Witness Name: Professor Christine Ann Lee

Statement No: WITN06440038

Exhibits: WITN06440039 - WITN06440042

Dated: 20 February 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR CHRISTINE ANN LEE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 20 June 2019 in relation to the witness statement of Witness W1002, Kathleen Stewart ("KS") regarding her late husband, AS Senior.

I, Professor Christine Ann Lee, will say as follows:

Section 1: Introduction

1. My name is Christine Ann Lee and my address is GRO-C GRO-C. My date of birth is GRO-C 1943. I hold the following professional qualifications – MA (Oxon) 1969 BM BCh (1969) MD (London) 1989, DSc (Med) (1996), FRCP (1990), FRCPath (1994) and FRCOG (2010). A copy of my CV is exhibited (**WITN06440039**).
2. I have held the following positions as a haematologist for the following organisations and set out below my roles and responsibilities in each of these positions:

Dates	Position	Roles and responsibilities
September 1974 - June 1976	Registrar to Dr J Fielding, Department of Haematology, St Mary's Hospital	Laboratory and clinical; responsible in a district general hospital for the general haematology service. Six-month on call for emergency out of hours haematology including blood

		transfusion.
November 1976 - December 1982 (part-time)	Senior Registrar to Professor PT Flute, Department of Haematology, St George's Hospital Medical School. This included appointments at St James Hospital, Balham, Royal Marsden Hospital Sutton and South London Blood Transfusion Centre.	This appointment was under government scheme HM (69)6, known as The Women Doctors' Retention Scheme, which enabled female doctors with family commitments to work part time. Provision of haematology service and preparation for Membership of Royal College of Pathologists qualifying examination, achieved June 1982. During this time I provided some care for the small number of patients with haemophilia who attended St George's Hospital.
January 1983 - October 1984	Research Senior Registrar to Dr PBA Kernoff and Dr HC Thomas, Royal Free Hospital	Action Research Fellowship to study non-A, non-B hepatitis in haemophilia patients. This work contributed to the dissertation for MD University of London awarded in 1989, entitled "The Natural History, Prevention and Treatment of Viral Hepatitis in Haemophilic patients."
November 1984 - November 1987	Senior Lecturer in Haematology, Charing Cross and Westminster Medical School and Honorary Consultant Haematologist, Queen Mary University Hospital, Roehampton, London	Single handed consultant haematologist responsible for the clinical and laboratory haematology service in the busy district general hospital, Queen Mary's University Hospital, Roehampton, part of Charing Cross and Westminster Medical School. I was also Senior Lecturer and provided regular

		teaching to undergraduate medical students.
September 1985 - November 1987	AIDS counsellor Richmond, Twickenham and Roehampton Health District	Responsibility for provision of HIV testing service using the newly developed test. Responsibility for providing education about HIV/AIDS to every secondary school within the borough of Richmond upon Thames.
April 1986 - November 1987	Honorary Consultant in Haematology Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, 2 sessions (1 day) per week.	There was no clinical responsibility as I had no honorary clinical contract and these sessions were to prepare research for publication.
November 1987 - December 2005	Consultant Haematologist Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, London.	Particular care for patients infected with HIV and hepatitis. Together with the director, Dr Peter Kernoff, I provided comprehensive care for people with haemophilia – the largest haemophilia centre in the UK with a patient population equivalent to the whole of Scotland and Northern Ireland. There was also provision of care for patients within the Royal Free Hospital who developed bleeding or thrombotic problems. There was a large anticoagulant clinic.
April 1991 - April 1992	Acting Director Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, London	The Director was not able to work again for health reasons. Overnight I had to take responsibility for the whole Unit as acting Director.

April 1992 - December 2005	Director Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, London	As Director I was responsible for service delivery and management of a staff of 70 including physicians, nurses, physiotherapists, laboratory scientists and counsellors. Although I was an NHS employee, I also conducted research. Relevant to this enquiry, 4 of 18 MD or PhD theses I supervised were about hepatitis: (1) Dr Paul Telfer 1991-4 MD University of Oxford 'HCV infection in haemophilic patients'; (2) Dr Helen Devereux 1992-6 PhD University of London 'The molecular biology of HCV infection in haemophilia'; (3) Dr Thynn Thynn Yee 1998-2001 MD University of London 'The side effects of therapy for haemophilia'; (4) Dr Esteban Herrero 1998-2001 PhD University of London 'The molecular basis of HIV and HCV interactions'.
January 2006 - present	Emeritus Professor of Haemophilia, University College London	The title Professor of Haemophilia within University of London was an honorary title awarded in 1997 for my work in haemophilia. There was international peer review of my contribution. It was the first professorship in haemophilia in the UK.
April 2007 -	Honorary Consultant	Responsibility for women with

April 2010	Haematology, Oxford Haemophilia and Thrombosis Centre	bleeding disorders.

3. Since May 2010, I have retired from clinical practice.
4. I hold and have held membership of the following committees or groups relevant to the terms of reference:
    a. April 2001 – December 2005: Member of UK Haemophilia Centre Doctors Organisation
    b. 1996-2003: Chair of International Haemophilia Training Centres Committee, World Federation Haemophilia
    c. 1993-2005: Member of Medical Advisory Panel, Haemophilia Society of UK
    d. 1996-2000: World Federation of Haemophilia Executive with special responsibility for WFH/WHO relationship.
5. I also gave evidence as an independent expert witness at the Tribunal of Inquiry into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters, which was chaired by Her Honour Judge Alison Lindsay in Ireland. The resulting report was published in 2002 and is available online.
6. I was the Founding Editor in 1995 and Chief Editor until 2013 of the journal *Haemophilia*, published by Wiley Blackwell.

