

Witness Name: Caroline  
Leonard  
Statement No.: WITN3449001  
Exhibits: WITN3449002 -  
WITN3449006  
Dated: 15<sup>th</sup> August 2019

## INFECTED BLOOD INQUIRY

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### FIRST WRITTEN STATEMENT OF CAROLINE LEONARD FOR THE BELFAST HEALTH AND SOCIAL CARE TRUST

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I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 22 May 2019.

I am Caroline Leonard, Director of Surgery and Specialist Services, Belfast Health & Social Care Trust (BHSCT). The Regional Haemophilia Comprehensive Care Centre falls within my Directorate and as such, I was nominated by my Chief Executive, Mr Martin Dillon to undertake a coordinating role in support of the Infected Blood Inquiry on behalf of BHSCT. I will say as follows:-

***"1. During the meeting held on 13 March 2019 at the Belfast City Hospital between various staff members of the BHSCT and three members of the Infected Blood Inquiry, the BHSCT described the exercise it conducted to locate and compile the medical records for all patients that received infected blood and/or blood products and consequently contracted HIV and/or the Hepatitis C virus. This was in anticipation that these patients may request their medical records for the purpose of providing evidence to the Infected Blood Inquiry. Please describe this exercise in detail."***

#### 1.1 IDENTIFICATION OF INDIVIDUALS KNOWN TO HAVE BEEN INFECTED/AFFECTED

1.1.1 Following receipt of correspondence from the Infected Blood Inquiry (IBI) on 15 August 2018 which sought documentation that could be of relevance to the work of the Inquiry, the Belfast Health and Social Care Trust (BHSCT) undertook to collate a list of individuals who were known to have been infected or affected by contaminated blood products.

1.1.2 This included a review of information across four different services:

- i) Haemophilia Comprehensive Care Centre (Haemophilia Centre)
- ii) Hepatology Service
- iii) Genito-Urinary Medicine Service
- iv) Virology Service

1.1.3 The BHSCT indicated in its letter of response to the IBI of 12 September 2018 that an on-going process of identification of information would be necessary to

refine the list of those individuals infected or affected. This process has in turn informed the search for medical records, which continues today.

## **1.2 INDIVIDUALS KNOWN TO THE HAEMOPHILIA CENTRE**

- 1.2.1 An initial list of individuals infected with Hepatitis C or HIV who were known to the Haemophilia Centre was compiled. Initially this list was compiled from a handwritten list of patients who had had an historical positive test for Hepatitis C following administration of blood products. This list was retrieved from a filing cabinet in the Haemophilia Centre. It is believed that this handwritten list had been compiled by Dr Elizabeth Mayne, Consultant Haematologist, who had worked in the Royal Group of Hospitals Health and Social Services Trust prior to the formation of the Belfast Health and Social Care Trust. This list was not dated and the BHSCT Haematology service has not identified any catalogue or index to indicate how, or why, the list of names was composed.
- 1.2.2 In addition to this list of patients, other uncatalogued, miscellaneous documents were retrieved from the same filing cabinet in the Haemophilia Centre. These documents have been furnished to the Infected Blood Inquiry as part of the BHSCT's upload of relevant documentation to the Egress System completed in early 2019.
- 1.2.3 The BHSCT Haematology service added to this historical list the details of other individuals who were known to have received care and counselling from the service after contracting HIV from contaminated blood. The list was also supplemented with names of those individuals with a positive Hepatitis C test, which were recorded as part of the verification process for claims to The Skipton Fund in the early 2000s.
- 1.2.4 The initial collation of individual names was subsequently reviewed to ascertain whether there was a sufficient level of detail available to support a search for medical records. This exercise found that there was very little information for a number of individuals included in the initial list – i.e. a surname with forename or first initial only. Therefore, a search was undertaken on the BHSCT's electronic Patient Administration Systems (PAS) to try to source unique identifiers, such as a date of birth and hospital number. This enabled the necessary information to be retrieved in the majority of cases, but not all.
- 1.2.5 In October 2018, the BHSCT administration teams subsequently commenced the retrieval of the medical records for the individuals on the list from the Organisation's record storage facilities, including off-site locations managed by three private contractors. This is described in more detail below.
- 1.2.6 The BHSCT Haematology service undertook a further validation check of the individuals known to the Haemophilia Centre in early April 2019 in advance of any potential communication process that may have been required by the Inquiry. Through this process the service rationalised and refined its list further, for example:
  - i) The details of three individuals were removed from the Haematology list due to the fact that the service had been unable to locate any uniquely identifiable data for them following an extensive search of the BHSCT Patient Administration Systems and it was not possible to

