Witness Name: Karin Jackson
Statement No.: [WITN26810026]
Exhibits: [WITN26810027 – WITN26810033, NHBT0000745]
Dated: 22nd September 2021

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF KARIN JACKSON, CHIEF EXECUTIVE, NORTHERN IRELAND BLOOD TRANSFUSION SERVICE (NIBTS)

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

I, Karin Jackson, will say as follows:

Section 1: Organisation history & structure

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

1. I am Karin Jackson. I have been CEO of the NIBTS since October 2016. My professional address is the Northern Ireland Blood Transfusion Service Headquarters, Lisburn Road, Belfast, BT9 7TS.

2. My date of birth is known to the Inquiry.

3. Professional Qualifications:
   Bachelor of Engineering in Mechanical Engineering and Industrial Management – University of Liverpool.

MSc in Manufacturing Management – University of Ulster
MBA - Queens University Belfast
Master of Laws in the Legal Aspect of Medical Practice – Cardiff University

4. I am a Chartered Engineer with the Institution of Mechanical Engineering

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

5. Below is a summary outlining the key roles and responsibilities of the Chief Executive. The full job description is also attached for further information if required, [WITN26810027].

6. As Chief Executive, I am the executive member of the Agency Board. I have overall responsibility for the management and performance of the Agency, including meeting Ministerial priorities as defined by the Department of Health and the Health and Social Care Board (HSCB), fulfilling statutory requirements, ensuring compliance with the Blood Safety and Quality Regulations (BSQR) 2005 (As amended), delivering against performance targets, securing continuous improvement and for providing safe, high quality and effective services within a clear financial framework.

7. The key roles and responsibilities of the post are:
   Ensuring the collection, testing, manufacture and supply of blood components meets the needs of patients in Northern Ireland and also meets the requirements set out in the Blood Safety and Quality Regulations (2005) (as amended).
   Ensuring NIBTS laboratory testing systems are compliant with ISO 15189.
   Providing leadership and developing the vision for the strategic direction of the Agency.
   Ensuring the Agency's corporate objectives are in line with the overall policies and priorities of the DoH and the HSCB in Northern Ireland.

8. Accountability for research, development and innovation to ensure a sustainable, safe supply of blood and components.

9. As the chair of the Senior Management Team I lead, contribute to and participate in the corporate management and governance of NIBTS.

10. I am also responsible for ensuring the Agency delivers on its vision, values and priorities, continually aligning these to the Agency's Strategic Plan and the regional Programme for Government.

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

11. The Blood Transfusion Service was established in 1946 by the Ministry of Health. In 1948, the Service became the responsibility of the Northern Ireland Hospitals Authority. The Service then came under the remit of the Eastern Health and Social Services Board (EHSSB) from its creation in 1972 to June 1994. In June 1994, the Northern Ireland Blood Transfusion Service (NIBTS) was established as an independent Special Agency of the Health and Personal Social Services in Northern Ireland.

12. The functions of the NIBTS are to ensure that all hospitals and other clinical units in Northern Ireland are provided with adequate supplies of blood and blood products and that these comply with all current national standards of safety and efficacy. In discharging this function, NIBTS is required to –
    - Assess and anticipate the needs of the health and personal social services in Northern Ireland for blood and blood products;
    - Recruit and maintain adequate numbers of healthy, voluntary, non-remunerated donors;
    - Ensure the health and safety of blood donors during their contact with the Blood Transfusion Service, also provide counselling to donors found to have abnormalities during routine screening;
    - Perform appropriate processing and testing of blood and blood components;
    - Ensure that an effective quality assurance programme is applied to all aspects of the production process and other areas of the Blood Transfusion Service;

- Provide an education and advisory service on the utilisation of blood and blood products by clinicians;
- Provide a reference laboratory service to all hospital blood banks in Northern Ireland;
- Provide a regional antenatal blood screening service in blood group serology, rubella, hepatitis B including the organisation of a perinatal hepatitis B immunisation programme;
- Provide in conjunction with the British Bone Marrow and Platelet Donor Panel, a bone marrow donor service including recruitment and counselling of donors and maintenance of the local donor panel;
- Provide advice on all aspects of transfusion medicine including certain aspects of immunohaematology and the antenatal service;
- Provide practical and theoretical instruction in all aspects of transfusion medicine and science to appropriate health service staff;
- Undertake relevant research and development to improve the services provided by the Blood Transfusion Service Agency; and
- Maintain appropriate links with organisations in Great Britain and elsewhere in pursuit of these objectives.

13. The above information is set out in the attached functions direction [WITN26810028].

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

4a) its staffing, in particular the roles and responsibilities of key decision-makers (for example the Director, the Medical Director, the Scientific Advisor etc.);

14. The management structure of the NIBTS is illustrated in the following Organisational Chart [WITN26810029].

15. The NIBTS Agency Board consists of a chair, three non-executive members and the Chief Executive. The Medical Director and the Senior Management Team also attend the Board to support the CEO.

16. The role of the NIBTS Board is to ensure that effective arrangements are in place to provide assurance on risk management, governance and internal control. The Board also has corporate responsibility for ensuring the NIBTS fulfils the aims and objectives set by the Department of Health (DoH) Northern Ireland.

