Witness Name: David Anthony Newsome
Statement No.: WITN3080001
Exhibits: None
Dated: 15 May 2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DAVID ANTHONY NEWSOME

1. I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 5 April 2019.

2. I, David Anthony Newsome, will say as follows: -

Section 1: Introduction

3. My name is David Anthony Newsome. My date of birth is GRO-C 1942. My address is GRO-B Lancashire GRO-B

4. My professional qualifications are MB ChB (St Andrews) 1967; MRCP (UK) 1971; FRCP (London) 1995.

5. I have been fully retired from medical practice since 2013 and am no longer on the Medical Register.

6. I was appointed as a Consultant in Haematology at the Blackburn District Health Authority in 1977. I was initially working at the GRO-B In 2006 GRO-B I moved to the Royal Blackburn Hospital (the Queens Park Hospital renamed) which was also part of the Blackburn District Health Authority.

7. Prior to my appointment as a Consultant, I was a Senior Registrar in Haematology, working on a rotational basis through the blood transfusion service in Manchester, at the North Manchester General Hospital and the Manchester Royal Infirmary [1974-1977].

8. It is not clear whether the Inquiry would be assisted by this, but in approximately 2000 a hospital transfusion committee was established at the GRO-B GRO-B I was a member of this committee. I advised on what guidelines should be written and made available to junior staff within the hospital: on when blood and blood products were likely to be used; how much; under what circumstances. I am sure that the committee would have advised on or made known the risk of transmitting blood-borne viruses in transfusions. I cannot, due to the passage of time, speak to any specific guidance or any more specific involvement in the committee.

Section 2: Response to criticism of Mrs A

9. Before addressing the specific questions asked of me by the Inquiry, I wish to make some preliminary observations.

10. I am grateful for the additional time afforded by the Inquiry to prepare this statement. I wish to assist the Inquiry and to address Mrs A's concerns as best I can.

11. I have read Mrs A's statement and I am sorry that she has had such a distressing time. I am very pleased to hear that she is now clear of the Hepatitis C virus. The management of this condition is of course outside my speciality; I have not been asked to comment on it and I do not feel qualified to do so.

12. I would like to point out that I have not had sight of Mrs A's relevant medical records. I understand the Inquiry has sought to obtain them (for which I am grateful), but understand that they are no longer available. This is of course disappointing. There may have been information in them to assist with this response. What I say below is from memory, prompted by Mrs A's statement, 32 years after I supervised her Factor VIII replacement; my memory may not be 100% accurate.

13. I cannot say that I remember Mrs A *specifically*. I do, however, recall to some extent a patient around the material time with the same features. The patient that I recall

had a diagnosis of Von Willebrand disease subsequent to a bleed following a dental extraction; she had pre-eclampsia and was undergoing a Caesarean delivery of her child, and I recall she was inquisitive about the proposed treatment. It was a unique set of circumstances which makes it memorable, as does the fact she was (commendably) enquiring about the nature and / or purpose of the proposed treatment, whereas most patients at this time did not question a doctor's approach. It is therefore likely, in my opinion, that I recall *Mrs A*, but of course I cannot say with certainty.

At paragraph 6 to her statement, Mrs A states that you informed her that she would be given prophylactic cryoprecipitate before the Caesarean delivery of her child to account for her Von Willebrand disease. She states that she questioned this decision as, up until that point, she had not had any problems with Von Willebrand disease.

14. I note that Mrs A suffers from mild Von Willebrand disease, diagnosed at the age of 18 after a routine dental extraction bled excessively.

15. Von Willebrand disease is caused by the missing or defective clotting protein, Von Willebrand factor.

16. If I recall correctly, I was asked to supervise the management of Mrs A's Von Willebrand disease when she was admitted for a Caesarean section in April 1987. The indication for the operation was pre-eclampsia.

17. In view of the fact that Mrs A had bled excessively following a dental extraction, and had been diagnosed with Von Willebrand disease, I believed it would have been appropriate to commence prophylactic (preventative) treatment to raise her Factor VIII (a clotting protein) level.

18. Cryoprecipitate was then the standard form of Factor VIII replacement in Von Willebrand disease. It was considered to be relatively safe (from a viral transmission point of view) compared to Factor VIII concentrate as it was prepared by the National Blood Transfusion Service (NBTS) from locally obtained voluntary donations (each unit came from a single donation); Factor VIII concentrate may have been made from paid donors, who may have covered up viral infections. It was also known to be more effective in treating Von Willebrand disease than the purer pooled concentrates.

19. A Caesarean section is a significant procedure, and there was a real risk of peri-operative and post-operative bleeding. It would have been important to raise the Factor VIII level to as near normal as possible and to keep it at that level for approximately three days after the operation.

