Witness Name: Prof Christopher Ludlam
Statement No.: WITN3428026
Exhibits: None
Dated: 14 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR CHRISTOPHER LUDLAM

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 20 June 2019.

I, Professor Christopher Ludlam, will say as follows: -

Section 1: Introduction

1) My full name is Christopher A Ludlam. My date of birth is GRO-C 1946. My address is known to the Inquiry. My professional qualifications are B.Sc, M.B.,Ch.B, MRCP, MRCPath, Ph.D, FRCP, FRCPath.

2) I have set out the positions I have held as a haematologist in the curriculum vitae held by the Inquiry (WITN3428002).

3) All past and present memberships of committees and groups relevant to the Inquiry's Terms of Reference are set out in my curriculum vitae (WITN3428002).

Section 2: Responses to criticism of W2168

4) I am sorry to learn of Mr Hutchison's distressing recollection of events of the past 40 years. I have tried to respond as fully as I can from my memory and from the information is his statement and the attached documents. I have not had access to Mr

Hutchison's medical records, other than the attachments to his statement which included letters and some of the information about vCJD

Mr Hutchison inquires in paragraph 4 of his statement as to what stored blood samples have been kept from him and whether I still have access to his 'files and samples' of blood. In paragraph 5 he states that 'I never gave consent for research and I believe that this is something that is still on going with my blood samples.' He states that 'Professor Ludlam was hesitant to give evidence to the Penrose Inquiry and he should be asked about how he has been treated people like me and what was done with our blood'.

5) As part of the routine standard care and monitoring of people with haemophilia blood samples are requested from patients which are analysed to monitor the effects of treatment and its potential side effects. Mr Hutchison indicates that as a child he was very frequently at the Haemophilia Centre. We would have explained to his parents, especially his mother who often accompanied him, what investigations we would routinely carry out. We had a policy of being very open with patients about arrangements for blood sampling and the giving of results. We will have explained that samples would be stored and might be used in future for research investigations. For example one of the sets of investigations was undertaken at the virology department, e.g. to monitor the hepatitis situation, and afterwards these would routinely be stored frozen, as was a standard arrangement with samples from all clinical sources, and was considered good laboratory practice. These could be used if further investigations were necessary. As a result of a breakdown of a deep freeze in the virology department a large number of samples were destroyed. Because of this unfortunate incident a back-up arrangement was made for small samples to be stored in haematology department as an insurance arrangement. When specific hepatitis tests became available it is possible that stored samples may have been used to assess Mr Hutchison's viral status so that he could be informed of the results and offered appropriate treatment. Knowledge about viral risks of treatment evolved over time and I did my best to ensure that I kept abreast of developments so I could undertake the most appropriate monitoring.

6) As I retired from the Royal Infirmary some time ago I do not know what samples may still be stored. I do not have access to these nor to Mr Hutchison's case notes. It is my understanding that for stored samples to be used in any way now or in the future, consent would be required.

7) I willingly gave evidence to the Penrose Inquiry on ten occasions and explained in detail about how patients' haemophilia was monitored with blood tests.

Mr Hutchison states in paragraph 9 that I was vague with his parents about the risks of treatment in the first half of the 1980s and that they were not given any information and offered alternative treatments.

8) I remember Mr Hutchison's parents, particularly his mother. I am quite sure that I, or another member of the team, will have explained about the risks of treatment, including hepatitis. At this time there was much uncertainty about the significance of non-A non-B hepatitis for which there was no specific diagnostic blood test. The patient indicates in Paragraph 11 his parents were informed of his non-A non-B hepatitis. Furthermore they will have been asked to sign a consent form, which mentioned the hepatitis risk, prior to the start of home therapy. This uncertainty about the significance of non-A non-B hepatitis may be why Mr Hutchison considers that not much information was given. We will have explained our then perception of the condition. His parents would have been reminded about hepatitis and could have asked for further information when blood was taken at the routine follow up clinics. His parents will have been remined about the hepatitis risk when he became infected with hepatitis B jn 1984 and they received injections to reduce the risk of them becoming infected.

9) The regular Bulletins and other literature from the Haemophilia Society was always available in the haemophilia waiting room – this covered a wide range of topics of interest and concern to patients and families including about viral infections.

10) It is likely he first became infected with non-A non-B hepatitis when initially treated at Leith hospital. The importance of regular monitoring the side effects of treatment was illustrated by the finding of him becoming positive for hepatitis B infection in 1984. As a result we were able to offer prompt protection to both his parents and to immunise his brother with a vaccine which had just become available.

