Witness Name: Dr Christopher Letchford Sheen
Statement No.: WITN4072001
Exhibits: WITN4072002-7
Dated: 19 MARCH 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF CHRISTOPHER LETCHFORD SHEEN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 30 September 2019.

I, Dr Christopher Sheen, will say as follows: -

Section 1: Introduction

1. My name is Christopher Sheen and my professional address is St Mary's Hospital, Parkhurst Road, Newport, Isle of Wight, PO30 5TG. My date of birth is GRO-C 1967 and I hold the following professional qualifications – MB BS (1991), BSc (1988), MD (2003), FRCP Edin (2003), FRCP (2006). I am a member of the British Medical Association (BMA) and the British Society of Gastroenterology (BSG). A copy of my CV is exhibited (**WITN4072002**).

2. I am currently practising as a Consultant Gastroenterologist and Physician at St Mary's Hospital in Newport, Isle of Wight. I trained at St George's Hospital in London and completed my training and research posts in London, on the South Coast and in Scotland where I was also a locum Consultant. I was appointed to my consultant post on the Isle of Wight in 2002.

3. I see patients in outpatient clinics and as inpatients where I will assess, review, investigate, diagnose and treat a variety of gastroenterological and hepatological conditions. These would include cancers of bowel, stomach, oesophagus, liver and pancreas, inflammatory bowel disease, functional bowel disorders, cirrhosis and liver failure, chronic liver diseases, pancreatic diseases and various other abdominal symptoms such as pain, weight loss and anaemia. I also perform a broad spectrum of therapeutic endoscopic procedures. For example, I remove colonic polyps, dilate strictures, place stents to palliate oesophageal and pancreatic cancer and remove gallstones from the bile ducts as well as performing diagnostic endoscopy to investigate symptoms.

4. I have leadership and management roles in providing a gastroenterological service to the population of the Isle of Wight. I have been involved in the supervision and training of junior doctors.

5. I hold private admitting rights at the Mottistone, a private unit attached to St Mary's Hospital, from where I run a private gastroenterology service. In that capacity I manage gastroenterological conditions as well as those involving the liver and pancreas. I offer diagnostic and therapeutic endoscopic services and accept referrals for many general gastroenterological conditions.

6. I work with an insourcing company to provide endoscopic services to other NHS hospitals to assist with their waiting lists

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

Section 2: Background Information

8. I make this statement in response to the concerns raised by witness W1303 in her statement to the Inquiry dated 25 February 2019. Specifically, at paragraphs 61-63 of that statement, witness W1303 addresses her husband's admission to the North Hampshire Hospital, Basingstoke, on GRO-B GRO-B 1998 where he died. I would like to take this opportunity to express my sincere sympathy to witness W1303 that the events concerning her husband's admission and treatment at the North Hampshire Hospital in GRO-B 1998 continue to cause such distress.

9. The Inquiry has made available to me the nursing records for the duration of this patient's admission and the medical records for GRO-B 1998. I exhibit these respectively at **WITN4072003** and **WITN4072004**. I have also been provided the following documents from the subsequent investigations into this patient's death, which I exhibit:

- Letter from the Chief Executive of North Hampshire Hospitals NHS Trust to witness W1303 dated 9 December 1999 (**WITN4072005**);
- Report of the NHS Independent Review Panel dated February 2001 (including the appended medical reports) (**WITN4072006**); and
- Report of the Health Service Ombudsman dated 27 June 2002 (**WITN4072007**).

10. It is now more than 20 years since my involvement in this patient's care and I have no specific recollection of the events or of my involvement in the subsequent investigations following his death. I therefore rely entirely upon the clinical records and investigation reports listed above.

11. At the time of my involvement in this patient's care, I was a gastroenterology trainee in my 5th year of training and I was the Registrar working with Dr Ramage. The records indicate that I was the on-call medical Registrar for the North Hampshire Hospital on Wednesday GRO-B 1998 which means that I started my shift on the morning of GRO-B and finished in the evening of GRO-B 1998. Witness W1303's husband was admitted to ward E1, the inpatient ward for gastroenterology and hepatology patients, which was one of a number of medical wards that I would have been covering as the on-call Registrar.

Section 3: Responses to criticisms of Witness W1303

Question 4: At paragraph 61 of her statement, witness W1303 states that her husband's doctors failed to properly record his fluid balance charts after draining fluid from him. They also allegedly failed to notice that his abdomen was refilling. Please comment on this.

12. The records available to me indicate that paracentesis was commenced on GRO-B 1998 and the drain was removed following a review by Dr Fowler at 9am on GRO-B 1998. My on-call shift began on the morning of GRO-B 1998 and therefore the clinical decisions regarding paracentesis appear to have been taken prior to my involvement in this patient's care.

