Witness Name: Caroline Leonard
Statement No.: WITN3449028
Exhibits: WITN3449029 - 41
Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF CAROLINE LEONARD

I provide this statement on behalf of Belfast Health and Social Care Trust in response to the notification under Rule 13 of the Inquiry Rules 2006 dated 3 June 2021 and the request under Rule 9 of the Inquiry Rules 2006 dated 2 August 2021.

I, Caroline Leonard will say as follows:

Section 1: Introduction

1.1 My name is Caroline Leonard. My date of birth is known to the Inquiry. My professional address is BHSCT HQ, "A" Floor, Belfast City Hospital, Lisburn Road, BT9 7AB.

1.2 I am the Director of Cancer and Specialist Services at Belfast Health and Social Care Trust (BHSCT); as such, I have responsibility for services provided at NI Cancer Centre, some medical specialities, renal transplant surgery, laboratories and pharmacy. The Regional Haemophilia Comprehensive Care Centre falls within my Directorate and as such, I was nominated by my Chief Executive, Dr Cathy Jack to undertake a coordinating role in support of the Infected Blood Inquiry on behalf of BHSCT.

Section 2: Response to Criticism of witness W0007

1) At paragraph 11 of his statement, witness W0007, who has haemophilia, states that between 1996 and 1997, the Royal Victoria Hospital moved the adult haematology department out of the main building and into a portacabin. The witness states, "They wanted us out of the way, or so it seemed and it felt very isolating."

2.1 To address this statement the Trust has sought the recollection of some staff members who worked in the Royal Victoria Hospital (RVH) Haematology service during the time outlined by Witness W0007.

2.2 One past employee worked in RVH Ward 22 Haematology from September 1981 to March 1993. This individual stated *"...it was my first ward as a student nurse in 1976. It wasn't just Haematology then; there were Neurological, Gastroenterology, Venereology and rehabilitation patients at that time as well as it having the Haemophilia patients. I don't remember Ward 22 moving to portacabins. The Haematology Outpatient unit however moved from Ward 8 to a portacabin when the main corridor of the old Royal Victoria hospital was being demolished. This was the Outpatient Department and not the Ward."*

2.3 Another staff member advised that Ward 22 did not relocate until 1 September 2001 when the Haematology service relocated to the Belfast City Hospital (BCH) to Ward 10N, following which Ward 22 was closed. This was part of the HSCB Acute Hospitals Reorganisation Project, which, among other service reconfigurations, centralised haematology services in Greater Belfast on one hospital site. They advised that Ward 22 was never relocated to a portacabin.

2.4 These accounts from former employees correlate with my personal recollection from that time. From December 1999 to June 2002, I was the Commissioning General Manager for Phase 1 of the RVH Redevelopment Project that involved the relocation of the old RVH corridor wards, as they were known, in to a new hospital facility and the decommissioning and demolition of the old corridor wards. This project involved decanting and relocating wards and departments to facilitate the commissioning of the new hospital and the decommissioning

and demolition of the old facilities, which may be what Witness W0007 is referring to. This work was necessary to progress development of improved facilities and services at the RVH. It was in no way designed to impact negatively on the experience of haemophilia or other patients. If that was the perception of Witness W0007, the Trust regrets that this should have occurred.

2) At paragraphs 13-14, witness W0007 states that his medical records show that he first tested positive for HCV in 1992, but neither he nor his parents were informed until 1995.

2.5 In addressing Witness W0007's concerns relating to a time delay between having a positive antibody test for HCV in 1992, and not being informed about a result until 1995, it may be helpful to explain the development of antibody testing and Polymerase Chain Reaction (PCR) testing in that period.

2.6 Staff from the Regional Virology Laboratories (RVL) within the Trust have advised that with respect to testing for HCV, the first antibody assays were available from 1992. However, a HCV antibody positive result only identifies that a patient has had exposure to HCV (either via a past or current infection) and is unable to determine whether a patient is currently infected or not.

2.7 PCR confirmatory assays to detect viraemia (active infection) were not routinely available in the early 1990s and were then only used in a research context. At this time, samples were sent to Edinburgh University or to Birmingham Public Health Laboratory for HCV PCR testing. The team advise that from the mid-90s some HCV PCR tests were performed in the RVL Belfast. However, none of the assays at this time were commercial assays and all these assays had intermittent sensitivity and specificity problems.

2.8 Until the mid-00s HCV PCR testing in the RVL was done in a variable way (either locally or sent away or both) and given issues with sensitivity and specificity, the clinical advice from the virology team was to look at the pattern of PCR results over a period of time rather than absolutely rely on any one result.

2.9 The Trust, having reviewed the medical records of Witness W0007, can confirm that a sample was taken from Witness W0007 in 1991 for HCV antibody testing and the result was issued to the Trust in 1992 indicating that Witness W0007 was Hepatitis C Virus (HCV) antibody positive. Those results are contained in the clinical notes.