Section 2: Background information regarding Witness W1002's husband, AS Senior

7. I make this statement on the basis of the medical records for AS Senior which have been disclosed to me by the Royal Free Hospital. I cannot say for certain if the records that have been disclosed are complete as there appear to be some letters and clinical notes missing. I therefore reserve the right to amend or supplement this statement if further records come to light.
8. I remember AS Senior well. In spite of difficult medical conditions and considerable adversity over many years he was largely cheerful. I looked forward to seeing him at the Centre. He was very popular with all the staff because he was so optimistic and positive. This is reflected in the regular fundraising with a collecting tin in the local pub

[**WITN06440040, 121-122**]. The Stewart family also recognised the affection with which he was held in the Centre [**WITN06440040, 132**].

9. AS Senior had von Willebrand's Disease ('VWD'), identified as Type 2M in the mid-1990s by genetic analysis (initially this had been described as Type 1). He was transferred from Great Ormond Street Hospital to the Royal Free in 1969. VWD is an inherited bleeding disorder arising from an abnormality and deficiency in the quality or quantity of von Willebrand factor ('VWF'), the carrier protein for Factor VIII that is required for platelet adhesion. Patients with VWD classically experience epistaxis (nosebleeds) and easy bruising. Women with VWD may experience heavy menstrual periods and blood loss during childbirth.

10. AS Senior was one of several members of the family (with his sons, MAS and AHS Junior and granddaughter, TS) who were treated at the Haemophilia Centre ('the Centre') for VWD. MAS is Witness W1000 in these proceedings. AS Senior's son was AHS Junior, whose widow, AHS, is Witness W1001 in these proceedings.

11. As the concerns raised by Witness W1002 are wide ranging and AS Senior's medical history is complex, I have set out below a chronological summary of my involvement in AS Senior's clinical care. I attach as Exhibit **WITN06440040** a paginated bundle of AS Senior's relevant records, in chronological order.

12. AS Senior was initially treated with cryoprecipitate between 3 October 1979 and 5 February 1980 [Exhibit 8]. He was given his first dose of Factor VIII concentrate on 11 January 1980 as he became allergic to cryoprecipitate [**WITN06440040, 1**]. I was not involved in AS Senior's clinical care at this stage.

13. At a review with Dr Peter Kernoff on 17 March 1980, AS Senior was presumed to have non-A, non-B hepatitis due to having treatment with BPL Factor VIII concentrate on 11 January 1980 [**WITN06440040, 2-3**].

14. I saw AS Senior for the first time in the Haemophilia Centre on 1 November 1983 [**WITN06440040, 4**]. He complained of aches and pains in his joints since his last episode of epistaxis and pain in the gut, like indigestion, which was worse on eating. He also had pale stools for the previous two weeks. His blood pressure on examination was 140/100 and I noted that he had a high blood pressure on several occasions prior to this. I arranged a referral to Dr Evans, cardiologist, for advice on his hypertension [**WITN06440040, 5**] – my referral letter is dated 2 October 1983 but in fact it should be dated 2 November 1983. My impression was that AS Senior might have non-A, non-B

hepatitis secondary to Factor VIII concentrate. I arranged blood tests to further investigate this.

15. On 3 November 1983, AS Senior's blood results were available and I noted that he had a high AST level [**WITN06440040, 4**], commensurate with the diagnosis of non-A, non-B hepatitis.

16. I saw AS Senior for a follow up appointment on 14 November 1983 [**WITN06440040, 6-7**]. He was still generally unwell. My impression was that he had had a second attack of non-A, non-B hepatitis. The plan was to follow him up in a fortnight to monitor his AST (aspartate aminotransferase) levels. I noted that he was due to see the cardiologists for his elevated blood pressure on 12 December 1983.

17. AS Senior was seen by the cardiologists on 15 December 1983 [**WITN06440040, 8**]. On 3 January 1984, Dr Robert Greenbaum, Senior Cardiac Registrar, wrote to me about AS Senior (note, his letter is incorrectly dated 1983 instead of 1984) [**WITN06440040, 9**]. Dr Greenbaum was not convinced that AS Senior had sustained hypertension and requested that we measure his blood pressure on several occasions before recommending treatment.

18. On 31 January 1984, I completed a hepatitis survey in respect of AS Senior [**WITN06440040, 10-11**]. At the Centre, we had a large number of patients with transaminitis (raised transaminases) and Dr Peter Kernoff set up a system of data collection in order to find out how best we could manage these patients.

19. There followed a number of hospital admissions for AS Senior, firstly for chest pain and later, for recurrent epistaxis.

20. The hepatitis C virus was not identified until 1989. In 1990, together with the Liver Unit, we developed a new in-house blood test at the Centre for antibodies to hepatitis C (formal screening for hepatitis C did not become available before 1991). We therefore tested stored specimens of our patients' blood samples. AH Senior's stored specimen from 5 March 1987 was tested and I received the result on or around 1 July 1990. I therefore wrote to AS Senior on 1 July 1990 confirming that he was found to be HCV positive on 5 March 1987 [**WITN06440040, 13**]. An offer was made to discuss this at AS Senior's next review or sooner. This letter would have been posted to AS Senior and copied to his GP. A review was booked for 8 March 1991.

