monitor for additional reports/data

368. To provide JPAC with oversight of the process an Annual Report is prepared which includes EIRs that required action, further discussion or monitoring by SACTTI in addition to examples of EIRs that required no action and the rationale for decisions (JPAC SACTTI Annual Horizon

Scanning Report 2020 **[WITN3530069]**. This process has recently been subject to review by the Government Internal Audit Agency.

369. The main actions in 2020 centred around SARS-CoV-2 and West Nile Virus (WNV) spread in Spain, Germany and the Netherlands.

370. Risk assessments are prepared on all infections known or thought to present a risk of transfusion transmission and are reviewed by JPAC on a regular basis. Risk assessment may lead to the introduction or change in policy in regard to donor selection or microbiological screening which is proposed by SACTTI, approved by JPAC and the UK Blood Service Medical Directors and issued to UK Blood Service Quality Directors as a JPAC change notification **[WITN3530070].**

b. risk reduction measures, including but not limited to donor selection policies, the screening of blood donations for infections, the tracing of blood donations and other policy measures;

371. Risk reduction in respect of transfusion transmitted infections is built on the complementary strategies of donor selection and testing.

Donor Selection

372. SNBTS employs a wide range of donor selection criteria to manage risks both to the donors from the donation process and those to recipients from health conditions in the donor including potentially transmissible diseases (such as some cancers), medications, and known or potentially transmissible infectious bacterial, viral, protozoal and prion diseases **[PRSE0000954]**. As noted elsewhere, deferral criteria are established at a UK level through the legal requirements of the BSQR and guidance from SaBTO and JPAC – in this case particularly its Specialist Advisory Committee on the Care and Selection of Donors (SACCSD). Donor deferral criteria do change in response to changing circumstances, for example a change in the geographic distribution of an infectious agent or evolution in our scientific understanding pertaining to a specific risk.

373. In addition, the SACCSD and SACTTI undertake ongoing review of evidence that informs future donor selection criteria. In some circumstances, SABTO may form subgroups to review specific donor selection policies and criteria and recommend changes as required. There have been three such subgroups established to review infectious risks related to sexual activity in 2010, 2018 and 2020. These recommendations if approved by SABTO are provided to the Departments of Health and Social Care and Ministers in the UK Government and Devolved Administrations for decision on implementation within each country.

374. Since the early 1980s there has been increasing focus on ensuring that donor selection criteria and processes reduce the risk of transfusion-transmitted infection. This is particularly important when it is not possible to test for the infectious agent. An example of Donor Selection reducing infectious risk in the absence of suitable tests is the range of donor selection criteria designed to reduce the risk of CJD transmission including:

- Exclusion of donors with familial history of CJD
- Exclusion of donors transfused after 1980 from donation
- Exclusion of cornea and dura mater transplant recipients
- Exclusion of the recipients of human growth and pituitary hormones
- Exclusion of donors with a history of spinal surgery

375. Effective donor selection not only requires clear evidence based criteria but also secure processes that optimise patient and donor safety. There are a number of key developments in practice that support the SNBTS process

- Development of the first national Donor Selection Guidelines for SNBTS in 1992/3 **[WITN3530083]**. This A-Z look up format was adopted by the SACCSD at UK level
- The implementation of the SNBTS tick box format questionnaire in 1997 **[WITN3530084]**.
- Implementation of personal donor interviews for all new and lapsed donors in 1998/99 after successful evaluation in Edinburgh.
- Introduction of the Clinical Support Team in 2014, to undertake pre-session assessment of donor eligibility by telephone and in response

to email enquiries that encouraged managed and informed self-exclusion

- Availability of the 'Can I Donate Quiz?' on Scotblood.co.uk
- The introduction of the online questionnaire prior to appointment booking to support implementation of the new FAIR Guidelines in June 2021

376. As an example of the effectiveness of Donor Selection in reducing risk prior to donation, in Scotland it is estimated that the HIV prevalence is around 0.1%. SNBTS recruits around 15-20,000 new donors each year and thus, if there was no donor selection, we would anticipate that SNBTS would detect 15-20 new cases of HIV in donors per annum. In fact, SNBTS has only detected 11 confirmed HIV positive donors since 2010 equating to 5 – 6.7% of the expected number. This is also true for other blood-borne infections.