20. Mrs A states that she questioned this as up to this point she had not had any problems with Von Willebrand disease. I think I recall the conversation. I do not propose to question Mrs A's account, but I believe that I pointed out to her that she had had problems with Von Willebrand disease as she had bled after a dental extraction. As part of this verbal consent process, I would (in light of the nature of the proposed operation) have discussed the risk of serious bleeding without Factor VIII replacement, and the need to take steps to minimise bleeding.

21. Whilst I cannot recall the full extent of the conversation, I would have been doing my best to persuade her of the necessity for Factor VIII in all the circumstances; I recall this patient (who I presume is Mrs A) took some persuading.

22. Today, I cannot remember how much we discussed the safety of cryoprecipitate from the hepatitis point of view. At the time, we knew that donors were asked about a history of jaundice and that donations were checked for Hepatitis B, but Hepatitis C was not yet discovered.

23. In paragraph 46 of her written statement, Mrs A mentions treatment with vasopressin. To the best of my knowledge, this had not been introduced in the treatment of Von Willebrand disease in 1987. Further, as the administration of vasopressin raises the blood pressure, I would have been reluctant to use it in a patient with pre-eclampsia.

At paragraph 7 to her statement, Mrs A states that she was given Cryoprecipitate on 6th, 7th, 8th and 9th April 1987, initially by you and then by junior doctors. Mrs A states that she questioned why she was being given the cryoprecipitate as she felt she did not need it, but was always told 'just in case'.

24. The term 'just in case' is not one that I am accustomed to using. Having said that, I can understand why the proposed course of treatment, such as in the circumstances of this case, may have come across as a 'just in case' measure. It was a preventative, precautionary plan of treatment, which in the event was based on an informed understanding of the relevant patient history and clinical circumstances.

25. I would have had a junior doctor (a Senior House Officer) working with me at the time. I cannot recall their name. It would not have been unusual for the junior doctor to administer cryoprecipitate in the way described by Mrs A.

26. The course of treatment, as described, appears reasonable, to account for any peri-operative and post-operative risk of bleeding, in the clinical circumstances referred to above.

At paragraph 8 of her statement, Mrs A states that she was not given any advice or further information about the blood product she received, but presumed that it had been heat treated.

27. I cannot comment with certainty on what advice, if any, was given about the blood product used. I do not think it was a point that was (generally) actively and thoroughly discussed back then. In Mrs A's circumstances, I would have been keen to press on with the intended procedure, given the urgency for the same and the risk (by delay) to both mother and child. I am sure, however, I would have discussed the rationale for the proposed course of action. I do not think I would have discussed the risk of transmission (of viral disease) as cryoprecipitate was deemed safe at the time.

28. Had Mrs A asked about whether the blood product was heat treated, I would have told her that it was not. Heat treatment is essentially a process of pasteurising the product; whilst it has the effect of killing viruses, it also has the effect of reducing the efficacy of Factor VIII by degrading it. I don't think it would have crossed my mind at the time that Mrs A might object to the treatment were she to know the cryoprecipitate had not been heat treated; I don't think I would have volunteered that it was not heat treated.

Section 3: Other Issues

29. In 1987, we rarely operated on patients with bleeding disorders in Blackburn. We would usually refer these patients to the Comprehensive Care Haemophilia Centre ('CCC') at the Manchester Royal Infirmary. Blackburn was, then, an associate haemophilia centre to Manchester.

30. However, maintaining adequate Factor VIII levels in patients with Von Willebrand disease is easier than in those with haemophilia, and therefore, from time to time,

operations were carried out in Blackburn on patients with Von Willebrand disease using cryoprecipitate. When this occurred, it was my usual practice to discuss these patients with medical staff at the CCC to ensure that they were happy for me to supervise the Factor VIII replacement in Blackburn, and to agree the regimen to be administered (returns were also filed each year, relating to what Factor VIII products had been administered; I am not sure where these returns ended up). As Mrs A was treated so long ago, I cannot be certain that I discussed her care in this way but I think it is highly likely that I did so.

31. We knew at the time of the risk of infection from blood products that were pooled, and which came from blood outside of the country; and that patients could get Hepatitis from a transfusion of blood or blood products. There was a suspicion that American-derived Factor VIII could transmit blood borne viruses. We were less concerned with domestic blood within the NHS. We knew the blood transfusion service checked for Hepatitis B. The Hepatitis A virus did not *persist* in patients, but we knew that donors were asked about a history of jaundice (an indicator). Hepatitis C was not known; what was known was that some patients developed jaundice who did not have Hepatitis A or B – we thought this was an acute problem that got better.

Statement of Truth

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

Signed GRO-C

Dated 15 May 2019