locate their historical medical records. Further, no members of clinical staff currently working in the service had any recollection of having treated individuals with the limited information for these persons (surname and forename/first initial only). There was therefore no robust means of confirming that these individuals had ever received haemophilia related care via the BHSCT.

- ii) One patient who had acquired Hepatitis C following a transfusion in Poland was removed from the list in view of the fact that his contamination had not occurred as a result of treatment he received in the UK.
- iii) One patient who had originally been recorded on the list collated by the BHSCT Hepatology service (please see below) was transferred to the list of patients known to the Haemophilia Centre as he had initially been referred by the Haemophilia Centre to the Hepatology team. This was to avoid duplication.

1.2.7 Following the IBI Hearings held in Belfast the week commencing 21st May 2019, a further validation of the list of patients was carried out with a particular review by the clinical team of those patients who had acquired HIV as a result of contamination with infected blood. This review resulted in a further small number of names being identified and the work to confirm these details is ongoing.

### **1.3 PATIENTS KNOWN TO THE HEPATOLOGY SERVICE**

1.3.1 In 2004, a Consultant Hepatologist created a database to capture the details of those patients waiting for treatment or the outcome of treatment for Hepatitis C, as indicated by a positive PCR (Polymerase Chain Reaction) test. Data was initially imported into the database in 2004 using information from an excel spreadsheet which had been created by a different Consultant Hepatologist in the department. The excel spreadsheet contained incomplete details and therefore the BHSCT is unable to verify the accuracy of the information that was gathered prior to 2004.

1.3.2 Since 2004, the BHSCT Hepatology Service has prospectively entered the details of all patients attending for Hepatitis C treatment. The database also contains information on patients who were referred to the service but who did not subsequently attend. This information is for the sole use of Belfast Health and Social Care Trust.

1.3.3 Following receipt of the correspondence from the Inquiry in August 2018, this database was reviewed by the BHSCT Lead for Viral Hepatitis in order to create a list of those patients who advised they had transmitted Hepatitis C by transfusion.

1.3.4 The database contains a column to record the mode of transmission of Hepatitis C. This column is often blank. If the database indicates that a patient's infection was acquired by transfusion, this information was derived from direct feedback from the patient, rather than any objective verification. Consequently, while the BHSCT Hepatology database was used to create a list of relevant patients, it is not a reliable source for confirming HCV transmission by transfusion and cannot be considered an authoritative reference point.

1.3.5 From approximately 2013/14 onwards, the BHSCT Hepatology service had additional support to maintain the database and therefore there is greater confidence in the quality of the data entered from this point.

1.3.6 The list was reviewed to identify those patients who were also attending the BHSCT Haemophilia Centre and any duplicates were identified. The names of 25 patients who stated that they had a transfusion outside of the UK were also removed from the list as this is out with the Terms of Reference of the Inquiry.

#### **1.4 INFORMATION HELD BY THE GENITO-URINARY MEDICINE SERVICE**

1.4.1 The BHSCT Genito-Urinary Medicine service advised that while they provide advice/support to these patients as required, they hold no separate medical records for those patients infected with HIV as they have remained under the care of the Haemophilia Centre.

#### **1.5 INFORMATION HELD BY THE VIROLOGY SERVICE**

1.5.1 Within the BHSCT Laboratory Service, the Regional Virology Laboratory (RVL) was identified as a potential source of information with possible relevance to the Inquiry.