21. I telephoned AS Senior on 3 January 1991 to discuss his most recent blood results [**WITN06440040, 16**]. His haemoglobin was low at 8.6 and he had severe iron

deficiency anaemia. He was not taking iron supplements due to a tendency to have constipation and was reluctant to have a blood transfusion. He informed me that he had told the nurses that he had haemorrhoids. I advised him that this needed further enquiry and a possible referral to the surgeons. On 5 February 1991, I made a referral to Mr Adam Lewis consultant surgeon, for AS Senior's brother, MAS, in error [**WITN06440040, 17**]. I later realised my mistake and correctly referred AS Senior to Mr Lewis on 4 March 1991 [**WITN06440040, 18**].

22. I next saw AS Senior for a review on 8 March 1991 [**WITN06440040, 19-21**]. His main problem was of epistaxis. He was taking medication for hypertension, atenolol, and that this seemed to be under control. He was overweight but reluctant to see the dieticians. He was anaemic although this was improving. AS Senior had chronic hepatitis C and we discussed treatment. At that time, the only treatment available for hepatitis C was Interferon which was part of a pilot study that had ethics committee approval. This involved intravenous injection of Interferon and the treatment was known to have side effects of anaemia and flu like symptoms. I offered the Interferon treatment to AS Senior which he declined. In view of AS Senior's multiple health problems, my plan was to review him once a year or sooner if he developed problems.

23. I wrote to AS Senior's GP following this consultation on 12 March 1991 [**WITN06440040, 22-24**]. Contrary to paragraph 31 of witness W1001's statement, my letter to AS Senior's GP does mention hepatitis C [**WITN06440040, 22-24**]. My letter states,

    "He has chronic hepatitis, we know that he had non-A non-B hepatitis in March 1980 when he had his first exposure to factor VIII which at the time was unheated. This is very well documented and we know now that he is anti-HCV positive."

    The reference to non-A, non-B hepatitis is in fact a reference to hepatitis C as at that time the test for hepatitis C virus was not yet available. The reference to AS Senior being anti-HCV positive is the same as stating that AS Senior had hepatitis C.

24. AS Senior came to see me on 16 April 1991 [**WITN06440040, 25**] asking for the results of an ultrasound he apparently had done on 21 February 1991. I wrote to the x-ray department the following day asking for the results of this ultrasound. At paragraph 32 of witness W1001's statement, she questions why I did not mention the ultrasound in my letter to the GP dated 12 March 1991. I do not believe that AS Senior mentioned the ultrasound investigation to me when I saw him on 8 March 1991 as had he done so,

I would have recorded it in my clinical note and mentioned it in my letter to his GP. I have been through AS Senior's records and there is no ultrasound report for 21 February 1991 or any radiology request. Nor are there any clinical notes or entries which would indicate why an ultrasound was needed. It is therefore not clear whether this ultrasound was ever carried out.

25. I next saw AS Senior on 25 April 1991 [**WITN06440040, 26**]. He had been seen by Mr Lewis in the rectal clinic on 7 April 1991 when medication for his haemorrhoids had been recommended.

26. On 10 June 1993, AS Senior attended the Centre for treatment with a new high purity Von Willebrand factor (known as Haemate P) in order to assess the correct, effective dosage [**WITN06440040, 33**]. It seems that he encountered some chest pain half an hour after this was administered. I discussed matters with Dr Goldman and recommended that he should go back on Factor VIII Y treatment [**WITN06440040, 34**].

27. Dr Goldman reviewed AS Senior at the Centre on 6 July 1993 [**WITN06440040, 34-35**]. He was having some chest pain so she referred him to the cardiologists [**WITN06440040, 36**]. AS Senior had a cardiology assessment and a number of cardiology reviews following this.

28. On 13 March 1995, Dr Coghlan, Senior Registrar in Cardiology, wrote to me requesting my opinion on the correct management for AS Senior in the event that he needed to proceed to angiography and possibly bypass surgery [**WITN06440040, 47**]. AS Senior had apparently previously been informed that this might make him too high risk for coronary surgery although it is not clear by whom. In response to this letter, Dr Pasi (a consultant appointed to the Centre in 1994 who had a specialist interest in VWD) wrote to Dr Coghlan on 4 April 1995 suggesting a meeting so that we could plan the appropriate management [**WITN06440040, 48**]. Dr Pasi also wrote to Dr Lipkin on 11 July 1995 to confirm that AS Senior's bleeding disorder could be managed if further cardiological investigations were warranted [**WITN06440040, 51**].

