

GRO-C

4/7/2020

Witness Name: Dr John Keith Ramage
Statement No.: WITN4134001
Exhibits: WITN4134002 – WITN4134013
Dated: March 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF JOHN KEITH RAMAGE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 2 October 2019.

I, Dr John Ramage, will say as follows: -

Section 1: Introduction

1. Name: John Keith Ramage, MB BS MD FRCP

Dob GRO-C 1955. Address: Department of Gastroenterology, Hampshire Hospitals Foundation Trust, Basingstoke, RG24 9NA

Current positions: Consultant Gastroenterologist and Hepatologist, Hampshire Hospitals Foundation Trust. I have held this position since 1996 and am the senior physician in the department of 11 consultants.

Honorary Consultant Physician, Institute of Liver Studies, Kings College Hospital, London, Honorary Senior Lecturer, Kings College, London, I have held this post since 1994 (part-time) and am the lead clinician for the neuroendocrine tumour service for Kings Health Partners (Kings College, Guys and St Thomas' trusts)

Visiting Professor University of Winchester. I have held this position since 2016 and am leading a collaboration between the University and Hampshire Hospitals.

I produce my full Curriculum Vitae as **WITN4134002**.

I have not been a member of the relevant committees related to the investigation.

Section 2: Responses to criticism of W1303

Review of Records

2. Before responding to the criticisms contained in paragraphs 29 and 60-65 of Witness 1303's statement, and summarised in paragraphs 4 to 10 of the Rule 9 letter, it may be helpful for me to set out a review of the patient's relevant medical history, from a liver perspective including a detailed analysis of his clinical management following his admission on GRO-B GRO-B 1998. The report of Drs Burrows and Ashton, the Professional Assessors to the Health Service Ombudsman for England is also informative in this regard, and is contained within the Ombudsman's report dated 27 June 2002, which I produce as **WITN4134003**. I have also referred to the report of the Independent Review Panel held at Parklands Hospital on 29 November and 6 December 2000 which I produce as **WITN4134004**. The only copy now available has been hand annotated by Witness 1303.

3. Because the events in question took place 21 years ago, I now have only very limited direct recollection of my involvement with the patient's care, and I am therefore heavily reliant upon the relevant clinical records and the evidential summaries in the Independent Review Report and Ombudsman's report. I produce the relevant extracts from the records, to the extent that I have consulted them in order to prepare this statement, collectively as exhibit **WITN4134005**. I also produce the relevant nursing notes as **WITN4134006**.

4. The patient had been diagnosed with haemophilia in 1969 at the age of 11. As a result of treatment of his haemophilia, probably during a procedure at Frimley Park Hospital in 1984, he became infected with the HIV virus, and with Hepatitis C, leading to cirrhosis of the liver.
5. In May 1998, the cirrhosis of the liver was probably responsible for an accumulation of fluid in the abdomen, known as ascites, which responded to treatment with spironolactone, a potassium sparing diuretic used in the treatment of liver disease.
6. In July 1998 the patient was diagnosed with a lymphoma of the throat, for which he was treated successfully with chemotherapy and radiotherapy.
7. The patient was first referred to me (by Dr Neilson, his clinical haematologist) for a second opinion regarding his ascites and general prognosis, on 11 August 1998, as a result of which I arranged for an ultrasound. The consultation is not directly relevant to Witness 1303's criticisms, but I highlight part of the entry which records:

*"HCV +ve
HB [hep B] core antibody positive."*

8. I produce my clinic letter to Dr GRO-B the patient's General Practitioner, dated 12 August 1998 as **WITN4134007**.
9. The ascites worsened in November 1998 and had not responded to medical therapy with spironolactone, and was therefore drained by a procedure known as paracentesis at the Royal South Hants Hospital on 4th and 5th November 1998, when in line with usual practice, 2 litres of fluid were drained without complication.