17. The Chief Executive is ultimately accountable to the Board and, as Accountable Officer, to the Minister for Health, for ensuring that the Board meets its obligation to perform its functions within the available financial resources. The Chief Executive has overall executive responsibility for the Agency's activities; is responsible to the Chair and the Board for ensuring that its financial obligations and targets are met and has overall responsibility for the Agency's system of internal control.

18. It is a duty of the Chief Executive to ensure that Members of the Board, employees and all new appointees are notified of, and put in a position to understand, their responsibilities.

19. The NIBTS Senior Management Team (SMT) consists of the Head of HR & Corporate Services, the Quality and Regulatory Compliance Manager, the Finance and IM&T Manager and the Laboratory and Donor Services Manager (recently replaced by the Head of Supply Chain and Testing). They report to the Chief Executive on all aspects of business related to their areas and are responsible for:
    - Ensuring that the sequence of performance reports, audits and independent reports, required by the Board as part of the performance management and assurance processes, are available.
    - Ensuring that governance and service improvement is embedded at all levels within the organisation and that risk management is an integral part of the accountability process.
    - Preparing and regularly updating a corporate risk register, which will inform the management planning, service development and accountability review process.

20. All Heads of Department and individual staff members are accountable to a member of the Senior Management Team. All staff have their individual roles and job descriptions. Ultimately, all staff are responsible for providing donors with the highest possible quality of care and service and for taking all appropriate actions to promote

donor, patient and staff safety by minimising risk. There is also an onus on each staff member to highlight any issues of concern, which they may have in relation to patient/client care and safety. Staff should also ensure that they assume responsibility for their continuing professional development.

4b) How, and by whom, key strategic decisions are made:

21. Key strategic decisions within NIBTS are made at Board level. Papers and proposals are also brought to the relevant Board committee for review and approval. The NI Blood Transfusion Management Statement and Financial Memorandum (MSFM) document is agreed by the Department of Health (NI) and the NIBTS. It details the roles, responsibilities and accountability arrangements of the organisation, the Board and key senior staff [WITN26810030]. This document can be made available if it would be of benefit to the Inquiry.

22. Every four years, the NIBTS Board develops a Corporate Plan that describes our four year Corporate Strategy, this reflects the Programme for Government priorities established by the Northern Ireland Executive [WITN26810031]. The annual objectives are described in a business plan that is reviewed and approved by the DoH in Northern Ireland [WITN26810032]. Copies of both of these documents can be made available if required.

4c) How it is funded;

23. NIBTS receives its funding through service level agreements with the Northern Ireland Health and Social Care Board (HSCB), (Commissioner) and Health and Social Care Trusts (health care provider organisations).

24. The HSCB funds NIBTS for the provision of regional services such as testing and screening and for expenditure incurred on haemophilia blood products.

25. HSC Trusts fund NIBTS for the supply of blood components and some plasma products.

4d) the structure, composition and role of its various committees or working groups;

26. Please see the following chart that shows the committees and working groups within NIBTS that support clinical governance [WITN26810033]. In addition, there is an Audit Committee that provides assurance regarding financial governance and a Remuneration Committee that advises the Board on salary and terms and conditions for the Chief Executive.

Governance and Risk Management Committee

27. Membership of the Governance & Risk Management Committee comprises three Non-Executive Members. Meetings are held on a quarterly basis with a report made to the next Agency Board meeting via the Chair of the Committee. The remit of the Committee is:
    - Reviewing the development and maintenance of an effective system of integrated governance (i.e. risk management, quality and regulatory affairs) and internal control, across the organisation's activities that supports the achievement of the organisation's objectives;
    - Ensuring effective governance arrangements are in place both at strategic and operational level across the organisation and
    - Ensuring that key governance priorities are addressed.

Audit Committee

28. The Audit Committee is a Committee of the Board. The Committee is authorised by the Agency Board to investigate any activity within its terms of reference. It is authorised to seek any information it requires from any employee and all employees are directed to co-operate with any request made by the Committee. The Committee is authorised by the Agency Board to obtain outside legal or other independent professional advice and to secure the attendance of outsiders.

Quality Improvement Review (QIR) Group

29. Reports from the QIR group are presented regularly to the Agency Board. The role of the group is to plan, review and monitor the effectiveness of all aspects of the Quality Management System within NIBTS.

Health and Safety Committee

30. The Health and Safety Committee reports to the Governance and Risk Management Committee. The Committee is responsible for the implementation of all aspects of health and safety including Fire Safety Management and Security Management. The committee will also assist the Organisation in the implementation of Health and Well-being events for staff throughout the year.

Medical Devices & Equipment Group

31. The Medical Devices and Equipment management group was established to develop, implement and review policies related to MDE across the organisation. This group should review the policies at least once a year and submit regular reports to the Governance and Risk Management committee and NIBTS Board. It will also:
    - Improve communication about MDE within the organisation and produce and review governance standards self-assessment and action plan.
    - Gain the agreement of clinicians, technical staff and users in relation to any proposed changes.
    - Reduce confusion about who is responsible for MDE management tasks, training and safe device operation.
    - Take guidance from:
      Guidelines for the blood transfusion services in the UK (red book)
      Guidance for pharmaceutical manufacturers and distributors (orange book)
      Good Practice Guidelines for Blood Establishments required to comply with Directive 2005/62/EC.
      EU Regulation on Medical Devices 2017/245 and In Vitro Diagnostic Medical Devices 2017/746.