11) Mr Hutchison was treated with plasma-derived coagulation factor concentrates containing factor IX which were effective prophylaxis and treatment for his bleeding disorder. At this time the only alternative would have been fresh-frozen plasma infusions which would have been less effective anti-bleed treatment, might have produced immediate reactions to infusions and with which there would still have been a significant risk of virus transmission. I remember his mother being taught to treat

Myles, and his brother, and this allowed for the family to greatly benefit from home treatment. Prior to this as Mr Hutchison states in his evidence there were many frequent visits to hospital with bleeds.

Mr Hutchison states in paragraph 11 and 12 that his parents were not given adequate information about non-A non-B hepatitis and hepatitis C in 1993.

12) I have responded to the non-A non-B hepatitis situation above. From Mr Hutchison's statement in paragraphs 12 and the attached documents it is clear that I met with both his parents in October 1993 and explained about hepatitis C and gave them the Haemophilia Society booklet on hepatitis along with our information sheet on the condition. It appears that they were very anxious about the hepatitis and I will have given them a full description of what was known at that time about hepatitis C. Because of difficulties in the family Mrs Geraldine Brown, the Haemophilia Social Worker, was already seeing Mr Hutchison and his brother, and I wrote to ask if she would see their parents as well as they were keen to meet with her. Mr Myles Hutchison saw Professor Hayes in November 1993 in connection with his hepatitis C.

In paragraph 11 Mr Hutchison states that 'my infection with both hepatitis B and C could have come from my first injection.' He goes on to state that 'Professor Ludlam said that they did not monitor every batch because the blood came from multiple sources'.

13) It is correct that Mr Hutchison's non-A non-B hepatitis infection is likely to have originated early during his treatment at Leith Hospital as a small child in the early 1970s. It appears from the attachments that Mr Hutchison provided with his statement that he became infected with hepatitis B in early 1984 (WITN2168002). Screening of blood donors for hepatitis B started in the early 1970s but as has been demonstrated by monitoring of patients in Edinburgh there was still a risk of infection with this virus because the screening tests were not sufficiently sensitive to detect all infectious donations (Stirling et al, J Clin Path 1983 36 577-80) It is correct to state that we did not monitor the effect of individual batches of treatment.

14) When an individual batch of treatment was used up, treatment from another was issued. Monitoring of patients was done periodically when they attended hospital for review. It is not clear what Mr Hutchison in referring to in 'every batch because the blood came from multiple sources.' The plasma-derived concentrates were

manufactured from pooled plasma donations from many blood donors. Meticulous records were kept of each treatment including the batch number. There were therefore good records of all treatments and regular assessment of these by monitoring investigations.

Mr Hutchison states in paragraph 12 that 'My Mum has told me since that it was like pulling teeth trying to get information from the doctors, both about the risks of the treatment and about my diagnosis with hepatitis B and non-A non-B hepatitis would mean for me and them' and that he should have been told earlier about his infections.

15) Mr Hutchison clearly acknowledges that his parents were inquiring about hepatitis. In response to such inquiry we would have responded at each particular time with what was known about the different forms of hepatitis and what was considered to be the consequences. Until 1988, when Mr Hutchison reached 16 years of age, our primary responsibility would be to ensure that his parents were conversant with the implications and effects of his treatment. We do not have direct evidence as to what they learned and appreciated. After 1988 we will have responded to all inquiries from Mr Hutchison about his hepatitis because he was then 16 years old.

Mr Hutchison states in paragraph 12 that 'I note that my depression appears to have been addressed separately from my hepatitis C diagnosis as if they were unconnected.'

16) I have been unable to access Mr Hutchison's principal case notes but I do recall he was seen in the 1990s by Dr Masterton, psychiatrist, on a long term basis (as is indicated in the letter of 2003 from Dr Masterton (psychiatrist) to Prof Hayes (hepatologist) (WITN2168010).

Mr Hutchison in paragraph 20 states 'I believe I was experimented on. There were lots of times when I had blood taken when I knew it was not just standard haemophilia check' from the age of 16 to his mid 20s.

