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Velindre University
NHS Trust



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Witness name: Mr Steve Ham
Statement No: WITN0719001

Exhibits: WITN0719002 –
WITN0719013

Dated 19th November 2018

THE INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF STEVE HAM, CHIEF EXECUTIVE, VELINDRE UNIVERSITY NHS TRUST

I, Mr Steve Ham, of Velindre University NHS Trust, 2 Charnwood Court, Heol Billingsley, Cardiff CF15 7QZ will say as follows :-

1. I am the Chief Executive of Velindre University NHS Trust (The Trust) . I have held this position since the 16th December 2015. Prior to that I was the Interim Executive Director of Finance from the 26th October 2009 to 30th September 2010, Executive Director of Finance from the 1st October 2010 until the 4th January 2015 and Interim Chief Executive from the 5th January 2015.
2. I make this statement in response to the formal request received by the Trust on the 23rd August 2018 under Rule 9(1), 9(2) and 9(4) of the Inquiry Rules 2006.



3. Velindre University NHS Trust is a statutory body within NHS Wales and under its governance arrangements the Welsh Blood Service (WBS) is termed an operational division. The Trust has been making every endeavor to pull together the range of information to support the work of the Inquiry, and is fully committed to supporting an open and transparent approach. As a Trust we will continue to work with other key stakeholder organisations in Wales and yourselves as the Inquiry progresses to ensure that all information that we believe has potential relevance to the work of the Inquiry is disclosed.
4. Please be assured that I have also taken all reasonable steps to ensure that documents and information, however held or controlled by the Trust, is preserved and not destroyed while the Inquiry is on-going.

Our approach and the identification of relevant evidence

5. The Inquiry has requested a range of information from the Welsh Blood Service but has also requested that we provide information from predecessor organisations, the functions or responsibilities of which have been transferred to the Welsh Blood Service, Velindre University NHS Trust.
6. As this request spans a wide timeframe and a number of predecessor organisations, the approach taken has been to outline the history of the blood service in Wales, primarily based on an article recently prepared by Dr G D Poole to mark 70 years of the service and to build on this through internet searches for material, a systematic search of Welsh Blood Service archive material and searches of the National Archive UK at Kew, the Glamorgan Archives in Cardiff and the National Library of Wales.
7. A summary of the historic arrangements for the organisations which previously oversaw the functions and responsibilities that have now passed to Velindre University NHS Trust through to the Welsh Blood Service is provided [**Exhibit WITN0719002**] *History of the Welsh Blood Service*.
8. The WBS team has reviewed the following source documents to facilitate this:
 - The Welsh Blood Service 70 Years of Continuous Change, G.D. Poole Transfusion Medicine, Review Article 3/11/2016;
 - <http://www.wales.nhs.uk/nhswalesaboutus/historycontext>: History of the NHS in Wales;
 - 50 years of the National Health Service in Wales 1948 to 1998. Delme Griffiths and Welsh Health Estates;

- Legislation.gov.uk: The Welsh Health Common Services Authority Regulations 1990; The Welsh Health Common Services Authority (Abolition) Order 1999;
- Wikipedia pages for “District Health Authority”, for “Area Health Authority” and “List of district health authorities in England and Wales”;
- Information on the area health authorities and district health authorities in Wales around 1974 to 1982: Reflections on 22 years in the NHS by Terry and Monica Dennis of Healthcare Alliances November 2009, updated 2011;

