Witness Name: Catherine O'Brien
Statement No.: WITN6876001
Exhibits: WITN6876002 -
WITN6876065
Dated: 25th October 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF CATHERINE O'BRIEN

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

I, Catherine O'Brien, will say as follows:

Section 1: Organisation history & structure

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

Catherine O'Brien MBE

GRO-C

Cardiff GRO-C

Date of Birth GRO-C 1964

Pharmacist registered with the General Pharmaceutical Council 2032987

1. Before addressing the specific questions I would like to make some general introductory comments which set the context of this evidence and the process which has been followed to gather information. At the outset of the Inquiry the Velindre University NHS Trust of which the Welsh Blood Service (WBS) is an operational

Division, committed to the principles set out in the Charter for Families Bereaved through Public Tragedy. As part of those principles I have committed to approaching this inquiry with candour and in an open, honest and transparent way and to assist the search for the truth. I have also accepted that, to the extent that there are past mistakes, to learn the lessons from those mistakes and from the findings of external scrutiny.

2. As the scope of the Inquiry covers many events which occurred in the late 80s or 90s these pre-date my time in the Service, and the establishment of WBS in its current form. I have prepared the information in this statement with the assistance of Dr Geoff Poole who is a Blood Transfusion Scientific Consultant and was previously a director of WBS between June 2007 and November 2013. Other than Geoff and one other staff member who left us recently, we have not contacted other former members of staff of National Blood Transfusion Service Wales (NBTS (Wales)) or WBS. As a result my knowledge of specific matters relating to earlier periods is limited to the organisational knowledge of those currently employed by WBS, who were in junior roles at that time, together with that from Geoff.

3. The work of myself and Geoff, in preparation of this statement, where it relates to historic arrangements, has necessarily had to rely heavily upon historical documents. In that regard, other than patient and donor data, the historical records of NBTS (Wales) are not held electronically in any searchable format. They are effectively microfiche photos of documents created at the time. We have provided access to all of these documents to the Inquiry, in accordance with the commitments we made at the outset to make full disclosure of relevant documents, and we have sought to identify the most relevant documents to the information requested, however due to the nature of the storage format and the volume of documents this has been challenging and to date we have not been able to identify all documents relating to specific lines of inquiry. This response is based on the documents we have been able to identify. Whilst VUNHST holds no responsibility for the archive for the predecessor parent organisations, we did identify a small number of meeting minutes in preparation for this Inquiry in the Glamorgan Archive for the South Glamorgan Health Authority ("SGHA") from the period 1979 to 1991. Our search was not exhaustive. We have not been able to locate the Welsh Common Health Services Authority "WHCSA"

organisational document archive, although we have located a limited range of reports in our archive.

4. As well as the limitations above we have been able to review some but not all of the documents which have been uploaded to the IT platform used by the Inquiry which may be relevant to WBS. I cannot guarantee therefore that we have located all of the relevant documents and to the extent that if further relevant documents are discovered after the provision of this statement those will be provided to the Inquiry team.

5. As the WBS was formed in 1999 and some of the questions relate in the main to predecessor organisations, I have provided a brief overview of the organisation history as an appendix to this document. The WBS predecessor was the NBTS (Wales), the Welsh Regional Blood Transfusion Service and the Cardiff Regional Transfusion Service. For the purposes of this statement, I have used NBTS (Wales) in reference to the historic arrangements and WBS from 1999.

6. NBTS (Wales) was a single Regional Transfusion Centre (RTC) which served hospitals in South Wales. Hospitals in North Wales continued to be served by the Regional Transfusion Centre in Liverpool, part of NHS Blood and Transplant (NHSBT) up until 2016 when management of North Wales Blood Service provision transferred from NHSBT to WBS.

7. Whilst NBTS (Wales) was responsible for the provision of services to hospitals in South Wales, in line with the other RTCs, it did not generally act independently or set its own policies but followed UK government policy which itself was based on recommendations from the professional advisory structure, or it followed professional guidance. This guidance was provided through the meetings of Regional Transfusion Directors up until 1988 and through the National Directorate after its formation in 1988. NBTS (Wales) had representation at the Regional Transfusion Directors' meetings and as part of the National Directorate. It is my understanding that in many cases where specific advisory or collaborative groups were set up to advise on specific issues, NBTS (Wales) and WBS (as one RTC) would not necessarily have a subject matter expert in that specific area and therefore would not form part of the advisory group. NHSBT, and NBA before that, by reason of its size, would therefore tend to take the

lead on such issues and WBS would rely on our ability to discuss with peers and keep abreast of developments and understand the work coming out of advisory groups and to provide input via peers or the Welsh Office as appropriate. NBTS (Wales) and WBS has therefore in many cases been involved in the implementation of policy or initiatives developed by others. Further as a tertiary service provider WBS (and NBTS (Wales) before that) are not directly "patient facing" and do not provide direct ongoing clinical patient care. Responsibility for delivery of direct clinical patient care lay with NHS Health Authorities and Trusts.

8. In 1994 the National Blood Authority (NBA) took executive control of English RTCs. NBTS (Wales) was not however incorporated into the NBA and retained its accountability (and funding mechanism) as part of WHCSA to the Welsh Office. In practice however there would have been professional links to the NBA after 1994, via discussion forums and professional groups with the other Regional Transfusion Centres.

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

9. I am the Chief Operating Officer of Velindre University NHS Trust, having previously been seconded from my post as Director of the WBS. I have held the latter position since November 2013.

10. WBS is an operational Division of Velindre University NHS Trust (VUNHST) which incorporates the WBS and the Velindre Cancer Centre (VCC).

11. In March 2019 I was seconded to the role of Interim Chief Operating Officer for VUNHST, and this was subsequently made permanent in October 2021. My previous substantive post is being delivered by a secondee.

12. In the role of the Chief Operating Officer, I am responsible for the successful system wide delivery of operational performance of all clinical services in the WBS and the Velindre Cancer Centre (VCC).

13. I am a member of the Trust's Senior Leadership Team and responsible for the strategic direction of the Trust, corporate policy making and development and delivery of the Trust's objectives.

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

Current Purpose, functions and responsibilities

14. WBS is an operational Division of The Velindre University NHS Trust. The responsibilities of the Trust are for two direct Divisions, Velindre Cancer Services and WBS.

15. WBS is there to provide and manage services relating to the collection, screening and processing of blood and its constituents and the supply of blood, plasma and other blood products.

16. WBS collects voluntary donations from the public across Wales, which are tested and processed into blood components, and distributed to customer hospitals in Wales, covering a population of 3.25 million. This arrangement has been in place since May 2016, prior to which the collection, processing and distribution of blood components to Betsi Cadwaladr University Health Board was undertaken by NHS Blood and Transplant (NHSBT) due to historic service delivery arrangements.

17. The primary site of the WBS and the location of its laboratories is Talbot Green, Llantristant. It also has smaller sites in Wrexham, Bangor and Dafen in Llanelli.

18. The WBS holds a Blood Establishment Authorisation and a Wholesale Dealer's Licence from the MHRA which allow operation as a Blood Establishment and as a Wholesale Dealer for commercial blood products which it supplies to the south regions of NHS Wales, again due to historic arrangements.

19. In addition to the collection of blood donations and the production and distribution of resultant components, WBS also includes a range of other functions.

20. The Welsh Transplantation and Immunogenetics Laboratory (**WTAIL**) within the WBS operates the Welsh Bone Marrow Donor Registry and provides direct support to providers of Renal and Stem cell transplantation. WBS also provides a Red Cell Immuno-haematology service and two external quality assurance (**EQA**) schemes. The Blood Health Team supports the delivery of the Wales Blood Health Plan and professional clinical advice is provided to NHS Wales on blood transfusion through the Clinical Services Department.

21. The WTAIL provides Histocompatibility and Immunogenetics (H & I) testing and a clinical advisory service to a variety of health care providers ranging from specialist transplant units to General Practitioners. WTAIL also operates the Welsh Bone Marrow Donor Registry which is licensed by the Human Tissue Authority for Procurement, Testing, Distribution and Import/Export of Tissues and/or Cells intended for human application.

22. There are two EQA services run by WBS. The Welsh Assessment of Serological Proficiency Scheme (WASPS) is a Laboratory Proficiency testing scheme designed to assist participating Transfusion Laboratories in monitoring and improving the performance of red cell antibody detection.

23. WBS also operates the UK National External Quality Assessment Scheme for Histocompatibility and Immunogenetics which provides a comprehensive range of EQA Schemes appropriate to laboratories operating clinical Histocompatibility and Immunogenetics or related services.

24. The WBS laboratories have a number of functions or services. The Blood Processing Laboratories manufacture blood components and store these (under controlled conditions) for distribution to hospitals in Wales in accordance with Joint United Kingdom Blood Transfusion Services Professional Advisory Committee Guidelines (JPAC) for Blood Transfusion. Components produced include red cells, fresh frozen plasma, platelets and cryoprecipitate for adult, paediatric and neonatal use.

25. The Automated Testing Laboratory tests for Infectious Disease Markers, Red Cell Phenotypes and Bacterial contamination of platelet components as required by Blood Standards and Quality Regulations SI 50, 2005 (as amended) (BSQR) and JPAC for Blood Transfusion guidelines.

26. The WBS Quality Assurance (QA) laboratory service monitors the quality of blood components so that they meet the JPAC specifications. The QA laboratory is also responsible for the calibration of all equipment that can have an effect on the final blood components.

27. Patient Testing services are provided by the Blood Transfusion Laboratories and the Welsh Transplantation and Immunogenetics Laboratory. This provides solid organ and haematopoietic stem cell recipient and donor compatibility testing, antenatal blood grouping and red cell antibody screening and a red cell antibody reference testing for patients who need a transfusion and have a complex profile. This also includes Human Lucokocyte Antigen typing as an aid to disease diagnosis and drug hypersensitivity and platelet immunology.

28. The Red Cell Immuno-haematology (RCI) Laboratory is the reference centre in Wales for the resolution of blood grouping and complex antibody problems. It also provides the All Wales Service for anti-D and anti-c quantitation in the management of Haemolytic Disease of the Foetus & New-born (HDFN). The Automated Serology Department is responsible for the routine blood grouping and red cell antibody screening of antenatal samples for some Health Boards in Wales.

29. The Clinical Services Department provides the advice and support to hospitals on complex blood transfusion as well as being responsible for the application of standards relating to donor wellbeing and eligibility to donate (donor selection). The department also provides specialist advice and assessment of donor eligibility, clinical advice and support to donors who have experienced adverse events following donation, clinical advice and support regarding recipient protection risks, counselling for donors who have tested positive to microbiology markers and onward referral to specialist centres.

30. The department provide and develop a range of donor information materials and local policies and guidelines to support blood collection.

31. The Blood Supply Chain function manages the planning, operational establishment of donation clinics, donor recruitment, transport for clinics and hospital distribution.

32. The Quality Assurance Department provides services to support regulatory compliance including the Quality Management System, Audit and Validation. It also provides the Business Continuity and Emergency Planning function.

33. Support services for Informatics, Workforce and Organisational Development, and Finance are provided by corporate VUNHST functions embedded within the WBS.

Historic Purpose, functions and responsibilities

34. A history of the WBS and its predecessor organisations was provided to the Inquiry in our statement of October 2018. We have provided a summary of that information as an appendix to this statement [WITN6876002].

35. Throughout the years, the Blood Service was known under a number of names and was managed within a number of different organisations. For example in reports to the South Glamorgan Health Authority the service is referred to as the Welsh Regional Transfusion Service, but externally within the blood services it is called the Cardiff Regional Transfusion Centre or NBTS (Wales). For consistency I have used the latter title in this statement or WBS if it refers to the current organisation as part of VUNHST.

36. I understand from information provided by colleagues that the functions outlined above have been in place since 1982 with the exception of the WBMDR being established in 1989, the Better Blood initiative (subsequently the Blood Health Team) being established from 2004 and NEQAS was relocated from UK Transplant in Bristol to WBS in 2000.

37. In terms of the delivery of the service to hospitals in Wales, until May 2016, the service to hospitals in north Wales was provided by NHSBT and its predecessors due to the historic developments of the Blood Transfusion Centres and the NHS prior to the establishment of the National Assembly for Wales in 1999. In May 2016, the service in north Wales was transferred to WBS via the All Wales Blood Service Programme under the direction of the Welsh Government.

38. A Wholesale dealer's License (WDL) has been in place since 05/11/1999. It covers handling of Prescription only medicines and biological products (blood products).

39. The Quality Manual for WBS is updated periodically with changes, dates from 2002 and includes a record of changes in managerial arrangements including variations over time made to the Responsible Person, License Holder contact (Director) and the Site Contact (Head of Quality Assurance and Regulatory Compliance). (See Section 5 Q23 for more details).

40. It has been difficult to establish details on the exact nature of functions and responsibilities before the 1980s either from staff experience or from the archive documents that we hold and have been able to review to date.

4. Please explain the current structure of WBS, 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.);

41. The WBS Director is part of the Executive Management Team in VUNHST. Prior to March 2019, the WBS Director reported to the VUNHST Chief Executive Officer, however with the establishment of the Chief Operating Officer role, line management is now via that post.

42. The responsibility of the WBS Director is to lead, sustain and develop WBS and be accountable for the quality of the services provided as well as ensure strategic development and that the organisation is developed in accordance with the Trust's objectives and with the requirements of the Welsh Government. The Director is

responsible for ensuring the organisation's performance in service delivery, financial planning and management and quality and regulatory compliance.

43. The Director is supported by a Senior Management Team. The structure of this is provided in the Organisation's meeting Structure July 2021 [WITN6876003]. The team consists of the following roles:

44. **The Medical Director** is responsible for clinical leadership of the safety, quality and regulatory compliance of services in WBS and its research and innovation activity. Consultants in Transfusion Medicine and Donor Medicine and other members of the Clinical Services department assist the Medical Director.

45. This covers Blood Collection, Processing and Distribution to hospitals in Wales, the Welsh Transplant and Immunogenetics Laboratories, delivery of the Research and Development strategy and supporting delivery of the Blood Health Plan for Wales. In addition ensuring a clear clinical strategy is in place to support the WBS in its provision of the Bone Marrow Donor Registry. They also have a role in enabling the provision of advice to hospitals on blood transfusion. The Medical Director is professionally accountable to the Executive Medical Director of VUNHST. They have responsibility for aspects of regulatory compliance.

46. The Medical Director is also professionally responsible for the Quality Assurance Laboratory and undergraduate and postgraduate training in Transfusion Medicine. As a member of the National Oversight Group for the Blood Health Plan, the Medical Director plays a role in the improvement of standards of practice of transfusion medicine. The Medical Director is the Caldicott Guardian for the WBS.

47. **The Chief Scientific Officer** has overall responsibility and accountability for the strategic and operational leadership, management, and service delivery of the WBS Transfusion Laboratories and WTAIL which include the Welsh Bone Marrow Donor Registry (WBMDR) and UK National External Quality Assessment Schemes (NEQAS) for Histocompatibility & Immunogenetics (H&I). This includes provision of professional expertise to inform strategy setting for the service that operates nationally and internationally. They are also the legally accountable person for

compliance with Blood Safety and Quality Regulations through the role of Responsible Person (RP), and for compliance with the Human Tissues Act as the Designated Individual. They lead collaborative work with the professional leads for WTAIL and Transfusion Laboratories to ensure compliance with regulatory and professional aspects of laboratory functions. This includes United Kingdom Accreditation Service (UKAS) accreditation under ISO15189, the Medicines and Healthcare products Regulatory Agency (MHRA) requirements for Blood Safety & Quality Regulations, the Human Tissue Authority Licence for Stem Cells, and the MHRA Good Clinical Practice for Research and Development (R&D) activities; ensuring processes and action plans are in place for inspections.

48. **The Collections Supply Chain Lead,** is responsible for the development and delivery of the strategy for blood collection. This includes the recruitment of donors, the planning and operation of blood collection clinics and the transport department. They lead the day to day review and monitoring of stock levels in collaboration with the Blood Health Team (for engagement with hospitals) and the WBS Hospital Issues to enable the planning of blood collection to meet the need of the NHS.

49. **The General Services Manager** leads the strategic planning and performance oversight of the Division, manages the estates function, the Service Improvement and Programme Management Office function.

50. **The Head of Quality Assurance and Regulatory Compliance** has responsibility for co-ordinating and managing all aspects of the systems and processes through which we ensure and assure regulatory and professional standards compliance. This includes the Quality Management System and acting as the Final Release Officer, in which they have the authority to prevent the routine release of any product that fails to meet specification.

51. **The Finance Business Partner** provides oversight of the Management Accounting/ Business Partnering requirements of services in ensuring robust financial stewardship of the Division. They provide both business and process support to management, as well as supporting the annual budgeting process and cost control, supporting service transformation.

52. **The Senior Workforce and Organisational Development (WOD) Business Partner** role is to influence and drive the strategic workforce agenda within the Division and provide or enable access to advice and expertise in WOD.

53. Together, these posts form The Senior Management Team (SMT) and each of the individuals within it make decisions within their professional expertise and their delegated authority. The SMT reports to the VUNHST Executive Management Board.

54. Where decisions need to be escalated this is done via the Executive Management Board and onward to the Trust Board as required.

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

55. The WBS Senior Management Team both informs the Trust strategy through the VUNHST planning processes and makes decisions with respect to operationalising that strategy in scientific and professional areas as well as informing the Executive Management Team and Trust Board on overarching strategy.

56. As a division of VUNHST, WBS is accountable to the Board through the Executive Management Team providing overall strategic management, with governance and oversight through the Trust-level board and committee framework.

57. The Executive Management Board (EMB) comprises the Directors that are the Senior Leadership Team of the Trust and assists the Chief Executive as Accountable Officer in the performance of their duties and is responsible for developing and implementing the Trust's policies and strategies. It is accountable for the operational and day to day management of the organisation and delivering against its Integrated Medium Term Plan (IMTP). The EMB is supported by an effective system of integrated governance, risk management and internal controls across the whole of the organisation's activities.