2.10 The first Polymerase Chain Reaction (PCR) test result from the RVL for Witness W0007 in the medical records is from December 1995 (Exhibit WITN3449029 refers). The receipt of this first positive PCR result is the first point where it can be said that Witness W0007 had an HCV infection. This is because the previous antibody positive results could only identify exposure to HCV (either past or current infection). They could not determine whether W0007 was currently infected or not. In a letter to Witness W0007's General Practitioner dated 14 June 1995 (Exhibit WITN3449030) Dr S I Dempsey, Consultant Haematologist indicates that in all probability Witness W0007 was a carrier of the virus – that he was infected. However, once the PCR positive result from the RVL became available confirming that Witness W0007 had a current HCV infection, his parents were informed accordingly.

3) At paragraph 23, witness W0007 states that he was never made aware that his blood was being tested for HCV, and although his parents may have consented on his behalf, he feels that at age 15 he had the right to be told.

2.11 On review of Witness W0007's medical records, Exhibit WITN3449031 is a letter dated 29 May 1995 from Dr S I Dempsey, Consultant Haematologist, to Witness W0007's parents that would indicate that his parents would have been aware of routine testing of Witness W0007's blood for evidence of exposure to Hepatitis C (HCV antibody testing). The letter refers to the fact that a sample had been taken 'some months ago' to test and provides the result of the test, offering an appointment for the parents to attend to discuss the result. It is not clear from the letter if Dr Dempsey is referring to the outcome of an antibody or PCR test.

2.12 With regard to Witness W0007's belief that at the age of 15 he had a right to be told about his blood being tested for HCV, the Trust would refer to section 4 of the Age of Majority Act (Northern Ireland) 1969 in practice at that time. This states people aged 16 or 17 are entitled to consent to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. Following the case of *Gillick v West Norfolk and Wisbech AHA* [1986], the courts held that children under 16 who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention. This is sometimes described as being "Gillick competent" and may apply to consent to treatment, research or tissue donation. As the understanding required for different interventions will vary considerably, a child under 16 may therefore have the capacity to consent to some interventions but not to others. Whether consent from a child under 16 should be sought, therefore is heavily dependent on the particular facts and circumstances of the individual case. It would appear from the medical records that the test results of Witness W0007 were discussed with his parents only.

2.13 It is thought to be unlikely that written consent was ever taken for a virology blood test from either parents or children but verbal consent may have been the practice then. I am advised written consent was only routinely taken for paediatric genetic testing at that time.

2.14 The Trust at present operates in line with the Department of Health NI Reference Guide to Consent for Examination, Treatment or Care (2003) (attached at Exhibit WITN3449032). Current practice in the Royal Belfast Hospital for Sick Children (RBHSC) is to ask the parents of a 15 year old to sign for consent at that age, with the option of the child countersigning for procedures if they wish.

4) At paragraph 40, witness W0007 states that he finds it "sinister" that he has had HCV since childhood but a biopsy has not been taken at any stage.

2.15 The Trust regrets that Witness W0007 found it "sinister" that a biopsy had not been taken at any stage since receiving a HCV diagnosis in childhood.

2.16 I am advised by Hepatology colleagues that liver biopsy was not routinely used to assess haemophilia patients with hepatitis C. This is due to the higher risk of bleeding and associated complications that may result following this invasive procedure for this particular patient group. Non-invasive radiology (usually starting with ultrasound scan) and blood tests were used to look for evidence of cirrhosis or portal hypertension. Liver biopsy was reserved for those in whom the biopsy result would be likely to alter management. Since 2008, the Regional Liver Unit has used Fibroscan as a non-invasive method for assessing hepatitis C patients for evidence of cirrhosis.

2.17 Blood tests, less invasive scans and indicators are routinely used to identify if there may have been changes or deterioration within the liver as a result of HCV infection.

2.18 Within the medical records of Witness W0007, there is evidence of these tests and scans having been carried out. Dr S I Dempsey refers in a letter to Witness W0007's GP dated 14 June 1995 (Exhibit WITN3449030 attached) to the fact that *"we have checked liver function tests on [Witness W0007] on a number of occasions and they are not at present significantly deranged."* Another extract from the letter states, *"should there be a deterioration in Liver Function tests undoubtedly Witness W0007 would require treatment with Interferon."* Dr G Benson, Registrar in Haematology in a referral letter to Dr Callender, Consultant Hepatologist dated 18 November 2003 (Exhibit WITN3449033 attached) advises "*we continue to monitor him… with alpha feto-protein and liver function tests at each review appointment. These are holding stable.*"

2.19 The medical records also contain the report of an ultrasound scan of Witness W0007's upper abdomen undertaken on 29 September 2004 in which "no focal parenchymal abnormality is seen within the liver" (Exhibit WITN3449034 refers). Dr N McDougall, Consultant Hepatologist and Gastroenterologist in a clinic letter dated 21 June 2007 (Exhibit WITN3449035) highlights that in respect of Witness W0007 "*a previous ultrasound of the liver was unremarkable.*"

2.20 Witness W0007 also attended hospital for an ultrasound scan of abdomen and pelvis on 28 October 2013, the result of which indicated, *"no focal defects noted in liver and spleen"* (Exhibit WITN3449036 refers). More recently, Witness W0007 had a Fibroscan on 12 November 2019, which was *'entirely normal'*. (Exhibit WITN3449037 refers). It is hoped that this information provides reassurance to Witness W0007 and explains why a liver biopsy has not been undertaken.