Donor Testing

377. SNBTS performs the following mandatory assays on all blood donations using commercial (CE marked) highly sensitive assays on high throughput analysers (the negative predictive value of these assays is very high i.e. the risk of missing a positive test result is very low):

- Hepatitis B Virus surface antigen (HBVsAg) and nucleic acid testing (NAT)
- Human Immunodeficiency Virus (HIV) serology (anti-HIV 1 and 2 antibodies) and NAT
- Hepatitis C Virus (HCV) serology (anti-HCV antibodies) and NAT
- Human T-cell lymphotropic virus (HTLV) serology (anti-HTLV I and II antibodies)
- Hepatitis E Virus (HEV) NAT
- Syphilis serology – anti-syphilis

378. Although the specificity of these assays is also high (i.e. they are unlikely to report a positive result in a person without the infection), their deployment in the context of an essentially healthy population means that the number of

false positives results outweighs the number of those that are truly positive (i.e. the positive predictive value of the assays is low). For this reason, donations which are reactive in initial screening are removed from the blood supply and discarded but further more detailed analysis of the sample is carried out by the SNBTS National Microbiology Reference Unit in order to confirm or refute the possibility of donor infection before s/he is informed.

379. Testing is also carried out on some donors with a geographical risk of exposure to specific infections:

- Malaria serology
- West Nile Virus NAT

380. In addition, some donations are tested for cytomegalovirus (CMV) antibodies to provide CMV negative blood for neonates and patients who are pregnant.

381. Platelet concentrates are also tested for potential bacterial infection using the BactAlert system.

c. sharing information with relevant stakeholders about infected donations;

382. SNBTS CGSG receives a quarterly report on the incidence of microbiology test positive donors provided by the SNBTS National Microbiology Reference Unit. It also reviews any potential transfusion-transmitted infections which are managed as incidents within the SNBTS QMS. A transfusion-transmitted infection would elicit an organisational Duty of Candour with regard to the recipient and would be reviewed by NSS Clinical Governance Committee.

383. SNBTS shares information monthly within the other three UK Blood Services regarding the number and type of infections in blood donors. The data on microbiology testing for all four UK Blood Services is collated by NHSBT / PHE and published as an annual report which is publically

available on the PHE (GOV.UK) website: Safe Supplies 2019: data in context - GOV.UK (www.gov.uk).

384. SNBTS also reports all adverse events associated with blood transfusion including any transfusion-transmitted infections both to the MHRA (through the SABRE reporting system) and to the SHOT database. SHOT releases an Annual Report which is also publically available on the SHOT website: SHOT Annual Reports and Summaries - Serious Hazards of Transfusion (shotuk.org) which is discussed at its annual meeting.

d. sharing information to the public about infections that may affect the safety of the blood supply;

Donor and Public Awareness

385. All prospective and current blood donors are provided with information on blood borne infections and on travel associated risks of infection using a number of routes

- The Donor Information leaflet
- The reverse of the donor session record stresses the need for blood safety and the importance of answering honestly
- The Scotblood Website offers extensive information of Donor Selection with detailed and accessible information on infectious disease risks and travel associated infectious risks
- The Website acts as a repository for publications
- Additionally, The Donor Marketing and Recruitment team and the Clinical Support Helpline are highly responsive in answering all donor queries and providing information or signposting donors to additional information and guidance.

As outlined above, data on microbiology testing is published on the PHE website and on adverse events associated with blood transfusion on the SHOT website.

Patient Awareness

386. All patients who might need a transfusion are given written information in advance in the form of a Patient Information Leaflet (PIL) which includes information on the risks and benefits of transfusion and, where appropriate, alternatives. The possibility of transmission of infection by transfusion is discussed in that document with specific reference to Hepatitis, HIV, vCJD and bacteria. Valid consent for transfusion is required in all elective situations and includes both the PIL and discussion with the responsible authoriser. In an emergency situation a patient may not have the capacity to give informed consent in advance, but they are provided with the PIL and informed of the transfusion so that they have the opportunity to have any concerns addressed before discharge.

e. achieving and maintaining self-sufficiency of the blood supply.

387. Information is provided above in Section 8 on the multidisciplinary approach that SNBTS have employed to develop effective management of the whole supply chain to maintain self-sufficiency of supply of blood components in Scotland. This has been increasingly challenging during the SARS-CoV-2 pandemic

45. How effective are SNBTS's current functions, policies and practices in ensuring the safety of the blood supply in Scotland? Please compare the current approach with the historical approach, highlighting significant differences and developments.

388. Effectiveness can be evaluated by calculation of residual risk of missing an infection with current donor screening systems and by the actual number of transfusion transmitted infections documented by the UK haemovigilance systems (SHOT and MHRA SABRE).

389. The residual risk that testing will not detect a potentially infectious window period infection in the UK is estimated using a model which has been peer reviewed and used by the International Society of Blood

Transfusion, Transfusion Transmitted Infection Working Party, Surveillance, Risk Assessment & Policy sub group.