Research Governance

32. The role of the Research Governance Group is to provide governance for research activity conducted within NIBTS and to ensure compliance with the Research Governance Framework for HSC.

The Risk Management Sub Group

33. The Risk Management Sub-Group is a sub-section of the NIBTS Governance and Risk Management Committee, responsible for supporting development and implementation of business resilience and risk management solutions. Key to their role is:

- The development, implementation and review of policies and procedures to minimise business risk in compliance with appropriate Risk Management standards
- The development, implementation and maintenance of business continuity plans.

Incident Management Group

34. The Incident Management Group is a sub-group of the Quality Improvement Review Group. The group is responsible for:
    - Supporting the on-going maintenance and development of Quality Incident Management systems in NIBTS
    - Providing an organisation wide review of incidents reported through the incident management system
    - Analysis of trends to provide further recommendations

Change Control Group

35. The Change Control Group is a sub-group of the Quality Improvement Review Group. The group is responsible for:
    - Supporting the on-going maintenance and development of Change Control systems in NIBTS
    - Identifying potential impacts of changes in operational/regulatory areas.
    - Reviewing action plans for changes to ensure identified impacts have been addressed.

Quality Monitoring Review Group

36. The Quality Monitoring Review Group is a sub-group of the Quality Improvement Review Group. The group is responsible for:
    - Supporting the Quality Monitoring programme in NIBTS;
    - Providing an organisation wide review of Quality Monitoring Results collated on a monthly basis.

4e) ***Its remit, including the geographical area it covered and the transfusion centres within this area;***

37. NIBTS collects blood throughout Northern Ireland. There is one central blood and platelet donation centre based in its headquarters building on the Belfast City Hospital site, Lisburn Road, Belfast. It also collects blood across Northern Ireland through mobile donation sessions. All blood collected is returned to the NIBTS HQ building for testing, processing and issue to all HSC hospitals throughout Northern Ireland.

38. In addition, NIBTS carries out testing and screening for all antenatal services in Northern Ireland.

4f) The legislative and regulatory framework under which NIBTS operates

39. The Northern Ireland Blood Transfusion Service is a Registered Blood Establishment with the Medicines and Healthcare products Regulatory Agency (MHRA) and holds a Blood Establishment Authorisation 11437/01. NIBTS is also licensed to hold and distribute pharmaceutical products and holds a Wholesale Dealers Licence WL11437/01.

40. NIBTS must comply with all relevant legislation including Blood Safety and Quality Regulations 2005 (as amended), environmental legislation, and UKAS Accreditation standards i.e. ISO 15189.

41. Legislative and regulatory requirements, as well as good practice guidance has developed over time. Below is a timeline of key developments in this area:
    - 1968 - UK Medicines Act
    - 1971 - Guide to Good Pharmaceutical Manufacturing Practice(GLP)
    - 1984 - First British Committee for Standards in Haematology Guideline
    - 1987 - Consumer Protection Act/Product Liability
    - 1988 - RCPath Accreditation Study
    - 1989 - EC Guide for Medicinal Products
    - 1992 – CPA (UK) Ltd Registered
    - 1996 - Serious Hazards of Transfusion scheme established
    - 1999 – The Good Laboratory Practice Regulations
    - 2001 - National Patient Safety Agency

- 2001 - Revised CPA Standards
- 2001 - A code of Practice for Tissue Banking
- 2002 - EC Blood Directive
- 2004 - Human Tissue Act (amended 2007)
- 2004 - Medicines for Human Use Regulations (amended 2006)
- 2005 - Blood Safety and Quality Regulations as amended (full implementation 2006)
- 2009 - CPA/UKAS ISO 15189 Medical Laboratories Requirements for Quality & Competence

5. How has the Structure Changed over Time

42. The core function and purpose of NIBTS has always been to provide safe and effective blood to Northern Ireland. The way in which these functions are carried out and the way in which NIBTS operates, has evolved over time. It is difficult to say exactly what changed and when as it has been an ongoing natural evolvement driven by many factors such as changes in regulations and practices, new regulatory requirements, advances in technology and development of knowledge. Where possible, throughout this response, I have provided detail of the current and previous systems and practices in place. However, as I took up my post in 2016, I do not have the personal knowledge of these systems and practices.

43. Donor recruitment and blood collection services were originally organised separately from the laboratory aspects of NIBTS. These were amalgamated in 1970 in a new facility in Durham Street, Belfast. In 1995, NIBTS moved to a purpose-built facility on the City Hospital site in Belfast. This remains the headquarters for NIBTS.