29. I saw AS Senior in the joint liver/haemophilia clinic with my colleague, Dr Patch, on 16 December 1996 (the clinic note was made by Dr Patch although the letter refers to Dr Mistry) [**WITN06440040, 64-65**]. We noted that his alcohol intake was heavy and that he was experiencing some hepatic pain. It was thought that his liver disease was due to a combination of factors including chronic hepatitis C, excessive alcohol drinking and steato-hepatitis against a background of gross obesity. I note that Witness W1002

questions the accuracy of this as she does not believe that AS Senior's liver disease could have been due to alcohol consumption. The clinical notes for 16 December 1996 clearly state, "*Mr AS' alcohol intake is rather heavy and he is experiencing hepatic pain usually after a binge of alcohol on Sundays...*". This history would have been obtained from AS Senior himself. It is also noteworthy that when seen by Dr Pasi on 20 November 1996 (a month before this appointment), AS Senior reported that he had in the past drunk in the order of 40 units plus per week but had reduced this to 10-15 units per week. [**WITN06440040, 60-63**]

30. At this appointment, we arranged a CT scan of his abdomen and liver. We were unable to recommend combination therapy, which at that time was Interferon and Ribavirin, due to his anaemia and ischaemic heart disease. Ribavirin is known to cause anaemia and AS Senior already had very low haemoglobin. There was therefore a risk that he might go into heart failure with this treatment. AS Senior was strongly advised to reduce his alcohol intake.

31. A CT scan on 3 January 1997 confirmed that there was mild splenomegaly but no evidence of chronic liver disease.

32. On 3 December 1997, the Centre wrote to AS Senior in relation to vCJD confirming that he had not been treated with one of the implicated batches [**WITN06440040, 66**].

33. Separately, on 12 January 1999, I wrote to AS Senior informing him that a batch of Haemate P had been withdrawn by the manufacturers [**WITN06440040, 78-79**]. Haemate P was made from US plasma and a donor that had contributed to the pool of plasma in the US had CJD (this is not the same as variant CJD/vCJD). It was FDA policy at the time to withdraw these batches. This was a batch that was in use over a year ago and I therefore considered it unlikely that it was still in use. I did not mention CJD in my letter to AS Senior as I did not wish to alarm him. I did, however, invite him to discuss this further at our next review.

34. On 28 January 1999, I wrote a further letter to AS Senior about a study we were conducting in relation to the occurrence of chronic fatigue in individuals with inherited bleeding disorders [**WITN06440040, 80**]. This was a study led by a psychiatrist at St Bartholomew's Hospital which had obtained ethical committee approval. I invited AS to complete a questionnaire which he duly did on 3 February 1999 [**WITN06440040, 85**]. I do not know if the study progressed as it was not published.

35. I next saw AS Senior on 2 February 1999 [**WITN06440040, 81-84**]. The plan was for him to continue with Haemate P (which was treating his bleeds effectively), refer him to the cardiologists and review him in the liver clinic.

36. I saw AS Senior at the Centre on 7 September 1999 for a review [**WITN06440040, 88-90**]. His VWD was under control but his major problem at that time was his coronary artery disease which was complicated by him being overweight. The records identify that by June 1999, he weighed 150 kg/23.6 stone.

37. AS Senior was reviewed in the combined liver/haemophilia clinic by myself and Dr Patch on 27 September 1999. The clinical notes and letter were written by Dr Patch [**WITN06440040, 91-93**]. His alcohol intake was noted still to be very high with him consuming 3 to 4 pints of lager per day (8 units/day i.e. 56 units per week). He had some features of chronic liver disease but no evidence of hepatic ascites. It was considered that an ultrasound of his liver would be of little benefit as he had been previously noted to have a fatty liver and this would complicate interpretation. There was no plan to treat AS Senior with antivirals (Interferon) in view of him having previously declined this treatment.

38. On around 22 March 2000, I saw AS Senior for a review appointment [**WITN06440040, 95**]. He was noted to be bleeding from his rectum and was anaemic as a result of this. He had been recently reviewed by the cardiologists who, on the basis of an angiogram and good ejection fraction, concluded that he did not have coronary artery disease although he was still complaining of chest pain.

39. On 9 May 2000, I reviewed AS Senior at the Centre [**WITN06440040, 97-98**]. The plan was to continue with Haemate P and check his haemoglobin levels.

40. I next saw AS Senior on 1 August 2000 [**WITN06440040, 99-100**]. By this point, he had been discharged from cardiology. He had also had a colonoscopy on 20 July 2000 when 2 benign polyps were removed.

41. I saw AS again on 31 October 2000 and wrote to his GP the same day summarising his health problems [**WITN06440040, 101-104**]. The plan was to arrange a blood transfusion for his anaemia.

42. On 1 December 2000, my colleague, Dr Simon Brown (who replaced Dr Pasi in 1999), wrote to AS Senior in relation to vCJD to give him the option of switching from UK plasma products to US plasma products [**WITN06440040, 105**].

43. I saw AS Senior for follow up on 30 January 2011 [**WITN06440040, 106-107**]. He continued to have angina and low haemoglobin.

44. AS Senior was reviewed in the combined liver/haemophilia clinic on 20 August 2001 [**WITN06440040, 112-113**], on 10 December 2001 [**WITN06440040, 118-119**] and again 18 February 2002 [**WITN06440040, 123-125**].

45. On 19 June 2002, one of the junior doctors discussed AS Senior's blood results with me [**WITN06440040, 126**]. AS Senior was anaemic and it was thought that his low haemoglobin could be secondary to GI bleeding. As there was already a management plan in place for the bleeding, I did not consider it necessary to expose AS Senior to further invasive investigations.

46. On 19 July 2002, AS Senior was admitted to the Royal Free Hospital with pain over the right hypochondrial region. He was informed of his diagnosis of carcinoma of the liver on 23 July 2002.