9. The following activities have been undertaken to date:

- Meeting on 30th August 2018 to scope the Terms of Reference and to consider areas where searches will need to be undertaken;
- Review of all paper records held at an off-site storage facility in Swansea, (owned by Transmedia Technology Ltd), to determine whether any records are held at this facility;
- Visit to the Welsh Blood Service Dafen site in Llanelli, Bangor and Wrexham to check if any paper records were being held on site;
- Review of records at the Talbot Green Headquarters held in the archiving room and archive storage CDs;
- Department by department review of all records held within offices across the organisation that exist outside of the archive at our Talbot Green premises;
- Review of all paper, electronic records and databases held by the organisation to determine archiving arrangements for the Welsh Blood Service;
- Discussions with previous staff and retired colleagues;
- Discussions with NHS Wales colleagues to identify and discount that any WBS material is included in the NHS Mamhillad store.
- Review of the National Archives at Kew [**Exhibit WITN0719003**] *Summary of file located at the National Archives, Kew List A (relevant to Wales).*, [**WITN07109004**] *Summary of files located at the National Archives, Kew List B (relevant to blood transfusion services in general).* Review of the Glamorgan Archives at Cardiff [**Exhibit WITN0719005**]. *Summary of the files located at the Glamorgan Archives.*
- Review of the National Library of Wales.

10. The Inquiry should be re-assured that the Trust has committed significant resources to respond as comprehensively as possible. This statement includes the information that we have at this current time. We have been in contact with the Inquiry team to arrange for you to visit and assist us further with additional searches required to support the work of the Inquiry.

11. I will now address each of the issues and matters you requested, taking each point in turn.

1. Welsh Blood Service archiving system

12. The Welsh Blood Service has a commercial contract in place with Transmedia Technology Ltd for its paper archiving service. This contract has been in place from 2004 to the present. Prior to this, we believe the Welsh Blood Service held a contract with Advanced Group from 1998 to 2004. Prior to 1998, it is not known if a contract was in place and searches undertaken have not found any record of an archive contract or system for this period.

Internal Archiving

13. The Welsh Blood Service archiving system for paper records is controlled by a Standard Operating Procedure (*Welsh Blood Service SOP: 015/FAC - Retrieval of Information*) [Exhibit: WITN0719006] under the management of the Welsh Blood Service Facilities Department. The SOP has been in place since 20/08/2003; last updated 25/02/2015. The following is a brief summary of the process:

- Papers for archive are placed into a numbered archive box;
- A standard form is completed by the department concerned, giving details of the contents of the box;
- The boxes are sent to an external organisation (Transmedia Technology Ltd);
- The paper records are scanned onto Compact Discs (CDs). The CDs containing document images are then returned to the Welsh Blood Service at its main headquarters in Talbot Green and subsequently stored inside locked cabinets in the onsite archive room. There is a basic access database giving general information on the contents of the CDs based on high level subject areas. Specific software is required to read the contents of the CDs. A full list of the codes is attached. [Exhibit WITN0719007] *WBS CD Archive codes from Archive Access Database*. The content of the CDs is outlined as an Exhibit. [WITN0719008] *WBS Archive Content List (as detailed in October 2018)*. We also submit [Exhibit WITN0719009] *Summary of Historic Paper Records Located at Talbot Green*.

14. The Welsh Blood Service has 1,698 Archive CDs, each CD containing up to 8,888 scanned images. Approximately 15 million images in total. We have not yet established how far back the records date, searches undertaken to date have identified Donor records that date back to 1950's and governance documents that date back to 1991.

15. The cataloguing system applied for records is not consistent or structured. As a result, it is extremely difficult to search and review older records in a timely and efficient manner. There would be a requirement for additional work to fully catalogue what is recorded on the CDs; this will need to be carefully considered in terms of the size and scope to resource such an exercise.

16. The Welsh Blood Service operates a Quality Management System to assure the quality and safety of the blood supply chain, in compliance with the Blood Safety & Quality Regulations (SI 2005, as amended) and Good Manufacturing Principles as defined in the Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017. Documents which support activities that may affect the quality and safety of the supply chain, i.e. Standard Operating Procedures, Management Procedures, Policies, Forms and Templates, are referred to within WBS as 'official documents' and form part of the WBS Quality Management System; these are controlled through a formal document control process, managed by the WBS Quality Assurance Systems Department.
17. Electronic copies of documents stored within the WBS computer system date back to 1997. There are approximately 6,000 official documents currently in use. Each official document and template is indexed and version controlled, with previous versions being stored electronically; paper copies of official documents are not archived. However, individual departments hold copies of completed paper records and forms generated as part of their working activities. Retention of completed records (including forms and templates) is the responsibility of the departments concerned and the relevant Senior Manager has responsibility for ensuring records management procedures are followed. Document retention periods are defined within the relevant supporting SOPs, Management Procedure and Policies and concur with legislative requirements for the type of record being retained.
18. All documents held in paper based filing systems are sent for scanning into the archive; details of the retention periods for primary records are documented in *Management Procedure for Records Management MP-018* [**Exhibit WITN0719010**].