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

44. Director NIBTS

1969 – 1980: Col. T.E. Field

June 1980 – May 1994: Dr Morris McClelland

45. Chief Executive

June 1994 – July 2009: Dr Morris McClelland
August 2009: March 2011 Dr Kieran Morris (Acting CEO)
March 2011 – August 2014: Dr Kieran Morris
December 2013 – March 2014: Glenn Bell (Acting CEO)
August 2014 – September 2015: Mervyn Berkley (Interim CEO)
September 2015 – September 2016: Paul Simpson (Interim CEO)
October 2016 – present: Karin Jackson

46. Deputy Director

August 1978 – May 1980: Dr Morris McClelland
Approx. Jan 1981 – March 2000: Dr Chitra Bharucha

47. Medical Director

June 1994 – July 2009: Dr Morris McClelland
November 2009 – May 2011: Dr Joanne Murdock (Acting Medical Director)
June 2011 – June 2014: Dr Joanne Murdock
August 2014 – September 2019: Dr Kieran Morris
May 2021 – present: Dr Joanne Murdock

48. Board Chairperson

June 1995 – November 2002: Dr Lucinda Blakiston Houston
December 2002 – November 2006: Mr S Costello
December 2006 – July 2007: Dr Morrell Lyons (interim Chair)
August 2007 – March 2019: Mr Jim Lennon
April 2019 – present: Ms Bonnie Anley

49. Non-Executive Board Members

June 1995 – November 2001: Professor John M Bridges
June 1995 – November 2001: Mr Edward Cartin
December 2001 – January 2011: Dr Morell Lyons
December 2001 – January 2011: Mr B Titterington
February 2011 – August 2011: Mrs S Rooney
February 2011 – present: Mr Ian Henderson
February 2011 – present: Mrs Lorraine Lindsey
November 2012 – present: Mr Philip Cathcart

7. Please describe NIBTS'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.

50. NIBTS has not previously been involved in any Inquiry in relation to HIV, HBV, HCV, or vCJD in blood and / or blood products.

Section 2: Record keeping arrangements

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

51. All NIBTS donor related information is stored in a computerised system called PULSE. This was introduced in February 1997.

    PULSE - February 1997 (approx.) - present
    MITHRAS – Approx. April 1996 – February 1997
    PACE - Approx. late 1985 – April 1996

52. PULSE is the electronic system used by NIBTS to log all donor information and track the processing and testing of all donations. Testing systems are linked to PULSE and all testing data automatically migrates into PULSE.

53. For a short period prior to PULSE (approximately April 1996 – February 1997) NIBTS used a system called Mithras. Both of these systems were provided and supported by Savant Limited.

54. From around late 1985 to April 1996, NIBTS used a system called PACE. Testing systems did not automatically feed data to PACE. Instead, data was entered manually. It is thought that only records of active donors were transferred from PACE to Mithras and then to PULSE. However, as it was some time ago, it is not possible to be certain of this.

55. Prior to PACE, a manual system was used for the management of donor records.

56. Currently, all donors complete a manual paper health check questionnaire prior to donating blood. A session slip is completed for all donors who donate. These records are reviewed by the donor administrative team and any relevant information, e.g. travel information, adverse events and deferrals, is added to the donor's PULSE record.

57. The paper records are stored by donation date. After a period of one year, they are moved to a secure off-site storage facility.

58. The donor records are retained for a period of 30 years.

9. Does NIBTS maintain a central database of blood donors? If so:

a. How long has this database been in operation?

b. What donor details does it record?

c. How is the information stored?

d. Who is able to access this information?

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

f. How long does NIBTS store this information for?

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

59. NIBTS maintains a central database of all donors on the PULSE system. PULSE has been in place since February 1997. The information stored is:

- Donor's personal details
- Blood group and blood characteristics
- Donation history
- Testing history
- Medical History, including reasons for not donating
- Additional relevant information supplied by the donor
- Any relevant notes recorded at donation
- Details of communications sent to donors

60. The information is stored on a computer-based system on the NIBTS servers. It is backed up every day and the back-up tapes are sent to an off-site storage facility.

61. Access to the PULSE system is controlled by the Access Privilege system which uses a combination of actions, roles and permissions, to ensure that the system is restricted to those staff who have a legitimate reason to access it, such as donor administrative staff, relevant laboratory staff and medical staff. It also ensures that certain areas of the system are restricted so that users can only see information that is relevant to their function. e.g., not all laboratory staff would have access to donor details, including their medical history.

62. NIBTS is not required to report to other organisations regarding the donor information stored.

63. The BSQR requires that donor records relating to the traceability of blood have to be retained for a period of 30 years.

64. As the PULSE system is not beyond 30 years old, the NIBTS has not destroyed or deleted any information from it.

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

65. NIBTS does not contribute to databases maintained by other organisations.

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

66. NIBTS does not hold medical records. The NIBTS Medical staff do create files for matters they are managing, e.g. post transfusion hepatitis reactions and providing clinical advice to some hospital practitioners. We do not have a specific retention

policy in place for these records. To date, the general practice has been to retain these records.

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

67. NIBTS is subject to the requirements set out in the Department of Health (NI) publication Good Management, Good Records (GMGR). This publication provides guidance to HSC organisations regarding the record keeping and retention requirements. It is based on legal requirements and good practice guidance. All NI HSC bodies have signed up to GMGR and therefore must abide by the retention requirements within. In addition, NIBTS is subject to the record keeping and retention requirements of the BSQR 2005 and those set out by The Royal College of Pathologists - The retention and storage of Pathological records & specimens (5th Edition, 2015). GMGR refers users to both of these.

13. **Does NIBTS 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.**

68. NIBTS does not record information on death certificates.

Section 3: Relationship of NIBTS to other UK blood services

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

69. While the four blood services operate independently from one another, all four UK blood services meet regularly and cooperate through the United Kingdom Blood

Transfusion Services' Forum (UK Forum). Further information is provided in response to question 15.