13. My records on GRO-B 1998 confirm that I continued to monitor the patient's abdomen and found no signs of gross ascites. Those entries are timed at 19:45, when I recorded '*on examination abdomen distended, little ascites*' and at 22.00 when I recorded, '*abdomen distended...minimal ascites*'.

14. I note that the reports from the NHS Independent Review Panel (February 2001) and the Health Service Ombudsman (June 2002) found no concerns with regard to the paracentesis and I refer specifically to the following paragraphs within those reports:

NHS Independent Review Panel

'*F9. High serum potassium and low serum sodium excluded any treatment other than paracentesis.*

F10. The panel was told that the treatment "to drain to dryness" was in line with recognised

practice. In this case, the treatment was relatively cautious in that the drainage was carried out over a period exceeding 40 hours.

...

F18. The protocol outlined in his notes and in the evidence presented established that the Trust's protocol for paracentesis was followed and understood well by the medical staff. Expert evidence confirmed that the protocol was professionally acceptable and in line with specialist practice in similar units.

F19. The panel finds that [the patient's] treatment of abdominal ascites at the North Hampshire Hospital's NHS trust in GRO-B *1998 was totally appropriate.'*

Health Service Ombudsman

'13. ...By the time he was admitted to hospital again on GRO-B *he had severe ascites. The Assessors are satisfied that this was managed appropriately and their only criticism is in the poor recording of fluid balance on* GRO-B *.'*

15. The conclusions of the NHS Independent Review Panel were drawn from clinical opinions obtained from a number of medical and nursing experts. On the issue of paracentesis, the following clinical opinion was provided by Dr (now Professor) John O'Grady, Consultant Hepatologist at Kings College Hospital:

'5. Paracentesis is a recognised intervention in intractable ascites. The decision to proceed to paracentesis in this case is entirely appropriate. In patients with well compensated liver disease, large volume paracentesis is a frequently used therapeutic intervention. This involves drainage of amounts of ascites exceeding 10 litres accompanied by intravenous infusion of a volume expander. The object of this is to reduce the risk of hypotension and renal failure. The protocol carried out in this case was relatively cautious in that the drainage was carried out over a period exceeding 40 hours. The volume expander was given appropriately in terms of timing and the overall amount infused.'

16. In terms of the recording of fluid balance charts, that task was carried out by the nurses and Health Care Assistants and was not therefore something I would have been involved in. This was reviewed by the NHS Independent Review Panel and the Health Service Ombudsman who reached the following conclusions:

NHS Independent Review Panel

'F14. Evidence was presented to the panel that the recording of fluid balance charts was poorly performed without adequate supervision. However, this breakdown in recognised practice had no bearing on the outcome of [the patient's] treatment.'

Health Service Ombudsman

'12(xxxviii). The sub-optimal part of [the patient's] therapeutic paracentesis was the poor recording of the fluid balance...The poor recording of fluid balance did not influence the drainage of ascitic fluid, nor the replacement of colloid in any way, but it did make it difficult to establish at a glance how much fluid was being lost. Careful fluid charts would have assisted in making the diagnosis (made later in time) of poor urine output (oliguria). However, it is our opinion that an earlier diagnosis would not have altered [the patient's] further deterioration and eventual death.'

17. The NHS Independent Review Panel received expert nursing input from Fiona Cowdell who concluded in her report dated December 2000 that, *'The nurses clearly failed to comprehend the importance of accurate monitoring of fluid balance during paracentesis...the nurses questioned suggested that the responsibility for completing fluid charts lay with the Health Care Assistants; they were slow to acknowledge the registered nurses (sic) accountability for the omissions. It was stated that training is now provided for HCA's (sic) in the maintenance of accurate fluid balance charts.'*

Question 5: At paragraph 61 of her statement, the witness claims that her husband was left overnight with soaking wet clothes. Furthermore, she felt that her psychological welfare and safety from infection had been ignored, as her husband's blood soiled dressings were returned to her in a bag after he died. Please comment on this.

18. The nursing records made available to me confirm that there was leakage of the drain overnight on GRO-B 1998. The nursing records confirm that, *'drain leaking. Padded with 9x9s. Refused to have sheets changed on bed where drain leaked. Drain remains clamped.'*

19. Thereafter a further nursing record made overnight on GRO-B 1998 confirms that, *'paracentesis site leaking - bed changed.'*

20. My on-call shift began on the morning of GRO-B 1998 and therefore the issues regarding the leaking drain appear to have taken place prior to my involvement in this patient's care. Nonetheless, I note that the Health Service Ombudsman report dated June 2002 addressed this concern and concluded that,

'12(xv). Unfortunately, the ascites leaked overnight from the site of the insertion of the drainage tube, as well as through the tube. Comment: This is not unusual after clamping of the drainage tube and particularly where there is massive ascites under pressure requiring to be drained, which then leaked out around the tube.

