Witness Name: Pippa Nightingale
Statement No.: WITN4572020
Exhibits: WITN4572021
WITN4572022
WITN4572023
Dated: 26th November 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PIPPA NIGHTINGALE

I provide this statement on behalf of Chelsea and Westminster Hospital NHS Foundation Trust in response to a request under Rule 9 of the Inquiry Rules 2006 dated 9 July 2021.

I, Pippa Nightingale, will say as follows: -

Section 1: Introduction

1. My name is Pippa Nightingale MBE. My date of birth is GRO-C 1974. I hold the following professional qualifications: Registered Midwife, BSc, MSc 1998.

2. I am Chief Nurse of the Chelsea and Westminster Hospital NHS Foundation Trust ("the Trust"). I am a full voting member of the Board of Directors. Amongst other duties, I am responsible for ensuring the high quality of patient care at the Trust and for providing professional leadership for all nursing and midwifery staff.

Section 2: Background to the West Middlesex University Hospital and Chelsea and Westminster Hospital

1. The West Middlesex University Hospital was not run by the Trust in 1995. At that time, the Hospital was operated by the West Middlesex University Hospital NHS Trust.

2. On 1 September 2015, the West Middlesex University Hospital NHS Trust ceased to exist and the Hospital became part of the Trust.

3. As such, the West Middlesex University Hospital was not run by the Trust at the relevant time, but it is currently operated by the Trust. The Trust therefore holds the historic medical records relevant to this case relating to care provided from 1995 to 2007.

4. The Trust was also managing the Chelsea and Westminster Hospital in 2017, which is noted to be the relevant time for this Witness as she received AbbVie 3D treatment at Chelsea and Westminster Hospital in September 2017.

5. By way of clarification, the Middlesex Hospital where the Witness received the transfusion in 1976 was never managed by the Trust. At the time of its closure in 2005, it was operated by University College London Hospitals NHS Foundation Trust.

Section 3: Response to Concerns of Witness W2042

6. Our sympathies go to Witness W2042 ("the Witness") and her family for the impact Hepatitis C has had on their lives. The Witness has raised concerns about the way she was informed about her Hepatitis C infection at the West Middlesex University Hospital in 1995 and the level of support thereafter. Although the Trust was not the managing authority of the hospital at the time, we want to do our best to address those concerns and share the information we have, in the interest of transparency. In order to do so, we have reviewed Witness's records and obtained input from Dr Michael Anderson, the Witness's consultant at the West Middlesex University Hospital in 1995.

7. The Witness also raised concerns about a delay in receiving treatment in 2017 whilst a patient at the Chelsea and Westminster Hospital. In order to address these concerns, we have reviewed Witness's records and have obtained input from Dr Suman Verma, the Witness's consultant at the Chelsea and Westminster Hospital in 2017.

Provision of Information in 1995

8. It is important to note by way of background that at the time the Witness developed jaundice following a transfusion in 1976 she would have been diagnosed with having non-A non-B hepatitis. It was recognised that the responsible agent was likely to be a virus but it was not known to be Hepatitis C. It was eventually identified in 1989 and became known as Hepatitis C. Routine blood tests to identify hepatitis C became available around 1991 – 1992.

9. On 22 August 1995 the Witness was referred to the Gynaecology Department at the West Middlesex University Hospital with an abnormal smear test. She attended colposcopy clinic on 26 September 1995 and was asked to attend as a day case for laser conisation of cervix. The history of an episode of post transfusion jaundice was noted and therefore the registrar at the clinic appropriately asked for a hepatitis screen. According to the records, the result of Hepatitis C test had been sent back from the laboratory after the letter from the clinic visit had been sent to the Witness, resulting in the Witness not being informed about it until the day of the procedure. I exhibit this page from the records as WITN4572021.

10. The laser conisation of cervix was performed on 30 October 1995. The Witness was informed by a doctor that the result of the hepatitis screen was that she tested positive for Hepatitis C. A letter was sent to Witness's general practitioner ("GP") informing the Witness's GP of this.

11. The Witness was understandably upset that she was simply informed of being infected with Hepatitis C without more explanation. Giving the

information in this way was insensitive and I offer my apologies on behalf of the Trust. This however would not happen now. At the time, Hepatitis C was a 'new disease' and a gynaecology registrar would not have known a lot about the condition which is why the doctor would not have been able to provide much in terms of further information. The Witness's gynaecology consultant subsequently discussed this with the doctor who informed the Witness of the Hepatitis C result.

12. On 23 November 1995 the Witness was referred to the Gastroenterology Department at the West Middlesex University Hospital by her GP due to Hepatitis C (HCV). The Witness was not referred to Dr Anderson by the Gynaecology Department directly because referrals between the departments for non-urgent conditions were discouraged at that time and the gynaecology registrar therefore referred the Witness back to her GP and the GP referred her to Dr Anderson. It was appropriate for the Witness to be seen by Dr Anderson or one of his colleagues. Dr Anderson had an established interest in viral hepatitis, and was very appropriately placed.