390. The risk of testing failing to detect a blood unit carrying a viral infection during the window period between 2017-2019 is estimated to be less than 1 in 1 million transfusions (Hepatitis B less than 1 in 1 million; HIV less than 1 in 23 million and Hepatitis C less than 1 in 145 million) (JPAC Position Statement: The estimated residual risk that a donation made in the infectious window period is not detected on testing: risks specific for HBV, HCV and HIV in the UK, 2017-2019. November 2020 **[WITN3530071]**.

391. It has recently been recognised, however, that there is also a residual risk from donors with occult HBV who have long-standing infection and may be negative for both HBVsAg and NAT. SaBTO has recently made a recommendation to Ministers to introduce additional testing for anti-HBV core antibodies to reduce this risk further.

392. The actual risk of transmission of these and other microbiological agents in the UK is captured by the SHOT haemovigilance reporting system. The NPEU acts as the national infections coordinator and collates data from all 4 UK Blood Services and a summated report from the unit is included in the Annual SHOT Report (SHOT Report, Summary and Supplement 2020, Chapter 21 **[WITN3530072]**.

393. In the last year there were no documented virus transmissions within the UK (denominator 2 million blood component transfusions). Over the past decade there have been 5 HBV transmissions, no HIV transmissions (last reported in 2002), no HCV transmissions (last reported in 1997), no HTLV transmissions (last reported pre-1996), 14 HEV transmissions (12 of which were prior to the introduction on HEV testing in 2017), 1 HAV transmission (2017), 1 Parvovirus B19 transmission (2012), 1 bacterial transmission (2015), no malarial transmissions (last reported in 2003), no West Nile Virus transmissions (never reported) and no vCJD transmissions (last in 1999)

reported within the UK (denominator @20 million blood component transfusions per decade).

394. SNBTS keeps its own data on transfusion transmitted infections. Over the past decade we have recorded 2 virus transmissions (I HAV and 1 HEV) against a denominator of around 2 million blood component transfusions which is proportionate to the incidence across the rest of the UK.

Section 10: Identifying risks associated with blood and blood products

46. Please explain SNBTS's approach to ensuring its staff keep abreast of medical and scientific developments and research in blood and transfusion-related matters. Does SNBTS delegate this responsibility to its staff members entirely, or does it maintain some control over this process? Has this changed over time?

395. All SNBTS staff are appointed against job descriptions with appropriate qualifications and experience specified. Further job specific training and competency assessment is provided as required. Furthermore, all professional staff are expected to undertake Continuous Professional Development appropriate to their responsibilities. For Consultant Medical and Scientist staff, this forms part of their appraisal processes. Clinical Leads have specific additional responsibilities as subject matter experts in their specialist fields. Study leave including attendance at relevant national and international scientific and medical conferences is agreed and supported by SNBTS. The responsibility for keeping abreast of medical and scientific developments is therefore shared between the individual staff member and the organisation.

47. What external advice, if any, does SNBTS seek to identify and assess the risks of infection associated with the use of blood and/or blood products?

396. As noted in our response to Question 44a, SNBTS principally takes formal advice from SACTTI and SaBTO. Under normal circumstances our Clinical Leads and other staff will attend various national and international conferences. In the event of an outbreak of infection localised to Scotland we work closely with our colleagues from Public Health Scotland.

48. What internal advisory and/or decision-making structures are in place at SNBTS to identify and assess the risks of infection associated with the use of blood and/or blood products?

397. SNBTS has a Consultant Virologist who leads the National Microbiology Reference Unit (NMRU) and provides subject matter expertise in transfusion-transmitted viral infections. The NMRU is responsible for confirmatory testing of donations, assay evaluation and validation, horizon scanning and risk assessment. Policy decisions with regard to management of risk of infection are the responsibility of SNBTS Clinical Governance and Safety Group.

49. Please describe the enquiries and/or investigations, if any, that SNBTS carries out or causes to be carried out in respect of the risks of the transmission of blood borne infections.

398. SNBTS derives most of its intelligence on the evolving risk of transmission of blood borne infection through the SACTTI horizon scanning process. SNBTS has representatives from both SACTTI and SaBTO. In addition, SNBTS has a small in house microbiology research group associated with the National Microbiology Reference Unit which carry out assay development and epidemiological work particularly on new and emergent infections. Since March 2020 the focus of the group has entirely been on SARS-CoV-2 supporting the development of new serological assays and epidemiological studies of seropositivity amongst Scottish blood donors.

