Witness Name: Dr May Hawkesworth

Statement No: WITN3825001

Exhibits: WITN3825002

Dated: 4 December 2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR MAY HAWKESWORTH

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 October 2019 in relation to the witness statement of witness 1002, KS.

I, Dr May Hawkesworth, will say as follows:

Section 1: Introduction

1. My name is May Hawkesworth and my address is GRO-C GRO-C North Yorkshire GRO-C My date of birth is GRO-C 1951. I hold the following professional qualifications – MB BS (1976), MRCP (1978) and MD (1983).

2. I am currently practising as a general practitioner at the Nidderdale Group Practice in Harrogate. I practise part-time, three sessions per week. I am also a GP appraiser. I have been practising as a GP since 1984.

3. The only position I have held as a haematologist was as a Registrar in Haematology at the Ealing Hospital and the Hammersmith Hospital in London between 1982 and 1984. This was a 2 year training post. I had not had any prior haematology experience. The first year at Ealing Hospital focused on general haematology and was split between lab work and clinical responsibility for general haematology disorders. The second year at Hammersmith Hospital was more specialised with a focus on white or red blood cells,

coagulation and genetic disorders. I did not in fact complete the second year for personal reasons. After this post, I began training in general practice.

4. Of relevance to the Inquiry, between 1979 and 1982 I worked as a Research Fellow in the Academic Liver Unit at the Royal Free Hospital in London under the supervision of Professor Dame Sheila Sherlock and Professor (then Dr) Howard C Thomas. I believe I was employed as a research fellow on an MRC grant. At that time I was known as Dr May Bamber. This was my first research role. I gathered the preliminary data for patients who were suspected to have non-A, non-B hepatitis. This included reviewing liver enzyme test results for patients with coagulation disorders who displayed these enzyme abnormalities in their liver tests. It was presumed that these patients had been infected with hepatitis virus.

5. I have not held membership of any committees or groups relevant to the Inquiry's terms of reference.

Section 2: Background information

6. I have prepared this statement on the basis of my limited recollection as these events took place almost 40 years ago and I have not had access to KS's husband's medical records.

7. Firstly I would like to express my heartfelt empathy to KS and her family. I was distressed to learn about her husband's diagnoses and passing.

8. I was involved in research which led to the publication of the article entitled, '*Short incubation non-A, non-B hepatitis transmitted by factor VIII concentrates in patients with congenital coagulation disorders*' ('the Article') which was published in Gut in 1981. I was the first author of this paper. A full copy of the Article is exhibited here (**WITN3825002**). The patients referred to in KS's statement were not included in this Article.

9. During my time at the Royal Free, I was not clinically responsible for the coagulation disorder patients; their treating doctors were the haematologists at the Haemophilia

Centre. My contact with these patients was limited to taking a small number of liver biopsies on behalf of The Liver Unit. I had been trained to do this and did this with the agreement of the haematologists. The Liver Unit, which I was part of, worked in close collaboration with the Haemophilia Centre in relation to non-A, non-B hepatitis.

10. Before my arrival at the Royal Free, I believe that Professor Kernoff and Dr Thomas had already had discussions about conducting investigations into the meaning of the persisting abnormalities in liver enzyme tests of haemophiliac patients. I was not involved in these preliminary discussions. The Haemophilia Centre facilitated my accessing the patient notes in order to allow collection of data for the purposes of this investigation.

11. I initially examined the clinical notes for all 95 of the haemophilia patients registered at the Centre at that time focusing on liver enzymes (transaminases). The period of observation was from 1 January 1979 to 31 December 1979. Blood samples had already been collected by the Haemophilia Centre. The data demonstrated that approximately 90% of these patients did have abnormalities in their liver enzymes and their clinical presentations were consistent with non-A, non-B hepatitis. I also recollect recording the patients' hepatitis B status.

12. Some patients who were noted to display raised transaminases for longer than six months also had liver biopsies taken. I carried out liver biopsies from a few of these patients after taking consent in line with the Liver Unit protocol at the time. This was predominantly in order to identify any abnormalities in the structure of the liver and to assess whether there was evidence of chronic liver disease. Patients were fully informed about the procedure and a signed consent was obtained.