58. The overarching strategic decisions are the responsibility of the Trust Board. The Trust Board has been constituted to comply with the National Health Service Wales, Velindre University NHS Trust (Establishment) Order 1993 No.2838 and subsequent Amendment Orders (1995 No. 2492, 1999 No.808, 1999 No 826, 2002 No.442 (W.57) and 2002 No.2199 (W.219 2009 No.2059), 2012 No.1261, 2012 No.1262, 2015 No.22, 2017 No.912, 2018 No.887).

59. The Trust Board is accountable for the frameworks for governance, risk management and internal control for those services directly delivered by the Trust.

60. There are a range of key strategic decisions on policy relating to blood, tissues and organs that will be made by the Welsh Government and then implemented by the WBS. For example recommendations that are made by the Advisory Committee on the Safety of Blood, Tissues and Organs [RLIT0000686] which "*advises 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. Its remit includes providing advice on the microbiological safety of gametes and stem cells, in liaison with the relevant regulatory authorities. The Committee will provide independent advice on risk management for Ministers, UK Health Departments, UK Blood and Transplant Services and the wider NHS to consider*".

c. how it is funded;

61. WBS which operates as a separate service division within Velindre University NHS Trust, is currently funded by an annual revenue budget allocation to the Trust from the Welsh Health Specialist Services Committee (WHSCC). WHSSC is a joint committee of each of the seven Local Health Boards in Wales and was established under the Welsh Health Specialised Services Committee (Wales) Directions 2009 (2009/35). The Joint Committee, which is established as a Statutory Sub Committee of each of the local Health Boards, brings Local Health Boards together to plan specialised services for the population of Wales.

62. WHSCC is not a separate legal entity but is a ring-fenced organisation operating as a hosted body within Cwm Taf Morgannwg University Health Board and is responsible for the joint planning and commissioning of Specialised and Tertiary Services on behalf of the seven Local Health Boards in Wales.

63. WHSSC commission the services of WBS on behalf of the seven Welsh Health Boards, with the annual revenue budget allocation being provided via a 'Block' agreement with agreed annual uplifts for pay inflation and discretionary increases as agreed by Welsh Government through the annual planning cycle and the Welsh Government's budget settlement with the NHS. Under the Block Agreement variations in performance levels in year will not normally result in any change to funding levels. This principle is subject to safeguards regarding any provider led disinvestment in the service that results in agreed performance or service delivery not being delivered. However there are agreed underpinning activity levels that are agreed annually with NHS Wales Health Boards as part of an annual process.

64. There is an annual planning process (IMTP) with meetings between the Trust and WHSSC at which each organisation shares its plans and general uplifts as well as any service developments or cost pressures are discussed. The Trust submits service developments and cost pressures relating to its blood service into the WHSSC annual IMTP process for investment consideration alongside all Specialised Services WHSSC commissions. This process involves an evaluation and prioritisation of submissions within the context of the financial planning envelope for investment agreed with WHSSC by the NHS Wales Health Boards. There are separate commissioning / contracting meetings between Velindre Trust and WHSSC during the year if required to resolve any issues regarding baseline funding or additional investment.

65. Under the WHSSC "Commissioned Services" list, WBS is included as part of the "Cancer and Blood" Programme. WBS receives its capital funding via the capital allocation processes adopted by Velindre University NHS Trust, who receive Capital funding direct from Welsh Government.

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

66. The Trust Board has been constituted to comply with the National Health Service Wales, Velindre University NHS Trust (Establishment) Order 1993 No.2838 and subsequent Amendment Orders referred to above. The Trust Board discharges its responsibilities through its Committees and scheme of delegation, which is set out in its Standing Orders. There are nine Committees/Partnership Forums reporting directly to the Trust Board, which is supported by sub-Committees/groups in the discharge of functions.

67. At a local level, the Trust Board has agreed Standing Orders for the regulation of proceedings and business. The Trust Standing Orders and Standing Financial Instructions have been adopted from the Welsh Government's Model Standing Orders for NHS Trusts in Wales and are designed to translate the statutory requirements set out in the National Health Service Trusts (Membership and Procedures) Regulations 1990 (1990/2024) into day to day operating practice. Together with the adoption of a scheme of matters reserved to the Trust Board; a scheme of delegations to officers and others; and Standing Financial Instructions, the SOs provide the regulatory framework for the business conduct of the Trust and define its 'ways of working'. These documents, together with the range of policies set by the Trust Board make up the Governance and Accountability Framework. This is then reported on in the Trust Annual Report each year.

68. WBS forms one division within the Trust and operates within this Governance and Accountability Framework.

69. The WBS Senior Management Team is the vehicle through which the WBS operates. Its role is to oversee the strategic planning and operational management of the WBS, ensuring the delivery of safe, effective and high quality services for the population of Wales in line with WBS and VUNHST strategic objectives.

70. It has established a number of groups that report to it covering the following:

Business Planning Group- To discuss, prioritise and co-ordinate and action all matters relating to business planning and contract management for the WBS and to make recommendations to SMT on business cases for further development in line with WBS strategic vision and the integrated medium term plan.

71. **Capital and Procurement Planning Group (CPPG)-** To co-ordinate and action all matters relating to procurement activities and contract management for the WBS and to scrutinize and monitor delivery of capital and revenue schemes for the WBS including collaborative work projects.

72. **Regulatory Assurance and Governance Group (RAGG) -** To provide Regulatory, Quality and Safety Oversight and Assurance to WBS Senior Management Team and the Trust Quality & Safety Committee on regulatory compliance and quality and safety issues including Donor and Patient Clinical Governance issues and monitoring of QMS (Quality Management System); escalating to the SMT and onward to the VUNHST Trust Quality and Safety Committee if required.

73. RAGG has three sub-groups:
Patient Clinical Governance- To provide assurance that appropriate governance mechanisms are in place to monitor patient related transfusion service provision and that services that impact on patient safety in relation to transfusion are based on best practice and regulatory and quality requirements are met. For example the Platelet Immunology Service, Feedback from Hospital Transfusion Committees (HTCs) and the Hospital Transfusion Laboratory Managers' forum.

74. **Donor Clinical Governance-** To provide assurance that appropriate governance mechanisms are in place to monitor donor blood and component collection processes and procedures and that all donor regulatory and quality requirements are met and the service is based on best practice for high quality, safe donor care.

75. **Welsh Bone Marrow Donor Registry (WBMDR) Clinical Governance -** To provide medical and scientific oversight and monitor regulatory compliance of the

WBMDR including policy making, horizon scanning developments and trends, and review of performance.

76. **Research, Development and Innovation Group (RD&I)** To oversee the implementation and ongoing development of WBS RD&I Strategy and alignment with that of Velindre University NHS Trust including guiding approved RD&I projects, and to monitor their progress and conduct to ensure they are carried out to the required standards of probity.

77. **Cynefin (Habitat) Group (formerly Estates and Facilities Management Group)-** To ensure that WBS is meeting regulations and standards relating to management of estates and facilitates service and sustainability for WBS.

78. **Operational Service Group Meetings-** To oversee the operational management and performance of a group of service functions within each of the service groups listed:

- General Services Group
- WTAIL Service Operations Group (WSOG)
- Laboratory Services Group

79. Groups are also established as required for major initiatives or as a Task and Finish Group for specific pieces of work. An example is the Blood Supply Chain Initiative established in 2017 which has been reconsidering WBS supply chain function, from recruitment and selection of donors to delivery of components to customer hospitals, to ensure it is fit for purpose and to address the service development and improvement opportunities that have been identified.

80. A Welsh Language Task and Finish Group has been established to coordinate the WBS response to the Welsh Language Commissioner's compliance review of the application of the Welsh Language Standards (No 7) Regulations 2018 to WBS and wider to VUNHST that impact on WBS.

81. The SMT also has oversight of the National Oversight Group for Blood Health which oversees the implementation of the national strategy for blood health, the Wales Blood Health Plan (published in 2017), formally reporting progress to the Welsh Government.

82. Collaborative working groups are also in place with Hospital Transfusion Laboratory Managers, via the Transfusion Laboratory Managers' (TLM) Forum and the All Wales Transfusion Practitioners' Group (AWTPG), Hospital Transfusion Practitioners and via representation on Hospital Transfusion Committees throughout Wales.

83. The AWTPG purpose is to identify areas in transfusion practice that require scrutiny or intervention, and take action where required to deliver Serious Hazards of Transfusion (SHOT) recommendations, Blood Health Plan objectives, support Transfusion Practitioners develop and progress national initiatives such as training and competency frameworks.

84. The Transfusion Laboratory Managers Forum reviews trends in transfusion, discusses incidents and exchanges information to improve hospital transfusion practice and collaborate in changes in practice.

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

85. WBS remit includes the whole of Wales since 2016 when the service in north Wales transferred from NHSBT. WBS is one transfusion centre as we are one operational unit with one set of standards and decision making. WBS collects blood at only two fixed sites in Wales, its Wrexham base and its Talbot Green base. We also operate a distributed collection model with blood collection being undertaken at circa 400 sites across Wales including work places, hotels, leisure centres and other facilities, although this has been reduced since the Covid 19 Pandemic due to the requirement to use larger venues for social distancing. Each site is fully assessed and managed in accordance with the regulatory requirements. The intention is to

return to as wide a geographical spread of locations as the pandemic requirements diminish.

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

86. The WBS operates under the legislative and regulatory framework for VUNHST, including some that are specific to the WBS in relation to blood, tissues and cells, and others that are more general organisational or NHS requirements. There are also a range of accreditations that are best practice. These include but are not limited to:

Legislation:

- The Blood Safety and Quality Regulations,2005 (as amended) (EU Directives 2002/98/EC, 2004/33/EC, 2005/61/EC, 2005/62/EC)
- Human Tissue 2004
- The Human Medicines Regulations 2012 (SI 2012/1916) - Regulation 18
- European Directive 98/97/EC on In Vitro Diagnostic Medical Devices European Directive 93/42/EC on Medical Devices
- HM Customs & Excise Act 2005
- Data Protection Act 2018; this is the UK's implementation of the General Data Protection Regulation (GDPR)
- Freedom of Information Act 2000
- The Health and Social Care (Quality and Engagement) (Wales) Bill
- Control of Substances Hazardous to Health Regulations
- The Health and Safety at Work Act 1974 and Regulations including The Management of Health and Safety Regulations 1999, RIDDOR, Control of Substances Hazardous to Health Regulation
- Welsh Government: Nurse Staffing Levels (Wales) Act 2016
- Welsh Language Commissioner Welsh Language (Wales) Measure 2011
- Consumer Protection Act 1987

Accreditations:

- ISO 15189/IEC:2012 Medical Laboratories - requirements for Quality and Competence Accreditation Regulations 2009 (SI No 315/2009) EC 765/2008
- ISO/IEC 17043:2010 Conformity assessment -- General requirements for proficiency testing; Accreditation Regulations 2009 (SI No 315/2009) EC 765/2008
- European Federation for Immunogenetics (EFI) EFI standards for Histocompatibility & Immunogenetics Testing, (Version 8 , effective January 2020
- World Marrow Donor Association (WMDA) Standards for Unrelated Hematopoietic Stem Cell Donor registries, (WMDA Standards 2020, effective on July 1, 2020.) An amendment to this standard became effective January 20, 2021

Standards:

- Health Education Inspectorate Wales (HEIW) on behalf of General Medical Council (GMC) for Medical Education Standards
- Health Professional Regulatory Standards:

  General Medical Council

  Nursing and Midwifery Council

  General Pharmaceutical Council

  Health Professions Council (HPC)
- Welsh Government: Health & Care Standards (April 2015)
- Welsh Risk Management Standards
- Corporate Health Standard

87. The Trust also has to operate within its legal framework which is contained within its Establishment Order and its Standing Orders. The Standing Orders are based on a model provided by the Welsh Government as outlined in section d above.

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

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

88. The current senior management team arrangement has been in place since 2019 as an interim arrangement following short term secondments. The Chief Scientific Officer post was created at this time recognising the benefit of oversight across all scientific functions and so bringing together the WTAIL and Blood Transfusion laboratories under a single manager. This was preceded for a short period between January and November 2019 where the senior management of the Blood Laboratories was merged with the Blood Collection department to facilitate the Blood Supply Chain service change initiative. I have been advised that, other than these changes, the key roles and responsibilities have been as outlined above within the memory of colleagues since 2004.

89. To date, review of the archive documents held by WBS have identified role and post holders from communication and meeting notes in files, however this has not revealed summary responsibility of decision makers for NBTS (Wales) prior to WBS and it being part of VUNHST.

90. Review of these files indicate the roles of Medical Director, Deputy Medical Director and a Managing Director, both within the service and the NBTS (Wales) parent organisation documents and their correspondence shows their engagement with Welsh Office officials with responsibility for the blood service provision as well as active engagement with the NBA and its predecessor organisations.

91. We have not been able to identify further detail prior to this time other than the establishment of the Quality Manager post (now Quality Assurance and Regulatory Compliance) in 1990.

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

92. The history of the incorporation and management of WBS is outlined in Question 3 above and in the appendix included [WITN6876002].

93. In summary I understand that the parent authorities through which the blood service was managed were:

1948 to 1982 The Welsh Regional Hospital Board (changed to Welsh Hospital Board in 1964)

1982 to 1991 South Glamorgan District Health Authority

1991 to 1999 Welsh Common Health Services Authority (WHCSA)

1999 to date Velindre NHS Trust (changed to Velindre University NHS Trust in 2018)

94. Until 1999 and the establishment of the National Assembly for Wales, NBT (Wales) reported through its parent authority as outlined above to the Department of Health and Social Services or from 1965 to the Welsh Office.

95. It is my understanding that key decisions on policy blood, cells, tissues and organs would have been made by the DHSS and Welsh Office on advice from specialist advisory committees. Further details are provided in Section 3 of this statement.

96. In 1994, the formation of the NBA changed the overarching governance of the other Regional Transfusion Centres. It was agreed that the NBA would not include NBTS (Wales) which continued to report to the Welsh Office until the establishment of the National Assembly for Wales in 1999 (the Welsh Government from 2017).

97. It is my understanding that key strategic decisions throughout each of these organisational arrangements would have been made in line with the policies set by government.

c. how it is funded;

98. Information on historic funding has been difficult to locate and records have been limited to a small number of financial discussions identified within South Glamorgan Health Authority documents that we located in the Glamorgan Archive in 2018 while preparing for the Inquiry. These records illustrate decisions made relating to the NBTS (Wales) including discussions on its funding with the Welsh Office.

99. The decision making on funding and investment in the NBTS (Wales) from around 1979 to 1991 would have been made within the management arrangements for the South Glamorgan Health Authority (in its arrangements as South Glamorgan Area Health Authority and South Glamorgan District Health Authority) and their arrangement with the Welsh Office for the funding of the "Regional Services".

100. We have been able to identify a number of reports through a limited search of the Glamorgan Archive that identified financial requests and transactions. For example there are minutes that note the poor conditions at the Rhydlafar site and staff shortages in 1979 and recognise the industrial unrest and staff cuts at that time [WITN6876004].

101. This challenge of staff levels, along with investment in the estate, had been identified in a letter from Dr Napier to the British Medical Association (BMA) Chairman in 1979 (BMAL0000023) and is noted in the Health Services In South Glamorgan During 1979 Report to the Area Medical Officer which includes the Blood Transfusion Service Report for 1979 [WITN6876004].

102. In 1980 there is a failure to secure Welsh Office funding for a new site for NBTS (Wales) which reference discussions with the Under Secretary of State [WITN6876005] to secure investment, although later renovations to the existing site were secured. Also included in meeting notes from 1980 was a list of the requests for central funding that would have been made by SGHA for the services that it delivered on a regional basis and not only for their local population in South Glamorgan [WITN6876006].

103. It is clear from the actions of Dr Napier in June 1981 that there were financial challenges in sustaining blood collection (DHSC0000796, DHSC0000797). He wrote to the Chairman of the South Glamorgan Area Health Authority to draw attention to the impact of cuts in the Health Authority funding, the comparative levels of scientific and technical staff at NBTS (Wales), the impact of these cuts on the other Welsh Heath Authorities blood supply without their involvement, and reducing donor numbers at a time when other centres were recruiting. I understand that this was within the UK context of aiming for self –sufficiency for blood products.

104. He also shared this concern with the Central Advisory Committee (DHSC0000799) who advised the Welsh Office that it was in receipt of this correspondence and was highlighting that this was not a matter for the committee.

105. Funding for additional blood collection teams were secured from the Welsh Office in 1983 [WITN6876007] and capital expenditure requirements were considered alongside that of the rest of the Health Authority.

106. From 1991 to 1999 financial arrangements for the service would have been made via WHCSA. The search of our archive to date has not identified any documents that provide details of financial discussions and we do not have access to the WHCSA archive.

107. The correspondence between NBTS (Wales) and the Welsh Office for funding for the implementation of the Hepatitis C look-back exercise in 1995 is outlined in Question 10 of the Rule 9(2) request dated 1st March 2021[WITN6876066] relating specifically to the look back exercises.

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

108. Again the historic structure and functions of the NBTS (Wales) have been difficult to determine from the review of archive documents that has been undertaken to date.

109. Within recent times, there have been a number of activity specific working groups to implement the new IT platform in 2015, to deliver the Designed to Donate service change programme in 2012 and establish the All Wales Blood Service in 2016.

110. We have not been able to identify specific detail of the historic structure, composition and roles of committees and working groups. However, I understand from WBS colleagues that the approach to the Senior Management Team and the

functions of the Working Groups currently in place (with the minor adaptations outlined in 4.d above) has been the basis of arrangements since 2004.

