

Witness Name: Dr Ian Maxwell Franklin
Statement No.: WITN4032025
Exhibits: WITN4032026 – WITN4032029
Dated: September 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR IAN MAXWELL FRANKLIN

I provide this statement in response to the request under Rule 9 of the Inquiry Rules 2006 dated 5 July 2021.

I, **IAN MAXWELL FRANKLIN**, will say as follows: -

Section 1: Introduction

1. My name is Ian Maxwell Franklin. My address is GRO-C Bristol. I was born on GRO-C 1949.
2. My employment history is set out in my curriculum vitae attached hereto as **[WITN4032002]**.
3. Of most relevance to this Inquiry:
 - a. Between October 1980 and August 1982, I worked as a Senior Registrar in Haematology at University College Hospital, London.
 - b. Between September 1982 and July 1992, I was a Consultant Haematologist at the Queen Elizabeth Hospital in Birmingham (employed by Central Birmingham Health Authority).
 - c. Between August 1992 and 1996, I was a Consultant Haematologist at Glasgow Royal Infirmary. I continued with an honorary consultant contract at Glasgow Royal Infirmary and its successor health boards until 2010.
 - d. Between 1996 and December 2010, I was Professor of Transfusion Medicine at the University of Glasgow and National Medical & Scientific Director of the Scottish National Blood Transfusion Service ('SNBTS').

- e. Between 8 January 2011 and January 2014, I was Medical & Scientific Director for the Irish Blood Transfusion Service at St James's Hospital in Dublin.
4. I retired from clinical practice and gave up my UK licence to practice in April 2014 but ceased clinical practice in the UK at the end of December 2010.
 5. This statement is made from my own personal recollection where stated and otherwise with reference to a selection of W2147's medical records for the period 1992-1997 as disclosed to me by NHS Greater Glasgow & Clyde.
 6. For the avoidance of doubt, I have not had access to the medical records for W2147's siblings. I have no recollection of every meeting any siblings of W2147.
 7. My recollection may be affected by the passage of time since the events in question.

Section 2: Responses to the statement of witness W2147

Background information regarding witness W2147

8. The records indicate that W2147 was diagnosed with acute lymphoblastic leukaemia ('ALL') in December 1980 for which she received blood transfusions [WITN2147003]. This document also confirms the diagnosis as common ALL and that the only adverse feature with regard to prognosis was a high white cell count $>50 \times 10^9/L$. Dr Gibson's summary of W2147's history in her letter to me dated 30 May 1995 [WITN4032026] states that she was treated in the UK Medical Research Council's eighth ALL trial (MRC UKALL VIII). W2147 was probably in the early part of the trial, which was not randomised - Eden et al, Br J Haematol, 1991: 78[2]; 187-196. I have only been able to access the abstract of this paper [WITN4032027], not the full version. It is not possible for me to say whether the parents of W2147 would have been informed that their daughter was being included in a clinical trial. This would have been good practice then, but may not at that time have been a strict requirement for trial entry. In a letter from Dr Gibson to W2147's GP Dr [GRO-B] dated 12 December 1994 [WITN2147004], Dr Gibson states that W2147 had been off treatment for 11 years and was at that time 15 years old. This suggests that treatment continued for at least two years. MRC UKALL VIII had a randomisation for the duration of maintenance chemotherapy between 2 years and 3 years, suggesting that W2147 may have been included in this trial's randomisation to length of maintenance. Whether written or other consent was obtained for this randomisation I do not know.