13. At present, clinicians at the Trust can refer a patient internally (consultant to consultant referral) for any urgent conditions, suspected cancer, etc. or for the same problem or condition which requires the expertise of another specialty or team. If there is an unrelated problem which is non-urgent then the referral would be made via the patient's primary care provider.

14. On 20 December 1995 the Witness was seen by Dr Anderson in clinic at the Teddington Memorial Hospital, it was an outreach clinic from the West Middlesex University Hospital. Dr Anderson saw her at length and the diagnosis was explained to her. We are sorry that the Witness feels that she was not given full information on this occasion. Unfortunately, there was little accurate information to provide at that time with Hepatitis C virus having only been identified recently and with the natural history of the infection being unclear. There was little further support or counselling available to patients after attending clinics. It is understood that many people with Hepatitis C at that time felt that they did not have enough support. This led to the

establishment of the Hepatitis C Trust, which was set up in 2004 by patients in order to help other patients cope with the many challenges of living with Hepatitis C.

15. The Witness reports being advised "to take care about blood contact but sexual relationships were most probably OK". Dr Anderson's letter to the GP of 28 December 1995, which I exhibit as WITN4572022, sets out that he discussed with the Witness the risks of transmission, particularly relating to her current and previous partners, and that the Witness was going to speak to all of those who might have been affected. The clinic letter of 2 February 1996, which I exhibit as WITN4572023, notes that the Witness attended with her partner, who was aware of the possible risk of transmission and understood that this was extremely low. Indeed it is understood that there is a 0.07% risk of acquiring HCV from a long-term partner who is HCV positive (there is some evidence that men are more likely to transmit the virus than women, but this is not conclusive). The risk may be higher with sex more likely to be associated with exposure to blood eg. sex during menstruation or anal intercourse.

16. The Trust currently has robust pathways for those newly diagnosed with Hepatitis C infection. The service is led cross-site by a Clinical Lead for Hepatology with support from a team of hepatology consultants and specialist nurses who have both dedicated clinics and a regular weekly cross-site multi-disciplinary team meeting.

17. The Witness was thereafter seen by Dr Anderson on 31 January 1996, 9 October 1996 and 24 September 1997, and in his clinic by the registrars on 26 August 1998, 24 February 1999, 25 August 1999 and 24 February 2000. On 23 August 2000 the Witness was seen by Dr Anderson again and was noted to be using Chinese herbal remedies and awaiting improvements to treatment. On 21 February 2001 and 21 August 2001 the Witness was seen by registrars, and on 20 February 2002 she was seen by Dr Anderson, he noted significant

In 2003, Dr Anderson moved to work at Chelsea and Westminster Hospital and the Witness thereafter continued to be seen in clinic by Dr Collins, Dr Beveridge and their respective registrars at West Middlesex University Hospital.

18. In 1995 there were no established treatments for Hepatitis C. Interferon, and later pegylated Interferon, became available in the early 2000's but was only moderately effective at best. In addition, when initially approved by the National Institute for Clinical Excellence (NICE), it was only available for those with advanced fibrosis or cirrhosis and the Witness did not meet these criteria. Importantly, Interferon has significant side effects meaning that many patients cannot tolerate this treatment. The Witness decided to use Chinese herbal remedies, as did many other patients. This was usually well tolerated but there was no evidence of any value to this treatment although the Witness did indicate that she found them helpful. During the time that the Witness was being followed up in clinic it was repeatedly explained that although there was no available therapy other than interferon, other antiviral drugs were in development.

19. Whilst being followed up at West Middlesex University Hospital the Witness had two liver biopsies performed in 2002 and 2004. These helped to confirm that the Witness had only mild liver disease at the time. She saw Dr Anderson in clinic a few weeks after one of these biopsies and explained that she had been unwell and briefly jaundiced. She was well by the time that Dr Anderson saw her in clinic but because of the reported jaundice Dr Anderson considered that there may have been transient haemobilia with a degree of biliary obstruction after the biopsy. This is a very rare complication and since the Witness had recovered there would have been no value in additional investigations at that time.

20. On 30 November 2007, the Witness was seen by Dr Anderson at Chelsea and Westminster Hospital following a referral from West Middlesex University Hospital. He provided her with an update on the treatment options available at that time and they agreed to continue with an expectant policy, i.e.

watchful waiting approach. Dr Anderson noted that the Witness had moved to Wiltshire and suggested that as new treatments became available the Witness could either be referred back to London or may wish to be seen at a more local centre such as Southampton or Portsmouth.

Delay in receiving treatment in 2017

21. The Witness was monitored yearly at the Trust with fibroscans that demonstrated no significant fibrosis. On 23 July 2013 she was reviewed by Dr Anderson and treatment was discussed again but the Witness was keen to adopt a wait-and-see approach pending the arrival of the direct acting antivirals (all tablet form). She was then lost to follow-up and was re-referred by her GP in March 2017.