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

111. Since 2016 the WBS covers the whole of Wales. Prior to 2016 North Wales was still under control of NHSBT.

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

112. We have not been able to identify a full list of the legislative and regulatory frameworks under which WBS has operated.

113. There are however a number of developments of those that relate to the quality and safety of the blood supply chain that have been identified and outlined within questions 41 to 45 in Section 9 which specifically deals with the quality aspects of the service.

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

114. A list of the individuals in decision making roles is attached. It has been compiled through interrogation of workforce records of VUNHST and documents held within the WBS archives. While we have made a comprehensive review, we are unable to determine if this is an exhaustive list [WITN6876008].

115. There are and have been a variety of decision making roles within WBS as a division of VUNHST and within the Trust management and Board. See attached document.

7. Please describe WBS'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.

116. WBS has not been involved or provided evidence for any previous inquiries or investigations of a general nature, although it is aware of one inquest in relation to an individual where the question of infected blood was considered.

117. Velindre Trust was a defendant in A vs. National Blood Authority, a group action under the Consumer Protection Act 1987. The claims were brought against the National Blood Authority, in England and the Velindre NHS Trust by 114 people. A limited number of cases arose in relation to Infected Blood following the class action.

Section 2: Record keeping arrangements

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

118. The recording and retention of donor records within WBS takes place in accordance with the Velindre University NHS Trust Information Governance Policies 'Policy IG1 Record Management' [WITN6876009] and the WBS supporting procedures, including Management Procedure MP - 018 Records Management [WITN6876010].

119. Until 1981 all donor records were in paper format and held manually on cards. These cards recorded donor details (name, address, Date of Birth etc.) and a limited amount of donation information (e.g. donation number, date of donation, type of donation, and reason for not donating). The donor record cards were filed by blood donor session or (clinic) name that the donation was made at. All records of tests on blood donations were kept on manual laboratory result sheets which would have been filed by date and session.

120. In 1981 a new computerised system was developed. WBS used a bespoke "in house" computer system known as TRACE (TRAnsfusion Computing

Environment), for managing the blood donor database and the control of the testing, production and issue of blood components from 1982 to May 2015. All donor demographic information and donation history was entered into the TRACE system together with 18 months history of laboratory test results on these donors donations

121. TRACE may be defined as a Blood Establishment Computer System (BECS), which is the term coined in the USA to describe systems designed to control the collection, testing and processing of blood to ensure regulatory compliance and the issue of safe blood components to hospitals.

122. System enhancements were managed by a TRACE Development User Group which reviewed national and business priorities to plan and deliver developments of the system.

123. Recognising some of the limitations of continuing to run a bespoke in-house system, it was agreed to procure and implement a commercial BECS. These limitations included capacity to deliver all potential future developments including regulatory requirements, the inflexibility to adapt some elements and include new departments and the need for management tools to make best use of data.

124. For example, only a retrospective snapshot of the donor history was available for the collection teams to view each week, and therefore quickly out of date. Furthermore this database contained limited donor information and did not permit any update of the donor record live on clinic.

125. TRACE facilitated the electronic capture of a significant amount of information about WBS donors and their donations. However, some key aspects of blood donation were, until 2015, recorded on paper. Most significantly, the pre-donation health self-assessment and screening was a paper exercise, with records retained / archived in accordance with regulatory requirements (30 years), to enable retrospective review should the need arise.

126. Since 2015, the WBS has used a commercial, 3rd party application – ePROGESA – to manage its blood supply chain activities. The TRACE system has been archived and remains available as a data source.

127. The ePROGESA application has wider functionality than TRACE and more than donor information. It is used by collections staff, working in community-based blood donation clinics and by laboratory staff at its primary processing / manufacturing site in Talbot Green (Llantrisant, south Wales) and a secondary distribution site in Wrexham (north Wales). Use of the system is governed via a role-based access model, meaning users are only to permitted to use modules of the system that relate to their area of work.

128. This system supports the electronic capture of the vast majority of information about donors and their donated blood products including:

- Donor demographics
- Donor clinic and the associated panel management
- Clinic planning
- Pre-donation health self-assessment and screening
- Whole blood, platelets and plasma donation
- Testing
- Component manufacturing
- Component storage and issue

129. The WBS also use a bespoke, in-house developed IT application for appointment bookings, which was introduced in 2016. The desktop (client) version of the WBS Appointments System is used by WBS staff to manage the booking of Welsh donors into whole blood and apheresis blood donation clinics. An online, public-facing version of the application allows Welsh donors to search for and book onto a blood donation clinic themselves. Built into the web-based version is email and SMS (text messaging) functionality that can be optionally used by donors for appointment reminders and cancellations.

130. A uni-directional interface from ePROGESA ensure scheduled clinics are appropriately displayed in the system for WBS staff and Welsh donors to book into. There is currently no feed of information from the WBS Appointment System to ePROGESA.

131. ePROGESA also interacts with a small number of other local IT systems, which relate to other aspects of the wider blood supply chain and other services provided by the WBS – for example, an outbound interface seeds data from ePROGESA to an IT system in the Welsh Bone Marrow Donor Registry (WBMDR), to enable the management of bone marrow volunteers (BMVs), who volunteer their services as part of their 'general' blood donation activities.

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

132. Yes, the current database is maintained on the ePROGESA Blood Establishment Computer System (BECS). The system provides WBS with a fully integrated flexible computer system that can be used by the whole organisation to collect, process, test and manage blood donation/donors within Wales.

a. How long has this database been in operation?

133. The current system e-PROGESA and has been in place since 2015 for South Wales and was introduced for donors in North Wales in 2016 when the transfer of responsibility passed from NHSBT to WBS.

b. What donor details does it record?

134. The donor record consists of two main elements. The first is those relating to the donor personal and donation information including information on their health. The second is the record of their laboratory test results for blood group, Rh type and the mandatory tests that are carried out on every donation. This includes HIV (Human Immunodeficiency Virus), HTLV (Human T-cell Lymphotropic Virus),

Syphilis, Hepatitis B, Hepatitis C and Hepatitis E. The system prevents the issue of blood components until these tests have been recorded and are negative.

135. Each donor has a unique donor identification number and the record includes the Donor demographics (name, DoB, address, phone etc.), number of donations, medical notes function to record all interactions with donors, donation record detailing previous donations given, blood results on every donation – both microbiology and haematology, deferral history and reason, record of letters sent to a donor, record of bespoke letters sent to donors and scanned copies of letters that have been sent are attached into ePROGESA, a "tests on next donation" function so that discretionary tests can be added to the system to ensure the donor is tested for that indication at the next donation, donor administration notes used by telephone centre staff and clinical nurses.

136. In addition to the record of whole blood and platelet donors, WBS has the Welsh Bone Marrow Donor Registry (WBMDR). The people who are on this register as potential donors have a full donor record with the addition of donor HLA (Human Leukocyte Antigen) type and infectious disease markers including some not routinely tested for blood donors e.g. Epstein Barr Virus.

c. How is the information stored?

137. The information is stored digitally in VUNHST database servers in line with all regulatory requirements for the digital security, data protection and local NHS policy and procedures. Back up data is securely stored on a separate VUNHST site as part of the Business Continuity Plans.

d. Who is able to access this information?

138. Access is given to staff with appropriate levels of access being determined by the role a staff member has. Donor contact centre staff only have access to the demographic data to facilitate booking donors into appointments and to the administration notes section. Nurses and Doctors have access to the medical notes or annotations, donation deferrals and all laboratory results sections. When a donor

is deferred from donating for any reason, there are appropriate controls in place to ensure that only the appropriate member of staff can lift this deferral and this depends on the deferral that has been set. Laboratory staff have access to donation information.

139. WBMDR staff will have the appropriate level of access commensurate with their role to register donor data. Transplant centres across the world can access the anonymised information on the donor HLA profile for WBMDR donors anonymously, to enable them to identify a potential donor match for their patients.

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

140. Anonymised information about donors with confirmed positive microbiology results is shared with NHSBT/Public Health England who use this information from the 4 UK Blood Services for epidemiological monitoring.

141. Non-anonymised information about donors with confirmed positive microbiology results (with the donor's verbal consent) is shared with Public Health Wales.

142. When a potential WBMDR donor is identified, preparatory tests are undertaken for this potential donor and the anonymised information is shared with the requesting transplant centre. This includes the donor medical questionnaire, medical assessment blood test results including HLA type and test results of the infectious disease markers.

f. How long does WBS store this information for?

143. Retention periods for donor information are set out in MP-018; Records management. Donor/Medical Records are kept for 30 years with the exception of Session (clinic) reports which are kept for 15 years.

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

144. The policy is the VUNHST Trust Information Governance Policies 'Policy IG1 Record Management' [WITN6876009], and the local implementation of this policy is outlined in WBS management procedure MP0-18 Records Management [WITN6876010]. This document was last reviewed and updated in August 2019.

145. Section 5.11.1 of MP-018 states that:

* Records at the end of their minimum retention period may only be disposed of with the authorisation of the appropriate Data Custodian. (Data Custodian of confidential medical records is the WBS Medical Director)

* Disposal may include transfer of records to a final permanent depository, but more usually destruction

* Destruction of records must be authorised by the Data Custodian as it is an irreversible event. Data protection legislation require that records with personal information are held for no longer than necessary, however at the same time, unauthorised destruction of records may breach the Freedom of Information Act or other legislation requiring records to be held for minimum periods.

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

146. Yes, as outlined in question 9 (e), WBS provide anonymised information about donors with confirmed positive microbiology results to NHSBT/Public Health England who compile the data for the 4 UK blood services for epidemiological surveillance. With donor consent the WBS also provide information to Public Health Wales. Blood donor data is collected by the NHSBT/PHE Epidemiology Unit through two parallel schemes: (i) blood donation testing and (ii) infected blood donors. Both of these surveillance schemes started in October 1995. The information is used to monitor donation testing reactive rates and infections detected in blood donors. Additional data providing more detailed information on the profile of all blood donors tested is also gathered.

147. The anonymised information on potential donors that is held by WBS as part of WBMDR is shared to create the UK donor database (UK aligned registry donor database), the European Marrow Donor Information System (EMDIS) donor

database and the global donor database managed by the World Marrow Donor Association (WMDA). These databases are made available to UK and worldwide registries to perform donor searches on behalf of their Transplant Centres.

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

148. WBS does not hold any full primary patient records. We keep limited medical information on donors and patients receiving transplant services from WTAIL.

149. The WBS only keeps limited medical information on donors that relates directly to their eligibility to donate.

150. For WBMDR we keep medical information (test results) relating to the (a donor's) eligibility to donate stem cells or bone marrow to ensure that they are fit to donate. This includes a medical assessment. Limited anonymous information is also available on the recipient, again for donation assessment.

151. For the Red Cell Immuno-haematology department, we hold diagnostic test results.

152. For transplant patients, we hold copies of information regarding the need for a transplant and sufficient patient information to enable transplant support services to be delivered.

153. The retention periods defined within the MP0-18 are based on those outlined in guidance from the Royal College of Pathologists and the Institute of Biomedical Science on the retention and storage of pathological records and specimens (5th edition issued April 2015) [RLIT0001474] and the Records Management Code of Practice for Health and Social Care 2021 [WITN6876011].

154. Record retention periods are defined in WBS Management Procedure MP-018, *Records Management.* The earliest version of this MP we have on (electronic) record is from 1999. At this time the record retention period for donor information

(including bone marrow volunteers' consent and record cards) and laboratory test results was 30 years.

155. I understand that codes of practice for managing records within the NHS will have drawn from statutory requirements and best practice and will have changed over a period of time .To date, we have not been able to identify historic versions of policies or procedures that predate 1999 however the legislative and regulatory requirements on which these are based are outlined in Question 12.

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

156. As a public body WBS is required by law to manage records appropriately, and in retaining information for only as long as necessary ensures we are maintaining records in compliance with our legal requirements and good practice guidance that includes:

- Data Protection Act 2018 (DPA) and the UK General Data Protection Regulation (GDPR)
- Public Records Act 1958
- Inquiries Act 2005
- Freedom of Information Act 2000
- Caldicott – and its principles covering the use of patient information
- Records Management Code of Practice for Health and Social Care 2016

157. The VUNHST policy adopts the Records Management Code of Practice for Health and Social Care 2016 guidelines on records retention and destruction, however the retention of records for the blood service accommodates the specific additional requirements for records relating to blood and blood products. Several iterations and sets of standards have been in place over the years. As a timeline of those that have subsequently been superseded, previous iterations of policies reflected on standards and guidance, to include: -

- Records Management: NHS Code of Practice 2009 as published by the Department of Health [WITN6876062] and [WITN6876063].

- Welsh Health Circular (WHC) (2000)71 – For The Record - Managing Records in NHS Trusts and Health Authorities [WITN6876065]
- WHC(89)60 - HSM: Preservation, retention, & destruction of records: Responsibilities of DHA's under the public records acts
- WHC(94)59 - Preservation, retention and destruction of health records

13. Does WBS 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

158. WBS has no role in death certification.

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

159. Each of the four UK Blood Services are accountable to their own parent organisations and governments and operate independently of each other. However, together they work together both formally and informally to ensure the safety of the blood supply chain, share expertise and information and identify ways in which they can work collaboratively for the benefit of patients, donors and citizens across the UK. This formal co-operation is through the UK Forum of Blood Establishments (UK Forum) and its activities, whose membership includes the respective Chief Executives/Directors, Medical Directors and Chair of JPAC, the role of JPAC is discussed further under response 15 below). It is through this mechanism that we also engage as the UK in Europe through the European Blood Alliance (EBA) and globally with the Alliance of Blood Operators (ABO). This onward engagement across the globe enables and facilitates a pan global approach to managing risk to the blood supply chain. On an informal basis, as the blood services are a small specialism within the NHS, there is naturally close professional working, particularly between areas of practice, for example Quality Managers.

160. I understand that the formal relationships and co-ordinating arrangements have changed over time and this has been outlined in Section 1 [WITN6876002].

161. Of particular note here is the relationship between England and Wales both from the inception of the services and through to 1994 and the establishment of the NBA. Until this time, the Regional Transfusion Centre in Cardiff, NBTS (Wales), operated in effect as one of the regions of England and Wales, although this is often referred to as England. It participated in Regional Transfusion Director (RTD) discussions and came under the remit of the co-ordination role of the Advisory Committee from 1980 to 1988 and National Directorate from 1988 to 1993. Under these arrangements the RTD from NBTS (Wales) was included in correspondence and other activities in line with arrangements for the other RTCs. In 1994, with the establishment of the NBA, NBTS (Wales) was not included in this organisation but retained its management via Welsh Health Common Services Authority (WHCSA) and accountability to the Welsh Office, however, it is clear from the implementation of the Hepatitis C lookback exercise that NBTS (Wales) continued to collaborate and be included in service development with NBA.

162. It was with the establishment of the UK Forum in 1999 that a more formal relationship for Wales with Scotland and Northern Ireland, separate from England, was established. This changed again when North Wales became part of WBS in 2016.

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.

163. 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 and its working groups, advisory groups and collaborative activities. The UK Forum was established in 1999 under the direction of the UK Department of Health to formalise collaborative working on matters of common interest [WITN6876012]. It has no executive authority over the services and is not a legal entity. The staff that undertake its activities are employed by NHSBT.

164. The UK Forum enables a joint approach to professional advice and standards that enable the input from the subject matter experts from across the UK. This is particularly important for the smaller services where expertise in every subject may not be found in every service due to the small size of the specialism. The collaborative working also extends to the establishment of programmes of work and commissioning of reports to support the development and implementation of policy and practice. An example of this is the changes to donor eligibility. A recent example of this is the For Assessment of Individual Risk (FAIR) project where the UK Forum responded to SaBTO advice in establishing a project to review donor eligibility criteria. This work, delivered through a UK wide steering group, devised a new assessment approach to enable risk to be assessed on an individual donor rather than population level basis. The changes were jointly planned together with the associated information and public awareness material and communication approach.

165. The UK Forum is also a means for providing a joint voice from the Blood Services with Governments and other organisations in the UK and globally. This includes our active participation in the European Blood Alliance, which provides a pan Europe and onward global collaborative approach to ensuring the safety and security of the blood supply chain [WITN6876013].

166. The constituent members of the UK Forum were the Chief Executives or Directors of the four UK Blood Services with the four Medical Directors. Other subject matter experts are invited to attend as required by the topics being discussed. The Forum itself meets 4 times a year in person (pre Covid 19) and also virtually.

167. The UK Forum has a number of ongoing established groups that report to it and are funded collectively by the four services.

    a. A number of professional groups are funded by and accountable to UK Forum including:

SHOT, the UK Haemovigilence function that enables reporting of adverse events in blood transfusion and produces information and recommendations based on that data and collective expertise.

b. JPAC provides expert advice on blood safety matters through its standing committees :

Standing Advisory Committee on Blood Components (SACBC)
Standing Advisory Committee on Care and Selection of Donors (SACCSD)
Standing Advisory Committee on Clinical Transfusion Medicine (SACCTM)
Standing Advisory Committee on Immunohematology (SACIH)
Standing Advisory Committee on Information Technology (SACIT)
Standing Advisory Committee on Tissues and Cellular Therapy Products (SACTCTP)
Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI)

The functions of JPAC are detailed in other evidence, and full details are provided on the JPAC website (RLIT0000687).

c. Evidence based practice in transfusion medicine is supported by the Systematic Reviews Initiative (SRI[CS3]) is a clinical research group set up to undertake systematic reviews and other research projects.

168. Alongside these formal mechanisms, there is also a notable informal advice and support network, collaborations on pieces of work, sharing of ideas and information by staff at all levels and in all areas of the service. Recent examples of this include staff secondments to other services.

169. There are a number of groups that provide a regular opportunity to share and collaborate including the UK Quality and Regulatory Compliance Group, the UK Procurement Managers Group, the Engagement and Communication Managers Group and the Business Continuity and Emergency Preparedness Managers

Group. An example of collaboration is in the Memorandum of Understanding relating to a shared approach to supplier audit [WITN6876014].

