Witness Name: Professor Charles Richard Morris
Hay Statement No.: WITN3289020
Exhibits: WITN3289021 - 022
Dated: 21st February 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR CHARLES HAY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 21 June 2019, in respect of Margaret Madden.

I, Dr Charles Hay, will say as follows: -

Section 1: Introduction and Background

1. Professor Charles Richard Morris Hay MBChB MD FRCP FRCPath
   Consultant Haematologist Manchester Royal Infirmary since December 1994. Director Manchester Adults Haemophilia Comprehensive Care Centre since December 1994
   Senior Lecturer in Haematology Liverpool University and Director Liverpool Haemophilia Centre, Royal Liverpool Hospital 1987-1994.
   Professor of Haemostasis and Thrombosis.
   Director, UK National Haemophilia Database since 2002.
   Member UK Haemophilia Centre Directors Organisation (UKHCDO) Regional Committee and then Advisory Committee since 2007.
   Vice Chairman, UKHCDO 1997 to 2005.
   Chairman, UKHCDO 2005-11.
   I attach my curriculum vitae as exhibit WITN3289021.

2. The Manchester Haemophilia Comprehensive Care Centre (Adults) is based in Manchester Royal Infirmary. This was the third largest haemophilia Centre in the United Kingdom in 1994. It is now the second largest with >2500 patients with

bleeding disorders registered. When I arrived in 1994, I was the only consultant specialising in adult Thrombosis and Haemostasis in the North West Region, assisted by a part-time clinical assistant. We now have four consultants with this specialism. In 1994, we had three Haemophilia Nurses, one of whom also did counselling and went into the community. There were no clinical research staff. There were no joint clinics and no formal liaison with any other supporting specialism or profession allied to medicine, such as physiotherapy. All the follow-up clinics were conducted in the Haemophilia Centre without any junior staff, nursing staff or physiotherapy input. There was no internal training rotation for junior staff so they spent all their time managing haematological malignancy. I was on call 1:1 i.e. 365 days a year except when away or on holiday.

3. In the first year, I introduced an internal training rotation for junior staff so that we had a registrar attached to Thrombosis and Haemostasis most of the time. I introduced weekly multidisciplinary meetings and arranged for Physiotherapy input for our patients. We introduced a multidisciplinary Haemophilia Follow-up clinic with doctors, haemophilia nurse specialists and physiotherapists in attendance and social workers available. I rapidly established joint clinics for Orthopaedics and subsequently Joint HIV clinics and Joint Obstetric Clinics and later Joint Adolescent Clinics with the paediatric service. Liaison with Hepatology was close throughout this period but not formalised around a clinic. As we acquired more consultants specialising in Thrombosis and Haemostasis, in 1999, 2003 and 2018, the patients were reallocated among the consultants. Almost all the HIV positive patients have remained with me and are joint-managed with Dr Ashish Sukthanker, Consultant HIV Physician.

4. We tried to manage the patients in a holistic and sympathetic way. Most had been attending for very many years and had a closer relationship with the centre than with their GP and would consult us about all sorts of things. Because of the hereditary nature of the condition, we would often be involved with other members or even generations of the family. It was common for patients to bring relatives or partners with them to clinic.

5. I have made extensive efforts to trace Mrs Madden's notes. It had been my instruction to the Centre on taking up post at MRI in 1994, that no notes were to be destroyed. I eventually traced two volumes of Mrs Madden's notes, one of which was clearly incomplete, which had been misfiled. This folder is labelled on the outside "*Volume 1 of 2. Case note history investigations and correspondence.*"

Unfortunately this volume includes some but not all of her investigations, mostly biochemistry and haematology, but nothing else. A further search has proved fruitless.

6. I was Mrs Margaret Alice Madden's Consultant Haematologist from December 1994 until her death from complications of vascular dementia on 8/12/2005, at the age of 79. I remember Mrs Madden very well since she was one of very few women with severe haemophilia, her father having had severe haemophilia and her mother being a carrier of severe haemophilia with a haemophilic brother. Her parents met at a dance. I remember her as a pleasant elderly lady with a good sense of humour but terrible joints. As time went by, she became increasingly forgetful and developed increasingly severe dementia. I never managed Mrs Madden's daughter Margaret or her grandson, who also had haemophilia.