22. On 31 March 2017 the Witness was reviewed by Dr Verma at Chelsea and Westminster Hospital. Dr Verma reported that in 1994 the Witness was diagnosed with Hepatitis C with a history of jaundice following a blood transfusion after splenectomy in 1976 at the Middlesex Hospital. In line with national guidelines and a necessity for procuring antiviral treatment, blood tests were requested to exclude other causes of liver disease and her Hepatitis C and Hepatitis B status. An ultrasound scan of liver was also requested to exclude any hepatocellular carcinoma and elastography to determine the level of fibrosis.

23. The Witness was made aware at that time that there was a Hepatitis C treatment waiting list and prioritisation was made on the level of fibrosis, with decompensated cirrhotics who had the highest risk of mortality or requiring a liver transplant at the top of the treatment waiting list. The Witness reported that if there was a significant wait she would investigate alternative methods to obtain Hepatitis C antiviral therapy.

24. On 17 May 2017 the Witness's ultrasound scan of liver and elastography were performed. These demonstrated that "the liver appears normal size and shape however hyperechoic in echopattern consistent with fat infiltration".

The elastography reading was 2.05 m/sec (SD 0.18 m/sec) which is consistent with early cirrhosis.

25. On 3 July 2017 the Witness had an appointment with Dr Verma to discuss the results, namely that she had genotype 1b Hepatitis C, elastography in keeping with early cirrhosis, fat infiltration as well as the benefits and side-effects of the direct acting antivirals appropriate for her stage of liver disease. During this appointment the Witness reported that she was consuming 15 units of alcohol a week (one and a half bottles of wine). Due to the direct harmful effects of alcohol on the liver, its calorie content and to prevent further fibrosis progression, advice was given for a graded alcohol reduction to complete abstinence. In addition, the Witness was also advised to have a low fat, low sugar diet and exercise to help dissipate fat from the liver as this can also cause progression of fibrosis. The Witness was also advised to stop taking liver tonics, Chinese herbal remedies and some supplements due to the risk of potential drug interactions with the direct acting Hepatitis C antivirals.

26. Later in July 2017, in accordance with NHS England policy, the Witness's case was discussed at the Operating Delivery Network (ODN) meeting for West London at St Mary's Hospital. The Witness was approved for treatment and added to the treatment waiting list at Chelsea and Westminster Hospital.

27. On 20 September 2017, the Witness commenced a 12 week course of Hepatitis C treatment which was completed on 13 December 2017.

28. In respect of the alleged delay to treatment, from the time of referral in March 2017 to treatment in September 2017 there was no impact on Witness's liver fibrosis or the outcome of her treatment and the Witness was treated in accordance with NHS England pathway. In 2017 NHS England operated a "regional run rate" system whereby NHS England allocated each region a fixed number of funded Hepatitis C treatments per month. Chelsea and Westminster Hospital was allocated 14-15 funded Hepatitis C treatments per month in 2017. The waiting list for treatment at Chelsea and Westminster

Hospital exceeded the number of funded Hepatitis C treatments allocated to it. As mandated by NHS England each patient was discussed at the St Mary's Hospital meeting (ODN for West London) for Hepatitis C treatment approval. Patients were prioritised, primarily on the level of fibrosis with decompensated cirrhotics who had the highest risk of mortality and highest risk of requiring a liver transplant at the top of the list, followed by compensated cirrhotics, severe fibrosis, moderate fibrosis and mild fibrosis. In July 2017, NHS England increased the number of funded Hepatitis C treatments allocated to Chelsea and Westminster Hospital by an additional 11 Hepatitis C treatments a month in response to the hospital's and West London's treatment waiting list, which enabled the Witness to be treated.

29. At present, there is no NHS England limitation on funded Hepatitis C treatments so patients are seen and commenced on treatment within a few weeks.

30. Following treatment, the Witness was followed up at 4, 12 and 24 week intervals post-treatment as mandated by NHS England to determine whether there was Hepatitis C relapse post-treatment (in which case another treatment could be utilised) or treatment was successful. Additionally, as the Witness had early cirrhosis she underwent an ultrasound scan of liver 6-monthly as part of hepatocellular carcinoma (HCC) surveillance given the yearly 1-4% risk of HCC development. Even though she had virological cure there was (and still is) no evidence that virological cure reduces the risk of HCC development in cirrhosis. Hence ultrasound surveillance needs to continue 6 monthly and the Witness's GP was asked to refer her to her local hospital for this surveillance on 6 March 2019. The Trust had no further involvement in the care of the Witness.

31. We hope that the Witness is now well and that there has been a satisfactory outcome.

Statement of Truth

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

Signed GRO-C

Dated 26-11-21

Table of exhibits:

Date	Notes/ Description	Exhibit number
December 1995	Medical records extract	WITN4572021
December 1995	Letter to GP	WITN4527022
February 1996	Letter to GP	WITN4572023