13. 8 patients with haemophilia A and 2 with von Willebrand's Disease who developed acute hepatitis following Factor VIII were identified and studied. All patients were followed up at regular intervals for more than six months. Serological examinations were performed to exclude other infections.

14. The aim of our evaluation was to describe the clinical, biochemical, serological and histological aspects of what was then known as non-A, non-B hepatitis (now known as hepatitis C) in patients with congenital coagulation disorders. We were looking to

identify any trends in order to aid clinical management. Ultimately, the goal was to identify the virus, provide treatment and prevent transmission in haemophilia patients and other at risk groups. Little had been known at the time about this presumed viral infection. The virus was thought to be parenterally transmitted and the haemophilia population was thought to be at risk because of the frequency with which they had received blood products for management of their bleeding episodes.

15. My work led to an MD thesis on non-A non-B hepatitis which I wrote in 1983. This thesis provides a historical background to non-A, non-B hepatitis as well as my findings about the epidemiology, clinical presentation, histology and serological tests relating to this infection. The Article was only one chapter of patients studied who had non-A, non-B hepatitis.

16. We worked very closely with Professor Peter Kernoff and his department. Professor Kernoff was one of the treating haematologists and also an author of the paper. Since he had regular contact with the patients, he had obtained the necessary consent from patients for blood tests and kept them informed of their liver test abnormalities. The blood sampling for liver tests (and other serological tests) had already been done by the Haemophilia Unit before I joined the Liver Unit. These tests were conducted as part of the patient's overall clinical care and my observations on these tests was retrospective.

17. The study enabled us to describe the epidemiology of non-A, non-B hepatitis in at risk patients including haemophiliacs. After my departure, my colleagues in the lab continued the project to identify the viral antigen. Patients were told of persistent liver enzyme abnormalities and followed up by the Haemophilia Centre. The virus had not been identified by the time I left in 1982; indeed hepatitis C was only discovered in 1989 by a lab in the US. Anonymised information was shared between the laboratories and once the virus could be detected and identified, this rationalised the management and treatment of this hepatitis condition. The research project that I was involved in at the Royal Free was early work which contributed to defining and evaluating the correlation between the circulating liver enzyme abnormality and any changes in liver architecture. Our work was designed with the aim of helping patients.

Section 3: Criticism by KS

Response to Question 4: At paragraphs 25 and 26 of her witness statement, witness W1002 states that she believes you used the test results of her husband and two sons in your paper, '*short incubation non-A non-B hepatitis transmitted by factor VIII concentrates in patients with congenital coagulation disorders*' without their knowledge or consent. Please comment on this.

18. As stated above, the test results for AS Senior, AS Junior and MAS were not used in the Article. The work which contributed to the Article as attached to this statement was carried out in 1979. This was before the time that AS Senior, AS Junior and MAS were thought to have contracted non-A, non-B hepatitis, i.e. 1980, 1981 and around 1999 respectively.

19. As stated above, the responsibility for obtaining patient consent for blood samples lay with the Haemophilia Centre as they had contact with the patients. The samples were taken as part of the patient's clinical care. The blood samples referred to in Exhibit WITN1002014 were requested by the Haemophilia Centre after changes in the circulating liver transaminases suggesting acute non-A, non-B hepatitis. The treating clinicians were seeking to confirm this diagnosis with the aid of serological tests from our laboratory. On the request form, it usually stated that the patient was displaying features of non-A, non-B infection, for example, in March/April 1980 when AS senior was thought to be suffering with this infection, after having received blood product BPL 2644. In relation to liver biopsies, for the few that I carried out on haemophilia patients, I took consent from the patient and warned about the risks of the procedure in line with the Liver Unit protocol.

Section 4: Other issues

20. At paragraph 26 of her statement, KS refers to a second study. I was not involved in that paper.

Statement of Truth

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

Signed GRO-C

Dated 4 December 2019

Table of exhibits:

Date	Notes/ Description	Exhibit number
1981	Article entitled, '*Short incubation non-A, non-B hepatitis transmitted by factor VIII concentrates in patients with congenital coagulation disorders*' ('the Article') which was published in Gut.	WITN3825002