

Witness Name: David Loughton

Statement No.: WITN4566002

Exhibits: Nil

Dated: 3rd September 2020

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF DAVID LOUGHTON ON BEHALF OF THE ROYAL WOLVERHAMPTON NHS TRUST

I, David Loughton, Chief Executive of The Royal Wolverhampton NHS Trust,
will say as follows: -

1. I make this statement further to my previous statement, WITN4566001. It is an amalgamation of that statement, with some additional observations and minor corrections. I wish for this statement to supersede my statement dated 19 March 2020.

Section 1. Searches, including search terms used

2. A search of Royal Wolverhampton NHS Trust ("RWT") Laboratory Information Management System ("LIMS").
 - a. The LIMS structure query language ("sql") database was searched using a locally compiled access database connection ("ODBC") query. The search parameters were designed to identify (patient screening requirements field and blood derivative stock descriptors) any patients within the database which had either a patient flag for haemophilia products or had

- been issued with coagulation factors since December 1996 (this being the go-live date of the LIMS). We do not believe there are any omissions based on the search parameters which were used to produce a list of patients from this data source.
- b. This was of limited success as the current system only dates back to December 1996. The previous system was not archived because prior to 2005, no regulations existed to mandate this approach.
 - c. It did however identify that haemophilia patients have received treatment as a starting point to assess if they may have received human blood factors in the 1970s & 80s. The records identified via the index card system contained data of some blood products/blood derivatives given during the 1970s and 1980s which were not recorded on any electronic database. The information recorded consisted of individual donation numbers or batch numbers (pooled blood donations) and the blood product/derivatives administered.
3. A search of the UK National Haemophilia Database (“NHD”) which is currently hosted externally by the United Kingdom Haemophilia Centre Doctors’ Organisation (“UKHCDO”).
- a. This identified further patients who have been registered in the UK with all types of bleeding disorders. This database identified patients who had previously had treatment or the potential for treatment with human blood factors.
 - b. The UK NHD is an externally hosted web-based system and using an allocated username/password the tools available allow an automatic listing of patients by disease status i.e haemophilia A, haemophilia B, etc. This data was then compared with the data derived from the LIMS database searched described above.
4. A local search by medical and laboratory staff of RWT laboratory archives for paper records prior to the inception of any electronic records.
- a. Local laboratory paper records prior to the use of LIMS (ledgers/index card systems) were found during the move from

the old pathology laboratories to the new purpose-built pathology block in April 2013. These records had information which did not appear on the local LIMS or the NHD and were transferred from the stores department in the new laboratory.

- b. Relevant paper records pre-dating 2008/09 were retrieved from the pathology archives and recovered during a physical search of those stores. They have now been transferred to an electronic media to preserve these in the event of fire/flood etc.
5. The physical processes involved were either electronic or a systematic search of the pathology premises with cooperation from the senior laboratory staff and stores keeper.
6. Previous employees of the Royal Wolverhampton NHS Trust had also been contacted to establish if other possible sources of information may be available – no other repositories were identified via this methodology.
7. The patient identifiers from these searches were supplied to the Health Records Department which included name, DOB, and NHS number for each patient that may have had treatment here at the Royal Wolverhampton NHS Trust. From these details a search was conducted on Patient Administration Services (“PAS”) to identify if any records were held within the Trust. The outcome of these searches showed that individual patients records were held in paper format, electronically or on a microfilm or were not registered and therefore no records are held.

Section 2. The Trust’s information repositories (from 1950 to present day) such as local authorities, University archives and The National Archives

8. The list below is a refreshed list of repositories, archives and places of deposit used by the Trust and other searches which were made, as follows:
9. LIMS operating system hosted by The Royal Wolverhampton NHS Trust information technology department and supported by the vendor Technidata UK.

10. The NHD is hosted by the UK Haemophilia Centre Doctors' Organisation which is located at City View House, Union Street, Ardwick, Manchester, M12 4JD, Email: support@ukhcdo.org
11. Paper format held either onsite at the Trust in the Health Records Library or off site with RESTORE, our document management company based in Birmingham, electronically (Clinical Web Portal), Microfilmed reels held onsite at the Trust in the Health Records Library.
12. The Royal Wolverhampton NHS Trust laboratories have no records relating to any collaboration with local universities in regard to the searches in relation to the Infected Blood Inquiry.

Section 3. Repositories and archives searched

13. As stated in Section 1, the following was searched:
 - a. The Laboratory Information Management System
 - b. The UK National Haemophilia Database
 - c. Laboratory archives at Royal Wolverhampton Trust that hold paper records
14. All laboratory electronic repositories were searched initially (October 2018) and the physical search of the laboratory store room followed at a later date (November 2019). The paper records were electronically scanned immediately after their discovery.
15. Health Record searches were conducted through PAS to identify if any records were held for the Trust. Outcome was some paper format records were held both onsite at the Trust in the Health Records Library or off site with RESTORE, our document management company based in Birmingham. Also, some records are held electronically on the Trust's "Clinical Web Portal" and some records are held on microfilmed reels held onsite at the Trust in Health Records Library.
16. The local Public Health England teams were also contacted to establish if HTLV-III antibody positivity was classed as a "notifiable disease" during the 1980s, and if they currently held any such records in their archives. Haemophilia patients may have been offered and tested for this antibody during the 1980s as part of their treatment. Public Health England have

confirmed they do not have any patient data for HTLV-III and HIV reporting was anonymised data only.

17. The above methods have currently identified 110 patients in the bleeding disorders cohort of which 38 have received human derived blood products prior to 1992.

Section 4. This section should only be used if documents have been destroyed. Please explain briefly and exhibit copies of the relevant document destruction record or policy to the statement.

18. No laboratory records relevant to the Inquiry's Terms of Reference either electronic or paper have been destroyed since 2018.
19. Health Records can confirm from the patient details provided by the previously described searches from the HND and the Trusts' LIMS/archive, that patient files have been identified from those who are registered with the Trust and are held either in a paper/electronic or microfilmed format and have not been destroyed.
20. The Head of Health Records, Ms Sam Smith will preserve from destruction any patient notes with a "red haematology" section prior to 1992 as these relate to patients who received single donation blood products as opposed to the haemophilia population who would have received concentrates made from hundreds of single donations sources from outside the UK.
21. All single and pooled blood products have been electronically recorded in the LIMS since 2005 and these records will be retained for a minimum of 30 years in accordance with the blood safety and quality regulations (BSQR).
22. Health records have placed restrictions on destruction of any records that have been identified as part of the search conducted in Section 1.

Statement of Truth

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

Signed

GRO-C

Dated **3 September 2020**