1.5.2 The Lead Consultant Virologist in the RVL identified several folders in a filing cabinet within the Virology Laboratory which he believed might be of relevance to the Inquiry. The information was contained in seven untitled folders and represented an amalgam of various items of information deemed to be of potential interest. The RVL team subsequently reviewed the information and any found to be of relevance was catalogued, scanned and uploaded onto the Inquiry's Egress System.

1.5.3 In 2011 the Standard Note SN/SC/5698 'HIV and Hepatitis C Infection from Contamination Blood and Blood Products' confirmed an increase in payments via the Skipton Fund to some of those infected with Hepatitis C. In addition, the Standard Note removed a provision preventing payments for Hepatitis C patients deceased prior to 29 August 2003. Dr Gary Benson, BHSCT Consultant Haematologist, can recall that in 2011 a reconciliation of patient names on the original handwritten list produced by Dr Mayne was carried out against virology records in order to identify those families who would now be eligible for payment under the Skipton Fund.

1.5.4 In summary, creation and validations of the list referred to above is an on-going process. The figures referred to in previous correspondence with the Inquiry and discussions with the Inquiry team have been amended to reflect emerging information.

#### **1.6 RETRIEVAL OF MEDICAL RECORDS**

1.6.1 In October 2018, the BHSCT administration teams commenced the retrieval of medical records for the identified individuals referred to above from the Trust's own records storage facilities and from off-site locations with the aim of bringing the records together in dedicated secure locations. This was carried out in anticipation of an increase in requests for access to medical records from patients and their families, in the context of the Inquiry's on-going investigation.

1.6.2 This search has been complex and extensive and remains ongoing. The complexity and challenging nature of this exercise is due to a range of factors, which include but are not limited to the following areas below:

**A) Legacy Trusts and Retention and Disposal**

- i) The BHSCT was created in 2007 from an amalgamation of six Health Trusts. BHSCT is the largest integrated health and social care Trust in the United Kingdom. While records management retention and disposal was covered by Departmental circulars and policy across Northern Ireland, with the span of time involved and the range of Organisations involved, practices have been found to differ in respect of destruction and the recording of same. This has added a layer of uncertainty and has on occasion made it challenging for Trust staff to make a definitive determination that records were destroyed when multiple searches over a period of time have not been successful.

**B) Multiple Locations and Teams with a Remit for Medical Records**

- i) Within the BHSCT, a Medico-Legal Team oversees responses to Hospital Subject Access Requests (SARs). A separate team manages SARs for Community (including Social Care) records. These teams are managed within the Health Records Service, which also manages Health Records libraries at Royal Victoria Hospital, Royal Belfast Hospital for Sick Children, School of Dentistry, Mater Hospital, Musgrave Park Hospital and Belfast City Hospital. Community records and some Hospital records are managed within the relevant Directorate. The Oncology and Haematology Service manage the Medical Records Department at the Northern Ireland Cancer Centre and Haematology Department. The number and nature of these Departments has contributed to the sometimes protracted nature of the search for each patient's medical records.
- ii) A variety of legacy operational arrangements were in place for various health care professionals to input to a patient's medical record. For example, physiotherapy records are contained within the body of the main hospital record however, occupational therapy and social work hold separate records that are held and managed within the respective Departments. Such record keeping arrangements that differ across a number of these Departments has also contributed to the complexity and extended nature of the search for each patient's medical records.

**C) Limited/Incorrect Demographic Details with which to Identify Patients and their Hospital Number**

- i) The information available to Trust staff seeking to compile a list of those known to have been infected was in many cases very limited and evolved as searches of electronic and physical records were carried out and new information discovered. Inadequate information was available at the outset of the process to confirm the identity of a large number of the patients, for example, staff had access to a first name and surname only with no date of birth or hospital number to draw upon. In a number of other instances, it emerged that 'known' names or middle names had been used to register patients, rather than the patient's actual forename.

Significant effort and resource was directed to try to find a unique identifier for these individuals through a multi-layered process of elimination spanning multiple PAS systems and using various combinations of names in searches.