17) During this period, which was from about 1988 to about 1997, with increasing knowledge about virus contamination of clotting factor concentrates it was important to assess these potential infectious agents in recipients of clotting factor concentrates. In some instances, there were known virus not previously thought to be transmitted by blood, e.g., hepatitis A, and for which those not immune could be given protective

vaccination. Others were more recently characterised viruses, e.g. hepatitis C, for which treatment might be possible. During this 10 year period it was not only important to know of infection by various viruses but also their subtypes, any changes over time and response to treatment. For example hepatitis C can be subdivided into different genotypes and the chance of responding to treatment depended upon genotype. Mr Hutchison had genotype 3 of hepatitis C and this is one that responds most readily to interferon therapy. I am pleased that this has fortunately happened in is his situation and that he is now negative by hepatitis C PCR.

18) I am sorry that Mr Hutchison did not apparently appreciate that we were monitoring his blood for these various viruses as well as all the other potential side-effects of treatment. Previously he learned that we were monitoring him because his acute hepatitis B infection was detected in 1984. Had he inquired I would have been delighted to have given him a very full account of all the factors we were assessing in his blood (both the long-standing investigations, e.g. inhibitor development, as well as the newer potential viral infections.)

Mr Hutchison indicates in paragraph 21 that I 'would refer to us 'pups' when we were children' which he appears to have thought was a 'term of affection' or later 'what our blood test results could tell about reactions to the products' received. Additionally he claims that children's blood was 'being analysed' without knowledge or consent of parents.

19) Mr Hutchison is correct in his interpretation of pups being 'previously untreated patients' (but not in any of the other interpretations set out in the paragraph).

20) These are patients who have never been treated with blood or a blood product, e.g. Factor IX concentrate in his case for haemophilia B. Mr Hutchinson was initially treated in the early-mid 1970s shortly after diagnosis and since then he has received many treatments for his relatively frequent bleeds. Therefore after his initial treatment he would not be classified as a pup. He had clearly heard use of the term pup but it would not have applied to him in the 1980s or thereafter.

21) Mr Hutchison claims that children's blood was being analysed without parental consent. It is not clear what the evidence is for this assertion. I do not recall his parents ever suggesting that we should not be analysing his blood samples to monitor his haemophilia.

The following are other matters aired by Mr Hutchison in his statement which I am not asked to comment on but which are deserving of attention,

In paragraph 10 of his statement Mr Hutchison states that 'there were a few times where they used a big hexagonal device that had about 20 needles with files on it'.

22) I think Mr Hutchison is remembering a small plastic device for testing skin responses to various common infections. This was a research investigation which was explained to patients in advance and their agreement sought. The technique was a simple way of assessing the overall activity of the immune system. The device consisted of 8 small feet each containing a different antigen (or an 'inactive form of an infection') and the device was placed on the forearm. Two days later the local reaction in the skin was carefully measured to quantify the response. The devices did not lead to any systemic reaction. A photograph of the device and the potential skin reactions is attached. The study provided evidence that the immune system could be depressed by treatment of haemophilia and that this was related to the purity of the treatment. This evidence was part of the future justification for developing purer concentrates for treating haemophilia. I have supplied a paper on the multi-test applicator which I refer to. (WITN3428043)

In paragraph 16 of his statement Mr Hutchison sets out his memory about what he was told about vCJD and he states that he was told 'the chances of me having this were very high', that a test would 'cost about £50,000 and as such, I would not be getting it.' Paragraph 19 states that the 'test was not cost-effective but they said there was a 90% chance that I have this (vCJD).

23) Mr Hutchison received information about vCJD as set out by the Health Protection Agency and Health Protect Scotland. He appears to have misunderstood the information because contrary to his statements the literature indicates that 'we believe that the chances you could develop CJD is very small.' (WITN2168008). It is unclear where he learned about a test costing £50,000 because I am not aware of any reliable test that would have been available.

24) I have no recollection of telephoning Mr Hutchison nor was it our practice to do so about vCJD. All patients were sent appropriate circulars authored by the Health Protection Agency.

In paragraph 17 Mr Hutchison states that 'I always felt that they used my brother as a bargaining chip against me'.

25) It is not clear what the evidence is for this assertion. We would have assessed Mr Hutchison and his brother independently and separately as individuals.

In paragraph 22 Mr Hutchison states that 'the receptionist said they were shredding my files upstairs for the period when I might have received contaminated blood' and further he states 'We were told it was practice to destroy things after a certain amount of time'.

26) I do not know the present status of his medical case notes, but I made strenuous efforts to maintain patient records especially in relation to treatments and potential infections. I know of no evidence that records were shredded nor was it practice to 'destroy things after a certain amount of time'

27) I hope my above responses may offer some further background information about how I tried to help Mr Hutchison with his haemophilic condition.

Statement of Truth

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

Signed GRO-C

Dated 14/11/20