170. Recognising the potential need for the services to provide support to each other, a formal Memorandum of Understanding [WITN6876015] regarding mutual aid and assistance is maintained to enable planned and unplanned cross service support.

171. Alongside these mechanisms, the community of practice in blood transfusion is also enabled by a number of institutions including the British Blood Transfusion Society, the Institute of Biomedical Science and the International Society for Blood Transfusion. Membership and participation with these institutions is encouraged and supported and they provide a network and education opportunity.

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.

172. Currently the Standing Advisory Committee on the Safety of Blood Tissues and organs (SaBTO) and the JPAC are the mechanisms for ensuring a UK wide approach to blood transfusion safety in the UK.

173. In terms of the changes over time, I believe that there have been a number of mechanisms for co-ordinated approach. The current team at WBS have little understanding of these committees and how they were appointed but I have summarised below my understanding based on historical documents.

174. 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 with the aim to develop scientific guidelines and standards for the quality and safety of blood and plasma products.

175. 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. There was no managerial role and each RTC was responsible for implementation.

176. In June 2001 the UK Forum changed the name of the Executive Committee to the Joint UKBTS / NIBSC Joint Advisory Committee with the remit to prepare and review guidelines under the direction of the Medical Directors.

177. In 2013 the Medicine and Healthcare Products Regulatory Agency and Human Tissue Authority were included and the name was changed to JPAC. Funding for this remained with the four UK Blood Services. The seven advisory committees are outlined in [para b above].

178. Some groups develop on specific issues. For example, a JPAC Working Group of the SAC on Transfusion Transmitted Infections (SACTTI) was convened between (November 2000 – March 2010) to provide advice on the risk of transmission of variant CJD which together with the Prion Filter Efficacy Working Group (Nov 2005 – March 2010) and the Prion Assay Working Group (August 2006 – March 2010) were merged to create the Prion Working Group in March 2010.

179. In 2008 SaBTO was created 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 [RLIT0000686]. Membership of this committee is by appointment based on specialist expertise, and there are observers from the UK Blood Services via the UK Forum. The Chair and Members are independently appointed by the Department of Health.

180. The Committee for the Microbiological Safety of Blood, Tissues and Organs (MSBTO) and Committee for the Microbiological Safety of Blood and Tissues (MSBT) were the predecessors to SaBTO.

181. The haemovigilance role of SHOT as outlined above was formed in 1996 as a pan UK organisation as an independent, professionally-led initiative. Again

implementation lays with individual organisations to whom it makes recommendations.

17. Does WBS 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.

182. WBS does not routinely share information with personal details of donors or people who attempt to donate and fail for a microbiological reason and then are not eligible to donate. This is known as a "deferred" donor. If during the follow up on a positive result for an infection with a donor it is identified that the donor had previously donated blood elsewhere in the UK within an appropriate period of time, then we would obtain their consent and share this information with the other service to enable a look back exercise for the previous donation.

183. Anonymised data on the number and type of infections identified in blood donors are shared with other services. This is collated on behalf of the UK Forum by NHS Blood and Transplant (NHSBT) in collaboration with Public Health England (PHE). This data is then published annually (RLIT0000688).

184. In terms of historic data sharing, we have not been able to identify any specific arrangements in the search of our archives to date. As in previous organisational arrangements the NBTS (Wales) operated as part of the co-ordinated England and Wales NBTS, we believe that there would have been information shared. Although NBTS (Wales) was not incorporated into the NBA in 1994, there are examples of donor information being shared during the HCV look back exercise where details of donors identified as HCV positive who had donated elsewhere were shared with the individual RTC [WITN6876016].

Section 4: Relationship of NHSBT to transfusion centres

185. WBS operates as one 'transfusion centre' delivering the collection, testing, processing and distribution of blood to its customer hospitals. This is based on the historic establishment of the Cardiff Regional Transfusion Centre which, through its development to WBS provided a service for South Wales until 2016 when the service in North Wales passed to WBS from NHS Blood and Transplant (NHSBT).

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

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

186. WBS has no authority over any other 'transfusion centre'.

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

187. There is no 'transfusion centre' for WBS to have authority over. In terms of the WBS position as a transfusion centre, WBS does not set plasma collection targets as the requirements for Fresh Frozen Plasma and Cryoprecipitate are met from the blood donations taken to supply the red blood cell component. Planning for blood collection is undertaken on an annual basis following discussions with hospitals. Following that stocks are planned via a collaborative exercise by the Hospitals Issues Department and the Blood Collection Department and input from the Blood Health Team via a Daily Resilience meeting which looks at the forward plans for the months and weeks ahead as well as daily stock positions.

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

188. WBS has no authority over any other transfusion centre.

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

189. WBS has no authority over any other transfusion centre.

19. Does WBS 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 WBS deems to be relevant to the Inquiry's terms of reference.

190. WBS has no authority over any other transfusion centre and therefore does not issue guidelines or directive relating to transfusion safety/best practice. However, as a transfusion centre, WBS develops, implements, and audits a range of standard operating procedures, as part of its Quality Management System, in line with regulatory and good practice requirements.

191. WBS implements the professional guidelines developed by expert groups including JPAC and its standing committees and SaBTO. These groups were outlined in Section 3.

192. These groups undertake regular review of transfusion guidelines in the light of developments in the field, both scientific and regulatory. The overall aim is to ensure as far as possible the safety of blood transfusion in the UK, for both the donor and the patient. WBS colleagues contribute to the development of these guidelines.

193. The WBS Medical Director is a member of JPAC, along with the WBS Head of Quality Assurance and Regulatory Compliance who represents the UK Quality and Regulatory Managers' Forum. WBS also has membership on each of the JPAC Standing Advisory Committees (SACs).

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

194. WBS operates as a single transfusion centre. Its record keeping requirements and the history that we have been able to identify have been outlined in Section 2,

questions 8 and 9 (f) and (g). WBS operates under a wide range of legal and NHS requirements for record keeping which is incorporated into the Velindre University NHS Trust Information Governance Policies 'Policy IG1 Record Management'. The record keeping for donors in North Wales commenced on the transfer of the service in 2016.

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

195. WBS operates as a single transfusion centre.

22. Does WBS 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?

196. WBS operates as a single transfusion centre. Information sharing between blood services is provided in question 17.

Section 5: Relationship of WBS to government

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

197. As an operational division of VUNHST, WBS has a direct relationship with Welsh Government as an NHS Trust. It is accountable to the Welsh Government as an NHS Trust under its establishment order. Under the Government of Wales Act, the health service in Wales is a function devolved to the Welsh Senedd since July 1999. VUNHST is an NHS Trust and operates within the National Health Service (Wales) Act 2006, Chapter 2 NHS Trusts, under the Velindre National Health Service Trust (Establishment) Order 1993. Velindre became Velindre University NHS Trust (VUNHST) in 2018 [WITN6877017].

198. The Chair of the VUNHST and the Board Independent Members are appointed by and accountable to the Minister for Health and Social Services.

199. Model Standing Orders are issued by Welsh Ministers to NHS Trusts using powers of direction provided in section 19 (1) of the National Health Service (Wales) Act 2006. National Health Service Trusts ("NHS Trusts") in Wales must agree Standing Orders (SOs) for the regulation of their proceedings and business. When agreeing SOs Trusts must ensure they are made in accordance with directions as may be issued by Welsh Ministers. They are designed to translate the statutory requirements set out in National Health Service Trusts (Membership and Procedure) Regulations 1990 (S.I. 1990/2024) as amended into day to day operating practice, and, together with the adoption of a Schedule of decisions reserved to the Board of directors; a Scheme of decisions to officers and others; and Standing Financial Instructions (SFIs), they provide the regulatory framework for the conduct of the business conduct of the Trust.

200. These documents form the basis upon which the Trust's governance and accountability framework is developed and, together with the adoption of the Trust's Standards of Behaviour Framework Policy are designed to ensure the achievement of the standards of good governance set for the NHS in Wales.

201. The VUNHST Integrated Medium Term Plan is approved by the Trust Board. This is then shared with Welsh Government officials for their overarching approval. The Trust Board is then responsible for assurance of performance against this plan. This process has been amended temporarily during the pandemic.

202. The Trust's Chair and Chief Executive are personally accountable to the Minister for Health and Director General respectively for Health within Welsh Government. Welsh Government Ministers and Officials have various mechanisms for reviewing performance of the Chair and Chief Executive in their respective roles for leading the delivery of performance against the agreed plan.

203. This includes various members of the executive team presenting on VUNHST performance through our quarterly Velindre NHS Trust Integrated Quality, Planning and Delivery Review Meeting with Welsh Government Officials and Joint Executive Team meetings with the Director General of Health and Social Services/Chief Executive NHS Wales and his senior team/ professional leads for NHS Wales.

204. On matters relating specifically to the WBS and its service delivery, engagement is in the main with the Healthcare Quality Population Healthcare Division within Welsh Government with the team responsible for matters relating to Blood policy. This also includes the office of the Chief Medical Officer and on occasion the Chief Pharmaceutical Officer and Chief Scientific Officer Health. Meetings occur as required with colleagues to discuss service development and on occasion provide advice or information that is within the specialist expertise of the WBS staff.

205. Engagement occurs with the Welsh Government NHS finance functions to determine some aspects of additional revenue funding for certain specific service development and/or improvement projects, including associated capital funding.

206. There are matters that are reserved to the UK Government which includes health regulation. For example, the Secretary of State for Health has designated responsibility for the authorisation and inspection of Blood Establishments, but has delegated this responsibility to the Medicines & Healthcare products Regulatory Agency (MHRA). WBS is accountable to the MHRA for compliance with the Blood Safety and Quality Regulations 2005 (as amended), and has been granted a Blood Establishment Authorisation (BEA) license and a Wholesale Dealers License (WDL) Authorisation.

207. The WBS takes advice from the government via the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) which *"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"* and provide independent advice on risk management [RLIT0000686].

208. The Welsh Government issues information, advice or requests for action to NHS organisations through Welsh Health Circulars. For example, Welsh Health Circular WHC (1999) 5, updated in 2005 [HSSG0000065], introduced the Better Blood Transfusion (BBT) initiative. This circular identified the action required of NHS Trusts and clinicians to improve transfusion practice, make blood transfusion safer, avoid unnecessary use of blood in clinical practice and provide better information to patients and the public about blood transfusion and ensure that Better Blood Transfusion is an integral part of NHS care. I understand that the requirements were originally based on recommendations of a symposium held by the UK Chief Medical Officers on Evidence-Based Blood Transfusion in London 6 July 1998, followed by wider consultation. This example illustrates the role that government has in leading and co-ordinating professional development and discussions with the NHS.

209. I understand that in Wales, the implementation of this guidance was originally monitored by the Welsh Assembly Government and the Blood Standards and Quality Group (BSQG). The BSQG was set up in 1999 to advise Velindre Trust on the standards to be set for monitoring the quality of WBS's services and to consider and provide advice to Velindre Trust, WBS, NHS Wales and National Assembly government on the strategic development of blood services in Wales.

210. This arrangement was revised in 2017 with the publication of the NHS Wales Blood Health Plan [HSSG0000017] and the establishment of a new national oversight group to replace the BSQG. This includes representation from Welsh Government, Health Boards and the Welsh Health Specialist Services Committee (WHSSC) as well as WBS and practitioners.

211. In terms of historic arrangements, I have been advised that prior to the establishment of the National Assembly for Wales in 1999, the predecessor organisations of WBS (NBTS (Wales) and the Cardiff or Welsh Regional Transfusion Centre) was accountable through local NHS and government structures to the UK Government. From 1965 this was through the Welsh Office.

212. I understand that the role of professional expert advisory structures was via a single overarching UK arrangement, the Committee for the Microbiological Safety of Blood, Tissues and Organs (MSBTO) and Committee for the Microbiological Safety of Blood and Tissues (MSBT) advising the blood services and the UK government and the four UK territorial health departments.

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

213. Above (in questions 23) is the outline of my understanding of the relationship with government.

214. WBS is a Division of VUNHST. The Trust is a statutory Health body established through its Establishment Order which operates as part of NHS Wales. The Trust's Chair and Chief Executive are personally accountable to the Minister for Health and Director General for Health respectively within Welsh Government which has devolved authority for Health Care in Wales.

215. In terms of regulation, although the safety and quality of blood is an area of devolved competence, standards are set nationally and agreed by the four UK devolved administrations under the terms of The Blood Safety and Quality Provisional Common Framework (2020). Under this framework, the MHRA an executive agency, sponsored by the Department of Health and Social Care remains the Competent Authority for the regulation of Blood and Blood components across the whole of the UK.

25. Does WBS 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?"

216. As VUNHST, WBS provides a range of reports to the Welsh Government through its governance and accountability as a NHS Trust. This includes the production of an Integrated Medium Term Plan and our report of our delivery against that plan. We report against our key performance indicators on a monthly basis and also report our achievements against the Welsh Health and Care Standards. Monthly financial reports are also submitted.

217. In addition, we report progress and financial expenditure for projects or programmes or work. For example, WBS manages Advanced Therapies Wales (ATW), a programme to deliver the Welsh Government Advanced Therapies Statement of Intent.

218. There are some occasions on which WBS is asked to provide information and advice to Welsh Government departments. An example of the type of advice that WBS would provide to Welsh Government is illustrated by the establishment of a programme to produce Convalescent Plasma as a treatment for Covid 19 during the pandemic. Here, discussions with Welsh Government colleagues in the Health and Social Services Group Coronavirus Planning & Response Group meeting on the emerging global discussions on the use of Convalescent Plasma (CP) as a treatment for Covid 19 led to WBS providing specialist advice on the way in which collection of plasma in Wales and participation in the clinical trials could be achieved. As a result, a programme was established to enable the CP to be produced in Wales.

219. A further example is the establishment of the All Wales Blood Service, where WBS provided information and advice to Welsh Government on the requirements underpinning any transfer of services from NHSBT to WBS that led to the establishment of the programme for the incorporation of the North Wales service into WBS in 2016.

220. In terms of contribution to expert independent advisory groups to governments, any WBS staff that undertake that role would be independently appointed as a member based on their own individual professional expertise or in attendance through a blood service role.

Section 6: Relationship of WBS to laboratories

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

221. WBS produces the blood components Fresh Frozen Plasma (FFP), and Cryoprecipitate. This is produced by WBS in its own blood processing laboratory from blood donations it collects from donors in Wales. It does not procure plasma for manufacturing of blood products, and it currently does not provide plasma for the manufacture of commercial blood products.

27. How have WBS's relationships with the various laboratories involved in manufacturing blood products for Wales changed over time? Specifically, please describe as far as you are able how WBS'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.

222. From the background history of the blood services provided to me by Dr G Poole, I believe that prior to the 1970s, the production of most blood components by blood centres was not possible, because blood was collected in glass bottles, which did not facilitate the manufacturing processes needed for blood component production. Consequently, the demand for components was also very small, with many clinical needs being met by the transfusion of whole blood. However, during this period, the Lister Institute of Preventive Medicine (established in 1891) and the Blood Products Laboratory (BPL) in Elstree (established in 1954 as part of the Lister Institute) developed manufacturing methods for a range of blood products including albumin, immunoglobulins and Factor V111 concentrate. This is detailed in the information produced by Bio Products Laboratories "Blood Relations" [WITN6877018]. The WBS has no records of how much plasma was procured for BPL in this period, but given the manufacturing constraints we believe it will have been very limited.

223. After the introduction of plastic blood collection bags by NBTS (Wales) in the 1970s, the manufacture of blood components became feasible and the amount of components increased over time in line with demand from hospitals.

224. I also understand from Dr Poole's work that during the 1970s and 1980s, plasma was also produced by NBTS (Wales) for despatch to BPL or the Plasma Fractionation Laboratory (PFL) in Oxford and that until 1988, plasma production targets for blood centres in England and Wales increased as demand for FVIII and other blood products increased. I understand that these targets were discussed and agreed at the meetings of the Regional Transfusion Directors. I understand the targets were ambitious, because the amount of plasma required was very large and blood centres had to balance plasma production for BPL / PFL against component production for regional hospitals, demand for which was also increasing. Blood centres also procured anti-D immunoglobulin from blood donors for BPL. In the SGHA report in 1983 [WITN6876007], NBTS (Wales) was noted as requiring three times the current plasma levels and that this will be ten times that of the late 1970s to move towards self-sufficiency.

225. The work of NBTS (Wales) in reaching these targets and the constraints in which they operated are outlined in the questions in Section 8 of this statement.

226. As a supplier of plasma to BPL, NBTS (Wales) would be subject to audit of its systems and processes. This is illustrated in the response by NBTS (Wales) to a BPL audit in 1998, providing the actions undertaken by NBTS (Wales) [WITN6876019].

227. In 1998, the use of UK plasma was ceased by the Committee on Safety of Medicines based on the risk of vCJD transmission [WITN6876020]. That situation has remained until the present day but is under review following recent UK Government and Devolved Administrations agreement to lift the ban on the use of plasma from UK donors to make these medicines on the advice of SaBTO.

228. In terms of the contractual or managerial arrangements under which NBTS (Wales) provided plasma to BPL, my knowledge is limited to the correspondence identified

in our archive that relates to discussions at the time that the use of UK plasma ceased, however they do illustrate the relationship and arrangements with BPL which was at that time directly managed by NBA.

229. Correspondence between NBTS (Wales) and BPL between May 1998 [WITN6876021] August and September 1998 ([WITN6876022];[WITN6876023]; [WITN6876024]; [WITN6876025] identify that the Welsh service acted as a *"stakeholder on behalf of individual hospitals"* and at that time wished to maintain the wholesaling and point of distribution role for its customer hospitals in the context of a new direct to hospital delivery being proposed by BPL with no prior discussion with NBTS (Wales).