Section 11: Public awareness

50. Once the risk of transmission of blood borne infections relevant to the Inquiry's terms of reference was known within SNBTS:

a. **What, if any, actions did SNBTS take to reduce the risk to patients of being infected?**

399. The current senior management of SNBTS is not in a position to provide a comprehensive answer to this historical question because, due to the passage of time, there is no longer anyone currently working in the organisation who was involved at a senior medical, scientific or managerial level prior to around 1997. As per our response to the IBI's Invitation for Submissions on the Penrose Inquiry we believe that the Penrose Inquiry's Preliminary and Final Reports provide a relatively comprehensive chronology of events and account of the actions taken by SNBTS to reduce the risk to patients of being infected within its reference period of 1st January 1974 to 1st September 1991.

400. Subsequent to 1991 there has been continuing refinement of existing donor selection criteria and tests and the introduction of a number of new tests and other key blood safety measures including:

- 1999: Hepatitis C Virus (HCV) Nucleic Acid Testing (NAT)
- 1999: Universal leucodepletion
- 1999: Ban on use of UK plasma for fractionation
- 1999: Malaria serology
- 2002: Human T-cell lymphotropic virus (HTLV) serology (anti-HTLV I and II antibodies)
- 2003: Human Immunodeficiency Virus (HIV1) NAT
- 2004: Importation of clinical Fresh Frozen Plasma for patients born since 1996
- 2004: Exclusion of blood donors who have received a blood transfusion since 1980
- 2004 Bacterial testing of platelets

- 2010: Hepatitis B Virus nucleic acid testing (NAT)
- 2013: West Nile Virus NAT
- 2016: Hepatitis E Virus (HEV) NAT
- 2019: Trypanosma cruzi serology
- SARS-CoV-2 serology and NAT

401. The other side of the coin, of course, is to try to ensure that blood components are only used when the benefit / risk balance is positive. As discussed earlier, SNBTS initiated work on the effective use of blood from 1992 focussed on variability and errors in the clinical transfusion process. A paper published in 1994 (McClelland DBL, Phillips P BMJ 1994;308:1205-1206) **[NHBT0000037_022]** recommended that all hospitals should establish clear and coordinated managerial responsibility for the transfusion process, all transfusion labs should have a process for recording transfusion errors and corrective actions and that a national reporting system for critical transfusion incidents and near misses be established (which it was as the SHOT haemovigilance scheme in 1996).

402. Following a UK-wide symposium in 1998, Scotland published a Medical Executive Letter MEL1999/9 https://www.scot.nhs.uk/sehd/mels/1999_9.html) containing the elements of the 'Better Blood Transfusion' initiative with the aim of making clinical transfusion practice safer and more appropriate to individual patients' needs . This included establishing governance arrangements within hospitals and the wider network and producing clinical standards for the use of blood and blood components. Education of all staff involved in blood transfusion and adverse event reporting to SHOT was essential.

403. Safe blood transfusion has been a particular priority of the Scottish Government who set up and funded the NHS Scotland (NHSS) Better Blood Transfusion Programme (BBTP) in 2003 with the overall strategy to reduce risks to patients from blood transfusion, mainly by reducing unnecessary, inappropriate transfusion and also through continuous quality improvement of all aspects of transfusion practice. In 2006, in order to measure the

effectiveness of the BBTP, the Effective Use of Blood Group developed Clinical Standards for Blood Transfusion. Quality Improvement Scotland conducted peer review visits to all NHSS board areas between September 2007 and April 2008 to assess performance against the standards. The report and recommendations for further improvement were published in October 2008.

404. The current level of safety of the blood supply in the UK and Scotland is discussed in our response to Question 45.

b. What, if any, actions did SNBTS take to:

I. identify patients who may have been infected through treatment with infected blood or blood products?

405. When donor testing for HIV was introduced in October 1985 lookback was implemented. When donor testing for HCV was implemented in September 1991 a pilot was carried out by the Edinburgh and SE Scotland RTC as described in the paper published by Ayob et al **[PRSE0001046]** and implemented in 1995 throughout the other SNBTS RTCs and across the rest of the UK.

406. More detail on these Lookback Procedures is provided in the Key Topic Paper prepared by Dr Jack Gillon for the Penrose Inquiry **[PRSE0004042]**. Chapter 35 of the Penrose Inquiry provides a report on its investigation into the steps taken in Scotland to identify patients who may have been infected within its period of reference.

407. SNBTS continues to carry out lookback investigations whenever a donor identified as having a new infection has previously donated blood or when a patient identified as having a relevant infection may have previously received blood.

II. make patients who had been treated with blood or blood products aware of the risk of infection?

408. The primary responsibility for ensuring that a patient gives informed consent with regard to the balance of benefit and risk associated with a medicinal product (such as a plasma product) or other medical intervention (such as a blood transfusion) lies with the prescribing clinician.