47. AS Senior signed a DNAR form on 2 August 2002 [**WITN06440040, 128**]. The clinical notes identify that this had been discussed with him [**WITN06440040, 129**].

48. On 22 August 2002, Dr Patch wrote to me suggesting that AS Senior should be considered for Lipiodol I [**WITN06440040, 130**]. This is a radioactive treatment for hepatic carcinoma. It appears that AS Senior was not keen on having this treatment and that Dr Yee discussed the treatment with him on 30 August 2002 [**WITN06440040, 131**].

49. AS Senior died on 7 September 2002. His family subsequently sent a thank you letter to the Haemophilia Centre [**WITN06440040, 132**].

Section 3: Criticisms by KS

Response to Question 4: At paragraphs 18 to 23 of her statement, W1002 outlines how her husband was not told of his HCV diagnosis despite the fact that he was thought to have been infected with the disease as far back as 1980. Please comment on this.

50. AS Senior was presumed to have non-A non-B hepatitis on 17 March 1980 [**WITN06440040, 3**]. HCV was known as non-A, non-B hepatitis at that time. Regular blood tests were arranged. This was all before my involvement in AS Senior's care.

51. When I saw AS Senior on 1 November 1983, he was very unwell with similar symptoms to those he had in March 1980. My impression was that he had non-A, non-B hepatitis secondary to concentrate and I would have informed AS Senior of this. I arranged blood tests to monitor this.

52. When the new in-house anti-HCV test became available in 1990, AS Senior's stored blood samples from 5 March 1987 were tested and found to be positive for HCV. He was informed about this by letter on 1 July 1990.

Response to Question 5: At paragraph 23, witness W1002 claims that her husband was never told that he could be at risk of Creutzfeldt-Jakob disease (CJD), in a consultation or otherwise contrary to what you had written in a clinical note. Please comment on this.

53. On 3 December 1997, the Centre wrote to AS Senior advising that there had been two recent recalls of BPL Factor VIII batches because it had been found that 'a donor had not met the current health requirements for CJD' [**WITN06440040, 66**]. This was a reference to the new vCJD. AS Senior was also advised that according to our records, he had never been treated with these implicated batches. AS Senior was invited to contact the Centre if he had any questions or concerns.

54. Separate to this, I wrote a further letter to AS Senior on 12 January 1999 to confirm that a batch of Haemate P had been withdrawn by the manufacturers [**WITN06440040, 79**]. This was because a donor contributing to the pool of plasma in the US had CJD (not variant CJD) and it was FDA policy to withdraw such patches. I considered it unlikely that AS Senior still had one of these batches as the batch was in use over a year ago. I did not mention CJD in this letter as I did not wish to cause AS Senior unnecessary alarm.

Response to Question 6: At paragraphs 24 to 26, witness W1002 states that she believes her husband was treated with Factor VIII without his knowledge for research purposes. Please comment on this.

55. From the records, it is clear that AS Senior was first treated with Factor VIII concentrate on 11 January 1980. This is because he was allergic to cryoprecipitate. I was not involved in AS Senior's clinical care until 1983.

56. The study referred to in paragraph 25 of Witness W1002's statement, which resulted in the article, *"Short incubation non-A, non-B hepatitis transmitted by factor VIII concentrates in patients with congenital coagulation disorders"*, partially exhibited at WITN1002013, is not a study that I was involved in.

57. The study referred to in paragraph 26 of Witness W1002's statement, also partially exhibited at WITN1002013, resulted in a publication entitled, *"High risk of non-A non-B hepatitis after a first exposure to volunteer or commercial clotting factor concentrates: effects of prophylactic immune serum globulin"* which was published in the British Journal of Haematology in 1985. A copy is exhibited at **WITN06440041**. I was involved in this study alongside Dr Peter Kernoff, Dr P Karayiannis and Dr H C Thomas. This was not research but an epidemiological study where we retrospectively analysed the data from our patients in order to establish what was happening. AS Senior's data formed part of this study.

58. I was the coordinator and corresponding author in another study which was published in a paper entitled, "*The natural history of HCV in a cohort of haemophilic patients infected between 1961 and 1985*", Gut 2000; 47: 845-851 [**WITN06440042**]. Once again, this was a retrospective study where patient data, including that of AS Senior, was retrospectively analysed.

Response to Question 7: At paragraph 31, witness W1002 states that her husband went to hospital ten times between 1990 and 1991 and you did not discuss his HCV infection and treatment options with him during this time. Please comment on this.

59. The relevant period is between 1 July 1990 and 8 March 1991. Witness W1002 asserts that her husband was seen 10 times during this period yet HCV and treatment options were not discussed.

60. When I wrote to AS Senior on 1 July 1990 confirming that his antibody test was positive for HCV, I invited him to discuss this further at his next review or sooner if he wished to make an appointment. A review appointment was confirmed for 8 March 1991.

61. According to the records, AS Senior was seen in the Centre on the following dates during the relevant period – 23 August 1990 [**WITN06440040, 14**], 14 September 1990, 20 October 1990, 25 November 1990 [**WITN06440040, 15**], 19 December 1990, 3 January 1991 (telephone call only), 27 February 1991 and 2 March 1991

[**WITN06440040, 16, 19**]. These attendances were not planned reviews but spontaneous attendances for management of major epistaxes hence it was not appropriate to discuss HCV. The only date I was involved was 3 January 1991 [**WITN06440040, 16**] when I telephoned AS Senior to discuss his most recent haemoglobin levels. He was reluctant to have a blood transfusion and was not taking iron supplements as these caused constipation. He told me he had haemorrhoids which resulted in my referring him to the general surgeons.