9. W2147 was almost certainly infected with the hepatitis C virus (HCV) from one of the transfusions she required during treatment for her leukaemia. The donation numbers were recorded for the transfusions administered at the time of her diagnosis and it is stated that a blood sample for virology was taken from W2147 prior to the administration of the transfusions. However, it is very unlikely at this distance in time that SNBTS, who would have collected, tested, processed and distributed the transfusions, could identify these donors, or that this sample remains. Also, SNBTS did not begin to retain an archive blood sample of all blood donations in Scotland until September 1985, when all donations were tested for HIV. In the early 1980s there was no specific testing for HCV possible until after the discovery of the virus in 1989.
10. As a child, W2147 was under the care of Dr Brenda Gibson, consultant haematologist, at the Yorkhill Children's Hospital in Glasgow. It would appear that W2147 was informed of her hepatitis C status on or around 9 December 1994 **[WITN2147004]**. The date of testing is not available in the papers provided to me. In all probability W2147 had been infected for at least 10 years at that time.
11. It is clear from the records provided that Dr Gibson and I would have planned to meet W2147 together in clinic at the Glasgow Hospital for Sick Children at Yorkhill (a district in Glasgow's west end). We did not have a routine joint clinic as I recall. This meeting took place sometime prior to 22 May 1995 **[WITN4032028]**. The formal hand-over of care of W2147 occurred via a referral letter from Dr Gibson dated 30 May 1995 **[WITN4032026]**.
12. I first met W2147 in May 1995 when she was aged 16. This was at a joint haematology clinic with Dr Gibson and W2147's parents were present. We discussed W2147's HCV status and I felt that she was a strong candidate for Interferon therapy. I was formally asked by Dr Gibson to take over W2147's care on 30 May 1995. I remember her quite well and confess I always considered the management of her hepatitis C to have been a success. I am sorry to hear that she has had such a struggle since.
13. W2147 commenced interferon therapy in June 1995 and I reviewed her periodically in clinic. She initially encountered some side effects but had an excellent response to treatment in that her liver function returned to normal.
14. In October and December 1995, her PCR test was negative for HCV. She had a positive PCR test in March 1996 but in July and October 1996, the result was again negative. In retrospect, this single positive test from March 1996 could have been a false positive, or might suggest that W2147 had a low level of virus present that just became positive on the one later occasion. At that time PCR tests for HCV were not

quantitative - that is, it was a yes or no test, not a measure of how much virus might be present.

15. I did not see W2147 after March 1996, she was seen by haematology colleagues, as I took up the post of Professor of Transfusion Medicine. Ultimately follow up was in the 'Late effects' clinic for patients who were long-term survivors of leukaemia and similar conditions. Dr John Murphy ran this clinic which provided an opportunity to consider issues many of which have indeed affected W2147. She was referred to the liver specialists in October 1996. Following a liver biopsy which showed evidence of HCV associated abnormalities, the plan was to commence combination therapy with interferon and ribavarin. However, this treatment was not actually commenced as she had a further negative PCR test and was deemed cured of her HCV.

Response to statement

16. I believe that some of the statements made by W2147 in paragraph 7 of her witness statement might be clarified. I address each of these below.
17. *"When I went to the clinic run by Dr Watson or Dr Franklin every six months..."* - The records indicate that I saw W2147 in clinic on 4 occasions – In May 1995 jointly with Dr Gibson and on 2 October 1995, 18 December 1995 and 18 March 1996 [WITN4032029].
18. *"...I would have my growth and hormones checked and I would get ultrasounds. I always questioned the purpose of this. I never really knew why and they never said why..."* - I cannot identify from the records that W2147 had any growth issues; in Dr Gibson's referral letter of 30 May 1994 she had been through puberty so there would have been no need to undertake hormone tests. W2147 was 5'4" tall. Measuring height would be a routine in a children's hospital. I do not recall arranging any ultrasound scans other than perhaps liver. Dr Gibson arranged a liver ultrasound which was carried out on 24 January 1995. A further ultrasound was carried out when W2147 was admitted to hospital for a liver biopsy but this was not whilst she was under my care. Ultrasound scans would have been carried out to assess any liver damage. Careful review of the copies of notes available to me shows mainly blood count, electrolyte and liver function tests. Occasional thyroid tests were done but no results for other hormones are present.
19. *"I believe they also checked my siblings [GRO-B] and [GRO-B]"* – I have no recollection of ever treating or meeting W2147's siblings. It is possible that they were seen at Yorkhill in case they were potential bone marrow donors should W2147 have ever needed such treatment. Happily that was not the case.