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.**

70. The four blood services all participate in the UK Forum. This group was established in 1999 to enable the four UK blood services to work together on both a formal and informal basis. The UK Forum consists of the Chief Executives/Directors and Medical Directors of each of the four UK blood services with other professionals invited as and when required. The professional groups listed below report to the UK Forum:
    - UK Blood Services Joint Professional Advisory Committee (JPAC). JPAC provides expert advice and guidance on blood safety matters.
    - Serious Hazards of Transfusion (SHOT). SHOT is the UK's independent, professionally-led haemovigilance scheme. SHOT facilitates the collection and analysis of anonymised information on adverse events and reactions in blood transfusion in the United Kingdom. Where risks and problems are identified, SHOT produces recommendations to improve patient safety.
    - The Systematic Review Initiative (SRI) is a clinical research group established in 2001. The primary objective of the SRI is to develop the evidence base for the practice of transfusion medicine.

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.**

71. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion and transplantation. The health departments and Ministers in the devolved administrations are responsible for the health policy in those parts of the UK.

72. The UK Blood Services Joint Professional Advisory Committee (JPAC) develops transfusion guidelines that reflect SaBTO advice and policy decisions made by the UK government and devolved administrations.

73. I have been advised of the following, but do not have direct knowledge of these events:

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

75. 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.

76. 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:
    - 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.

77. 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.

78. The organisation now consists of seven standing advisory committees, (SACs): Care and Selection of Donors, Blood Components, Immunohaematology, Transfusion Transmitted Infections, Clinical Transfusion Medicine, Tissues and Cellular Therapy Products and Information Technology.

17. Does NIBTS 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.

79. No, NIBTS does not share information about excluded donors with the other blood services. The services share statistical information regarding the number and type of infections detected in donated blood but they do not share the personal details of the donors.

Section 4: Relationship of NIBTS to transfusion centres

18. Please explain the relationship between NIBTS and the transfusion centres within its remit.

80. The following covers questions 18 – 22 as NIBTS does not have any transfusion centres.

81. NIBTS operates from one central headquarters on the Belfast City Hospital site. There are no other transfusion centres in Northern Ireland. The headquarters facility incorporates:
    - Whole blood and plateletpheresis collection unit.
    - Processing and testing laboratories;
    - Donor administration;
    - Medical team;
    - Nursing team (which provides staff for headquarters and mobile blood collection teams);
    - Quality and regulatory compliance department including the quality control laboratories; and

- Corporate functions including Finance, Human Resources (HR) and Information Technology (IT).

82. Additionally, NIBTS has a satellite blood collection team based in Omagh Hospital and Primary Care Centre. There is also a static donation facility in College Street, Belfast which is used approximately once a month as well as a purpose-built Blood Mobile Unit that supports the collection of blood across Northern Ireland.

83. All blood collected at all donation sessions is returned to NIBTS HQ for testing, processing and issue.

Section 5: Relationship of NIBTS to government

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

84. I have been unable to obtain information regarding the relationship between NIBTS and government departments before 1972 other than the transfusion service in Northern Ireland was established in 1946 by the Ministry of Health.

85. Between 1972 and 1999, the health system of Northern Ireland was managed by the UK government via the Northern Ireland Office (NIO). In Northern Ireland, the NHS was merged with the broader social care system in 1973 and called the Health and Personal Social Service (HPSS) and later the Health and Social Care (HSC) system, rather than the NHS. This meant that, until 1999 when devolution was restored in Northern Ireland, public and social policy decisions were taken at Westminster and communicated through a Secretary of State within the Northern Ireland Office, who answered directly to the UK Government. During the period of direct rule in Northern Ireland (1972 – 1999), the default position in terms of reform and the development of policy and strategy in health and social services was to mirror English policy decisions.

86. NIBTS was established in June 1994 as a Special Agency (akin to a non-departmental public body). The role and functions of the NIBTS were set out in the DHSSPS functions direction document, copy attached [WITN26810028] which came into force on 1st June 1994.

20. **To what extent is NIBTS accountable to government departments? To what extent is NIBTS's decision-making authority affected by government oversight?**

87. The NIBTS is accountable to the Department of Health (DoH) NI which was previously the Department of Health, Social Services and Public Safety (DHSSPS) NI.

88. The NIBTS performance framework is determined by the Department of Health in light of its wider strategic aims, and of current Programme for Government (PfG) objectives and targets. NIBTS sets out the key targets, standards and actions to be delivered in its Business Plan, a subset of its longer term corporate Strategic Development Plan.

89. The Health Minister is accountable to the Northern Ireland Assembly for the activities and performance of the NIBTS. They are responsible for approving the NIBTS Business Plan which must support the Department's wider strategic aims and contribute, as appropriate, to the achievement of the PfG and Priorities for Action (PfA) targets.

21. **Does NIBTS 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?**

90. The DoH conducts biannual reviews of NIBTS performance, its current and future activities, any policy development relevant to those activities, safety and quality issues, financial performance, corporate control / risk management performance, and other issues as prescribed by the department. NIBTS also reports annually on performance

against key targets in the NIBTS annual report and accounts. NIBTS does not advise government departments in respect of its responsibilities or functions.