409. With regard to blood components, Dr Brian McClelland edited the first edition of a Handbook of Transfusion Medicine in 1989 on behalf of the Directors of the UK Blood Services, which was made available to all relevant NHS and private health sector staff with the aim of giving clinicians the information that they and their patients needed to have about the benefits and risk of transfusion and to provide a guide to the appropriate use of blood components and plasma products **[PRSE0003047]**. This book is now in its fifth edition (2013) and available online as well as in print version of the JPAC website (5th Handbook of Transfusion Medicine (1).pdf). From 1990 SNBTS augmented this with a Compendium of Blood Products and Blood Component Information to provide information to clinicians about the range, indications for, and risks of its products. Subsequent EU-funded work, again led from Scotland, was the EU Optimal Use of Blood project initiated in 2006 with the aim of promoting and sharing best practice in transfusion across the EU. In 2004 Scotland started to develop the Learn Blood Transfusion (LBT) e-learning modules accessible to all and mandated throughout Scotland for all involved in the transfusion process.

410. Patient information explaining the risks and benefits of transfusion was recommended in the second edition of the Handbook of Transfusion Medicine (1996). It was around this time that UK Blood Services started to develop patient information leaflets. SNBTS now produces its own leaflet 'Receiving a Transfusion' the next version of which will be a UK-wide leaflet covering all blood components for transfusion to adults and children.

411. Although a consent process has always been in place for surgical and other invasive procedures, consent for treatments such as blood transfusion was not specifically required, unless included within the consent for a surgical procedure. In 2010 Scotland was represented on a group convened by SaBTO to make recommendations on consent for transfusion. Following extensive stakeholder consultation between March and May 2010 guidance was issued in 2011 and recently updated in 2020 (SaBTO consent December 2020 Guidelines from the expert advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) on patient consent for blood transfusion - GOV.UK (www.gov.uk) that valid consent was required for transfusion (WITN3530067 SNBTS Leaflet: Receiving a Blood Transfusion). Since then LBT has developed an educational module on consent, patients have been offered patient information leaflets and the opportunity to discuss the risk and benefits of, and alternatives to, transfusion. In the event that transfusion takes place in an emergency, patients should be given the information about risks and benefits after the transfusion as well as the opportunity to ask questions and have their concerns addressed.

412. With regard to plasma products, as a pharmaceutical manufacturer PFC was not permitted or expected to engage in direct contact with patients. Until 1994 the regulatory requirement was for Technical Information Leaflets directed at healthcare professionals only; these were not an appropriate vehicle for providing information to patients. The position changed in 1994 when Patient Information Leaflets became a regulatory requirement and SNBTS thereafter issued appropriate patient information, approved by MHRA, with PFC products.

413. Chapters 33 and 34 of the Penrose Inquiry provide a report of that Inquiry's investigation of the systems in place in Scotland to inform patients of the risk of infection.

c. What, if any, arrangements were made to provide patients infected through blood products with medical treatment for their condition?

414. SNBTS is not in a position to answer this question because responsibility for provision of patient care rests with the territorial health boards and their clinicians.

d. What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?

415. SNBTS is not in a position to answer this question because responsibility for provision of patient care rests with the territorial health boards and their clinicians.

51. Do you consider that the decisions and actions of SNBTS in response to any known or suspected risks of infection were adequate, appropriate, and proportionate to the risk and severity of infection? If so, why? If not, please explain what you believe could or should have been done differently.

416. SNBTS recognises the importance of this question and the need for it to consider its past performance in response to known or suspected risks of infection. SNBTS is committed to actively supporting the Infected Blood Inquiry in its ongoing investigations and in reaching its conclusions. The current senior management of SNBTS will reflect again on SNBTS's performance as an organisation at the conclusion of this Inquiry. It will consider in full the evidence presented by the Inquiry and set out the results of that process of reflection in its submissions. At this point, the current senior management of SNBTS would wish to fully acknowledge the pain and suffering caused by transfusion-transmitted infections to both patients and their families.

417. Over the past 30 years, SNBTS has implemented major changes in the governance of the blood supply, and there have been significant advances in blood safety, as outlined in previous sections in this statement. These changes ensure that the blood supply is as safe as possible, and that any further improvements to blood safety, including any response to known or emerging risks, are assessed and implemented as soon as possible.

52. Did SNBTS encounter any difficulties in obtaining sufficient funding for the identification, notification and / or treatment of people who were infected with blood borne infections relevant to the Inquiry's terms of reference?

418. The current senior management of SNBTS are not aware of any specific funding issues relating to internal lookback processes i.e. the identification of previous donations by a donor found to be positive for an infectious marker, the re-testing of samples (where available), the tracing of components to the relevant hospital blood banks and, in the case of the 4 hospital blood banks managed by SNBTS, the identification of recipients and the notification of the clinicians responsible for their care.