External Archiving

19. The Welsh Blood Service also holds a number of archived records off site, at Transmedia Technology Ltd premises in Swansea West Industrial Park (Units 2 & 4). [**Exhibit - WITN0719011**] *Records Held in Archival Storage at Transmedia at 13th September 2018* provides a breakdown of the total number of records held at this facility.

2. Welsh Blood Service Repositories

Internal Repository

20. The Welsh Blood Service has an internal archiving facility (see paragraph 13) that stores documents and information on compact discs and microfilm located at its Talbot Green premises.
21. We have undertaken an initial review of the WBS archive CDs based on an assessment of the subject codes within the database to identify the files most likely

to be relevant to the Inquiry. To date 23 CDs have been identified as potentially relevant to the inquiry and a file by file search has commenced. Each file has a number of pages, each page contains an image of a record. These have been searched page by page, and the detail recorded in a spreadsheet. **[Exhibit WITN0719008]**.

22. A file by file search on a departmental basis has been undertaken to locate any physical records, as defined in *MP – 018*, **[Exhibit WITN0719010]** held across all departments of the Welsh Blood Service including Dafen, Wrexham and Bangor. Any historic documents relevant to the inquiry have been logged and are included in the catalogue of records *Summary of Historic Paper Records Located at WBS Talbot Green* **[Exhibit WITN0719009]**.

23. The Welsh Blood Service has a shared network (e: drive) which currently holds in excess of 1 million documents. This includes a wide variety of documents and information, in particular, project management documents (from 2005), trial management documents (from 1994), minutes and papers of Welsh Blood Service Committees (from early 2000's), Blood Collection Clinics (from 2008), & Change Control Information (from 2010). Minutes and papers of the Senior Management team meetings are readily available electronically from 2002.

24. The Welsh Blood Service has a number of IT systems in use. Blood donor and donation records are held in two IT systems. The current IT system is called ePROGESA (introduced 02/05/2015); the legacy IT system is called TRACE (introduced 1983). The IT systems store a record of all blood donations including laboratory testing for mandatory disease markers. The current system also contains medical correspondence with donors, and donor health histories. The systems keep records of where all blood components were issued.

25. The Welsh Blood Service has two Laboratory Information Management (LIMS) systems, one for the Histocompatibility and Immunogenic Service which holds patient, donor and potential donor records relating to blood, stem cell and solid organs, supported by various test results. The other system is for the Patient and Antenatal Referral Service (called SERIF), which in the main contains antibody results. The systems are due to be replaced as part of the procurement of a new national All Wales LIMS.

External Repositories

26. WBS has a commercial contract with Transmedia Technology Ltd. Some records are currently stored by the Transmedia Archive Company in Swansea (see paragraph 19 above). Transmedia hold a number of boxes of historic microfilm records. These have been copied onto CDs, which are stored at the Welsh Blood

Service premises in Talbot Green. Transmedia also hold 4 boxes of memorabilia, photographs, and donor newsletters and press cuttings. They hold 25 boxes of laboratory Human Leukocyte Antigen (HLA) typing results, including population genetics studies, and 1 box of blood grouping records for antenatal patients 1986-1989.

27. At this stage we do not have any information on which repositories predecessor organisations used for the storage of their documents other than those identified at the National Archives, Glamorgan Archive and the use of the Welsh Office Archive, as proposed in the Welsh Health Common Services Authority policy as outlined in paragraph 34.