7. We would have reviewed Mrs Madden every six months and in between, as required. We offered a drop-in service for all our patients with bleeding disorders and they have open access to the service. These consultations would usually last between 30 and 60 minutes depending on the clinical complexity of the patient and whether there were current or new problems that needed to be addressed. The patients would see a consultant, sometimes a trainee haematologist, Haemophilia Nurse Specialist, usually a physiotherapist and sometimes a social worker. It was a multidisciplinary clinic. After each consultation we would write to the GP and any other relevant doctor involved in the patient's management.

8. In later years, Mrs Madden also frequently had to be brought into the department by ambulance for us to administer her prophylactic Factor VIII to prevent her bleeding. She became unable to self-administer because of her advancing dementia. As one would expect of a patient born during the very early years of haemophilia treatment, she had severe arthropathy, and was also reviewed in the joint orthopaedic clinic and underwent hip arthroplasty, covered with recombinant factor VIII (Refacto).

9. Her liver disease was monitored from the 1970s with liver function tests every 6 months and periodic liver ultrasound examinations. Since her liver function tests had been entirely normal for at least the last 25 years of her life and her liver ultrasound examinations were also normal, her hepatitis C never gave rise to any concern and, given her other medical conditions, it was never felt appropriate or necessary to offer her antiviral therapy. Mrs Madden's daughter's evidence appears to confirm that non-

A non-B hepatitis was discussed with her mother in the 1980s. She would have undergone hepatitis C testing in 1992 under the care of one of my predecessors, Dr Richard Wensley or Dr Guy Lucas.

10. Having been born in the pre-treatment era for haemophilia, she was one of the few survivors, since the life expectancy for haemophilia at the time of her birth was estimated at 10-15 years. She almost bled to death giving birth to her daughter Margaret. Judging from data submitted to the UK National Haemophilia Database, (which showed exposure to an average of more than 40 donors per year for the many years when the standard treatment was Cryoprecipitate) on the balance of probabilities, she would have contracted Hepatitis C from Cryoprecipitate in the 1960s or 1970s before her first exposure to Factor VIII concentrate, which was of UK manufacture. (see extract from the National Haemophilia Database, WITN3289022).

11. As far as we can determine, she was never treated with batches of UK concentrate which included donations from donors who had developed variant Jacob Kreutzfeld (vCJD) disease and so was not considered at risk for vCJD.

12. Her liver disease did not give rise to concern. She did not have cirrhosis as far as I am aware. Our position about that was set out in WITN1364004, a letter to the Skipton Fund, prepared with access to her medical records. The evidence which Mrs Madden's daughter has submitted to suggest that she had cirrhosis at the time of death (WITN1364006) is a page of the clinical record from another hospital which includes the differential diagnosis on admission including in the list of possible diagnoses *"?due to progression HepC/Cirrhosis"*. This was a possibility raised as a hypothetical rather than an actual diagnosis. There was never any evidence of cirrhosis and her liver function tests (ALT and AST) were entirely normal for at least the last 25 years of her life.

13. It was therefore not appropriate to treat this patient with Interferon and Ribivarin, given the absence of any evidence of progressive liver disease, her advanced age, severe vascular dementia, her inability to comply with treatment and the expected side effects of HCV treatment.

14. She did not have vCJD as she had not had exposure to any concentrate from infected individuals. She did suffer from progressive dementia over a number of

years and sadly died from the complications of this. The course of her dementia was quitetypical of vascular dementia and bore no resemblance to variant Jacob Kreuzfeld disease, a diagnosis which was never entertained, partly because the natural history and features are quite different and partly because her treatment history showed that she was not at risk. Even in 2019, no patients with bleeding disorders have developed vCJD. Her death was unrelated to her haemophilia or any of the treatments for it.