230. We have not been able to identify the details of the financial transactions for the plasma although a letter dated 9th April 1998 provides information on the agreement of the Department of Health to provide funding to BPL for England and Wales and this being the "normal channel of funding" (DHSC0004383_020).

231. In July 1998, with the introduction of NAT testing as the final release for FFP in April 1999, NBTS (Wales) approached BPL to undertake their NAT testing. This was agreed [WITN6876025] and so BPL became a third party service provider for NBTS (Wales) for this period.

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

232. As outlined in Question 26, WBS has no relationship with laboratories involved in manufacturing blood products and none are produced specifically for Wales.

Section 7: Relationship of WBS to pharmaceutical companies

29. Please explain WBS'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.

233. The WBS currently has no relationship with any pharmaceutical companies involved in the production, manufacture, sale and/or importation of blood products. There is a contractual arrangement in place to enable the procurement of these products that is outlined in Question 30.

234. Historically, WBS used to pool recovered plasma from whole blood donations which was blast frozen before being transferred to the then state owned fractionator BPL (Blood Products Laboratory and then Bio Products Laboratories).

235. The products produced by BPL would then be held and distributed by NBTS (Wales) to hospitals in South Wales. Further details are included in Section 6 of this statement.

30. Does WBS 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.

236. WBS contracts with a number of pharmaceutical companies. The WBS holds a Wholesale Distribution Authorisation (Human) (WDA-H) with the Medicines and Healthcare products Regulatory Agency (MHRA) and acts as a wholesale distributor on behalf of NHS Wales for prescription only medicines (POMs) that fall into the categories 'Medicinal products derived from blood' and 'immunological medicinal products'. The WBS coordinates the procurement of these medicines for hospitals in south Wales from a national framework agreement negotiated by NHS Wales Procurement Services as well as through National UK Commercial Medicines Unit contracts. The frameworks do not guarantee procurement or supply of set amounts of the medicines on the contract. WBS holds stock for onward distribution to hospitals based on the clinical need and product use

determined by the hospital clinical teams. Due to the historic NHSBT arrangement for North Wales they procure their own supply directly under the same national contracts.

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

237. The role of the WBS is as a wholesaler or stockholder providing a supply service and as such does not have a role in the use of these products. The decision on use is made by the appropriate treating clinician.

32. Has WBS 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. WBS has no role in prescribing or administering commercial blood products.

239. The role of WBS has been and is as a wholesale provider of these products for customer hospitals in south Wales.

240. We have not been able to identify any information in our archive that relates to the establishment of the service by which the predecessors of WBS commenced this stock holding and distribution function. Section 6 includes documents that provide some information on the arrangements for stock holding and distribution with BPL.

241. As outlined in paragraph [237] the choice of product remains with the treating clinician or tertiary care specialist. These arrangements, and the separate arrangements for patients receiving home treatments, were detailed in the evidence to this Inquiry of Dr Saad Al-Ismail in WITN3761005.

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

242. There are two methods through which declarations relating to the WBS involvement with a pharmaceutical company could be made.

243. The VUNHST has a Standards of Behaviour Framework policy [WITN6876026]. This places an obligation on Independent Board Members and Employees to make an annual declaration of interest, usually in April each year. A register of interests is maintained as a formal record of interests declared by Employees and Independent Members. The register includes details of Directorships, pecuniary (financial) and non-pecuniary interests in organisations that may have dealings in the NHS and members of professional committees and third sector bodies. Where relevant it will also include details of interest of close family members or civil partners.

244. The register is reviewed formally by the VUNHST Audit Committee and Trust Board on an annual basis. In addition, at the commencement of all formal Trust meetings, members are asked if they have anything to declare in relation to the items being considered which are then recorded.

245. Secondly, VUNHST operates within the UK government regulatory framework for public services and supplies. Since 2015, the Public Contract Regulations have included a specific requirement relating to declaratory requirements to review and declare any conflicts of interest. Section 2 point 24 relates to this requirement. As part of any procurement exercise, VUNHST require the procuring officer to sign off a declaration of interest for any suppliers known in the marketplace for the requirement in question.

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

246. WBS has no engagement with pharmaceutical companies on medical research studies.

Section 8: Sufficiency of modern blood supply

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

247. Sufficiency of supply is a principle that underpins the operation of WBS and it continually works to ensure a sufficient supply of blood components for patients in Wales through its planning and operational delivery and also through work with hospitals to support the appropriate use of blood and reducing waste. In doing so it works with hospitals to understand their changing need for blood components based on their clinical services and plans to collect sufficient blood donations to meet this need.

248. This currently does not include the provision of plasma for the production of Plasma Derived Medicinal Products (PDMP) due to the 1998 changes made by the Committee on Safety of Medicines as a safety measure for new variant CJD.

249. It is my understanding that NBTS (Wales) provided plasma for the production of plasma derived medicines prior to the changes being brought in and that historically sufficiency of supply also included sufficiency of plasma for PDMPs.

250. To date we have not been able to identify documents in our archives that relate directly to the sufficiency of supply, however documents identified within the archive of SGHA clearly demonstrate the challenge that NBTS (Wales) encountered in providing sufficiency of supply during the 1980s as a result of both its resources to collect blood and plasma but also due to the limitations of facilities and staff during some periods.

251. In the Blood Transfusion Service report of 1979 [WITN6876004], it is reported that the limitations in the size and the quality of the accommodation in the Cardiff Centre and staff shortages impacted on the service expansion, although the industrial unrest at this stage in the NHS and severe weather was also a contributing factor to enabling supply meeting demand. In January 1980, funding for a new centre was not made available by the Welsh office and an update to the existing facilities was agreed [WITN6876005].

252. Despite the upgrade to facilities, in 1980 [GLAR0000054] there still had to be a policy of matching blood collection to the financial resources. It was also noted in this 1980 report that the Central Advisory Committee for the National Blood Transfusion Service was established and it is reported that *"one of its first tasks will be to establish targets for procurement of sufficient plasma to make the UK entirely self-sufficient in blood products.* The report outlines the aim to increase the level of donations taken by NBTS (Wales) by 50% and to procure plasma by plasmapheresis and the difficult financial circumstances in which this would be undertaken.

253. In the SGHA meeting notes in 1983 [WITN6876007], the expansion of blood collection is noted along with the rebuilding of the Blood Products Laboratory at Elstree, both of which seek to correct the balance of UK self- sufficiency versus the use of imported plasma products. It is noted that for NBTS (Wales) this will require three times the current plasma levels and that this will be ten times that of the late 1970s.

254. In 1989/90 the Operational Programme of SGHA [WITN6876027] section 6.1.2 identifies that again the accommodation for NBTS (Wales) is overcrowded and unsuitable and that there is *"insufficient capacity with which to achieve self-sufficiency for blood products".*

255. In terms of overall collection of blood donations Rule 9 (2) question 7 provides details on donation volumes through the 1980's and 1990's.

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

256. The remit of WBS (VUNHST), the Welsh Government, WHSSC and the Local Health Boards are outlined in Section 1 questions 4-6.

257. The active engagement with Health Boards and Welsh Government to produce an approved Integrated Medium Term Plan ensures that sufficient blood components are produced and the Wales Blood Health Plan provides the intent and mechanism through which WBS and Health Boards to work collaboratively to ensure appropriate use and management of waste.

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

258. WBS is a single transfusion centre. It ensures sufficiency of the supply chain in Wales through its strategic and operational planning. This is further outlined in Question 39.

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

259. The WBS has its own blood processing and testing laboratory. This team includes the hospital issues department who meet daily with the blood collection team to plan collection. Through the mutual aid arrangement, in emergency situations, WBS would work with NHSBT to facilitate business continuity use of blood testing facilities at their Filton base. An example of this occurred when WBS temporarily donated one of their testing platforms to Public Health England to support Covid 19 testing and in return NHSBT undertook some of the WBS blood testing activity.

260. In terms of the hospital blood laboratories or Blood Banks, the sufficiency of the supply is ensured by engagement and planning and a strategic level through an annual meeting with each Local Health Board in Wales to determine the projected requirements for the following year, recognising planned service change as well as overall changes in service demand. This is then built into the WBS annual plan in the VUNHST Integrated Medium Term Plan. On a day to day basis, liaison with hospital Blood Banks enables close management of stocks between hospitals and WBS.

261. There will always be short term local variation in demand and on infrequent occasions this can lead to a stock shortage for a limited period of time while donations are increased.

262. The WBS Business Continuity Plan details the escalation process including convening the Emergency Planning Team and declaring a Blood Shortage Alert.

263. The three blood shortage categories are Blue, Amber & Red with associated stock management requirements for WBS and hospitals to manage stocks until they return to required levels are contained in the WBS Business Continuity Plan – Blood Shortage. ([WITN6876028] BCM 108).

264. Engagement with the relevant professionals and clinicians is another way in which effective use to ensure sustainability is taken forward, although clearly the primary driver is safe and effective use of blood for patients.

265. A key activity for the WBS is engagement with Hospital Transfusion Committees, Transfusion Laboratory Manager and Transfusion Practitioner networks through regular meetings, and directly with hospital clinical teams.

266. Implementation of best practice has been progressed through the Better Blood Initiative and the subsequent Wales Blood Health Plan with guidance, educational resources and algorithms based on national guidance and advice to support clinical decision making. Participation in the Blood Stocks Management Scheme, SHOT haemo-vigilance scheme and participation in National Comparative Audits and sharing data on blood component issues and wastage have all contributed to improvements made within the field of transfusion and are promoted by both hospitals and WBS. In the past four years, improved engagement with hospitals has also enhanced the Resilience and Demand Planning within WBS. This has been particularly beneficial during the current Covid 19 pandemic where close liaison with hospitals has informed the day to day plan to maintain sufficient blood stocks.

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

a. public information campaigns to recruit donors;

267. The recruitment of donors has developed with advances in technology and has moved away from recruitment staff visiting work places and schools and sending invitation letters to a more dynamic and flexible digital approach:

1. Communications and Marketing

268. WBS fully utilises its website and social media to reach citizens of Wales to recruit new and returning donors. The communications team at WBS cover national and local media, marketing, social media and the divisional website (welshblood.org.uk and gwaedcymru.org.uk) with planned seasonal campaigns as well as responsive targeted calls for donation that may be required on a local level to utilise specific clinics or perhaps a call for blood donors with a specific blood group. Where possible, WBS uses case studies at a local and national level to encourage appointment uptake, particularly in areas where additional recruitment is needed. The use of digital marketing monitoring tools enables the team to understand its most successful outputs for future improvements.

2. Partnerships

269. Partnerships with key organisations across Wales are utilised to encourage people to become donors. For example, working with comprehensive schools, colleges, universities and large businesses to host blood donation sessions. Partnering with national organisations that have local networks allows us to reach local communities in new audiences. For example, in 2020 we were appointed the first ever recipient of the Football Association of Wales Cymru Leagues Community Partnership enabling us to work with 53 local men and women's teams across Wales.

3. Local Engagement

270. The WBS has a small team of donor engagement coordinators who work with influential people and organisations in local communities ahead of upcoming

donation sessions, using advocates and influencers to maximise engagement. Staff are trained using the latest engagement techniques and follow standard operating procedures. Key influencer's success is measured via the number of appointments made through their networks and reviewed for future engagement opportunities.

4. Retaining donors

271. After becoming a donor, WBS sends invites for upcoming donation clinics based on a donor's: a) eligibility to donate, b) venue preference, and c) blood type, including the hospital demand for this blood type. When demand fluctuates, the Donor Contact Centre can vary invitations by altering these criteria. A combination of letters and SMS and outbound telephone calls are also used to boost appointment uptake if necessary and the ePROGESA system enables us to access and use donor information.

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

272. The WBS operates as a single Transfusion Centre and plans its infrastructure and geographical coverage for blood donation clinics to ensure that we reach and provide an opportunity for as many as possible of the citizens of Wales to donate. This is currently constrained by operating in a COVID environment where use of our mobile trailers and some small venues has been ceased for infection control purposes.

273. The following reflects our non Covid 19 Pandemic environment operation.

274. We operate eight blood collection teams across Wales which provides resilience and flexibility with a collection plan usually determined 16 weeks in advance of the donation clinic. Sessions are delivered at over 300 booked independent venues spread across Wales. The two fixed sites at Talbot Green HQ (houses a single whole blood clinic and all apheresis donations for the whole of Wales) together with

Pembroke House in Wrexham. Our collection plan is ultimately determined by the forecast demand of blood products from Welsh Hospitals.

275. The independent venues include community venues such as hotels, leisure centres, sports clubs and schools, colleges and universities. Our mobile donation units usually attend large supermarkets, retail parks and business parks. Compliance with regulatory and professional requirements for a blood donation clinic determine the suitability of any specific venue.

276. A critical part of the plan is ensuring appropriate geographical coverage across Wales, enabling access where people live, work or access education and training. This is viewed in line with the Wellbeing of Future Generations Act, specifically the objective for a more equal Wales.

277. The alignment of access to existing donors, venues and accessing new donors is under a process of continual review. This recognises that workplaces, populations, venues and donor requirements change. In 2016 we undertook a major exercise to map the population of Wales against the demographic of our donors and clinic venues to identify areas of new population where we should expand our clinic offering and took a range of actions based on this information to realign our plans. Clearly the impact of the Covid 19 pandemic on work location and work life balance will require a review of our ongoing plans.

278. Strong links in the planning team with both the Donor Contact Centre and Donor Engagement function means that there is collaborative discussion where there is a review of the collection plan and Donor feedback is used to plan for the future sessions.

279. Staff plans, equipment and logistical arrangements that underpin our blood donation clinics are planned through the day to day management arrangements of WBS and wider VUNSHT to ensure that they are adequate, safe and effective and make best use of resources. Their development are included each year in the VUNHST Integrated Medium Term Plan.

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

280. The WBS operates under a formal Quality Management System in line with Blood Safety and Quality Regulations 2005 (as amended) and audited by the competent authority MHRA on a bi annual schedule.

281. The comprehensive procedures in place for the storage and distribution of blood components and blood products include; validated storage equipment such as walk-in fridges, freezers, incubators and room temperature store rooms, temperature mapping and monitoring, preventative maintenance contracts, validated blood component and products transport systems (transport boxes and temperature controlled vehicles).

282. Distribution is via a WBS fleet of vehicles which is fully managed to be compliant with all vehicle fleet regulatory requirements as well as those for blood products. The WBS Stock Holding Unit in Wrexham, which is the distribution centre in North Wales, supports the timely issue of blood components to the regional hospitals.

283. Through agreed order and distribution schedules with all Hospitals in Wales, WBS maintain the efficient management of blood stocks across the transfusion chain.

284. All of these services are underpinned by an on call provision of scientist expertise and full Business Continuity plans.

285. Any incidents in the storage and distribution systems are reported and investigated and corrective and preventative actions identified and implemented under the WBS quality management processes.

286. In terms of blood products, the WBS wholesale provision and supply to hospitals is managed and overseen by a senior member of scientific staff and is also stored and distributed via these logistical and infrastructure arrangements. The procurement of these products is supported by the NHS Wales Shared Service Partnership (NWSSP) procurement team.

287. The replacement or upgrade of the equipment or any new requirements are planned within the business planning process for WBS which maintains and manages both capital and revenue resources plans for equipment and infrastructure which feeds into the resource planning for the VUNHST.

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

288. The range of blood components (primarily Red Cells, Fresh Frozen Plasma, Platelets, and Cryoprecipitate) that can be produced from each blood donation varies and are interdependent in terms of production methods and the blood collection process. These are detailed in the Red Book and ensure safety and optimised production. These methods determine the range and combination of products that can be produced. As a result we carefully plan based on demand and stocks held to maximise stocks of the different components.

289. Instructions are planned and in advance but can be changed on weekly or even daily basis if demand requires. All of these parameters are assessed and reviewed in the Resilience and Demand planning meetings.

290. The yield of the processes for the production of PDMP is under the control of their manufacturers and not the remit of WBS.

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

291. WBS does not set specific targets for the collection of plasma. As outlined in (d) above, the plasma for FFP, cryoprecipitate is recovered plasma from whole blood donation. Whole blood collection targets are set annually following review with LHBs, monthly for operational planning services and daily through the Resilience and Demand Planning meeting.

40. How effective are WBS's current functions, policies and practices in ensuring the sufficiency of the blood supply in Wales? Please compare the

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

292. I consider that the current functions, policies and practices are effective, however there is a culture within the service of striving for continuous improvement.

293. There are two activities that I can use to demonstrate this continuous improvement:

294. The Wales Blood Health Plan (HSSG0000017), the work of the National Oversight Group for the Blood Health Plan and the collaborative work between the WBS Blood Health team and hospitals in Wales support sufficiency through developments in the safe and effective use of blood and reducing waste.

295. The Blood Supply Chain 2020 (BSC20) initiative has reconsidered the WBS supply chain function, from recruitment of donors to delivery of components to customer hospitals, to ensure it is fit for purpose and to address the service development and improvement opportunities that have been identified. WBS began work on the BSC20 initiative in 2017 and was due to be completed by July 2021 (timeline extended due to COVID). The programme has employed a holistic tripartite approach based on three domains: human, technology and programme planning and delivery.

296. The BSC20 vision [WITN6876029] sets out the context for the initiative. Developed through active engagement with staff, hospitals and feedback from donors, it is formulated as a series of 6 aims focussing on the following areas:

- Donors as Partners
- Retention, Recruitment and Donor Experience
- Clinic Planning
- Blood Processing & Testing
- Logistics
- Hospital Issues and Liaison

297. Successes include increasing efficiency of blood stock ordering and distribution process, enhancement of the data analysis and process for demand planning and

the establishment of the Resilience and Demand Planning function, and the development of the donor recruitment approach to make best use of technology and implement appointment booking. These are just a small number of outcomes of a comprehensive development programme.

