

Witness Name: Professor Michael Makris

Statement No: WITN4033017

Exhibits: WITN4033018 - 22

Dated: 6 October 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR MICHAEL MAKRIS

I provide this statement on behalf of Sheffield Teaching Hospitals NHS Foundation Trust in response to a request under rule 9 of the Inquiry Rules 2006 dated 18 March 2020.

I, Professor Makris, will say as follows:

Section 1: Introduction

1. Please set out your name, address, date of birth and professional qualifications.
2. I am Michael Makris and my professional address is the Department of Haematology, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF. My date of birth is GRO-C 1959 and my professional qualifications are MB BS, MA, MD, FRCP, FRCPath.
3. Please set out your current role at the Trust and your responsibilities in that role.

4. I am an honorary consultant haematologist providing care for patients with bleeding and thrombotic problems including patients with haemophilia.
5. **Please set out the position of your organisation in relation to Royal Hallamshire Hospital (for example 'ABC NHS Foundation Trust ("the Trust") operates from Hospital X and Hospital Y (formerly Hospital Z)').**
6. My employer is The University of Sheffield and I have an honorary haematology consultant contract with the Sheffield Teaching Hospitals NHS Foundation Trust. The Trust has two main hospitals, the Royal Hallamshire Hospital (where the Haemophilia Centre is located) and Northern General Hospital.

Section 2: Response to Criticism of W0472

1. **At paragraph 11 of his statement, witness W0472 states that doctors carried out tests on him because he was turning yellow after he first began treatment with Factor VIII in 1983/1984, but they did not say what for. Their explanation was that he was jaundiced and his liver and kidneys were infected. Please comment on this.**
2. You ask what tests were performed in 1983/1984 when he turned yellow after his first exposure to FVIII. His first exposure to FVIII was not in 1983/1984.
3. It is documented in his medical notes that he had some FVIII in 1977. He was admitted on 31 March 1977 with a massive thigh haematoma after a fall. He was treated with Kryobulin and Lister FVIII. He had to be readmitted with jaundice on 21 May 1977. It was believed that his jaundice related to his FVIII treatment and was due to Hepatitis B. These medical records are exhibited at WITN4033018 .

4. He had another leg haematoma following an accident on 26 April 1982 and was admitted for FVIII concentrate treatment. Following discharge, he was reviewed on 13 May 1982 on the ward with jaundice that was thought to be due to his FVIII treatment and to be due to non-A, non-B Hepatitis. The records of this are exhibited at WITN4033019 .
5. The tests performed were a full blood count, kidney function, liver function and clotting that are the standard tests performed in any patient with acute Hepatitis. He was also tested for Hepatitis A and B. There was no test for Hepatitis C at the time because the Hepatitis C virus was not discovered until 1989.
6. **At paragraph 12 of his statement, witness W0472 states that he knew something was wrong after he was later sat down with two eminent doctors. In this meeting they said, "you are infected and we must tell you because you might infect your wife". Witness W0472 explains that they did not make clear what he was infected with. Please comment on this.**
7. This refers to his comment in paragraph 12 mentioning that he was sat down and told that he was infected and could pass it onto his wife, but was not told what the infection was. Since he says he was told he was infected, it must relate to Hepatitis C (and not to HIV as he is HIV negative). There is no date for this consultation in W0472's statement. I presume this happened in the early 1990s but I can find no entry in the medical notes of this consultation visit. Despite the absence of a record in his medical notes, it would be unusual for two doctors to have a specific consultation with a patient for the purpose of informing him that he was infected and not to mention what the infection was during the consultation.
8. **At paragraph 14 of his statement, witness W0472 states that the doctors did not tell him anything about his infection but he found out about "Hepatitis C, HIV, [and] AIDS" in the papers, as famous people such as Freddie Mercury died from it. Please comment on this.**

9. This question is around his point 14 that he was not informed about his infection and he found out about the importance of Hepatitis C and HIV from the newspapers. His medical notes do not contain entries about him being informed of the results of his Hepatitis C and HIV status. However, I do believe that he was informed about both the results.

a) Hepatitis C

As discussed in point 7 above, he had a consultation with two doctors to tell him he was infected. Furthermore, the possibility of liver disease after concentrate use in W0472 was not new; he was considered to have non-A, non-B Hepatitis after his 1982 episode of jaundice, he was followed in clinic to monitor his liver function and in 1988 he had a liver biopsy, something that was very rarely done in patients with inherited bleeding disorders. This is demonstrated within exhibit WITN4033020 I.

b) HIV

There is no entry in the notes that he was informed he was negative, although the medical notes indicate that he was HIV negative.