Section 2: Responses to criticism of Ms Margaret Madden

1. I have been asked to comment on statements attributed to me from routine consultations at which Ms Margaret Madden (Junior) was present. These are paraphrased by Ms Madden and presented without context. I have no recollection of Mrs Madden's daughter or of the consultation in question. Mrs Madden generally attended the Centre on her own, and by ambulance, during the time that I knew her.

Question 4:

> *"During her oral evidence, Ms Madden stated that during a routine appointment where Ms Madden, her mother and you were present, Ms Madden asked you about her mother's Hepatitis C status and how long her mother had had the virus. Ms Madden then states that you told her `it is nothing to do with you` and were dismissive of the question."*

2. Mrs Madden's account seems factually inaccurate and unlikely in clinical terms. I can only imagine that there must be some misunderstanding or misremembering on her part.
3. I have read Ms Madden's evidence to the Inquiry on the 14 June 2019 and in particular her answer on page 111 of the transcript. However, I also draw attention to paragraphs 13 and 14 of her statement dated 25 April 2019.

4. In paragraph 13, she describes a conversation with her mother following receipt of a letter from the Centre in the mid-1980s:

> *"...she was also told that she was infected with something but it was not AIDS. She said that the doctors told her not to worry about it and that it would*

not kill her and nothing would happen, it is just something found in the blood now and again. I believe that the doctors told her at the time that she had non–A, non-B (NANB) hepatitis."

This accords with the information being provided to patients at that time and prior to the identification of the HCV.

5. Paragraph 14 of the statement may describe the same consultation from which the criticism arises in her oral evidence to the Inquiry, to which I am now invited to respond;

> "*I saw in her medical records that she tested positive for Hep C and negative for HIV. I questioned the doctor about the results, but he said that there is nothing to worry about. We were not told that she would be tested for Hep C or HIV, it was a routine appointment that we attended and I found out. The doctors did inform me that my mother was told and if I was not told then it was nothing to do with them. The doctor said [is] that there is nothing to worry about."*

6. I would never have told Ms Madden (or any other relative attending) that her mother's HCV was none of her business, since I would have taken the relative's presence as evidence of the patient's consent to discuss her medical issues. If she had asked why she was not told earlier, I may have advised her that clinical explanations about medical issues would have been communicated to her mother over the years and it was a matter for her mother, as the patient, who else she wished to be informed. Her mother's HCV was clearly a legitimate area of interest for Ms Madden and we speak with relatives with the patient's consent, so long as the patient has capacity to give it. I may not have not spoken with Mrs Madden's daughter because she had not previously attended with her mother or requested to speak to us. I would not have been dismissive of Mrs Madden's liver disease but would have explained that it was not an active concern since her liver function tests, monitored regularly, had been normal for so very many years. Thus she had no evidence of progressive liver disease. Furthermore, her progressing vascular dementia and the continued management of her haemophilia, were our principal concerns at that time.

Question 5.

"Ms Madden also stated that you had told Ms Madden that her mother had been `in contact` with variant CJD but that during this appointment, you did not want to talk about the variant CJD of Ms Madden's mother."

7. It is extremely unlikely that I would have refused to talk about vCJD. However, Mrs Madden had not, as far as we knew, been exposed to an implicated batch of Concentrate and was not therefore considered at risk. It is likely that Mrs Madden had been confused by the letter in 2003 about vCJD, as had very many other patients and had described it to her daughter in confused terms, particularly since she was suffering from dementia. She had classical vascular dementia and did not have vCJD; the clinical pattern of her dementia and its time course bore no comparison with that of vCJD. I would be likely to have offered qualified reassurance. I am sorry that this has been perceived as being dismissive as this would never be my intention.

Question 6.

8. I refer to my responses in relation to questions 4 and 5 – see above.

Statement of Truth

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

Signed GRO-C Dated 21st February 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
-	Prof CRM Hay CV	WITN3289021
1969 - 2005	Extract from the National Haemophilia Database in relation to Mrs Margaret Madden	WITN3289022