298. In terms of comparisons with historic approaches, again my understanding of them is constrained by the limited detail we have been able to determine from the review of our archive to date and the experience of our current staff.

299. I understand and have outlined in the response to Question 35 that previously colleagues have operated in an environment where their facilities, staff and financial resources have been limited in an environment of increasing demand, and of being required to supply blood components and plasma for PDMPs.

300. Developments in quality management and standards, equipment, processes, automation and facilities have all increased efficiency and reduced waste which in turn have supported sufficiency.

301. The development of improved health care interventions such as keyhole surgery, advances in science and technology such as Cell Salvage, and clinical changes in blood component use, have all led to reduction in the use of blood per head of population in the UK in recent times.

302. This does not mean that we are not challenged in the use of our resources and have to justify investments in our services.

303. The cessation of use of UK plasma for the production of PDMPs also reduces the challenge of sufficiency as the UK public and blood services have not been providing plasma for this purpose since 1998. This is now being considered following the UK Government and Devolved Administrations agreement to lift the ban on the use of plasma from UK donors to make these medicines on the advice of SaBTO), based on updated knowledge on factors that led to the ban.

Section 9: Safety of modern blood supply

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

304. The safety of the Blood Supply chain is at the core of the WBS, its culture, planning and delivery. This includes the WBS responsibility for the collection, testing, processing and distribution of blood components, as well as the role it has in promoting the safe and appropriate use of blood components through its Blood Health Team, and its support for hospitals in the implementation of the Blood Health Plan (HSSG0000017) and the predecessor Better Blood Transfusion initiative (NHBT0017355) (HSSG0000074) [WITN6876030].

305. The WBS achieves this through the implementation of formal and/ or legal responsibilities, as well as rigorous quality systems to ensure that professional standards are met.

306. This responsibility for the safety of the blood supply is articulated through the obligations laid out in the regulatory frameworks in which we operate as outlined in Section 2 and 3, and the recently published Health and Social Care (Quality and Engagement) (Wales) Act 2020 also sets out a clear future duty of quality and candour.

307. Our responsibilities are discharged through the application of systems and processes that comply with the regulatory frameworks and professional guidelines as defined within our Quality Manual.

308. WBS operates under the Blood Safety and Quality Regulations (BSQR), UK Statutory Instrument 2005 No. 50. These Regulations, which came into force on 8th February 2005 and were implemented on 8th November 2005, impose safety and quality requirements on human blood collection and storage. The requirements apply to blood establishments in the UK, these being the blood transfusion services in England, Scotland, Wales and Northern Ireland.

309. The WBS holds a Blood Establishment Authorisation and a Wholesale Dealer's Licence from the MHRA which allow WBS to operate as a Blood Establishment and as a Wholesale Dealer for commercial blood products. Continuation of these licences is through MHRA regulatory inspection against the Council of Europe Good Practice Guidelines for Blood Establishments Required to Comply with Directive 2005/EC, which came into force on 15/02/2018. Prior to this, regulatory inspection was undertaken against the relevant sections of the MHRA Rules and Guidance for Pharmaceutical Manufacturers and Distributors (The Orange Guide), last published in 2017. WBS is audited by the Medicines and Healthcare products Regulatory Agency (MHRA) under a regular biennial schedule.

310. Assurance of the WBS compliance with its regulatory and professional standards is undertaken through the review by the WBS management arrangements as outlined in Section 1 and through the overarching VUNHST governance arrangements to the Trust Board via the Executive Management Board and Committee structure.

311. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises: Health Ministers in England, Wales, Scotland and Northern Ireland; the UK Health Departments; the UK Blood services; and the NHS more widely on the most appropriate ways to ensure the safety of blood for transfusion. The Committee provides independent advice from medical and scientific experts and patient representatives on risk management for Ministers, UK Health Departments, UK Blood and Transplant Services and the wider NHS to consider. Recommendations by SaBTO are considered by Welsh Government and implementation plans drawn up as appropriate. Much of the detailed evidence on which SaBTO deliberates is the result of work by Blood Services staff and the JPAC Standing Advisory Committee on Transfusion Transmitted Infections.

312. The terms of reference of SaBTO dated September 2014 (RLIT0000686) state that in formulating its advice, the Committee will:

- take into account sufficiency of supply, and the need to maintain adequate supplies of blood of appropriate quality;

- consider the efficacy of transfusion and consider the cost-effectiveness of interventions, including the introduction of new safety measures and/or the reduction, phasing out or withdrawal of current measures;
- interpret and where appropriate, commission risk assessments from a wide range of sources, including DH and Health Protection Agency Analysts, UK Blood Services, other advisory committees such as the Advisory Committee on Dangerous Pathogens, and independent researchers;
- take full account of scientific uncertainty and assumptions used in reaching conclusions, and clearly convey the nature and extent of such uncertainties with its advice;
- identify where research to reduce uncertainty is most urgently required, and where possible identify specific research needs;
- monitor and influence the EU Directives on blood to ensure that the guidance of the committee is consistent with the directives in conjunction with the relevant competent authorities;
- consider the potential impact of its advice on both donors and recipients.

313. JPAC prepares detailed service guidelines for the United Kingdom Blood Transfusion Services, and reports to the Medical Directors of the individual UK Services who are themselves individually accountable to the Chief Executives of the Services. Decisions on policy and implementation are vested in the individual Chief Executives and their Service boards and, where appropriate, their respective Health Departments. It is the responsibility of JPAC to ensure that all relevant aspects dealing with the safety of blood in the UK are covered, and that the professional advice emanating from JPAC is communicated in a timely fashion to the UKBTSs for further decision making if required. JPAC may commission expert independent advice if this is required.

314. The WBS has established, documented and implemented a Quality Management System (QMS) in line with BSQR, the Orange Guide and latterly the Good Practice Guidelines to demonstrate its ability to provide a consistent service that meets customer and applicable statutory and regulatory requirements, including processes for continual improvement and the prevention of non-conformity. The

QMS is based upon the "Plan-Do-Check-Act" methodology which can be applied to all processes. The robustness of the QMS is audited internally and externally by the MHRA on a regular basis.

315. There are other elements that protect the safety of the blood supply. The WBS ensures that the culture of the organisation is one where every member of staff understands that quality is core to every role, and that all issues, concerns, near misses or incidents are reported and learnt from. Our Research, Development and Innovation Strategy outlines our commitment to the development of the service; and our education plan, supports our staff development. The WBS is also part of a wider blood service community of practice that supports and promotes continuous improvement of their services and processes, as outlined in Section 3.

Changing responsibilities over time

316. Given the lengthy period of time being considered by the Inquiry and the evolution of healthcare and the approach to quality and safety it is inevitable that the approach to responsibility for safety, and the implementation of it, has evolved over time. It is difficult to give a complete picture of these changes given the time period involved and the issues faced by WBS in relation to historical documentation; however, with the help of colleagues and documentary evidence available, we have put together below an outline of some of the key events or evidence demonstrating how the legal and professional environment (in which NBTS (Wales) and WBS have operated) have developed.

317. These are set in the context of the history of the WBS [WITN6876031] and draws on the document Composition and Structure of Committees 1973-1990 (BPLL0004826). The latter demonstrates that within the management arrangements of the Blood Transfusion Centres and their engagement with government, a range of eminent experts were convened on a range of subjects to develop proposals and recommendations, which once agreed were implemented by RTCs. I understand that safety, sustainability and sufficiency of the blood supply underpinned this approach. For example I am aware that an *Advisory Group on Testing for the Presence of Australia (Hepatitis Associated) Antigen and its*

Antibody (the Maycock Group), originally set up in September 1970, was re-convened on 6 December 1973.

318. I understand that from 1948-1978 a Consultant Advisor to the DHSS on Blood Transfusion chaired ten meetings annually with RTC Directors; the Regional Transfusion Directors Committee was reconstituted in 1980. These meetings were the focal point for formal, professional discussions at RTC Director level on all matters relating to the UK blood transfusion service.

319. I have noted from a paper written by Dr Geoff Poole [WITN6876031] that there was a Standing Medical Advisory Committee that considered matters relating to blood transfusion until the establishment of the Central Committee of the NBTS (CCNBTS) in 1975, which I believe was replaced by the Central Advisory Committee in 1980 and understand these would have given policy direction to the Chair of the RTDs' meetings, but I have no archives available to me that would clarify the nature of these relationships.

320. I understand that the role of the UK Blood Transfusion Services (BTS) / National Institute for Biological Standards and Controls (NIBSC) Joint Liaison Group, formed in 1987, was to develop scientific guidelines and standards for the quality and safety of NBTS blood and plasma products through three working groups. The development of this arrangement, through JPAC and associated Standing Advisory Committees, has been subject to comprehensive review since 1998. To reflect this clarity of role, the name of Joint UKNBTS/NIBSC Executive Liaison Committee was changed to Joint UKBTS/NIBSC Professional Advisory Committee on 14 June 2001. In 2013 the name was again changed to JPAC to reflect the inclusion of the MHRA and HTA, and that only the four UK Blood Services contribute financially to JPAC.

321. The first edition of the UKBTS Guidelines was produced by JPAC and NIBSC in 1989.

322. I understand that the National Directorate of the NBTS was formed on 1st October 1988 to coordinate policy and the work of the regional transfusion centres (RTCs),

develop and oversee the implementation of a national plan for the supply of blood and blood products for hospitals and the Bio Products Laboratory (BPL) and to promote the most effective use of blood and blood products. The appointment of a National Director for England and Wales paralleled the earlier appointment of a National Director in Scotland. The first edition of the UKBTS (Red Book) [NHBT0000027_030] Guidelines stated: "The National Directors in England and Scotland are responsible for the implementation of national policies and co-ordination of the work of the RTCs. The Headquarters Unit for Scotland was established in 1974 and the National Directorate for England and Wales in 1988".

323. I have been advised that The National Directorate took a lead role in developing the Quality Assurance role of the Regional Transfusion Centres, under the leadership of Dr R. Moores, the Deputy Director of the English and Welsh National Directorate, and provided education and training for the newly appointed QA Managers. The Directorate also implemented a peer review audit system for the NBTS. I have also been advised that a system of National and Divisional QA meetings was set up by the National Directorate to enable sharing of best practice.

324. I understand that NBTS (Wales) adopted a focus on Quality Assurance, and notes from October 1989 [WITN6876061] outlining the role of the Quality Assurance Manager describe the responsibilities of the new role as:

- Developing and implementing a Quality Assurance policy for the Welsh Regional Blood Transfusion Service, by taking '*guidance from the Guide to Good Pharmaceutical Manufacturing Practice and from NIBSC/NBTS Guidelines for Blood Transfusion Services in the UK. The intention will be, in addition to upholding high standards with regard to safety and efficacy, to conform to requirements of the Medicines Act*
- Formation of close working relationships with senior staff across the organisation and with the Quality Department of BPL at Elstree and, where requested, to discuss matters of common interest with Hospital Transfusion Laboratories to secure a high level of quality assurance in all aspects of blood transfusion

- Management of dedicated quality control staff and to receive and approve quality control data from within the Welsh Regional Blood Transfusion Service
- Approval of all SOPS – the principles of SOP composition were approved by the Director
- Advising senior managerial staff with regard to implementation of QA objectives within their sections and assuring commonality of approach

325. These notes also identify three essential elements that are recognised for implementation of Quality Assurance: bringing the quality policy to the forefront of all staff's attention; having a staged implementation plan; and the introduction of quality audit.

326. WBS subsequently appointed its first Quality Assurance (QA) Manager in 1990, and the following extract from the Job Description published in January 1990 [WITN6876032] highlights the objectives of the post. The QA Manager was accountable to the Medical Director, and had responsibility for appropriate liaison with:

- Senior Management at the Blood Transfusion Centre
- BPL Quality Assurance staff
- Department of Health Medicines Control Agency
- Other departments of the Welsh Regional Transfusion Centre
- Other Regional Transfusion Centres about related professional matters

327. The post holder was expected to: be aware of current legislative position; keep abreast of modern development in QA principles and practices; advise the Director about formulation of a QA programme for the Blood Transfusion Service; provide leadership and assurance to ensure the quality assurance programme was implemented; and ensure that the quality and safety of blood and blood components met relevant legislative standards.

328. The NBTS (Wales) QA manager was the WBS representative on the National NBTS Quality Strategy Group, Chair of the National QA Managers Label Working Party, and Chair of the Western Division QA group. At this time, the NBTS (Wales)

was working towards compliance with the Guide *to Good Pharmaceutical Manufacturing Practice (Orange Guide) 3rd edition, 1983*, and the *Guidelines for the Blood Transfusion Service in the UK (Red Book) 1st edition, 1990 [NHSBT0000027_030],* and had applied to the Medicines Control Agency (MCA) for a Manufacturers 'Special Exemption' Licence and a Wholesale Dealers Licence. Both licences were granted.

329. In 1994 NBTS (Wales) became the 2nd UK transfusion centre to receive ISO9002 (BS5750) certification.

330. I have been advised that the advisory mechanism to the UK Government and the territorial health services and subsequently the Devolved Administrations, was the Committee for the Microbiological Safety of Blood and Tissues (MSBT) and Microbiological Safety of Blood, Tissues and Organs (MSBTO) was followed in 2008 by The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). The SaBTO Chair and Members are independently appointed by the Department of Health and its role is 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.

331. I understand that the implementation of the Blood Safety (and Quality) and Regulations (BSQR), UK Statutory Instrument 2005 No. 50 brought Blood Services and blood banks and transfusion services fully within the MHRA framework. The BSQR clarified the responsibility for the traceability of all blood components, and therefore of the patients who received them, and placed an obligation on clinicians, blood banks and the transfusion service to report serious adverse events formally to the MHRA.

332. The establishment by the UKBTSs SHOT scheme in 1996 created the UK's independent, professionally-led haemo-vigilance scheme. Since 1996 SHOT has been collecting and analysing anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that are involved in

the transfusion of blood and blood components in the United Kingdom, thereby contributing greatly to safety. Reports of adverse events can be made to the MHRA and SHOT through a single gateway.

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

333. WBS has responsibility for the safety of the supply chain from donor recruitment to supply to the hospital, and also has a role in the safe and effective use of blood through the work of the Blood Health Team and its predecessors. On delivery to the hospital, responsibility for the supply chain passes to the Local Health Board Blood Bank who are also required to comply with BSQR 2005 for their element of the supply chain.

334. As an NHS organisation, WBS quality and safety is reviewed and assured by the VUNHST Board through its governance structure and operates within the legislative requirements and standards set by the Welsh Government. The accountability to the MHRA is also a pathway through which WBS is accountable in the delivery of the quality and safety requirements set by government.

335. In terms of shared responsibility there is an interface between WBS and the Welsh Government in terms of policy in relation to the blood service and its development in which safety of the supply chain is core. Similarly with the WHSSC through which the blood service is commissioned on behalf of the health boards in Wales. Again in the service development proposals that are submitted, safety is always a core consideration.

336. WBS also has a leadership role in working collaboratively with hospitals in safe and effective transfusion practice. One example of this is the establishment of the Better Blood Transfusion (BBT) team in Wales, which was the result of the implementation of the Welsh Health Circular: WHC (2002) 137 (HSSG0000074). The WHC was part of a four-nation approach via the Chief Medical Officers to establish safe and effective transfusion practice throughout the UK, and aimed to

make blood transfusion safer, avoid unnecessary use and provide better information to patients and the public about blood transfusion. It saw the establishment of a Transfusion Practitioner network in Wales to champion and promote safe and effective transfusion practice.

337. In 2017 the Blood Health Plan (BHP) for Wales; WHC (28)2017 (HSSG0000017) was published. The BHP was led by WBS and developed with colleagues across the NHS in Wales to reflect the achievements of BBT and to set the next stage of objectives. A Blood Health National Oversight Group (BHNOG) was established to support its delivery and WBS work in collaboration with hospitals through the support of the Blood Health team.

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

338. As outlined in Section 4, WBS does not have transfusion centres.

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

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

339. The work of SaBTO and JPAC examines emerging or changing threats to the safety of blood transfusion, including the risks of infection. These organisations are described above. They produce recommendations for action in line with their terms of reference. JPAC produces extensive Guidelines for the UKBTSs as Change Notification process.

340. The work of the WBS is therefore (apart from contributing where required to the work of SaBTO or JPAC) to ensure that the policies in place are followed. This is assured throughout the WBS by, for example, adequate levels of professionally qualified staff, breadth of training in place for all staff, and high standards of equipment, test kits and monitoring systems. These areas, and many more, are

covered by the WBS's comprehensive Quality Management System (QMS), which is itself subject to audit by the MHRA. The QMS is based on the Red Book, Orange Guide and Council of Europe Good Practice Guidelines for Blood Establishments [WITN6876033] and includes the preparation of audited policies and procedure.

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

341. Donor selection and donor screening are essential measures at the beginning of the blood supply chain. WBS aligns its donor selection and testing (screening) procedures and processes with the JPAC guidance used by all four UK nations, and updates its procedures in line with any new guidance published. Our procedures and policies are also based on the guidance and requirements detailed in the Red Book, Orange Guide and CoE Good Practice Guidelines for Blood Establishments.

342. Donor selection starts with information and advice given to the public about blood donation and eligibility to be a donor. Before an appointment is booked, donors answer a question set to check whether they are eligible. They can also access advice from our Contact Centre. Immediately prior to donating, all donors complete a 'Self-Assessment Health History' (SAHH), which gathers information on the individual's medical history, travel history and lifestyle. Any declared history that does not comply with donor selection requirements or could put the donor's health, recipient health or staff safety at risk will be explored through further questioning of the donor, and clarified prior to accepting the donor for donation. In 2015 WBS introduced an electronic questionnaire which transfers data directly to the electronic donor record.