62. When AS Senior attended for his review as planned on 8 March 1991, treatment for HCV was fully discussed. AS Senior declined to have that treatment.

Response to Question 8: At paragraph 40, witness W1002 states that although her husband had suffered from abdominal pain since around 1982, this was not investigated by the Haemophilia Centre until in and around August 2001. Please comment on this.

63. Paragraph 40 of Witness W1002's statement refers to AS Senior's abdominal pain being investigated '10 years later' in August 2001, i.e. she implies that there was a failure to investigate abdominal pain from 1991 until 2001.

64. Between 1991 and 2001, I had encounters with AS Senior on the following dates:

    a. 3 January 1991 [**WITN06440040, 16**] – a telephone discussion. There was no mention of abdominal pain;

    b. 8 March 1991 [**WITN06440040, 19-21**] – review at the Centre. There was no mention of abdominal pain. I referred AS Senior to Mr Lewis for haemorrhoids.

    c. 16 April 1991 [**WITN06440040, 25**] – AS Senior attended the Centre asking about an abdominal ultrasound that had been carried out on 21 February 1991. I followed this up by contacting the x-ray department but no record was found for an ultrasound request or report.

    d. 25 April 1991 [**WITN06440040, 26**] – I saw AS Senior but the notes were with Mr Lewis. There was no mention of abdominal pain.

    e. 16 December 1996 [**WITN06440040, 65**] – review in the joint liver clinic with Dr Patch. He complained of hepatic pain which led to us arranging a CT of his abdomen and liver. This showed no signs of chronic liver disease.

f. 17 September 1998 [**WITN06440040, 73**] – seen in the combined orthopaedic/haemophilia clinic with Mr Goddard. There was no complaint of abdominal pain.

g. 2 February 1999 [**WITN06440040, 81-82**] – review at the Centre. There was no complaint of abdominal pain.

h. 7 September 1999 [**WITN06440040, 88-89**] – review at the Centre. There was no complaint of abdominal pain.

i. 27 September 1999 [**WITN06440040, 91-93**] - review in the joint liver clinic with Dr Patch. AS Senior did not report any abdominal symptoms and there was no evidence of ascites on examination.

j. 22 March 2000 [**WITN06440040, 95**] – review at the Centre. There was no complaint of abdominal pain.

k. 9 May 2000 [**WITN06440040, 97-98**] – review at the Centre. There was no complaint of abdominal pain. I noted that AS Senior was due to see Dr Hamilton, gastroenterologist, for his rectal bleeding.

l. 1 August 2000 [**WITN06440040, 99**] – review at the Centre. There was no complaint of abdominal pain. I noted that AS Senior had recently had a colonoscopy which confirmed the presence of 2 benign polyps.

m. 31 October 2000 [**WITN06440040, 101-102**] – review at the Centre. There was no complaint of abdominal pain. I noted that AS Senior had been diagnosed with haemorrhoids.

n. 30 January 2001 [**WITN06440040, 106**] – review at the Centre. There was no complaint of abdominal pain.

Response to Question 9: At paragraph 41, witness W1002 refers to the letter that you and Dr Patch wrote to Dr Malik, dated 20 August 2001, in which it is stated that her husband was too overweight to have a CT scan, despite the fact that earlier clinical notes of the witness's husband refer to him having CT examinations conducted on his abdomen and liver. Please comment on this.

65. I did not in fact see AS Senior in the combined liver clinic on 20 August 2001 [**WITN06440040, 112**]; he was seen by Dr Patch and my colleague, Dr Niamh O'Connell. I did not write the letter to AS Senior's GP but signed if off as the consultant haematologist in line with usual practice.

66. I note from the records that AS Senior previously had CT scans on 17 September 1985 [**WITN06440040, 12**] and 3 January 1997 [**WITN06440040, 65**] but he weighed less than he did in 2001. In July 1985, AS Senior's recorded weight was 119 kg/18.7 stone. In January 1997, AS Senior weighed approximately 140 kg/22 stone. By August 2000, his weight was recorded as 153.8 kg/24 stone. He had therefore gained 2 stone since the previous CT scan. I recall that there was some difficulty with AS Senior fitting into the CT scanner due to his obesity.

Response to Question 10: At paragraph 45, witness W1002 states that doctors should have been aware of her husband's liver cancer a year prior to his diagnosis due to his raised alpha-foetoprotein levels. Please comment on this.

67. AS Senior was diagnosed with liver cancer on 23 July 2002.

68. On 31 July 2001, AS Senior was seen by Dr Yee and his AFP level noted to be 9 [**WITN06440040, 110**]. On 2 August 2001, his AFP levels from 31 July 2001 were noted to be 72. This was discussed with Dr Yee who recommended an urgent CT before the planned combined liver clinic appointment on 20 August 2001.

69. When AS Senior was seen by Dr Patch and Dr O'Connell in the combined liver clinic on 20 August 2001, an elevated AFP level of 72 was noted and an ultrasound was arranged as he was too overweight to have a CT scan.