- ii) The BHSCT has three separate PAS systems, which are stand alone. They are the RVH PAS, the combined BCH and Musgrave Park Hospital PAS and the Mater Hospital PAS. The RVH PAS comprises patient administration information for the RVH, RBHSC and the School of Dentistry. A single search for a patient, which might comprise a search against a multitude of different name and date of birth combinations, also has to be conducted across at least two of the three PAS systems.

#### **D) Multiplicity of Locations where Health Care was provided and where Medical Records could be located**

- i) The Hepatology service in the now BHSCT has always been based at the Royal Victoria Hospital site, which was previously the Royal Group of Hospitals HSS Trust. The Hepatology medical records form one part of a composite 'Royal Victoria Hospital' record, which may contain information pertaining to an individual's care under other specialities provided on the Royal Victoria Hospital site.
- ii) By contrast, the Haematology service which incorporates the Haemophilia service, and which cared for patients with HIV as a result of infected blood between the 1970s and 1990s, transferred from the Royal Victoria Hospital to the then Belfast City Hospital HSS Trust in 2002. All the medical records held by the Haematology service were transferred between the Trust sites at this time, although the BHSCT administration teams have been unable to locate a list of exactly which medical records did or not transfer. The working assumption was that all active Haematology records moved from the RVH to the BCH however, subsequent searches have identified some deceased patients' records were also transferred and some were not. This has added to the complexity of the search for Haematology records.
- iii) In addition, a number of current and deceased patients in the initial lists that Trust staff were working with had received healthcare as a child. This extended the search for records to the Royal Belfast Hospital for Sick Children (RBHSC), which has a further separate medical records repository. Records were also searched for in the School of Dentistry on the Royal Victoria Hospital site, which also has its own separate medical records repository.

#### **E) Volumes of Medical Records**

- i) In January 2018, a new case note tracking system known as the I-Fit System was introduced on the RVH site of the BHSCT which includes details of medical records across the RVH, School of Dentistry and RBHSC. This system made the search for medical records easier on the RVH site as it allows Trust staff to see the exact number of volumes of records held for most patients.
- ii) Unfortunately, haematology and haemophilia patients are registered on the BCH PAS and its casenote tracking function does not record the number of volumes of medical records in existence for a particular patient. This information could only be confirmed once the first medical record for a patient

was retrieved, as each record has the number of volumes handwritten on the front cover for example, 'Volume 1 of 4'. However, it has been identified that on occasion the handwritten cataloguing has been recorded incorrectly, for example a patient's records may have erroneously been labelled as 'Volume 2 of 3', whenever only 2 charts ever existed for that individual. This has suggested a 'missing' volume when in fact the chronology of the handwritten notes in the available medical records indicated no gap in the patient's medical history and therefore no missing volume.

- iii) As a general point, due to the ongoing nature of the care and treatment associated with this patient cohort, many patients had or have a substantial number of volumes of medical records spanning more than one decade. This undoubtedly has contributed to the complexity and extended nature of the exercise BHSCT has been engaged in.

#### **F) Limitations of Cataloguing of Historical Records in Off Site Facilities**

- i) In seeking to retrieve Haematology medical records from off-site storage, the Trust became aware of a wide range of inconsistencies with how the historical cataloguing of records off-site had been implemented, leading to mis-filing. Consequently, the Trust undertook an exercise to further scrutinise the cataloguing and filing arrangements to identify how mis-files could have occurred and other possible locations as to where records could be stored.
- ii) The off-site storage facility was searched by Trust staff using an electronic search function for the Trust's 'Haematology Account'. This search has proved challenging for a number of reasons:
  - Cataloguing of records by Hospital Number was not consistent – spaces between letters and numbers were included in some entries and not in others.
  - BCH Hospital Numbers on some occasions had an additional 'H' indicating haematology.
  - Numbers within the Hospital Number had been entered incorrectly.
  - Haematology medical records with a BCH Hospital Number were found to have been filed using the patient's RVH Hospital Number.
  - Haematology medical records were found to have been filed in the off-site storage's 'Oncology Account', an entirely separate account and filing system.
- iii) Over the duration of the search, the BHSCT staff became more experienced in the variety of approaches to take when searching for medical records in the off-site storage facility. Advice was sought from the off-site storage company about how to maximise the effectiveness of this process and the company itself has on occasion been provided with a list of medical records and it has been able to identify some of these through its own additional searches and expertise.