12(xvi). The nursing notes record the patient's refusal to have his sheets changed.

12(xxxvii). The leakage of the ascitic fluid once the drainage tube was clamped was a consequence of the clamping and not a complication. The nursing notes record that the nurses looking after [the patient] were aware of this, but the patient was reported as not wanting to have the sheets changed. One clearly presumes he was asked. The colloid replacement would have covered this additional loss by leakage.'

21. In terms of witness W1303's concerns regarding the return of her husband's soiled clothes and dressings after his death, this is not something I am able to comment upon. Following the patient's death, I would have attended to other patients on the medical wards and as the on-call Registrar I would not have been involved in the process of returning a deceased patient's belongings to their family.

Question 6: At paragraph 62 of her statement, witness W1303 asserts that her husband continued to be drained despite the fact that he had withdrawn his consent for it. Please comment on this.

22. The records available to me indicate that paracentesis was commenced on GRO-B 1998 and the drain was removed following a review by Dr Fowler at 9am on GRO-B 1998. My on-call shift began on the morning of GRO-B 1998 and therefore the clinical decisions regarding paracentesis and the consenting discussions for that procedure appear to have taken place prior to my involvement in this patient's care.

23. Witness W1303 subsequently spoke to me on the evening of GRO-B 1998 about her concern that her husband had withdrawn consent for continuation of the drainage. My record is timed at 18:00 and records that witness W1303 was, *'very concerned at husband's deterioration. Feels that he did not give consent for drain to be left in overnight and as a consequence of this has developed life-threatening hypovolaemic shock...I explained that we had tried to explain to [the*

patient) why we were leaving drain in, and have apologised if we have failed to make this as clear to him as we thought...She has informed that she now wishes to know of every single Rx/action we do on her husband and why we are doing it. I have said that we will endeavour to explain everything but time is limited and we do not usually get written consent for simple procedures. I again apologised regarding communications with her and husband and we will try and explain further actions more carefully.'

24. There appears in the medical records a postscript entry from Dr Ramage entered at 09:05 on GRO-B GRO-B 1998 which reads, *'(witness W1303) was concerned about consent for continued drainage of the ascites. I discussed this with (the patient) on the morning of* GRO-B *'98 and he gave verbal consent for this to be done. I felt that draining only 5 litres would not improve his symptoms enough to make much difference to him.'*

25. The issue was considered by the NHS Independent Review Panel who concluded that,

'F2. The Panel was surprised to learn that the method of consent for paracentesis was not written but a verbal consent. However the Panel were satisfied that (the patient) was able to make a proper judgement about his continuing treatment, and had given his consent for the procedure to be carried out.'

26. That conclusion was supported by the independent clinical experts as follows:

Dr M Semples

'Jane Brown gave evidence that (the patient) wanted his drain to be removed on GRO-B *and to go home that evening. She stated, however, that (the patient) did not withdraw his consent for continued paracentesis. This information did not appear to have been recognised by medical or nursing staff who all stated that (the patient) did not ask for his drain to be removed...The conclusion was drawn that (the patient) gave full verbal consent for paracentesis in line with local protocol, and that while he expressed a wish for curtailment of drainage on both* GRO-B *he at no time withdrew consent.'* (appendix 3)

Fiona Cowdell

'All the information given by the staff that were questioned indicate that (the patient) himself did not at any time withdraw his consent for paracentesis.' (appendix 4)

27. The Health Service Ombudsman's report dated June 2002 considered the same issue and reached the following conclusion:

'12(xx). There is a note on GRO-B *from the haematologists, who reported that [the patient] had complained that he had not given permission to stay in hospital overnight. It was explained that continuous drainage could have been dangerous, and so the drainage tube was left in the abdomen to drain in stages, and thus avoid a further procedure of re-inserting the tube into his abdomen. Comment: this was appropriate and correct management particularly as [the patient] was a haemophiliac (and, therefore, likely to bleed). It was specifically noted that [the patient]: "seemed to understand".'*

Question 7: At paragraph 62 of her statement, witness W1303 claims that you told her that her husband's problems were mainly psychological, and that she was the cause of it. According to her, she was told that nothing was going to happen that night and that she should go home. However, the witness states that, one hour later, she received a phone call asking her to give consent for a CVP to be conducted on her husband, and warning her that he would not survive the night. Please comment on this.