419. SNBTS is not able to comment on any funding issues relating to the 28 hospital blood banks managed by the Territorial Health Boards or to the notification and treatment of recipients infected with blood borne infections which were and are the responsibility of the clinicians responsible for their clinical care.

Section 12: Financial support

53. What if any involvement did SNBTS have with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund, EIBSS) that were set up to provide financial support to people who had been infected through infected blood products?

420. SNBTS does not have, and to the best of our corporate knowledge has never had, any involvement with the trusts or funds established to provide financial support to people who had been infected through blood products. From time to time SNBTS is approached by a patient, his or her clinician, MSP or other representative or by one of the trusts or funds to try to establish whether they have been infected through blood transfusion or not. To establish this, the donation numbers of the blood components they received are needed. These should be documented in the patient's clinical notes or in the hospital blood bank records. If these are available, then for relatively recent transfusions, where SNBTS had a unified national IT system (i.e. since the introduction of Progesa in 1998), it should be possible to trace the original donation and donor. Data will be available on the tests which were carried out on the donor's blood samples at the time and on any subsequent donations that that donor made. SNBTS also maintains an archive of samples dating back to 1998 so it may be possible to retest the original donation samples if required. If the transfusion was between 1987 and 1998 then it may be possible to trace the original donations through the legacy DOBBIN and LABLAN IT systems, but prior to 1987 it becomes much more difficult due to the paper-based nature of the records.

54. To what extent did SNBTS inform patients about the different trusts or funds?

421. SNBTS rarely has direct contact with the patients who receive its blood components or plasma products because these are administered by clinicians within the NHS Scotland Territorial Health Boards. A normal route of communication would be, for example, a diagnosis of an infection in a patient and a request to SNBTS to carry out a lookback process to try to establish whether or not s/he was infected by a historical blood transfusion as noted above. In such a context or if a donor was found to be positive for a potentially transfusion transmissible infection, SNBTS would also look for evidence of infection in previous donations and where possible trace any other recipients of positive donations – however these patients would also be contacted principally through their attending hospitals and clinicians

because SNBTS would not have their personal details or access to their medical records. It would therefore be the attending clinician who informs the patient and conveys information on the availability of the various Trusts and Funds (reference SHHD letter 21st April 1992 and HDL 2004 /31 **[WITN3530074]** and **[WITN3530075]**.

55. Did the SNBTS have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

422. To the best of knowledge SNBTS did not have a policy in this regard because this would be the function of the attending clinician with the full knowledge of the patient and his / her clinical condition to do so. SNBTS would rarely be in possession of the personal or medical information required to perform this task.

56. What kind of information, if any, did the SNBTS provide to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?

423. If approached by a trust or fund to establish whether a patient had been infected through a blood transfusion or not, SNBTS would require the donation numbers of the blood components they received. SNBTS would then attempt to trace the original donation and donor. Data will be available on the tests which were carried out on the donor's blood samples at the time and on any subsequent donations that that donor made. SNBTS also maintains an archive of samples dating back to 1998 so it may be possible to retest the original donation samples if required. This information would then be passed on to the requester.

57. Did SNBTS act as a gateway for determining or advising whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were, how they were applied, and by whom. Was SNBTS or any of its staff involved in determining applications made by

patients for assistance from the trusts or funds? If so, please describe that involvement.

424. SNBTS does not know and, to the best of our knowledge, has not in the past acted as a gateway for determining or advising whether patients meet the eligibility criteria for assistance from any of the trust or funds. Likewise, to the best of our knowledge, neither SNBTS nor its staff have been involved in determining applications made by patients for assistance from the trusts or funds. SNBTS has and does respond to enquiries from patients, their representatives or trusts / funds as outlined above.

58. To the extent that you feel able to answer, do you consider that the trusts and funds achieved their purposes? Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

425. SNBTS is not in a position to comment on this issue.

Section 13: Other issues

59. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Inquiry. To assist, we have provided a list of issues (attached). Confidentiality I draw your attention to the General Restriction Order ("the Order") made by the Inquiry Chair pursuant to section 19 of the Inquiries Act 2000