70. AS Senior was reviewed in the combined liver clinic on 10 December 2001. His ultrasound showed no evidence of liver cancer. As he was clinically stable, we planned to repeat his AFP levels and review him in the combined liver clinic in 6 months' time.

71. On 3 January 2002, AS Senior was admitted to the Royal Free for a hepatic angiography to investigate his raised AFP levels [**WITN06440040, 120**]. His angiogram demonstrated normal hepatic arterial anatomy and therefore did not identify a source for his raised AFP levels.

72. AS Senior was seen in the combined liver clinic on 18 February 2002. Unfortunately, AS Senior was too overweight to have a CT scan. A further review was arranged for six months' time.

Response to Question 11: At paragraph 47, witness W1002 states that there was a 'Do Not Attempt Resuscitation' ('DNAR') form in her husband's medical records in 2002. In the witness's view, this seemed to her as if the doctors had already

decided her husband's fate between themselves. She also states that she was not consulted about the DNAR. Please comment on this.

73. The records show that AS Senior signed a DNAR form on 22 August 2002 [**WITN06440040, 128**] and this had been fully discussed with him [**WITN06440040, 129**]. It was not hospital policy to consult with relatives in relation to DNARs in circumstances where the patient agreed to this.

Response to Question 12: At paragraphs 52 and 43, witness W1002 states that her husband was not given any treatment for his liver cancer. Please comment on this.

74. AS Senior's diagnosis was made on 23 July 2002 [**WITN06440040, 127**]. It was for the consultant hepatologists to advise on treatment options for liver cancer. I note that Lipiodol had been discussed as a treatment option and AS Senior was not keen on this.

Response to Question 13: At paragraph 55, witness W1002 denies that her husband said that he should be left out of an Interferon study to treat his HCV. Please comment on this.

75. I discussed interferon treatment with AS Senior at the review appointment on 8 March 1991. My contemporaneous notes and letter to AS Senior's GP accurately record what AS Senior told me, i.e. that he did not want this treatment.

Response to Question 14: At paragraph 62, witness W1002 claims that it seemed as though you overruled recommendations for treatment of her husband (such as those mentioned at paragraphs 59 to 61) and that you and Dr Mistry would not recommend combination therapy treatment in 1992 because of her husband's ischaemic heart disease (paragraph 81). The witness's husband was found not to have ischaemic heart disease. Please comment on this.

76. The treatment recommendations which witness W1002 alleges I overruled and which are referred to at paragraphs 59 to 62 include: (a) ranitidine for chronic gastritis; (b) coronary surgery; (c) combination therapy.

77. I had no involvement in any decision making regarding treatment for chronic gastritis and did not overrule Dr Pasi's suggestion – this would have been a medication for AS Senior's GP to prescribe. I note, however, from the records that AS Senior had a

negative breath test for H Pylori on 19 December 1996 which may be the reason why he was not given this medication.

78. I did not inform AS Senior that he was too high risk for coronary surgery.

79. In relation to the suitability for combination therapy, AS Senior did have a history of heart disease. He was on atenolol for high blood pressure in 1991 and repeatedly assessed by the cardiologists for chest pain. As at 12 September 1994, AS Senior was thought to have angina and coronary surgery was being contemplated in March 1995. As stated above, in December 1996, combination therapy (Interferon and Ribavirin) was contraindicated due to his anaemia and ischaemic heart disease. It was only in June 1997 that AS Senior was deemed to be free of angina and stable from a cardiological point of view. This does not mean that he did not have ischaemic heart disease at the time.

Response to Question 15: At paragraph 63, witness W1002 refers to a clinical note dated 19 June 2002 where you noted that her husband appeared to be bleeding internally but that it should not be investigated. The witness further states that her husband appears not to have been seen for a month after that clinical note was made. Please comment on this.

80. As stated above, AS Senior was already being managed for his GI bleeding and I did not wish to expose him to further invasive investigations.

Response to Question 16: At paragraph 64, witness W1002 refers to a letter from Dr Patch to you dated 22 August 2002 where it is stated that the witness's husband should be considered for Lipiodol I. The witness states that she cannot recall her husband being consulted about this treatment. Please comment on this.

81. The records indicate that AS Senior was consulted about treatment with Lipiodol, a treatment that was suggested by Dr Patch. On 30 August 2002, Dr Yee discussed this treatment with AS Senior [**WITN06440040, 131**] when he was provided with some information.

Response to Question 17: At paragraph 69, witness W1002 refers to your letter to Dr Malik dated 31 October 2000 and states that she is surprised that you did not

mention her husband's HCV infection, but instead referred him to other doctors in different fields. Please comment on this.

82. AS Senior's GP, Dr Malik, was already aware of the HCV diagnosis from previous correspondence [**WITN06440040, 90, 95, 96**]. AS Senior had a number of medical issues which needed attention and I appropriately referred him to other specialists.

Response to Question 18: At paragraph 79, witness W1002 states that despite what was in your letter dated 12 March 1991 and in some of her husband's medical records, the witness's husband was not reviewed annually. Please comment on this.