28. This issue was identified but not determined by the Health Service Ombudsman in their 2002 report.

'10. [Witness W1303] had been very upset by her conversation with the Specialist Registrar, six hours before her husband died, during which he had said that her husband's problems were psychological and that she was upsetting him. That conversation was not witnessed by anyone but the conversation at 1am on GRO-B *when the Specialist Registrar said it was perfectly safe for [witness W1303] to leave the hospital, was witnessed by [witness W1303's] daughter and by a nurse. [Witness W1303] considered that the Specialist Registrar should have contacted the Consultant much sooner and should have been asked to account for his actions.'*

29. Given the passage of time, I am now unable to recall my conversations with witness W1303 on the evening of GRO-B 1998. The records of those conversations make no reference to my belief that her husband's problems were psychological however I may have made reference to an earlier comment from the patient that witness W1303 was overloading him with information and appeared to be causing him some anxiety. That entry appears in my records timed at 19:45 and

reads, 'He asked his wife to leave, feels she is asking him too many questions and is overloading him with information.'

30. It would not have been my intention to suggest that this patient's condition was psychological in origin; he was plainly seriously ill with a complex medical history. Accordingly, I can only now surmise that I was trying to defuse a very stressful time for witness W1303 and her husband who were undoubtedly in high emotional states at that time. I accept that my comments may have been delivered clumsily and, if that was so, I extend my sincere apologies to witness W1303 as this would never have been my intention.

31. Insofar as my subsequent conversation with witness W1303 is concerned, during which I indicated that she could go home, I cannot now recall what was discussed. The clinical records on the evening of GRO-B 1998 confirm that there had been no gross deterioration in her husband's condition albeit he was still seriously clinically unwell. As a result of this and my continued review of the patient at 00:30 I telephoned the consultant, Dr Ramage, who agreed to come in and review the patient. Following his review of the patient, Dr Ramage telephoned witness W1303 to indicate that her husband's condition had deteriorated and that he might not survive the night.

32. I offer my apologies to witness W1303 for any distress that was caused by her having to return to the hospital so soon after a conversation in which I reassured her that it was safe for her to leave to get some rest.

Question 8: At paragraph 62 of her statement, witness W1303 states that samples of her husband's body were taken, despite her lack of consent to this and her refusal for Variant Creutzfeldt-Jacob Disease ("vCJD") research to be conducted on him. When she protested, she was allegedly told that: "Haemophiliacs make an excellent model for this kind of study". Please comment on this.

33. I was not involved in the taking of post mortem samples from this patient for research purposes. That was carried out by Dr Noakes and was addressed by the NHS Independent Review Panel and Health Service Ombudsman as follows:

<u>NHS Independent Review Panel</u>

'F27. Dr Noakes gave evidence to the panel that [witness W1303] was understandably very distraught following the death of her husband. He felt that to ask for her consent for the removal of samples from [the patient] may have distressed her further. He accepted that by not asking for [witness W1303's] consent her distress had been added to.

F28. The panel heard that HM Coroner had given consent for samples to be removed from the body of [the patient] and that legally further consent from [witness W1303] was not required.

F29. ...the decision to remove samples without the consent of [witness W1303] was not appropriate.'

Health Service Ombudsman

'19. The following conclusion was made by the Professional Assessors in respect of this aspect of [witness W1303's] complaint:

> *xi. Removal of Tissue*
>
> *Consent was obtained from the coroner, who was in charge of the post-mortem. It is regrettable that [witness W1303] was not informed, but the clinical staff looking after [the patient] had no knowledge of this and could not have supplied her with this information...*

20. It is not disputed that tissue was removed all that [witness W1303] was not consulted about that. The Trust apologised again about that in the Chief Executive's letter of 2 August 2001.'

Question 9: At paragraph 63 of her statement, witness W1303 claims that no one ever told her the results of the vCJD testing on her husband's body, and that it was left to her to track the results down. Please comment on this.

34. Once again, the issue of reporting of the vCJD testing was not something I was involved in. Following the patient's death, I would have attended to other patients on the medical wards and as the on-call Registrar I would not have been involved in, or aware of, the reporting of any vCJD test results. I am not therefore in a position to comment further on this matter.

Section 4: Other Issues

35. I have no further information that I consider relevant to the matters raised by witness W1303.

Statement of Truth

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

Signed GRO-C

Dated 19 MARCH 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
Current	CV of Dr Christopher Sheen	WITN4072002
21-24/12/98	Various nursing records from North Hampshire Hospital for Witness 1303's husband	WITN4072003
23-24/12/98	Various medical records from North Hampshire Hospital for Witness 1303's husband	WITN4072004
09/12/99	Letter from the Chief Executive of North Hampshire Hospitals NHS Trust to witness W1303	WITN4072005
Feb 2001	Report of the NHS Independent Review Panel (including the appended medical reports)	WITN4072006
27/06/02	Report of the Health Service Ombudsman	WITN4072007