10. I next saw the patient in an outpatient clinic on 13 November 1998 after the ascites had worsened. I advised increasing spironolactone at 200mgs a day with increased protein and decreased salt in his diet. I planned to see him in 2 weeks' time for review and a further ultrasound. I needed to exclude cardiac cause for his symptoms.
11. I saw him again on 24 November 1998, when his ascites and general condition had improved. I produce my follow up letter to the General Practitioner as **WITN4134008**. A further review was scheduled for 15 December 1998
12. When I saw the patient on 15 December 1998, his ascites had worsened but was not painful. He was feeling more tired. The treatment plan involved further liver function tests, and if the liver enzymes were raised we would try Prednisolone. At the time it was believed that steroids may benefit the treatment of Hepatitis C, but this has since been disproved. If that proved ineffective, then I was contemplating a referral to William Rosenberg, a Hepatologist at the Royal Southampton Hospital. The patient was to be telephoned with the test results. I produce my follow up letter to Dr Rosenberg dated GRO-B 1998 as **WITN4134009**, although the referral never in fact took place, as a result of the supervening events described below.
13. I also telephoned Dr Moyle, the patient's HIV specialist at the Chelsea & Westminster Hospital, in order to discuss whether his anti-retroviral medication could be a causative factor for his ascites. Dr Moyle advised that the Nevirapine was not responsible, and that on balance the patient should continue to take Septrin. Septrin was prophylaxis against a particular type of pneumonia common in HIV positive patients and it was felt that this should continue since it was unlikely to be causing liver problems. It was agreed that he was not suitable for a liver transplant. Liver transplant was not performed for HIV positive patients because of the severe

risk of overwhelming infection. The picture emerging was one of a complex medical history and a patient in a poor and progressively worsening condition. There was no clear reason for the deterioration of his liver, and treatment options were limited.

14. I recall that over the following days we had a number of contacts from the patient and his wife, reporting that his abdomen was swelling, and his condition was getting worse. We therefore agreed he should be admitted.

15. Amongst the records there is an undated note in my hand, which is a message to my secretary.

I believe this written on Friday GRO-B I produce this as **WITN4134010**. The note reads:

*"[The patient]
No reply
Please phone him
Ask him to reduce Spironolactone to 100mgs/day
and come into hospital
here on Monday for
repeat paracentesis."*

16. As agreed, on GRO-B 1998 the patient was admitted electively for symptom control by way of further paracentesis. There is a detailed clerking note by Dr Fowler, a Senior House Officer, who I recall was extremely competent. Dr Fowler's note is self-explanatory and records that the patient had developed severe ascites, was feeling unwell and exhausted, and was jaundiced. The note confirms that the ascites was for drainage, and that Dr Fowler discussed the case with Dr Noakes the Consultant Haematologist, and in particular the need for Factor VIII prior to paracentesis. The blood test results that follow Dr Fowler's entry, and in particular the potassium and sodium readings were both suggestive of kidney and liver compromise, as a result of which spironolactone was decreased to 100mgs per day.

17. The next entry, which is untimed but again dated [GRO-B] 1998, confirms that I then saw the patient during the course of the consultant ward round. The note reads as follows:

*"WR JKR
Feeling very tired
For Factor VIII now
Then paracentesis plus gelofusin 1 unit at the start and 1 unit at end
40mgs frusemide +)
100mgs spironolactone) Start tomorrow
Echocardiogram (? increased jugular venous pressure)"*

18. There follows an entry by the Consultant Haematologist, Dr Tim Noakes:

*"The cause of this gentleman's tense ascites is not
totally clear – probably secondary to cirrhosis but he
does have lymphoma – fluid should be sent
for cytopsin to haematology as well as protein culture
plus cytology
He should be OK after 150 IV Factor VIII 50% dose
for his weight and I would not anticipate further Factor VIII
On examination no palpable nodes
JVP + 6cm
Heart sounds normal
Abdomen – ascites ++
Impression: cause of ascites uncertain
Keep overnight post tap (paracentesis)
? baseline prothrombin positive. ? needs Vitamin K"*

19. The paracentesis was performed at 16:15 on [GRO-B] 98 and is recorded in Dr Fowler's note:

*"Ascitic tap performed
Aseptic technique
2% 5mls lignocaine infused
10mls ascitic fluid drained straw coloured
Samples sent to:
Haematology
White blood cells
Total protein + glucose
MCV [Microscopy Culture and Sensitivity]
Cytology
500mls gelofusin start now
500mls after 5 litres drained (or drained to dryness) clamp after 5 litres drained if
continuing to
Drain*

? for Vitamin K

Repeat urea and electrolytes, liver function tests, clotting, full blood count in the morning."

20. The intention was to drain 5 litres of fluid rapidly in the first instance and then clamp. The drainage tube after 5 litres had been removed. Gelofusin is volume expander and protein replacement and is used for any significant paracentesis, in order to minimise the risk of volume depletion. The alternative, Albumin, was associated with increased mortality and therefore not the treatment of choice. I refer to the paper "Human Albumin Administration in Critically Ill Patients: Systematic Review of Randomised Controlled Trials" by the Cochrane Injuries Group Albumin reviewers [BMJ volume 317 July 1998] – **WITN4134011**, which suggests an increased mortality in ITU patients that had received Albumin.