#### **G) Lack of Organisational Memory**

- i) Due to the significant historical timeframe, which is the subject of the Inquiry, the team of staff involved in the oversight and handling of the retrieval of medical records have no organisational memory of key events, such as decisions around the destruction of medical records and the transfer of records between hospital sites. Had this organisational memory been available, it would have undoubtedly supported a more expeditious search and retrieval process.

### **1.7 STORAGE OF RETRIEVED MEDICAL RECORDS**

- 1.7.1 The process to retrieve medical records for patients is ongoing as is the process to confirm an accurate list of the individuals who have been infected/affected.
- 1.7.2 As medical records are retrieved, they are being securely stored. Haematology records are being stored in the Northern Ireland Cancer Centre medical records library. I would refer to exhibit [WITN3449002] which shows two photographs of the secure location of medical records in the Northern Ireland Cancer Centre.
- 1.7.3 Hepatology records have been securely stored either in the RVH medical records library or in the Transplant Secretaries Office. All RVH records on the RVH site have been able to be tracked using the I-Fit case note tracking system.
- 1.7.4 While the I-Fit system has not yet been rolled out Trust wide, the plan is for the haematology records to now be tracked using this system. This will further enhance the security of these records. Do not destroy labels have also been placed on each set of medical records.

**2. "On 16 May 2009, the Inquiry was informed by Counsel instructed by Watkins and Gunn that the BHSCT had located several volumes of medical records for a number of their clients that are giving oral evidence at the Belfast hearings. In witness evidence heard by the Inquiry on 21 May 2019, it was stated that Dr Gary Benson was the clinician who progressed the pending Subject Access Request and was involved in identifying the location of the documents."**

- 2.1 The Trust also notes that during legal submissions at the Belfast Hearing on 21 May 2019, Ms Richards, Senior Counsel for the Inquiry stated *'the Trust only found and disclosed some hundreds or thousands of pages of medical records in the last few days'*.
- 2.2 The Trust welcomes the opportunity to clarify the facts in respect of this matter. It is our view that the medical records delivered to Watkins and Gunn from which the concern arose relate to the medical records of two Subject Access Requests pertaining to :

- A) Mr [GRO-A] (deceased), who was the father of the witness who advised the Inquiry on 21 May 2019 that it was Dr Benson who progressed the Subject Access Request; and
- B) Mr [GRO-A] (deceased)

**"(a)Describe the exercise that the BHSCT were carrying out when they came across the missing medical records and who was responsible for locating them"**

- 2.3 The exercise BHSCT were carrying out is described above in section 1. The Health Records Service of the Directorate of Performance, Planning and Informatics were responsible for carrying out the searches of the RVH, RBHSC and School of Dentistry libraries and off-site storage relating to these libraries. The Medical Records Department of the NI Cancer Centre and Haematology Department of the Directorate of Surgery and Specialist Services were responsible for carrying out the searches of the NICC and Haematology libraries and off-site storage relating to these libraries.



- 2.4 Questions **2 b) to 2 e)** within the Inquiry's Rule 9 Request will be considered and addressed in respect of these two Subject Access Requests below.