20. *"I thought this was a cover up"* – I am not sure what W2147 means by this. I was always open with her in relation to the treatment for her HCV diagnosis.
21. *"There are a couple of medical trials I was part of in relation to my leukaemia. There were trials in Edinburgh and a trial in Oxford Street with children with leukaemia. I recall that the Oxford trial I was part of lost some samples at one stage. I am unable to locate details about the trials in my medical records however."* – It is true that W2147 was treated within the MRC UKALL VIII trial at diagnosis of her leukaemia at Yorkhill in 1982, as stated in the referral letter to me from Dr Gibson in May 1995. This trial was coordinated from Oxford, I believe. I was not involved in this trial. I was not involved in any trials in Edinburgh or Oxford Street, other than one for Chronic Myeloid Leukaemia led by an Edinburgh colleague. Nor do I believe that I recruited W2147 into any of the clinical trials that I was involved in. I do not recall carrying out trials in hepatitis C treatment at all. I was involved in a European Bone Marrow Transplant Group study of Hepatitis C in bone marrow transplant patients. W2147 never had a transplant so was not part of this study.
22. In the impact statement of the witness, at section 5 in her statement, W2147 mentions having possible symptoms relevant to HCV infection prior to the discovery that she was positive. It is likely that W2147 had Hepatitis C for many years, possibly as early as her first admission to the Children's Hospital for her leukaemia, prior to the positive test in c.1994. I cannot say what the longer term impact would be, especially since she has now been free of HCV for over 20 years. Despite this she did manage to get decent exam results at school and subsequently got a degree from an excellent university. This in spite of Hepatitis C and the probable impact of cranial irradiation, so a good achievement notwithstanding her subsequent problems.

Section 3: Other Issues

23. At paragraph 8 of her statement, W2147 says, *"I do not really know what was specifically said to my parents about hepatitis C. Doctors did not include me in discussions initially. I feel that as a family we were given very little information...My dad researched information for us and shared what he discovered with a doctor at one point"*. – I do not know if W2147 is referring to me when she refers to doctors not including her in any discussions but in all my consultations with W2147, I would have explained any recent test results and the status of her HCV infection, and we would have discussed how she was getting on with the interferon treatment. This is made clear in my detailed comments about the interferon therapy in my notes of December

1995 [WITN4032029], and my detailed clinic letter from that consultation [WITN4032029]. I had considerable experience in the side effects of interferon alpha at higher doses as used in chronic myeloid leukaemia at that time. My practice in regard to younger patients was always to confirm that they wished a parent or other person to be present. I always directed comments and explanations to the patient, not to any third party such as a parent. This point was made by me in my previous evidence to the IBI, in which I referred to a young man transferring to my care in Birmingham who was unaware of their HIV status.

24. With regard to the witness's father researching information, I do remember that in this era the internet was in its infancy and many patients would come to clinic carrying printed details they had found on the internet. Searching in the pre-Google era (Google was founded in 1998) was quite variable depending on which search engine was used. So it was not unusual to discover new studies from patients own searches. In this clinic interview I acknowledged that there was a useful publication I was previously unaware of.
25. At paragraph 15 of her statement, W2147 says, *"I would say that I was tested without my knowledge or consent as I was a child for much of my time having my blood taken"* Prior to W2147 being seen by me in May 1995, I could not comment on the issues relating to consent for testing and treatment of children, or her case specifically. When W2147 attended my adult clinic after that time we would have discussed the need for further monitoring tests in relation to HCV, which included PCR testing. I considered W2147 to be an adult, albeit a young adult. I had about 20 patients who had acquired HCV from blood transfusions received during bone marrow transplantation prior to HCV screening of blood donations being introduced. So this was a regular activity for me, monitoring patients for hepatitis C. Consent for testing would have been implied following discussions, given that the HCV positive status was already known.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

Signed

GRO-C

Dated

10 Sept. 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
September 2020	CV of Dr Franklin	WITN4032002
30.05.95	Letter Dr Gibson to Dr Franklin	WITN4032026
1991	Abstract of Results of Medical Research Council Childhood Leukaemia Trial UKALL VIII <i>Eden et al, Br J Haematol, 1991: 78[2]; 187-196</i>	WITN4032027
22.05.95	Letter Dr Franklin to Dr GRO-B	WITN4032028
Various	Clinic notes made by Dr Franklin	WITN4032029