21. The patient was then seen during the course of the SHO ward round on the morning of 22.12.98, which is documented by a House Officer

*"5 litres drained overnight
Patient feels more comfortable now
On examination much improved
Reduced distension
Plan: continue drainage with more gelofusin
? home later today
Chase bloods/tap cytology
Echocardiogram"*

22. There follows an entry by Dr Fowler:

*"Discussed with Dr Ramage
to drain ascites to dryness with further gelofusin
cover. Drain can then be removed
Keep overnight; re-check bloods in the morning
Echocardiogram today
Home tomorrow morning."*

23. Having drained 5 litres of fluid over the night of **GRO-B** the treatment plan was then to proceed to drain to dryness with further Gelofusin cover following which the patient would be monitored overnight on **GRO-B** and then if well enough, discharged the following

morning. This approach over a relatively prolonged period, with two drainage sessions separated by a period of clamping and observation, and with fluid replacement throughout, was appropriate and conservative management. I refer to the paper "Total Paracentesis Associated with Intravenous Albumin Management of Patients with Cirrhosis and Ascites" by Tito et al [1990] - **WITN4134012** which confirms that total paracentesis (draining to dryness) was considered safe and usual practice at that time.

24. There is then an entry in my hand (next to a note of the blood results), which has been erroneously dated by the SHO as **GRO-B** 1998, although from the subsequent entries, it is clear that this was written on **GRO-B**

*"Plan to remove drain and observe blood pressure and urine output today? leave tonight or tomorrow morning
Need to ask GP to check serum sodium and potassium next week. I have referred him to Dr Rosenberg at Southampton."*

25. This again refers to my letter to Dr Rosenberg already produced as exhibit WITN .

26. An entry in the nursing notes timed between 20:00 and 20:30 on **GRO-B** 1998 is of relevance at this point:-

"[Witness 1303] telephoned this evening and is very distressed about her husband's condition and care. It appears from her comments that they have had generally bad experiences in hospital and that lack of consideration played a major part. This includes this stay in hospital. It was fully explained to [Witness 1303] reasons for treatment and why [her husband] is to remain in hospital overnight, and it was reiterated that Dr Ramage's team would be informed of concerns tomorrow. Dr Cowlshaw from the on call team is aware and will review the situation as [the patient] was also asking to see his medical notes. Nurse manager aware of telephone conversation

Dr Cowlshaw reviewed and explained the doctors on call system and that it would be better to discuss any concerns and discharge dates with Dr Ramage's team tomorrow. [The patient] appeared satisfied with this."

27. At 21:10 on the evening of [GRO-B] 1998 there is an entry by the on call Senior House Officer which reads as follows:

*"Asked to see patient
Patient asking to be told his blood results
+ angry about still being in hospital
Explained Dr Ramage's wishes for ascites to drain to dryness
Drain still draining large quantities of fluid.
Explained questions best left to Dr Ramage's team in the morning
Patient did not mention about blood results."*

Because this is not my entry and I was not present, it is difficult to comment. However it appears that the patient's concern was with his continued stay in hospital rather than the presence of the drain. It is also clear that the on call SHO communicated to the patient my plan that the ascites should be drained to dryness. This was clearly taking longer than anticipated because of the volume of the ascites, although there is no suggestion that the patient objected at that stage. Any objection regarding the continued paracentesis was not communicated to me overnight. Removal of a (still draining) drain would be a significant decision, and not one that I would expect an SHO would contemplate in those circumstances. The safer course would be to defer until the following morning, when an informed and considered decision could be taken, following consultant review. The nursing notes confirm that the ascites continued to drain throughout the night of [GRO-B] 1998.

Although slightly contradictory, I would infer from the note that the patient was informed of his blood test results and did not have any comments upon them at this stage.

28. The first entry for **GRO-B** 1998 is by the haematologist Dr Noakes:

*"[The patient] is concerned that his stay was longer than anticipated and that he did not give permission for drain to stay in overnight
I explained that it would have been dangerous to drain all off at once and keeping the drain avoided
another procedure. Also I was sure he will have been informed of the intention. He seemed to understand.
I gather if stable, he is to go home tonight. I would consider Vitamin K a sensible addition to medication.
He is very keen to be told results of all investigations."*

29. The point being made by Dr Noakes is that it would have been unsafe to drain off such a large volume of fluid in one session (even if this hastened the patient's discharge) and good practice required the two-stage approach we adopted, initially draining 5 litres, then clamping and keeping under observation, before resuming the paracenteses in order to drain to dryness followed by a period of further monitoring. It was still hoped at that stage that if stable the patient would be discharged that evening.