343. The WBS product specifications are based on those detailed in Chapter 7 of the Red Book *Specifications for Blood Components.* The WBS tests all donations for HIV, HTLV, syphilis, hepatitis B, hepatitis C and hepatitis E. Donors are advised that WBS tests every donation for the mandatory microbiology markers: HIV, hepatitis B, hepatitis C, Hepatitis E, syphilis and HTLV, and undertakes malaria

antibody screening on a discretionary basis, the need being indicated by the donor's travel history.

344. Where any donor blood sample gives repeat reactive (positive) screening results, samples are sent to the Microbiology Services Laboratory at NHSBT Colindale (reference laboratory) for confirmatory testing. Any components associated with this index donation are discarded.

345. The WBS Clinical team actions are defined within the WBS recall process, and any risk to patient or donor health is assessed and followed up appropriately. Any donor who has a microbiology positive result, confirmed by a reference laboratory, is contacted by telephone, advised of the result, and advised about appropriate follow up testing and treatment via referral to their GP or specialist clinic, as necessary. A follow up letter is sent to the donor summarising the telephonic discussion and confirming details of the clinic they should attend. The donor is also signposted to NHS websites for the relevant further information about their infection. If required, a lookback investigation is instigated on the donor's previous donations. Public Health Wales (PHW) and Public Health England (PHE) are also notified of any confirmatory positive test results.

346. In addition, all platelet components are monitored for bacterial growth for the duration of their shelf life (7 days). If bacterial growth is identified any affected components are recalled. Hospitals will return any component/products that have not been transfused and these will be subjected to further testing to establish the causative organism and any risk to donor or recipient health. WBS may undertake further investigations to determine whether the source of the organism is from the donor and could affect their health.

347. There are occasions when donors contact the WBS after donation to provide updated or additional information on their health. A process is in place for action in response to this information which is escalated if required to initiate product recall.

348. When a donor has a positive microbiology results the WBS recall procedure requires the Consultant in Donor Medicine to review the donor's record for past donations to assess whether a look-back investigation is required. If so, the Consultant Haematologists and Transfusion Laboratory Managers of the hospitals where the relevant blood components were issued and transfused are contacted, advising that all recipients are appropriately followed up.

349. When WBS receives information from a clinician or hospital about a patient that has seroconverted for one of the blood donation mandatory markers after receiving a blood component, a trace-back investigation is initiated. This will investigate all the donors who provided blood components for the index patient.

350. The WBS Blood Establishment Computer System (BECS) ensures full traceability of blood components from collection to the point of issue to a customer hospital. The system also records the donor's full donation history, allowing complete look-back and trace-back, where required.

c. Sharing information with relevant stakeholders about infected donations

351. Information on infected donations is shared where necessary and appropriate with a range of stakeholders. Internally, quality monitoring information is reviewed and discussed at Donor Clinical Governance, Patient Clinical Governance and Regulatory Assurance and Governance Group meetings.

352. In terms of immediate response to an infected or potentially infected donation, the WBS routine quality monitoring processes collate information on infected donations detected through routine screening and late donor information; this information is immediately shared with hospital blood banks via the WBS product recall process which ensures products are not used or that, if they have been transfused, appropriate patient follow up is arranged.

353. WBS reports any serious adverse blood reactions or events to MHRA via their SABRE reporting portal, as per regulatory requirements, and a full root cause analysis investigation will be undertaken whenever a potential risk to patient safety

has been introduced through a failure of the quality management system. WBS follows the SABRE reporting decision algorithm to determine the necessity to report. Appropriate incidents are also reported to SHOT.

354. The UK Quality and Regulatory Managers' Forum (which meets quarterly) also reviews a benchmarking scorecard that allows comparison of all four blood services' data on product recalls, bacteriological monitoring, serious adverse events of donation and SABRE reporting.

355. Information and learning from incidents and events would be shared in the consideration of the WBS JPAC standing advisory committees that manage TTI risk: Standing Advisory Committee on Care and Selection of Donors (SACCSD), Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) and Standing Advisory Committee on Transfusion Transmitted Infections – parasites (SACTTI – parasites).

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

356. The provision of information to the public starts with the intent to donate. Donors, patients, and the general public can access information about blood donation, risks associated with transfusion and transfusion transmitted infection via the WBS website.

357. The website contains links to a series of information leaflets (published by WBS) that describe the risks associated with blood donation and blood transfusion. Some leaflets contain links to additional information such as the Transfusion Guidelines, SHOT (for further information on the risks of transfusion) and information on variant CJD.

358. Information on infections that may affect the safety of blood supply is also shared when a member of the public contacts WBS to make an appointment to donate, at donor screening and then, where necessary, at post donation follow-up.

359. WBS shares information with the wider public on the safety of the blood supply by interacting with the other UK Blood Services, contributing to guideline development by the government Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and JPAC who then publish their guidance and donor selection guidelines on publically available websites. If there is a safety issue that needs to be immediately brought to the attention of the public, the Welsh Government will take the lead in public engagement and communication; however, WBS will support this activity. For example, the announcement of the introduction of HCV testing was led by the Welsh Office Chief Medical Officer in 1995 and supported by NBTS (Wales).

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

360. WBS maintains self-sufficiency through close monitoring of blood stocks against the clinical demand by established communications between the Collections, Manufacturing & Distribution and Business Intelligence teams, as well as the input from the WBS Blood Health Advisory Team, which is the link with the Hospital Transfusion Laboratories.

361. There is a daily Resilience and Demand Planning meeting which focuses on the status and assesses blood donation figures of the previous day. In this meeting, the collection plans for the upcoming days (up to a week) are also shared which gives the opportunity to identify any immediate challenges.

362. The Resilience and Demand Planning group is established to oversee the Governance and Performance of the Blood Supply Chain in WBS with the following remit:

- To ensure the blood supply chain will meet demand prudently in the next week and up to 16 weeks beyond;
- To provide assurance that the controllable risks to maintaining a prudent supply chain are being mitigated;
- To provide insight into the risks associated with maintaining a prudent supply chain;

- To identify and recommend interventions which would mitigate against future risks to maintaining a prudent supply chain;
- To monitor:
  - Performance vs planned
  - Supply vs demand
  - Issuing vs Forecast
  - Stock movement
  - Wastage
- To assess:
  - Root cause of any short stock position and or importation activity
  - Root cause of any major stock wastage
  - Risk mitigation interventions undertaken and their effect on the supply chain
  - Interventions recommended to mitigate against future risks to maintaining a prudent supply chain, including requests for Business Intelligence development activity

363. Where certain components are limited in availability and stock levels may not be sustained in a service, there is an ability to provide mutual support between the UK services via a Memorandum of Understanding.

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

364. The quality management system at Welsh Blood is a continuously evolving set of processes and procedures based on best practice as set out in the Council of Europe Good Practice Guidelines for Blood Establishments [WITN6876033]. These standards are regularly updated based on feedback from regulatory bodies across Europe. Compliance with these standards is evidenced by a robust program of internal audits and biennial inspections by the Medicines and Healthcare Products Regulatory Agency. Any regulatory inspection findings are rectified by means of action plans agreed with the inspectors. In addition, WBS testing laboratories are accredited by the UK Accreditation Service to international

standard ISO 15189; Medical laboratories - Requirements for quality and competence. Ongoing compliance is evidenced by annual UKAS audits and a full re-accreditation inspection conducted every four years.

365. No quality management system can realistically claim to be 100% effective in preventing incidents but, in compliance with best practice, The WBS follows a clearly defined process of prospective risk assessment in the design and validation of critical processes, as well as using retrospective learning from process deviations and incidents as a basis for process development and evolution. Learnings from incidents are shared across the UK blood services via the UK Quality Manager's forum to disseminate best practice as widely as possible, and where appropriate are shared with the MHRA via the Serious Adverse Blood Reactions and Events (SABRE) and SHOT schemes.

366. The culture of the organisation is also essential in ensuring that staff report incidents, near misses and deviations, and that we respond to them and learn from them. In each of the MHRA inspection report sessions that I have attended since joining WBS, the Lead Inspector has made a comment on the active engagement of the WBS staff and their willingness to share and to discuss areas of practice. I feel that this indicates that we have the right culture.

367. I understand that the UKBTSs have made significant progress since BSQR came into force in 2005 and have benefitted from the application of Pharmaceutical manufacturing principles, consistent Good Manufacturing Practice, Good Distribution Practice and Good Automated Manufacturing Practice approaches. The involvement of multiple regulators and accreditation bodies with blood establishments (MHRA, HTA, UKAS etc.) has required them to develop and maintain robust quality management systems which encompass proactive risk assessments, risk-based process design and validation, documentation, record keeping (with data integrity a key focus) as well as the process for recording, managing and demonstrating learning from deviations and incidents. The WBS continues to participate in the blood services community of practice in the UK and through the European Blood Alliance, which helps disseminate key learnings across all blood establishments.

368. The functions, policies and practices of NBTS (Wales) and WBS have inevitably evolved significantly throughout the period from 1946 to 2021 in response to, for example, changing technology and emerging infections. Several steps in this evolutionary process have been described in response to question 41 above.

Section 10: Identifying risks associated with blood and blood products

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

369. WBS takes a collaborative approach to the professional development of staff, recognising their own professional obligation for competence in their role as well as WBS as an organisation to support that. WBS also actively encourages and supports the attainment of professional qualifications relevant to staff roles. Staff attendance at relevant scientific and educational meetings and conferences is funded via the WBS Education and Training Panel (ETP), thereby giving all staff equitable opportunity to attend conferences and courses and access information on the latest medical and scientific developments and research from across the world. ETP also supports the funding of three post-graduate MSc courses each year.

370. WBS also supports Higher Specialist Scientist Training; this is a five-year workplace-based training programme for Clinical Scientists to train to become a Consultant Clinical Scientist. The training programme includes research, education and practice requirements. Higher Specialist Scientist Trainees are experienced scientists.

371. Access to relevant education and training opportunities is planned and coordinated to effectively meet the professional development needs of staff; such needs may be identified by the individual or their manager and are formally recorded through

an individual's Professional Development and Appraisal Review (PADR). There is also a structured Laboratory Education & Training Programme. In addition, scientific and clinical staff are required to complete Continuing Professional Development (CPD) activities as part of their professional registration with the relevant professional body, such as the Health and Care Professions Council (HCPC), the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC). Such organisations set standards for the education, training, and practice of its members.

372. It is the responsibility of individual staff members to maintain their registration, complete the required revalidation and CPD activity, provide proof of (continued) registration and inform their line manager should their registration lapse. WBS can also check any member's registration status via the live registers available on the internet.

373. CPD activities include staff participation in national and international conferences including, but not limited to:

- British Blood Transfusion Society (BBTS)
- International Society for Blood Transfusion (ISBT)
- Serious Hazards of Transfusion (SHOT)
- Institute of Biomedical Science Congress (IBMS)
- Blood Group Serology (BGS) Transfusion
- UK National External Quality Assessment Scheme (NEQAS)
- Network for the Advancement of Patient Blood Management, Haemostasis and Thrombosis

374. Staff who access funding from ETP are required to provide formal feedback to colleagues about the event they attended and what they have learned; this can be by a variety of means including internal departmental meetings and formal presentations.

375. In addition, some WBS staff actively participate in research and development activity across the themes in our RD&I strategy. These include - blood products, donor care and public health, therapies and transplantation. Projects are

undertaken collaboratively with academic institutions, UK and non-UK healthcare providers, commercial bodies and other bodies such as the BEST (Biomedical Excellence for Safer Transfusion) collaborative and the European Blood Alliance (EBA).

376. RD&I activity is shared with WBS staff and the wider scientific community via a series of Show & Tell events.

Changes over time

377. I understand that WBS has always strived to provide considerable opportunities for personal and professional development, which can be evidenced by a number of staff who commenced their employment with WBS as junior trainees and now hold management and senior management positions within the organisation. The approach to staff scientific training and education has become more formal in the last ten years, with the development of a scientific education strategy and the appointment of a Laboratory Training Manager since 2003.

378. I understand that historically, training budgets were held within individual departments, but this was devolved to a central fund in 2015 (managed via the ETP) to ensure alignment with the organisational need as well as that of individuals. It also enabled monitoring of access of funding by departments and helped to ensure we develop a learning organisation.

379. Within the memory of existing staff, State Registration for Biomedical Scientists has been a requirement since at least the early 1980s, firstly with the Council for Professions Supplementary to Medicine (CPSM) and then the Health Professions Council (HPC), now the Health & Care Professions Council (HCPC).

380. The requirements for doctors and nurses are determined by the General Medical Council and Nursing and Midwifery Council and have also developed over time. Both organisations provide historic profiles of their developments.

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

381. WBS operates within the relevant UK regulatory and professional advisory frameworks/structure (as outlined elsewhere in this statement) and a community of best practice.

382. UK regulations and guidance are based on EU and, where applicable, global regulations/professional advice.

383. WBS follows the Transfusion Transmitted Infections (TTI) risk reduction strategies as identified and defined by the Blood Safety and Quality Regulations (BSQR) 2005, the government Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and JPAC Transfusion Guidelines (as defined in the Guidelines for Blood Transfusion Services in the UK, 8th Edition).

384. WBS Consultants discuss queries about the optimal management of difficult cases with fellow professionals at NHSBT/PHE/PHW who have more experience in this area to ensure WBS practice is aligned with theirs.

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

385. The WBS quality system incorporates a range of internal advisory and decision-making structures.

386. Overarching these is the Regulatory Assurance Group (RAG) which in turn reports to the WBS Senior Management Team and provides onward assurance to the Trust via its committees to the Trust Board.

387. Working to the RAG are the Quality Review Group, Donor Governance and Patient Governance Groups, who examine the detail of our data and performance or external incoming information or guidance and make recommendations to RAG

which are then implemented. Implementation is overseen by the WBS Donor Governance and Patient Governance Groups who provide assurance that relevant information is reviewed and acted upon.

388. Where changes require access to resources, a proposal will be submitted to the Business Planning Group which looks at resource and capacity to deliver change and reviews prioritisation if required.

389. In addition to these structures, on a day-to-day basis the WBS operational systems and processes deliver risk-based interventions to reduce the likelihood of transfusion transmitted infection. Where necessary any potential risks identified through routine microbiology and bacteriological screening, or via information received from donors post-donation, will be escalated to the relevant subject matter expert for decision and action if required. If necessary, product recalls are sanctioned by a Consultant, Specialist Nurse or the Responsible Person (as named on the Blood Establishment Authorisation (BEA) License).

390. All reference laboratory microbiology results are to be reviewed by a Medical Consultant. The risks to the donor and the risks to the safety of the blood supply are assessed and appropriate actions are taken for both the donor and the safety of the blood supply if investigation shows a lookback investigation is indicated.

391. There is a weekly clinical discussion forum where any queries about how best to manage a donor's microbiology results can be discussed further with fellow members of the clinical team to ensure an approach is taken that is agreeable to all members of the clinical team.

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

392. The answer to this question assumes that 'enquiries and investigations' refers to the proactive interventions WBS makes to ensure the safety of the blood supply. These include:

- Stringent donor selection processes via pre-donation screening questions at the time an appointment is made and completion of a donor self-assessment health history (SAHH) questionnaire, with referral to a registered nurse for further assessment where the donor's answers to a question(s) indicate a level of risk
- Bacteriological monitoring of all platelet donations
- Routine microbiology screening, including testing of selected donors to determine cytomegalovirus serological status and additional screening of donors who have visited susceptible malarial areas
- Repeat in-house testing of first screen positive microbiology results
- Referral of repeat reactive samples to a national reference laboratory for confirmatory testing
- Review of national reference laboratory results by a consultant in transfusion medicine
- Instigation of a product recall, donor look back and/or patient trace back
- Root cause analysis investigation of SABRE reportable incidents (whereby a patient may have been put at risk)

393. WBS will inform and arrange for the appropriate onward referral to investigate further any donor with positive microbiology results. The WBS Donor Consultant then reviews the donor's record for past donations to assess whether a lookback investigation is indicated. If so, the Consultant Haematologists and Transfusion Laboratory Managers of the hospitals where the relevant blood components were issued and given to patients are written to, advising that any recipients are appropriately followed up.

394. When WBS receives information from a clinician or hospital about a patient that has seroconverted for one of the blood donation mandatory markers after receiving a blood component, a Trace back investigation is initiated.

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 WBS:

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

395. From the review of the documents in our archive that have been identified to date, I believe that the action that would have been taken by NBTS (Wales) would have been in the context of and determined by the policy, advice and guidance provided by the Government (for Wales via the Welsh Office), through the collaborative discussions of the Regional Transfusion Directors, the National Directorate or the different advisory committees which considered the information on these infections and the resultant risks.

396. The history of these committees and groups are outlined in sections 1 and 3. It was the responsibility of the NBTA (Wales) to implement these guidelines.

397. The principal actions that the UK blood transfusion services have taken to reduce the risk of transfusion-transmitted infection (TTI) are appropriate blood donor selection, and testing for infectious agents. In addition, the processes and procedures that the service employs need to ensure that all steps (including but not limited to donor selection and testing) from blood collection through to blood component issue meet the required quality standards. In specific areas, the blood transfusion service may also have a role in supporting information for patients.

Donor selection

398. During the period before the HIV test became available, donor selection procedures were clearly important and I understand that they would have been expected to change as knowledge of transmissibility improved. A review of our archives of meetings of the SGHA (to which NBTS (Wales) reported at the time) indicates in the Welsh Regional Blood Service (NBTS (Wales)) Report for 1984 that donor selection procedures had been "reconsidered...in an attempt to discourage and exclude 'high risk' donors" [WITN6876034].

399. This change in donor selection procedures at NBTS (Wales) was confirmed in the minutes of the November 1984 SGHA meeting that "In terms of precautions, the blood service had already redesigned its procedures to discourage unsuitable

donors [WITN6876035], and the Welsh office had indicated that the transfusion service was not suspect."