**2.5 Mr [GRO-A]**

- 2.5.1 A Subject Access Request (SAR) was received from Watkins and Gunn on 19 November 2018 for Mr [GRO-A]'s medical records. I would refer to exhibit [WITN3449003] which is a copy of the request made. At this stage, the standard search for medical records was conducted and none were found. However, as the Trust was in receipt of a folder of information pertaining to Mr [GRO-A] as part of the miscellaneous documents thought to have been retained by Dr Elizabeth Mayne, this documentation was released via the Trust's Medico-Legal Team to Watkins and Gunn on 5 December 2018. The SAR was closed on 5 December 2018. I would refer to exhibit [WITN3449004] which is the BHSCT response to Watkins and Gunn. This is the standard template letter used by the Trust in closing SARs.
- 2.5.2 Subsequently during ongoing searches, two volumes of Mr [GRO-A]'s records were retrieved from off-site storage and delivered to the Haematology Medical Records Department on 22 January 2019.
- 2.5.3 Unfortunately, the significance of these records was not identified, as it was not known to the Haematology Medical Records Department that these records had been requested via a SAR or that the Medico-Legal Team had 'closed off' the SAR. The Haematology Medical Records team logged the two volumes of medical records on the search database and they were stored safely in a secure location. While the updated search database was shared internally in February 2019 there was unfortunately no specific review of this list in the context of previously closed SARs.
- 2.5.4 When Dr Gary Benson, Consultant Haematologist, met Mr [GRO-A]'s daughter on 15 May 2019 she raised the lack of medical records with Dr Benson, who undertook to make enquiries. It was his enquiry, which prompted a review of Mr [GRO-A]'s entry on the database, which discovered that the two volumes had been located and were being securely stored. Action was taken immediately to process and electronically scan the records to Watkins and Gunn on 17 May 2019.

**2.6 Mr [GRO-A]**

- 2.6.1 A Subject Access Request (SAR) was received from Watkins and Gunn on 18 October 2018 for Mr [GRO-A]'s medical records. I would refer to exhibit [WITN3449005] which is a copy of the request made. At this stage, the standard search for medical records was conducted and one volume was found and released via the Trust's Medico-Legal Team to Watkins and Gunn on 20 December 2018. The SAR was closed on 20 December 2018. I would refer to exhibit [WITN3449006] which is the BHSCT response to Watkins and Gunn. This is a standard letter template used by the Trust in closing SARs.
- 2.6.2 Subsequently during the on-going search process, five further volumes of Mr [GRO-A]'s records were retrieved from off-site storage and delivered to the Haematology Medical Records Department on 22 January 2019.

2.6.3 Unfortunately, the significance of these records was not identified, as it was not known to the Haematology Medical Records Department that these records had been requested for a SAR or that the Medico-Legal Team had 'closed off' the SAR. The Haematology Medical Records team logged the five volumes of medical records on the database as retrieved, and the updated database was shared internally in February 2019 however, there was no specific review of this list in the context of previously closed SARs.

2.6.4 Following receipt of statements by Directorate of Legal Services in advance of the Belfast Hearings, DLS made an enquiry on 1 May 2019, regarding the possibility of missing records relating to Mr GRO-A to the Trust. It was this enquiry that prompted a review of Mr GRO-A's entry on the search database when it was discovered that five additional volumes had been located and were being securely stored. Action was taken to process and electronically scan the records to Watkins and Gunn on 17 May 2019.

## 2.7 In Summary and in response to question 2 (f)

2.7.1 The BHSCT regrets the delay in securing medical records and any uncertainty family members experienced as a result of an internal communication deficiency within the organisation. The BHSCT hopes this information will reassure the Inquiry that at no stage did the Trust set out to withhold or obstruct the supply of records. The learning from these two cases has served to tighten and refine our processes to prevent such a scenario arising again.

2.7.2 Our search and retrieval process for records pertaining those patients we understand to be infected/affected will continue. All SARs received by the Trust related to the Infected Blood Inquiry have been reviewed to check that no further medical records have been retrieved subsequent to a SAR being closed off and not supplied to the requestor. In the interests of completeness, the Trust is also revisiting all IBI SARs to determine if further Community (Allied Health Professional or Social Work) records exist. These records are not usually provided in response to a SAR for hospital/medical records and, should any be located, these will be sent to the requestors. The Trust does not intend, at this time, to communicate with patients or relatives who have *not* requested medical records. If the Trust, however, receives an appropriately made request for records, either under the auspices of or outside the Infected Blood Inquiry, it will of course act upon it and conduct all necessary searches.

### Statement of Truth

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

Signed GRO-C

Dated 15 August 2019.