30. It appears that after the patient had objected during his discussion with Dr Noakes, the drain was removed at the first safe opportunity, and in this regard I refer to the nursing notes. The entry dated **GRO-B** 1998 at 08:00 records:

*"[Witness 1303] has telephoned this morning expressing serious concern about **GRO-B**'s care and general treatment.
It was explained that everything was being done as per Dr Ramage's instructions but she was still not satisfied with this. Reassurance was given and time taken from nursing staff to explain all care and reasons for **GRO-B** remaining in hospital.
Nurse manager aware of telephone conversation.
Dr Fowler contacted at 9am and reviewed*

GRO-B, drain to be removed. Dr Fowler aware of concerns from both [the patient].”

31. At 14:45 on [REDACTED] 1998 my Registrar, Dr Sheen was asked to review the patient. Dr Sheen was a very competent Registrar in whom I had full confidence. He had at least two years' experience as a Gastroenterology registrar and was a good communicator. His entry reads as follows:

*"Asked to review
Drowsy
Unwell
Blood pressure 96/58 lying 69/29 standing
Tender abdomen
Bowel sounds ✓
Impression 1) dehydration
2) spontaneous bacterial peritonitis
Needs aggressive fluid replacement – colloid
crystalloid
Plus IV cephalexin and metronidazole
Stop diuretics
NB
[Witness 1303] (wife) has expressed concern re use of
gelofofusin as he is vegetarian
Discussed with pharmacy. Dextran is not animal based
Use 1 litre Dextran 70 in 24 hours"*

32. Until this point because the patient was so unwell that neither I nor anyone else involved in his care had made the connection between the fact that he was a vegetarian, and that Gelofusin contained animal products. Because Dextran has no protein, it is less than ideal and it was not usual practice to use it for the purposes of fluid replacement during paracentesis, although its use had been endorsed and in this regard I refer to the paper “Paracentesis with Dextran 70 vs Paracentesis with Albumin in Cirrhosis with Tense Ascites” by Fassio and others 1991 **WITN4134013**. Dextran was used in this instance because of the vegetarian aspect referred to in the notes extract in paragraph 32 above.

33. The low blood pressure is probably the result of volume depletion, despite the use of Gelofusin, and is often seen some 12 hours after paracentesis has been completed.

Consequently in high risk patients it would be usual practice to keep the patient in hospital to avoid or to treat this complication. Lower risk patients might well go home on the same day as the paracentesis.

34. The next entry, timed at 18:00 on GRO-B 1998, is again in Dr Sheen's hand and records a long discussion with Witness 1303:

"Discussed with [Witness 1303]:

*She is 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
wishes also to know of options of treatment and why
ascites has recurred so rapidly.*

Is not happy if he has developed infection.

*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.*

*I also explained that we often drain large volumes
of fluid with gelofusin cover to
limit risks of hypovolaemia.*

*Infection can also occur and I am trying to limit
infection/further hypovolaemia with plasma expansion
and intravenous antibiotics.*

*[Witness 1303] questioned availability of transplant etc
I am not sure of options for treatment. It would
seem likely that immunosuppression could exacerbate
liver damage in a transplant.*

*She has informed that she wishes to know
of every single treatment/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 don't usually
get written consent for simple procedures.*

*I again apologised regarding communication with her and
husband and we will try and explain further actions
more carefully."*

35. There follows a series of entries by Dr Sheen, the first of which is at 19:45:

*"[Witness 1303] feels husband is even worse
Reviewed [the patient]
Feels better
Moderate tachypnoea (increased respiration)
Bowels not open 2 days
On examination abdomen distended Blood pressure 110/70
Little ascites
Bowel sounds ✓
Heart sounds normal
Pulse 110
Chest clear
Impression
In my opinion patient remains stable and possibly improved
He asked his wife to leave, feels she is asking him too
many questions and is overloading him with information
Plan 1) Slow with fluids
2)Continue antibiotics"*

36. Dr Sheen conducted a further review at 22:00

*"Reviewed
Nauseated
Drowsy and vague but co-operative
On examination pulse 110 regular Blood pressure 110/70
Heart sounds normal
Chest very few basal crackles
Respiratory rate 28 per minute
Abdomen distended
Bowel sounds ✓
Minimal ascites
It is possible he has further hyponatraemia (low sodium)
and pseudo-obstruction
Needs abdominal x-ray
Chest x-ray
Full blood count/urea and electrolytes plus amylase
Slow intravenous infusion"*

37. The blood test results from the evening of GRO-B 1998 have then been entered. These
portray progressing abnormality and deterioration. The patient's kidney function is poor,
which is consistent with hypovolaemia and resulting kidney injury. Dr Sheen has reviewed the

x-rays and notes that the abdominal x-ray and confirms air in the large and small bowel, and calcified renal shadowing adjacent to the L3 vertebrae, the significance of which was not clear.