Section 6: Relationship of NIBTS to laboratories

22. **Please outline the laboratories currently engaged in manufacturing blood products for Northern Ireland from plasma procured by NIBTS.**

91. The NIBTS is not currently engaged with any laboratories manufacturing blood products from plasma.

23. **How have NIBTS's relationships with the various laboratories involved in manufacturing blood products for Northern Ireland changed over time? Specifically, please describe as far as you are able how NIBTS'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.**

92. I am not able to provide detail regarding the relationship NIBTS had with the various laboratories referred to above. Dr McClelland may be able to address this in his statement to the Inquiry.

24. **Please outline the arrangements in place, if any, to enable cooperation between NIBTS and the various laboratories involved in manufacturing blood products for Northern Ireland, including any reporting lines or forums established to aid this cooperation.**

93. The NIBTS is not currently engaged with any laboratories manufacturing blood products from plasma.

Section 7: Relationship of NIBTS to pharmaceutical companies

25. **Please explain NIBTS'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.**

94. The NI Blood Transfusion Service has no direct involvement with pharmaceutical companies involved in the production, manufacture, sale and/or importation of haemophilia blood products.

95. There has been a longstanding, historic arrangement where the funding and budget for haemophilia products used in Northern Ireland is allocated to NIBTS which provides financial reporting on product used. This is the limit of its involvement with haemophilia products.

26. **Does NIBTS 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.**

96. No, NIBTS does not contract directly with pharmaceutical companies involved in the production, manufacture, sale and or/ importation of blood products. However, NIBTS does have contractual arrangements for the procurement and supply of other plasma products to the HSC system. In addition, NIBTS currently has an arrangement where surplus plasma from blood donations is supplied to a commercial pharmaceutical company under a tendered contract.

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

97. No.

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

98. No.

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

99. NIBTS has a Conflict of Interest Policy which all staff must be aware of. The purpose of this Policy is to ensure that conflicts of interest are identified and managed in a way that safeguards the integrity of staff and Board members and maximises public confidence in NIBTS's ability to deliver public services properly. In addition, Board members and all employees are required to complete a declaration of interest form and update if their circumstances change.

30. **Does NIBTS provide any pharmaceutical companies with results from medical research studies undertaken? If so, please provide details.**

100. No, NIBTS does not provide any results from medical research to pharmaceutical companies.

Section 8: Sufficiency of modern blood supply

NIBTS "exists to fully supply the needs of all hospitals and clinical units in the province with safe and effective blood and blood products and other related services".

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

101. As referred to in the response to question 3, when the NIBTS was established as a Special Agency in 1994, the HPSS issued a functions direction detailing the responsibilities of NIBTS. While this has not changed over time, the Agency continually reviews and updates how these functions are best achieved in response to changes in legislation and best practice.

102. NIBTS continually assesses the volume of blood components required. It has a responsibility to ensure there are adequate donors to meet the demand. NIBTS engages with the NI population to encourage them to donate blood for use in Northern Ireland.

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

103. The Minister for Health and the Department of Health have delegated the responsibility to ensure the sufficiency of the blood supply to the NIBTS. However, other Health Service bodies such as the Public Health Agency and the Health Trusts, assist NIBTS by promoting blood donation, for example they will promote blood donation within their publications and through advertising on their vehicles. Trusts,

supported by the Northern Ireland Transfusion Committee and local Trust transfusion committees, also have a responsibility to ensure that components supplied are transfused in accordance with current guidelines.

33. **To what extent does NIBTS ensure the sufficiency of the blood supply through its management and oversight of its transfusion centres?**

104. N/A – NIBTS has only one central transfusion centre.

34. **To what extent does NIBTS ensure the sufficiency of the blood supply through its engagement with laboratories?**

105. N/A – NIBTS uses its own in-house laboratories for testing purposes, it does not engage with other laboratories. NIBTS does however have contingency arrangements in place with HSC Trusts and other UK blood services to use their laboratory facilities if those in the NIBTS were to become unavailable. This helps to ensure blood collected could be tested, processed and issued.

35. **Please explain how NIBTS's functions and practices contribute to maintaining the sufficiency of the blood supply in Northern Ireland.**

106. NIBTS engages in numerous functions and practices which contribute to maintaining the sufficiency of the blood supply in Northern Ireland including:

- Regular advertising including on local radio stations, billboards, public transport and social media.
- Seasonal campaigns promoting blood transfusion, e.g. at Christmas time.
- Reviewing the demand for blood and planning the session calendar in response to this demand. If and when required, additional sessions are held to help boost supply.

- Planning the date and location of each donation session to ensure the most efficient collection regime. For example, before Christmas and other public holidays they will plan sessions in areas where they know we will get a large number of donations, this helps to maintain stocks over the holiday period.
- Routinely assessing facilities used for blood donation sessions such as leisure centres, church halls and community centres to ensure they are sufficient and identifying potential new locations for donation sessions.
- Ensuring there are sufficient staff and transport facilities for each donation session.
- Working with hospitals to assess the use of blood and blood products to help reduce wastage.

NIBTS does not collect plasma. Plasma is removed from blood donations; a sufficient amount is retained for clinical use as fresh frozen plasma and cryoprecipitate.