3. An account of the process for archiving Welsh Blood Service documents and information at the National Archives or places of deposit in Wales.

28. Velindre NHS Trust (Welsh Blood Service) has not to date sent any documents to any national archive or place of deposit. The Trust was established less than 20 years ago and we have not yet been required to deposit documents, as the process is that documents over 20 years old should be transferred to a place of deposit in accordance with Appendix 3 of Records Management Code of Practice for Health and Social Care 2016.

29. The Welsh Blood Service have undertaken a search of the online database of the National Archive at Kew to identify any deposit made by our predecessor organisations. The following terms were used for the search; Welsh Hospital Board, Blood Service, South Glamorgan Health Authority, Welsh Health Common Services Authority (WHCSA), Blood and Transfusion.

30. The Welsh Blood Service has developed a catalogue of these records, and for ease of reference, documents relevant to Wales is included at **[Exhibit WITN0719003]**. However we wish to highlight that we have also identified that minutes and papers of the National Blood Transfusion Regional Director's Meeting (dates 1969 to 1981) are held there, and so are the meeting minutes of the Advisory Committee on the National Blood Transfusion Service (1981 to 1985). The Welsh Blood Service (under its previous names) participated in these groups. A catalogue of these is attached **[Exhibit WITN0719004]**.

31. The Welsh Blood Service have undertaken a search of the online database of the Glamorgan Archive at Cardiff to identify any deposit made by our predecessor organisations. The Welsh Blood Service has developed a catalogue of these records, and for ease of reference, this is included in **[Exhibit WITN07190005]**.

32. The Welsh Blood Service have undertaken a search of the online database of the National Library for Wales to identify any deposit made by our predecessor organisations. No records were found.

4. An account of the Welsh Blood Service's retention and destruction policies and processes from 1948 to date, together with an account of any material known to have been destroyed with potential relevance to the Inquiry's terms of reference.

33. The Welsh Blood Service currently adheres to the Velindre University NHS Trust Information Governance Policies 'Policy IG1 Record Management' [**Exhibit WITN0719012**]. It has its own supporting procedures, including *Management Procedure MP - 018 Records Management* [**Exhibit WITN0719010**]. This procedure has been in place since 19/10/1993, and was last updated 25/05/2018 in line with the General Data Protection Regulations. This procedure gives general guidance on records management and record retention periods. The current procedures reference Royal College of Pathologist Guidance on The Retention and Storage of Pathological Records and Specimens (5th edition) and the Records Management Code of Practice for Health and Social Care, 2016. Individual departments also have record management Standard Operating Procedures (SOP). E.g. SOP: 052/MOI Records Management within the Clinical Services Department, SOP: 019/LAB Laboratory Record Management. The Welsh Blood Service are required to keep records in accordance with the Blood Safety and Quality Regulations 2005 (as amended). This includes keeping records for 30 years to allow full traceability of blood components from donor to patient.

34. We do not have a record of the retention or destruction policies of predecessor organisations. However we have located a proposal for the retention and destruction of records that was considered by the WHCSA Management Executive on 2nd November 1998 on the dissolution of the organisation which was subsequently sent to the Welsh Office for approval and onward circulation. We have no record that this was the final version issued, however with some minor exceptions, it identifies that records will be transferred to the Welsh Office Archive. This is attached. [**Exhibit WITN071913**] *WHCSA – Retention and Destruction of Records*.

35. We are not yet in a position to confirm what, if any material with potential relevance to the Inquiry's Terms of Reference has been destroyed as we have not been able to identify any records relating to destruction. However, we will continue to review of our archives to enable us to determine this.

36. I would like to assure you that we will continue to search for other relevant information and will continue to submit evidence and support the Inquiry as it continues.

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

Signature GRO-C

Steve Ham
Chief Executive, Velindre University NHS Trust

Date: 19/11/18