38. Dr Sheen then sets out his assessment and plan:

*"A – Note sodium normal but developed mild degree of renal failure
This is likely to be pre-renal in view of the previous findings of significant postural drop (i.e. dehydration)*

B – It is possible that he has hepatic encephalopathy, but apart from mild confusion there is little else to support

C - ? Atypical infection – pneumocystis pneumonia (a recognised complication of HIV, but unlikely in the circumstances)

Plan *Continue IV fluids slow dextrose drip
Intravenous antibiotics
Oxygen if needed
Lactulose
Watch urine output
Repeat all blood tests tomorrow.*

*NB The wife is concerned that he has developed cerebral oedema. This refers to the fact that [the patient] had cerebral oedema when he had lymphoma.
I have told her that this seems unlikely, but I cannot fully exclude
She also pointed out that when he had chemo the ascites went.
I will discuss with Dr Ramage tomorrow the need for CT head and whether this is really indicated."*

39. Dr Sheen reviewed the patient again at 00:30 on GRO-B 1998:

"Review
*More confused but rousable
Tachypnoeic
In view of slow deterioration discussed with Dr Ramage
? abdominal bleed
Needs central venous pressure line + catheter
Dr Ramage will come in and review*

*Discussed with Dr Milne (haematologist on call)
If risk of bleed cover with Factor VIII
1500 units now + 1500 units 11 hours later"*

40. As a result of my telephone discussion with Dr Sheen just after midnight, I then attended at 2.00 am and reviewed the patient. My note reads as follows:

*"Decompensated (not working) liver disease Hepatitis C/HIV/recent lymphoma
Confused. Acidotic breathing. Hypotensive. Oliguric (low urine output)
Needs blood gasses, central venous pressure line with or without albumin infusion.
Antibiotics
One dose dexamethasone (apparently had cerebral
oedema before which responded to steroids).
I have spoken to [Witness 1303] about his condition. She has
given consent for the CVP [central venous pressure] line. I have explained that he is
seriously ill and that he could deteriorate and die tonight."*

41. Dr Sheen's note timed at 2.15 am on GRO-B 1998, then includes details of the insertion of the CVP line. The blood gas results that follow indicate severe lactic acidosis, which is incompatible with survival in a patient with liver disease and may have been the combined effect of the HIV medications and paracentesis. A value of 6.7 (7.4 is normal) is extremely hard to correct in the presence of severe liver disease and renal failure.

42. Human albumin was given together with 2.5mgs of Dopamine for kidney function. 50mls of 8.4% bicarbonate was given in an attempt to correct the acidosis. Dr Sheen's note concludes with the following assessment:

*"His prognosis is dire. I have discussed with Dr Ramage.
In the event of cardiac arrest with a diagnosis of
multi organ failure it is extremely unlikely
that he will recover.
Therefore in the event of a cardiorespiratory arrest
not for resuscitation.
Keep comfortable."*

43. The patient then sadly passed away, and his death was certified at 03:40 am on GRO-B 1998.

44. There follows a retrospective note entered by me and timed at 09:05 on **GRO-B** 1998:

*"[Witness 1303] was concerned about consent for continued drainage of ascites. Discussed this with [the patient] on the morning of **GRO-B** 1998 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."*

This relates back to the entry by the SHO on **GRO-B** 1998 discussed in paragraphs 17 to 23 above.

Response to Specific Criticisms

45. I turn now to the individual criticisms made by Witness 1303 to which I have been invited to respond. I should emphasise that my involvement with the patient occurred solely in my capacity as a consultant gastroenterologist. Consequently I am able to comment only upon those criticisms that relate to my clinical management, or the actions of my medical team. I do not hold (and did not hold in 1998/1999) any managerial role within the Hampshire Hospitals Foundation Trust or its predecessor the North Hampshire Hospitals NHS Trust. Consequently I cannot comment directly in relation to the alleged acts or omissions of the nursing staff (questions 6 and 7) or in relation to the tissue samples taken for the vCJD testing (questions 9 and 10).