36. **How effective are NIBTS's current functions, policies and practices in ensuring the sufficiency of the blood supply in Northern Ireland? Please compare the current approach with the historical approach, highlighting significant differences and developments.**

107. The current functions, policies and practices of the NIBTS are effective at ensuring the sufficiency of the blood supply in Northern Ireland. On very rare occasions, the NIBTS imports blood and/or platelets from NHSBT and the Irish Blood Transfusion Service. NIBTS has contingency arrangements in place for such occurrences.

Section 9: Safety of modern blood supply

37. **How does NIBTS understand its responsibility to ensure the safety of the blood supply in Northern Ireland? Has this responsibility changed over time in nature and / or extent? If so, please provide details.**

108. As referred to in response to question 3, when the NIBTS was established as a Special Agency in 1994, the HPSS issued a functions direction detailing the responsibilities of NIBTS. While this has not changed over time, the Agency continually reviews and updates how these functions are best achieved in response to changes in legislation and best practice.

109. The legal framework defining the quality and safety standards for blood and its components is set out in European Directive 2002/98/EC, also referred to as the European Blood Directive [NHBT0000745]. It covers all steps in the transfusion process from donation, collection, testing, processing, and storage to distribution. As a blood establishment, NIBTS understands we have a responsibility to abide by the Directive and the requirements of the BSQR 2005.

110. Please also see the response to question 4 regarding the development of legislative and regulatory requirements and good practice guidance over time.

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

111. The Minister for Health and the Department of Health have delegated the responsibility to ensure the safety of the blood supply to the NIBTS.

39. **To what extent does NIBTS ensure the safety of the blood supply through its management and oversight of its transfusion centres?**

112. NIBTS is regulated & inspected by MHRA.

113. NIBTS is required to have a Responsible Person who is appropriately trained and qualified. BSQR (2005) (as amended requires the Responsible Person to have:

- (a) a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of—
  - (i) a university course of study, or
  - (ii) a course recognised as an equivalent course by the Secretary of State; and
- (b) practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under these Regulations for at least 2 years, in an establishment (or more than one establishment) authorised in any Member State in to undertake activities related to the collection or testing (or both) of blood and blood components, or to their preparation, storage and distribution.

114. NIBTS maintains and updates a Quality Manual as part of its Quality Management System.

115. Testing areas are audited by UKAS & hold UKAS accreditation against ISO 15189.

116. Regularly participate in National External Quality Assessment Schemes (NEQAS).

117. NIBTS has an extensive internal audit program to continually monitor performance and compliance with regulations, SOPs and good practice standards.

118. Standard operating procedures (SOPs) are in place for all processes. These are regularly reviewed and updated through the Q-Pulse document management system.

119. NIBTS has incident reporting and management requirements in place.

40. **Please explain how NIBTS's functions and practices contribute to maintaining the safety of the blood supply in Northern Ireland.**

120. NIBTS receives regular JPAC updates on best practice and guidance. A gap analysis is performed to identify practices and procedures to be reviewed and updated in response to the JPAC notification.

121. All donors are required to complete a donor health-check questionnaire prior to donating.

122. All blood is screened for a range of infections. If a sample tests positive, the donation is removed from the supply chain to ensure it cannot be issued to patients.

123. NIBTS is required to notify the Public Health Agency when any donations test positive for Hepatitis B, C and E.

124. Incident management processes ensure incidents are identified, categorised and responded to in an appropriate way. NIBTS reviews and update policies and procedures in response to incidents that may potentially affect the safety of the blood supply.

125. NIBTS follows the good practice guidance and standards provided in the "Red Book" and the GMP standards in the Orange Guide.

126. NIBTS regularly trains staff in Good Manufacturing Practice (GMP).

127. NIBTS has a change control system in place to ensure changes are managed and implemented without any detriment to the safety or quality of the blood.

41. **How effective are NIBTS's current functions, policies and practices in ensuring the safety of the blood supply in Northern Ireland? Please compare the current**

approach with the historical approach, highlighting significant differences and developments.

128. NIBTS regularly reviews and updates its policies, procedures and practices to ensure the safety of the blood supply in Northern Ireland. This coupled with the actions described in response to questions 43 and 44 ensure that there are effective functions, policies and practices in place to ensure the safety of the blood supply in Northern Ireland.

129. As I am not familiar with the historical approach and effectiveness of previous functions, policies and practices, I am unable to compare these with current practices.

Section 10: Identifying risks associated with blood and blood products

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

130. Biomedical scientist staff are required to ensure they participate in continuing professional development (CPD) to maintain their professional registration.

131. Medical staff have to participate in a regular cycle of appraisal and revalidation.

132. The Medical Director attends SaBTO meetings as an observer.

133. NIBTS offer learning opportunities via funding for formal courses, lunchtime lectures on topics of interest and funding for a number of places for staff to attend scientific conferences.

134. The annual staff development review process is used to identify training requirements and opportunities.

135. Team meetings are used to update staff on changes and developments as appropriate.

136. NIBTS is part of JPAC & other committees which communicate details of changes and developments in blood transfusion practices.

137. When practices are changed, staff must be trained in the new practice prior to being allowed to carry it out, they often also have to complete training and competency assessments.