I believe he was informed of his HIV negative status due to an unusual event. Nurse Joy Farnsworth (Senior Haemophilia Nurse) recalls being in a consultation with Professor Eric Preston when they saw W0472 and told him his negative result. She mentioned to me that she recalls W0472 was so relieved to be told the test was negative and he is the only person to have brought her and Professor Preston a bottle of Champagne each.

[Clarification: Sister Farnsworth does not recall whether W0472 brought her the bottle of Champagne after the information about the HIV or Hepatitis C result. My assumption is that this happened after the negative HIV result since the Hepatitis C result was positive].

10. At paragraph 37 of his statement, witness W0472 states that doctors told him he had jaundice due to his drinking but he had never been a big drinker. Please comment on this.

11. I can find no information in the notes about him being told that his jaundice was due to his alcohol intake. Actually, the notes exhibited at WITN4033021 , make it clear that the jaundice was thought to be due to his recent FVIII exposure.

12. At a later clinic visit in 1992 there is an entry exhibited at WITN4033022 , stating that his alcohol intake was 40 units per week, which is higher than recommended for men in the UK. His occupation was a publican at the time.

13. He had low level raised liver transaminase enzymes (indicating liver inflammation) and in 1988 he had a liver biopsy to try and differentiate between excessive alcohol intake and chronic non-A, non-B Hepatitis. The liver biopsy actually showed minimal abnormalities and was not supportive of either diagnosis. The record is exhibited at WITN4033020 .

14. At paragraph 39 of his statement, witness W0472 states that he received letters warning him that he may have variant Creutzfeldt–Jakob disease (vCJD). However, a later letter (dated 18 November 2004) confirmed he did not receive an infected batch, made from donors who developed vCJD. He explains that this letter only covers the Royal Hallamshire Hospital and does not otherwise confirm that he does not have it. He states he has never been tested for vCJD. Please comment on this.

15. All of his FVIII treatment was given in Sheffield, as far as we know. Records of all treatment given are kept in the Haemophilia Centre, which is located in the Royal Hallamshire Hospital in Sheffield. He states that he has never been tested for vCJD but there is no readily available test for this infection. The only way to diagnose it is through a brain biopsy, which is obviously inappropriate in a patient with no signs or symptoms of the disease.

Section 3: Other Issues

- 1. If there are any other issues in relation to which you consider that you have evidence which will be relevant to the Inquiry's investigation of the matters set out in its Terms of Reference, please insert them here.**
- 2. His bleeding disorder diagnosis is Type 2N von Willebrand disease. This disorder was first described in world literature in the early 1990s. W0472 was diagnosed with von Willebrand disease decades earlier but the subtype was not confirmed until the early 1990s, when the relevant test became available.**
- 3. He does not respond well enough to desmopressin (DDAVP). This disorder does not respond well to recombinant FVIII either. The only treatment, to this date, is intermediate purity FVIII.**
- 4. Hepatitis C was discovered in 1989.**
- 5. Virally inactivated clotting factor concentrates were introduced in 1985.**

Statement of Truth

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

Signed

GRO-C

Dated 6 October 2020

Table of Exhibits

Date	Notes/Description	Exhibit number
31/03/1977 - 30/05/1977	Medical Notes Pages 276-285	WITN4033018
26/04/1982 – 18/07/1982	Medical Notes Pages 289-292	WITN4033019
05/02/1986 – 23/09/1991	Medical Notes Pages 299-306	WITN4033020
13/05/1982 – 29/07/1987	Medical Notes Pages 291-292; 294-295 and 299	WITN4033021
23/09/1991 – 23/02/1994	Medical Notes Page 307	WITN4033022