426. SNBTS does not have any other issues it wishes to raise at this time.

Statement of Truth

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

Signed GRO-C

Dated 7th October 2021

Table of Exhibits

Date	Notes/ Description	Exhibit number
Jun 2021	Strategic Management Group; Terms of Reference	WITN3530008
Nov 2020	Clinical Governance and Safety Group Terms of Reference	WITN3530009
Jun 2021	Operational Management Group Terms of Reference	WITN3530010
Jun 2021	Health and Safety Committee Terms of Reference	WITN3530011
Apr 2018	Partnership Forum Terms of Reference	WITN3530012
1990	Girdwood (1990) Fifty Years of an Organised Blood Transfusion Service in Scotland *Scottish Medical Journal 35: 24-28*	PRSE0003986
Oct 2011	Scottish National Blood Transfusion Service Governance and Financing Governance and Financing the Blood Supply in Scotland 1974-2009 (2011) Penrose 2011/00141	WITN3530013
1997	SNBTS Strategic Review 1998/99	WITN3530014
29 Jul 2009	Legal and Administrative Structure of SNBTS since 1970	WITN3530015
Jun 2021	Donor Information Leaflet NATL 020 v08	WITN3530016
Jun 2021	Donor Session Record and Health Check NATF155 v17	WITN3530017
Jan1984	B. McClelland Report following a visit to NY and WHO Conference 1983	WITN3530018
Dec 1992	Price Waterhouse Computer Audit 1992	WITN3530019
Jun 2020	DSR Scanning NATS DAD 066 v02	WITN3530020
Dec 2020	National Post Session Clear Up & Administration Functions in eProgesa NATS DAD 050 v18	WITN3530021
1990	Red Book Editions 1,2 and 4 records retention guidance.	PRSE0002989

Sep 2010	Donor Selection Policies and Procedures (Pen 2010-00056)	WITN3530022
May 2020	eProgesa System Description NAT ITD 009 02	WITN3530023
Sep 2018	NSS Document Storage, Retention and Disposal Policy NATS QAD 057 07	WITN3530024
1977	NBTS Memorandum of the Selection, Medical Examination and Care of Blood Donors 1977	PRSE0004358
1983	NBTS Memorandum of the Selection, Medical Examination and Care of Blood Donors 1983	WITN3530025
1987	NBTS Memorandum of the Selection, Medical Examination and Care of Blood Donors 1987	PRSE0004115
Jan 2021	SNBTS Policy on Records Management NATP QUAL 030 01	WITN3530026
Sep 2019	UK Blood Transfusion Services Forum Constitution	WITN3530027
2004	JPAC Terms of Reference	WITN3530028
Sep 2014	Advisory Committee on the Tissues and Organs (SaBTO) Terms of Reference	WITN3530029
Jul 2021	Donor and Transport Services National SOP Report	WITN3530030
Apr 2014	Transforming the Donation Experience Review (2014/5)	WITN3530031
Oct 2011	Regulation of the Manufacture of Medicinal Products Derived from Blood Plasma (PEN 0172723 and 2011/00082)	PRSE0002556
2016	Foster PR. *The manufacture of blood plasma products in Scotland: a brief history*, Scot Med J 2016, 61, 34-41).	WITN3530032
Sep 1982	Letter from SHHD to DHSS, *Blood Transfusion Service: Protein Fractionation Centre, Liberton.*	DHSC0002333_018
1973	Middleton SM, et al. *A therapeutic concentrate of coagulation factors II,IX &X from citrated, factor VIII-depleted plasma,* Vox Sang 1973, 24, 441-456	PRSE0003648
1975	Kingdon HS, et al. *Potentially thrombogenic materials in factor IX concentrates.* Thromb Diath Haemorrh 1975, 33, 617-631	WITN3433033
	NP31518 Albumin Products	WITN3530034

	NP32617 Human Normal Immunoglobulin (Ig)	WITN3530035
Jun 2017	NP34917 Specific Immunoglobulins (Anti-D Immunoglobulin, Hyper Immune Globulin and Prothrombin Complex Concentrate (PCC)	WITN3530036
Jan 2017	NP32617 Strategy V1.1	WITN3530037
Feb 2017	2017-OJS039-070527-en (Contract Notice that outlines Technical and Professional requirements)	WITN3530038
2017	NP32617 Important Introductory Information V01.0 (Final)	WITN3530039
Feb 2017	ITT_ itt_16583 - NP32617 Supply of Intr..	WITN3530040
2017	NP32617 Tender Specification v01.0 (Final)	WITN3530041
2017	NP32617 Tender Specification Appendix A V01.0 (Final)	WITN3530042
	NP32617 Scoring Illustration V01.0 (Final)	WITN3530043
Dec 2020	Plasma Products Strategy V1 (includes general commodity area and market overview)	WITN3530044
Dec 2020	Appendix B NP32621 Strategy V1	WITN3530045
Mar 2021	Bleeding Disorders Framework Briefing Document v11 extended til 300622	WITN3530046
Feb 2019	NP350/18 CMU Recombinant Factor IX (rFIX) products for the treatment of Haemophilia B	WITN3530047
Jul 2020	NP43420 NHS National Framework Agreement for the supply of products for the treatment of Haemophilia A	WITN3530048
Jun 2018	NP489/18 Icatibant and C1 Esterase Inhibitor	WITN3530049
Apr 2021	NHS National Services Scotland (NSS) Standing Financial Instructions (SFIs)	WITN3530050
January 1999	NHS MEL(1999)9 Better Blood Transfusion	WITN3530051
2003	NHS HDL (2003) 19	WITN3530052
2005	NHS HDL (2005) 25	WITN3530053