138. Staff must continually participate in training and development to ensure they are up-to-date and capable.

139. NIBTS has access to Transfusion Medicine peer-reviewed journals.

140. Developments and research is also discussed at the UK Forum meetings.

43. **What external advice, if any, does NIBTS seek to identify and assess the risk of infection associated with the use of blood and/or blood products?**

141. External advice is mainly provided by JPAC. NIBTS have representation on JPAC and also on several sub-committees. The NIBTS Medical Director is generally responsible for approving JPAC notifications on behalf of NIBTS.

142. NIBTS participates in the UK Forum and UK Quality & Regulatory Forum to share knowledge between four UK Services.

143. NIBTS participates in NEQAS exercises to verify our testing procedures.

144. NIBTS is inspected by the MHRA and UKAS. These regulatory bodies provide advice and guidance as part of the inspection process.

145. NIBTS can access SABRE and SHOT reports.

146. NIBTS has an agreement with Belfast Trust whereby the Trust will provide specialist advice & follow up if required.

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

147. NIBTS has a system in place to review and implement JPAC notifications as appropriate, this process is managed via the change management system. JPAC advise when notifications are approved and released for implementation, this notification is received by a number of senior NIBTS staff including the Medical Director, Quality & Regulatory Compliance Manager and Chief Executive.

148. Algorithms are built into NIBTS testing processes, for example, a sample which tests positive must be repeated twice.

149. The NIBTS incident management system ensures all incidents are risk assessed and appropriate corrective and remedial actions are implemented. The system is also used to identify trends and respond accordingly.

150. The NIBTS risk management processes ensures risks are identified, assessed and logged on the relevant risk registers.

151. The Governance and Risk Committee reviews the NIBTS risk registers.

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

152. NIBTS actively encourages hospitals to contact us with concerns regarding any potential transfusion reactions.

153. If a donation is found to present a risk of transmission of infection, NIBTS has a look back procedure in place to investigate the fate of recipients of previously donated blood or components.

154. NIBTS has a trace back procedure in place if they are advised of a patient being identified with a transfusion transmissible infection following the transfusion of blood or blood components.

155. NIBTS has a recall procedure which it implements to ensure any potentially infectious components are removed and quarantined.

156. NIBTS retains an archive of blood samples for three years so they can be retested if required.

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

46a) What, if any, actions did NIBTS take to reduce the risk to patients of being infected?

157. I am advised that NIBTS introduced testing for blood borne infections when it became available.

158. I am also advised that Donor health-check questionnaires were reviewed and updated once the Agency became aware of any blood borne infection and the associated risk factors.

46b) ***What, if any, actions did NIBTS take to:***

46b(i) identify patients who may have been infected through treatment with infected blood or blood products?

159. I am advised that when testing for any blood borne infection was implemented, NIBTS performed a look-back on any donors who tested positive. This would entail checking if the donor had donated before and tracing the units of blood they had donated.

160. Hospital blood banks were required to assist NIBTS to identify recipients of any potentially infected units. Those recipients would be contacted, advised of the situation and asked to make themselves available to be tested. If required, patients would be offered counselling.

46b(ii) ***make patients who had been treated with blood or blood products aware of the risk of infection?***

161. I understand that the NIBTS was not directly involved in making patients aware of the risk of infection.

46c) **What, if any, arrangements were made to provide patients infected through blood products with medical treatment for their condition?**

162. I am advised that the NIBTS would not have been involved in the medical treatment of patients infected through blood products. This would have been the responsibility of the relevant specialist unit(s) in Northern Ireland.

46d) ***What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?***

163. I am advised that infected patients were contacted and offered counselling. NIBTS were not involved with arranging psychological, social work or other support.

47. Do you consider that the decisions and actions of NIBTS 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.

164. As I was not in post at this time, I have insufficient information and knowledge as to what exactly took place at the time. I am, therefore, unable to comment on these aspects.

48. **Did NIBTS 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?**

165. As I was not in post at this time, I would believe that Dr McClelland would be best placed to respond to this question.

Section 12: Financial support

49. **What if any involvement did NIBTS 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?**

166. To the best of my knowledge, NIBTS did not have any involvement with the Trusts referred to above.

50. **To what extent did NIBTS inform patients about the different trusts or funds?**

167. To the best of my knowledge, NIBTS did not have any involvement with referring patients to the trusts or funds referred to above.

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

168. I am not aware of any policy or guidance for staff in relation to referring patients to the trusts and funds for support.

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

169. As per question 51 above.

53. **Did NIBTS 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 NIBTS 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.**

170. As per question 51 above.

54. **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?**

171. As per question 51 above.

Section 13: Other issues

55. **Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Inquiry.**

172. I have nothing further to add.

Statement of Truth

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

Signed GRO-C

Dated 22/09/2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
01/06/2017	Job Description of NIBTS Chief Executive	WITN26810027
1990	NIBTS Functions Direction	WITN26810028
N/A	NIBTS Organisational Chart	WITN26810029
N/A	NI Blood Transfusion Management Statement and Financial Memorandum (MSFM) document	WITN26810030

2002	Quality and safety standards for blood and its components is set out in European Directive 2002/98/EC	NHBT0000745
Unknown	Corporate Plan including corporate strategy that reflects the Programme for Government priorities established by the Northern Ireland Executive.	WITN26810031
Unknown	Business Plan describing annual objectives that is reviewed and approved by the DoH in Northern Ireland	WITN26810032
N/A	Board Governance & Risk Management Committee Chart	WITN26810033