400. In the November 1984 meeting minutes [WITN6876036] it was noted under matters arising that notes on the infection instructions given to donors and a draft health education leaflet had been circulated. I have not yet been able to identify the January 1985 minutes to explore this further. In the Welsh Regional Blood Transfusion Service (NBTS (Wales) report for 1984 [WITN6867060] the revision of donor screening (selection) is again highlighted along with a note that anticipates the impact of testing.

401. In March 1985 again the SGHA minutes [WITN6867064] identify discussions with Dr Napier that a revised donor questionnaire had been devised for all donors to complete.

402. The reporting of these developments in Wales aligns with an article by Contreras *et al.* (British Medical Journal (1985), 290, 749-750) (NHBT0000030_013) indicated that the DHSS had written a leaflet for the NBTS for distribution at blood donor sessions, advising that male homosexuals should not donate blood.

403. In our archives we have found a copy of an NBTS (Wales) donor selection protocol dated "1984 to 1990" [WITN6876037]. A disqualification from donating, relevant to HIV was: "male homosexuals; drug abusers, partners of the above, haemophiliacs who have received FVIII and their consorts"; and haemophilia carriers who have "received coagulation factor concentrates" [WITN6876038]. A separate document, also of uncertain date, adds another disqualification from donating for prospective donors who have had "sex with African men or women living in Africa at any time since 1978". [WITN6876039] (Note that this may not necessarily mean that this is a later addition to the selection guidelines). An NBTS questionnaire for donors dated 3/8/87 confirms these selection procedures [WITN6876040]. A collection of leaflets for donors, written in English and Welsh and concerning AIDS, has been found in our archives [WITN6876041], as has an undated questionnaire that was given to donors before being accepted for donation [WITN6876042]. These leaflets appear to have been updated in January 1993 where new guidance for donors

regarding AIDS was introduced. There is accompanying documentation about the rationale for the changes [WITN6876043].

404. As from 1989, the UKBTSs began to follow the newly produced JPAC / NIBSC Guidelines for the Blood Transfusion Services and, at the time of writing, are in their 8th Edition. Numerous updates have been made to the website version and issued as change notifications. All chapters have been reviewed in preparation for this latest edition, revised where appropriate, and in addition some chapters have been removed and one added. The Guidelines for the Blood Transfusion Services and the associated Donor Selection Guidelines remain perhaps the single most important reference for the UKBTSs.

405. We have found in our archives entire copies of the first edition of the UKBTS Guidelines and of the second edition, produced in 1993. The 1989 and subsequent edition of the Guidelines require quality audits to be undertaken [WITN6876044]. This would have been overseen by the Quality Manager post established in NBTS (Wales) at that time, although we have not been able to identify audit records in the search of our archive to date.

406. The 1989 Guidelines contain an entire section [WITN6876045] on the selection of donors, including a list of situations in which the potential donor would be temporarily deferred or permanently excluded. There were also the following general requirements relating to HIV [WITN6876046]:

- All potential donors must be provided with information on AIDS
- Donors must be asked to read the notices so that consent for the test is obtained
- Potential donors who are blind, partially sighted or illiterate should be informed of the contents of the literature

407. Because the HCV virus was not discovered until the year of publication, there was no mention of HCV in this first edition. We can find no archives that relate to the selection of donors between this date and the second edition, although it is possible that amendments were produced nationally.

408. The second edition of the UKBTS Guidelines was written between 1989 and 1992, and published in 1993. Regarding HIV, there is a specific mention of a DH leaflet [WITN6876047] for self-exclusion of persons at risk of HIV infection. By this time, routine anti-HCV testing of UK blood donors had been introduced.

409. I understand that prior to HCV testing, donor selection excluded people who had jaundice or hepatitis.

Testing donations for potentially infectious agents

HIV

410. It is my understanding that a screening test for HIV (or HTLVIII as it was known at the time) was introduced by the UKBTSs in October 1985. A report of the October 1985 meeting of the SGHA noted under point 861.4 that some additional funding for HIV testing, and a report reviewing the 1985-86 year confirmed that the test had been introduced at NBTS (Wales), the testing laboratory having been "planned, funded and made operational in a matter of months" [WITN6876048]. The Blood Service report to a meeting of the SGHA one year later recorded that there had been one donation that tested HIV positive in 100,000 donations tested [WITN6876049].

HCV

411. To date we have not been able to identify records in our archive relating to the events leading up to a screening test for HCV in NBTS (Wales), although records that we have identified relating to the HCV Look back exercise identify that testing started in 1991.

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

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

412. The role of NBTS (Wales) in identifying patients who may have been infected through treatment with infected blood or blood products has been provided for HCV

in the response to the Rule 9(2) Request dated [01.03.2021] relating specifically to the look back exercise, in particular paragraphs [21, 24 , 25, 52,53 and 54].

413. In summary, NBTS (Wales) participated in the UK wide 'look-back' exercise, which I believe was formulated following advice to the Department of Health and the three other territorial Health Departments by the Advisory Committee for the Microbiological Safety of Blood and Tissues (MSBT). In doing so it followed the protocol issued by the working party under direction of the Welsh Office.

414. The 1995 look-back exercise was designed to identify blood donors who tested anti-HCV+ and then identify patients who had previously received blood components donated by these donors before testing was introduced.

415. Further, as a tertiary service provider, the NBTS (Wales) did not provide direct ongoing clinical patient care or have access to patient details. It would have been unable to implement anything without the agreement of government and the participation of the Trusts and Health Authorities. We have not located any documents in the WBS archive that relate to any steps that may have been taken by the Welsh Office or Welsh hospitals in this regard.

416. For patients who may have been infected with HIV, with the implementation of testing in 1985 (all RTDs had implemented by 14th October) (DHSC0002365_002), I understand that there was a look-back exercise that took place alongside the testing implementation, although the search of our archives to date have not yet identified any record of the implementation or look back in NBTS (Wales). Documents considered by the Penrose Inquiry (PRSE0000623) and released to this Inquiry (DHSC0002365_002 and CBLA0002212) illustrate that the look-back exercise was taken at the introduction of testing with aligned information provided.

417. We have a record of the information relating to the donor testing and patient identification that I understand was compiled by a recent WBS Medical Director in 2018. The source of the data used in this report is however unclear and we have been unable to validate it by reference to any historic records.

418. This shows summary figures for both HCV and HIV and was based on data available in 2018 [WITN6876050].

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

Advice to patients

419. The search of our archives has identified that NBTS (Wales) produced a leaflet in May 1987 for patients concerned about blood transfusion. The leaflet [WITN6876051] describes the risk of infection from HIV, and discusses the safety and practical issues related to autologous transfusion and conventional heterologous transfusion. This leaflet was made available to consultant haematologists in South Wales for use at their discretion.

420. More generally, a letter dated December 1986 shows that the Welsh Office was clearly involved in advising medical staff in Wales about AIDS, both as regards to the public education campaign, and to inform doctors about advice that may be offered to those who think that they were at risk [WITN6876052]. There is also reference in the letter to the misconception in the minds of sections of the public that there is a possible risk of acquiring AIDS from blood transfusion, and the need to reassure donors. A letter from the DHSS, which I understand is dated 6 January 1987 [WITN6876053], gives support to the approach taken by the NBTS.

421. For HCV, from our archives, to date we have only been able to identify records that relate to discussions on HCV from circa 1995 and the look-back exercise. I understand from the documents identified that NBTS (Wales) provided hospitals with support to identify and that there was a plan to counsel the patients identified as recipients of infected blood components.

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

422. As a tertiary service provider NBTS (Wales) role was not directly "patient facing" and did not provide direct ongoing clinical patient care. Responsibility for delivery of direct clinical patient care lay with NHS Health Authorities and Trusts. However our archives contain correspondence between Dr Hutton at NBTS (Wales) and a Consultant Gastroenterologist at the University Hospital of Wales dated 10th August 1995 [WITN6876054] seeking preliminary information on the likely number of patients that would be identified through the look-back exercise by Health Authority to enable their bid for funding for treatment of these patients. It also includes a response from Dr Hutton providing this detail [WITN6876055].

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?

423. It is my understanding that the support for patients infected through blood products has been provided through a number of mechanisms including the schemes raised in Section 12, which are being considered as part of this inquiry .The current VUNHST role in delivery of the Wales Infected Blood Support Scheme (WIBSS) is included also in Section 12.

424. In terms of the patient facing role of the NBTS (Wales), I understand that this was limited to the look-back exercises and active participation in the identification of patients for onward referral to counselling as required as part of those exercises. This was then followed by onward referral to specialist care.

425. In terms of donors, the NBTS (Wales) procedure and the WBS procedure for those that have a positive microbiological test includes initial supportive discussion with that donor.

51. Do you consider that the decisions and actions of WBS 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.

426. I am not able to respond to this question as I do not have sufficient personal expertise nor access to it within the WBS. Nor do we have access to the complete information on which such an assessment could be made.

52. Did WBS 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?

427. As outlined in our previous statement in response to the Rule 9(2) Request dated [1st March 2021] relating specifically to the look back exercise, in question 10c, searches of our archives have identified documents that relate to the provision of funding by the Welsh Office for the 1995 look-back exercise [WITN6876077] and [WITN6876078] . I have not identified documents relating to funding of a look-back exercise prior to this date or local discussions on Look-back.

428. In terms of HIV testing, search of our archives to date have not identified any documents relating to funding. However the archive of the SGHA includes minutes of the meeting in October 1985 in which the provision of funding for HIV testing of donors by the Welsh Office was noted [WITN6876056]. I believe this included the look-back to identify patients.

429. Treatment of patients was the responsibility of Health Authorities and the contribution made to this by NBTS (Wales) is provided in Question 50 (c).

Section 12: Financial support

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

430. It is my understanding that the WBS did not have any involvement with the different trusts or funds that were set up to provide financial support to people who had been infected through infected blood products.

431. From a review of our archives, the WBS were sent a letter by the Welsh Government Chief Medical Officer on 1st July 2004 announcing the Skipton Fund and seeking support in drawing attention of staff to the scheme to enable support to be provided for applicants in completing forms. A memo to the Velindre Chief Executive from the WBS Director on July 15th 2004 [WITN6876057] notes that the WBS involvement is limited to potential undertaking of look back for HCV. A request on 27th August from Welsh Government [WITN6876058] to display an information leaflet relating to the Skipton fund was actioned in September 2004 [WITN6876059].

432. Currently, VUNHST has a role in the delivery of the Wales Infected Blood Support Scheme (WIBSS). I understand that further details in this regard have been provided by my colleague Alison Ramsey.

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

433. It is my understanding that the WBS did not have any involvement in informing patients about the different trusts or funds other than in promoting the Skipton scheme as outlined in question 53, paragraph [431].

434. Currently VUNHST has a role in promoting the current WIBSS scheme to patients and this is outlined in the evidence of my colleague Alison Ramsey.

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

435. It is my understanding that the WBS did not have any policies or guidance for staff in relation to referring patients to the different trusts or funds and that its role was in highlighting the scheme as outlined in question 53.

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

436. From the search of our archives to date, we have not been able to identify any information that indicates any provision of information, however the memo dated 15th July 2004 from the Director at WBS to the Velindre Chief Executive identifies that the WBS role would be in undertaking any look back [WITN6876057]. Information on the look back (and Trace back) is included above.

437. The WBS staff have no role in relation to current schemes although, VUNHST has a role in the delivery of the WIBSS as outlined above and in the evidence from Alison Ramsey.

57. Did WBS 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 WBS 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.

438. It is my understanding that WBS did not get involved in determining or advising whether a particular patient met the eligibility criteria for support from the legacy trusts or funds other than to provide information from any look back exercise. WBS have no direct involvement in WIBSS, which is managed and delivered by colleagues in NWSSP and the Cancer Centre.

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?

439. I do not have sufficient understanding or knowledge of the legacy trusts and funds to be able to answer this question.

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

440. In our work in preparation of the responses to the two Rule 9 Requests (or otherwise) I do not believe that there are any other issues which should be brought to the Inquiry's attention, however we are continuing to review information in our archive and will notify the Inquiry if we reveal anything we believe to be of relevance. We shall continue to monitor the position as the Inquiry continues.

Statement of Truth

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

Signed GRO-C

Dated 25th October 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
03.08.2018	A brief history of the establishment and management of the Welsh Blood Service	WITN6876002
20.05.2020	Organisational chart WBS	WITN6876003
09.01.2014	Terms of reference for the Advisory Committee on the Safety of Blood, Tissue and Organs	RLIT0000686
19.11.1979	Letter from J A F Napier of the Welsh Regional Transfusion Service to Mr R J Williams of the Welsh Medical Committee, entitled Future Planning of the Blood Transfusion Service.	BMAL0000023
1979	The health services in South Glamorgan during 1979	WITN6876004
1984	SGHA minutes	WITN6876005
06.09.1981	Letter from JAF Napier to Mr R Cory re: staff cuts to the Welsh Regional Transfusion Service and the impact on self sufficiency	DHSC0000796
	Staffing and Finance of the Welsh Regional Transfusion Centre	DHSC0000797
	SGHA request for funding	WITN6876006

13.07.1991	Letter from S Godfrey to DG Thomas re: Cardiff blood transfusion centre.	DHSC0000799
1983	Update on funding	WITN6876007
	List of staff	WITN6876008
19.12.2017	Records management policy	WITN6876009
28.08.2019	Management procedure for records management	WITN6876010
	Staffing and finance of the Welsh Regional Transfusion Centre	RLIT0001474
2021	Records Management Code of Practice	WITN6876011
	Records Management, NHS Code of Practice Part 2	WITN6876062
	Records Management, NHS Code of Practice, Part 1	WITN6876063
2000	For the record - managing records in NHS trusts and health authorities	WITN6876065
06.09.2019	United Kingdom Blood Transfusion Services Constitution	WITN6876012
2015	Amendment to the Articles of Association European Blood Alliance	WITN6876013
	Remits of the JPAC Standing Advisory Committees	RLIT0000687

	Memorandum of Understanding	WITN6876014
	Memorandum of Understanding	WITN6876015
2019	Monitoring of blood safety	RLIT0000688
03.04.1995	Letter from Dr Napier to Dr Hewitt	WITN6876016
12.07.2005	For the record - managing records in NHS trusts and health authorities	HSSG0000065
2018	The Velindre National Health Service Trust (Establishment) (Amendment) Order 2018	WITN6877017
	BPL Blood Relations	WITN6877018
28.09.2017	NHS Wales Blood Health Plan	HSSG0000017
13.02.1998	Reply to BPL Audit	WITN6876019
14.05.1998	BPL correspondence: plasma supply and vCJD	WITN6876020
28.05.1998	BPL correspondence: conversion to non-UK plasma	WITN6876021
07.08.1998	BPL correspondence: distribution of finished goods	WITN6876022
13.08.1998	BPL correspondence: distribution of finished goods	WITN6876023
16.09.1998	BPL correspondence: Meeting	WITN6876024

	arrangement	
20.10.1998	BPL correspondence: Confirmation of NAT testing	WITN6876025
09.04.1998	Letter from D. W. Evans to B. Savery, National Blood Authority, re: plasma sales 1998/99	DHSC0004383_020
09.09.2020	Written statement of Dr Saad Al-Ismail	WITN3761005
2019	Standards of behaviour policy	WITN6876026
1980	Report on the Health Services in South Glamorgan	GLAR0000054
1983	SGHA accommodation problems	WITN6876027
2018	WBS Business Continuity Plan	WITN6876028
2017	Welsh blood supply chain	WITN6876029
18.12.1998	Letter from Dr. Mike McGovern	NHBT0017355
2002	Better blood transfusion guidance	HSSG0000074
2007	Sustainable development toolkit	WITN6876030
12.02.2017	The Welsh Blood Service – 70 years of continuous change article	WITN6876031

	Composition and Structure of Committees - 1973-1990	BPLL0004826
01.09.1989	Guidelines for the Blood Transfusion Services in the United Kingdom 1989	NHBT0000027_030
	Quality Assurance Manager Notes	WITN6876061
1990	Quality Assurance Manager Job Description	WITN6876032
2002	Better blood transfusion Circular WHC	HSSG0000074
2005	Guidelines for blood establishments	WITN6876033
1984	SGHA report	WITN6876034
1984	SGHA minutes	WITN6876035
1984	SGHA minutes	WITN6876036
1984	NBTSW report	WITN6876060
20.02.1985	SGHA minutes	WITN6876064
09.03.1985	Blood donors at high risk of transmitting the acquired immune deficiency syndrome	NHBT0000030_013
	Disqualification list	WITN6876037
	Disqualification list	WITN6876038

	Disqualification list	WITN6876039
1987	Donor questionnaire	WITN6876040
1987	AIDS leaflet	WITN6876041
	Donor questionnaire	WITN6876042
1983	AIDS leaflet	WITN6876043
	Red book quality audits	WITN6876044
	Red book donor selection guide	WITN6876045
	Red book HIV requirements	WITN6876046
	DOH leaflet	WITN6876047
1986	SGHA report	WITN6876048
1986	SGHA report	WITN6876049
09.10.1985	Minutes of the 197th Regional Transfusion Director's Meeting at Elstree	DHSC0002365_002
	Dr John Gillon - Witness Statement in relation to HIV Lookback	PRSE0000623
10.07/1985	Minutes of the 196th meeting of Regional Transfusion Directors	CBLA0002212
30.09.1985	HCV HIV lookback	WITN6876050
1987	Leaflet on blood transfusion concerns	WITN6876051
09.12.1986	Welsh Office advice on AIDS	WITN6876052
06.01.1987	DHSS letter	WITN6876053

10.08.1996	Letter from AB Hawthorne to Dr Hutton	WITN6876054
18.08.1995	Letter from Dr Hutton to Dr Hawthorne	WITN6876055
1985	SGHA report	WITN6876056
08.07.2004	Update on Skipton Fund request	WITN6876057
27.08.2004	Update on Skipton Fund request	WITN6876058
21.09.2004	Memo to display poster	WITN6876059