Dec 1998	Health Service Circular 1998/224 Better Blood Transfusion	WITN3530054
2011	Carter et al (2011) Transfusion and Apheresis Science 45 31-43	WITN3530055
Aug 2002	Donor Services Review Formal Consultation Document	WITN3530056
Mar 2011	Martin Bruce Penrose Inquiry Witness Statement (PEN 2011/00077)	WITN3530057
Mar 1997	SNBTS Strategic Review Implementation Donor Project Report – M Thornton	WITN3530058
Jun 2016	Rutherford et al (2016) 23rd Annual EurOMA Conference 2016, Trondheim, Norway	WITN3530059
Jul 2021	Hospital Blood Bank Dashboard	WITN3530060
Mar 2021	MoU between UK Blood Services	WITN3530061
2005 and 2020	Blood Shortages Plan 2005 updated 2020	WITN3530062
Jul 2021	SNBTS Donor Services Awards	WITN3530063
Apr 2019	Busch MP et al. Prevention of transfusion transmitted infections. Blood 2019; 133 (17): 1854-1864,	WITN3530064
Aug 2009	Stramer SL et al. Emerging infectious disease agents and their potential threat to transfusion safety. Transfusion 2009; 49: 1S – 29S	WITN3530065
Jan 2021	JPAC Horizon Scanning Management Process Description January 2021	WITN3530066
May 2020	JPAC Position Statement on Emerging Infections May 2020	WITN3530067
May 2020	JPAC Position Statement GDRI - addition and removal of specific country risk May 2020	WITN3530068
Mar 2021	JPAC SACTTI Annual Horizon Scanning Report 2020	WITN3530069
May 2021	JPAC CN 2021 16 Changes Required for Implementation of FAIR Study	WITN3530070
Sep 2010	Donor Selection Policies and Procedures (PEN 2010/00056)	PRSE0000954
Nov 2020	JPAC Position Statement: The estimated residual risk that a donation made in the infectious window period is not	WITN3530071

	detected on testing: risks specific for HBV, HCV and HIV in the UK, 2017-2019. November 2020	
July 2021	Annual SHOT Report (SHOT Report, Summary and Supplement 2020, Chapter 21	WITN3530072
Jul 1994	Ayob et al. Risk of Hepatitis C in Patients who received Blood from Donors subsequently shown to be carriers of Hepatitis C Virus. Transfusion Medicine 1994;4,229-272	PRSE0001046
2010	Jack Gillon Key Topic Paper Lookback (PEN 2010-00014a)	PRSE0004042
1989	Handbook of Transfusion Medicine 1st Edition	PRSE0003047
Jul 2021	SNBTS Leaflet: Receiving a Blood Transfusion	WITN3530073
Apr 1992	SHHD letter 21st April 1992	WITN3530074
Jun 2004	HDL 2004 /31	WITN3530075
May 1968	Minutes from meetings held between the SHHD and the Blood Transfusion Services of England and Scotland	WITN3530076
Nov 1968	Minutes from meetings held between the SHHD and the Blood Transfusion Services of England and Scotland	WITN3530077
Mar 1969	Minutes from meetings held between the SHHD and the Blood Transfusion Services of England and Scotland	WITN3530078
Jun 1969	Minutes from meetings held between the SHHD and the Blood Transfusion Services of England and Scotland	PRSE0000210
Nov 1969	Minutes from meetings held between the SHHD and the Blood Transfusion Services of England and Scotland	WITN3530079
Jul 1971	Minutes from meetings held between the SHHD and the Blood Transfusion Services of England and Scotland	WITN3530080
Mar 1973	Minutes from meetings held between the SHHD and the Blood Transfusion Services of England and Scotland	PRSE0003839
Mar 1977	Minutes from meetings held between the SHHD and the Blood Transfusion Services of England and Scotland	WITN3530081
Aug 1977	Minutes from meetings held between the SHHD and the Blood Transfusion Services of England and Scotland	WITN3530082
1994	McClelland DBL, Phillips P BMJ 1994;308:1205-1206	NHBT0000037_022
1992/1993	National Donor Selection Guidelines for SNBTS 1992/3.	WITN3530083

1997	SNBTS tick box format questionnaire in 1997	WITN3530084