5) At paragraph 46, witness W0007 states that after repeatedly receiving notices from the School of Dentistry that he had missed appointments, which he had not booked, he was subject to a 'three strikes' policy and removed as a patient. He states that as a result he lost at least seven years of dental care.

2.21 A review of the data held on the School of Dentistry appointments system indicates that between 1993 and 2009, 29 appointment dates were offered to Witness W0007. There were 19 appointment dates which were noted as having been attended by Witness W0007, 4 from the total number were cancelled by the hospital, 2 dates were cancelled by Witness W0007 and 2 dates were listed where Witness W0007 did not attend (DNA). There were also two dates where the 'outcome' of the appointment unfortunately was not noted.

2.22 Exhibit WITN3449038 provides a summary table of the appointment times and outcomes for Witness W0007 associated with the School of Dentistry records together with an explanation of same.

2.23 With regard to the scheduling of appointments, the Trust follows the NI regional Integrated Elective Access Protocol (IEAP) Guidance, which was implemented in 2008 by DHSSPS. Exhibit WITN3449039 refers.

2.24 As part of the 'partial booking' process within this guidance, a letter is sent to the patient to request the patient contact the appointments office to arrange a suitable date & time for them to attend; patients have 2 weeks to respond. If after 2 weeks they do not contact the service, a second letter to the patient is sent, allowing a further week to respond. If there is still no contact, the patient

will be sent a letter informing them that they are discharged from the service but have a further 4 weeks to make contact and arrange an appointment.

2.25 It is noted that Witness W0007 was discharged from the School of Dentistry on 10.06.2009 having failed to make contact with the service following letters issued on 18.05.2009 and 02.06.2009, in keeping with IEAP guidance. There is no record of further referrals or appointments having been made for Witness W0007 since this date.

6) At paragraph 47, witness W0007 states that while he understood the need for the School of Dentistry to take precautions to prevent the transmission of infection, he was upset to witness the tools used in his dental treatment being prepared for destruction because "it makes you feel horrible being treated so differently."

2.25 The Trust would advise that the extant Infection Prevention Control guidance was followed at this time. This guidance (attached at Exhibit WITN3449040) advised the use of single-use disposable instruments as far as possible for patients with a known risk of viral transmission or that non-disposable instruments be quarantined or incinerated after use. Universal precautions are recommended for all patients within the British Dental Association Infection Control in Dentistry Advice Sheet (Exhibit WITN3449041) which includes wearing a mask, apron, goggles and gloves due to the risk of splashing, splatter and aerosol generated from dental procedures.

2.26 It is now common practice to use single use instrumentation in dentistry. The Trust regrets the upset caused to Witness W0007 in following the regional guidance as instructed at this time.

Section 3: Other Issues

3.1 The Trust recognises that whilst treatment and care were delivered in keeping with extant guidance at the time, it accepts that some aspects of the treatment may have resulted in Witness W0007 having a poor patient experience. The

Trust hopes that the additional information contained in this statement goes some way to address the concerns raised.

Statement of Truth

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

Signed GRO-C

Dated 1October 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
6 December 1995	HCV PCR test result report	WITN3449029
14 June 1995	Clinic letter from Dr SI Dempsey to Dr Mercer	WITN3449030
29 May 1995	Clinic letter from Dr SI Dempsey to the parents of Witness W0007	WITN3449031
March 2003	Department of Health NI: Reference Guide to Consent for Examination, Treatment or Care (2003)	WITN3449032
18 November 2003	Referral letter from Dr G Benson to Dr Callender	WITN3449033
29 September 2004	USS scan result report	WITN3449034
21 June 2007	Clinic letter from Dr N McDougall to Dr O McNulty	WITN3449035
28 October 2013	USS Abdomen and Pelvis scan result report	WITN3449036

01 February 2020	Clinic letter from Dr J Cash to Witness W0007 with Fibroscan result attended on 12 November 2019	WITN3449037
8 June 1989 - 10 June 2009	Summary table of School of Dentistry appointment times and outcomes for Witness W0007	WITN3449038
30 April 2008	Integrated Elective Access Protocol from Department of Health. Social Services and Public Safety, NI	WITN3449039
2001	Royal Hospitals Infection Control Manual: Ch 8 - Prevention of Infection in Hospital Dentistry	WITN3449040
December 2009	BDA Dec 2009: Infection Control in Dentistry:	WITN3449041