83. According to the records, AS Senior was reviewed in the Haemophilia Centre on the following dates post 12 March 1991:

a. 16 April 1991 [**WITN06440040, 25**] – came to see me to discuss ultrasound results;
b. 25 April 1991 [**WITN06440040, 26**] – medication prescribed;
c. 14 August 1991 [**WITN06440040, 27**] – seen in combined orthopaedic/haemophilia clinic;
d. 4 September 1991 [**WITN06440040, 27-28**] – seen in combined orthopaedic/haemophilia clinic;
e. 4 December 1991 [**WITN06440040, 27, 29**] – seen in combined orthopaedic/haemophilia clinic;
f. 19 May 1992 [**WITN06440040, 30**] – seen by Dr Telfer to discuss Ribavirin trial;
g. 18 March 1993 [**WITN06440040, 31-33**] – general review by Dr Taher;
h. 6 July 1993 [**WITN06440040, 34-35**] – review with Dr Goldman;
i. 7 April 1994 [**WITN06440040, 37-38**] – seen in Haemophilia Centre after cardiology review;
j. 9 May 1994 [**WITN06440040, 39-40**] – seen in Haemophilia Centre;
k. 23 June 1994 [**WITN06440040, 41-44**] – review by Dr Pasi one month after starting Haemate P;
l. 5 September 1994 [**WITN06440040, 44-46**] – review by Dr Pasi;
m. 10 July 1995 [**WITN06440040, 49-53**] – routine review by Dr Pasi;
n. 30 October 1995 [**WITN06440040, 54-56**] – review by Dr Pasi;
o. 12 February 1996 [**WITN06440040, 57-59**] – review with Dr Pasi;

p. 18 November 1996 [**WITN06440040, 60-63**] – review with Dr Pasi;

q. 16 December 1996 [**WITN06440040, 64-65**] – seen in joint liver/haemophilia clinic by myself and Dr Patch;

r. 2 February 1998 [**WITN06440040, 67-71**] – seen by Dr Pasi;

s. 15 April 1998 [**WITN06440040, 71**] – review by Dr Pasi;

t. 17 June 1998 [**WITN06440040, 72**] – review by Dr Pasi;

u. 17 September 1998 [**WITN06440040, 73-74**] – review in combined orthopaedic/haemophilia clinic with myself and Mr Goddard;

v. 14 October 1998 [**WITN06440040, 75-77**] – review with Dr Pasi;

w. 2 February 1999 [**WITN06440040, 81-84**] – review with myself;

x. 27 April 1999 [**WITN06440040, 86-87**] – review with Dr Murphy;

y. 7 September 1999 [**WITN06440040, 88-90**] – review with myself;

z. 27 September 1999 [**WITN06440040, 91-94**] – review in combined liver/haemophilia clinic with myself and Dr Patch;

aa. 22 March 2000 [**WITN06440040, 95**] – review with myself;

bb. 9 May 2000 [**WITN06440040, 97-98**] – review with myself;

cc. 1 August 2000 [**WITN06440040, 99-100**] – review with myself;

dd. 31 October 2000 [**WITN06440040, 101-104**] – review with myself;

ee. 30 January 2001 [**WITN06440040, 106-107**] – review with myself;

ff. 31 July 2001 [**WITN06440040, 108-110**] – review with Dr Yee;

gg. 20 August 2001 [**WITN06440040, 111-113**] – review in combined liver/haemophilia clinic;

hh. 11 October 2001 [**WITN06440040, 114-115**] – review with Dr Chowdury;

ii. 2 November 2001 [**WITN06440040, 116-117**] – review with Dr Payne;

jj. 10 December 2001 [**WITN06440040, 119**] – review in combined liver/haemophilia clinic;

kk. 18 February 2002 [**WITN06440040, 123-124**] – review in combined liver/haemophilia clinic;

84. The above summary does not include attendances where AS Senior was treated for recurrent nosebleeds or reviews by other departments such as cardiology, ENT etc.

85. I therefore consider this statement to be factually incorrect.

Response to Question 19: At paragraph 81, witness W1002 claims that you and Dr Patch refused to give her husband an ultrasound in 1999 because you both 'assumed' that he would have a fatty liver. Please comment on this.

86. This refers to the combined liver/haemophilia assessment with myself and Dr Patch which took place on 27 September 1999 [**WITN06440040, 91**].

87. There was evidence from AS Senior's records that he had previously been noted to have a fatty liver which could make any ultrasound interpretation difficult.

Section 4: Other issues

88. At paragraph 35 of her statement, Witness W1002 states that there is a lot of reference in AS Senior's records to him drinking a lot of alcohol which is not true. The records represent an accurate note of the history provided by AS Senior to his treating doctors. Alcohol is a known factor in the causation and progression of liver disease and it is important to be aware of a patient's level of alcohol consumption and give advice accordingly. In the face of other causes of liver inflammation, it would be usual practice to advise reducing or abstaining from alcohol.

Statement of Truth

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

Signed GRO-C

Dated February 20th 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
18.04.2019	Professor CL's CV	WITN06440039
Various	Paginated chronological bundle of AS Senior's	WITN06440040

	relevant records from the Royal Free Hospital	
1985	*"High risk of non-A non-B hepatitis after a first exposure to volunteer or commercial clotting factor concentrates: effects of prophylactic immune serum globulin"* - British Journal of Haematology.	WITN06440041
2000	"*The natural history of HCV in a cohort of haemophilic patients infected between 1961 and 1985*", Gut 2000; 47: 845-851	WITN06440042