Question 4

"At paragraph 29 of her statement, witness W1303 claims that her husband was never told he had HBV. However the witness refers to a letter that you sent to her husband's GP dated 12 August 1998 in which you wrote that he was both HBV core antibody positive and HBV surface antibody positive."

46. The patient's Hepatitis B status is referred to throughout the hospital records and correspondence. HBV core antibody positive and HBV surface antibody positive results indicate *immunity* to Hepatitis B, and are not suggestive of current Hepatitis B infection. In other words they confirm that patient had contracted Hepatitis B in the past, had recovered from it, and had developed immunity. In those circumstances I would not normally comment on such results, since no action would have been required to be taken at the time, since the virus had already cleared from the blood. It is for that reason that the patient's Hepatitis B status was not considered relevant for the purposes of the Post Mortem report. Conversely his chronic Hepatitis C infection had progressed to an advanced cirrhosis and was highly relevant.

Question 5

"At paragraph 60 of her statement, witness 1303 claims it was very difficult for her and her husband to obtain information from you. According to her, after contacting your secretary, her husband was called in for paracentesis without any explanation. She also recalls that there was a lot of confusion regarding whether he had in fact been called in for a test or not and that there was a delay in when her husband was told about his results."

47. This paragraph contains several criticism. In terms of contact with Witness 1303 and her husband prior to his admission on GRO-B 1998, the records and clinic letters offer some assistance. Our discussions during the consultations of 11 August, 13 and 24 November and 15 December 1998 appear to have been detailed. It would not have been standard practice at that time to have copied clinic letters to the patient.

48. I cannot recall whether Witness 1303 accompanied her husband to these consultations. Nothing in the records suggests that Witness 1303 and her husband had experienced any

difficulty in obtaining information from me or my team prior to or indeed after his final admission.

49. My recollection is that there had been a number of calls from Witness 1303 and her husband to my secretary, concerning the patient's worsening condition. When the patient was contacted it was explained that he had so much ascites that something needed to be done. It was agreed that I would admit him for paracentesis and I believe he then drove some 50 miles to hospital and that a bed had been arranged for the purposes of an overnight stay.

50. I believe that the reason for the decision to admit was fully understood by Witness 1303 and her husband; medical management with spironolactone had proved ineffective, and the patient was in discomfort from the worsening ascites. The reason for the admission was to enable a second paracentesis. This is confirmed by the note to my secretary asking her to arrange admission, and by the clerking note of [GRO-B] 98 which opens with "*Admitted electively for paracentesis*". This is echoed in the nursing note at 11.00 am on [GRO-B] "*For admission for paracentesis with Factor VIII cover.*"

51. I should also emphasise that Witness 1303 and her husband were already familiar with the paracentesis procedure, as the patient's ascites had previously been drained at Southampton Hospital under Dr Sweetenham on 3 November 1998 – that is some 6 weeks before the events in question. On that occasion they had only taken 3 litres of fluid, and the subsequent CT scan confirmed that there was still a considerable volume of fluid present, following which his condition again deteriorated confirming that drainage of a small amount of fluid had not alleviated his symptoms.

52. The background information in the report of the Independent Review Panel, which I have already produced as **WITN4134004**, is also of relevance. At page 3 of the report it states:

"Numerous telephone conversations took place between staff at the North Hampshire Hospitals NHS Trust and [Witness 1303 and her husband] on Friday [GRO-B] 1998. [The patient] informed staff that his ascites was causing him great discomfort and that he was feeling extremely unwell. Arrangements were made for admission on [GRO-B] [GRO-B] However [Witness 1303] was against this course of action as she felt it would [GRO-B]

[The patient] was admitted to Ward E1 on [GRO-B] for paracentesis, having driven himself to hospital from his home in [GRO-B] Consent for the procedure was verbally given. It was anticipated that some ascetic fluid would be removed and that [the patient] would then go home.

Five litres of ascetic fluid was drained during the course of that day, and subsequently the drain was clamped. The following day more fluid was drained and Dr Ramage took the decision to drain to dryness."

53. The records confirm that both Witness 1303 and her husband were fully and actively involved in all significant treatment decisions, to the extent that this was possible in a gravely ill and rapidly deteriorating patient.

54. The tests results received on [GRO-B] 1998 appear to have been communicated to the patient the same day during an attendance by an on call registrar at 21:10. An entry in the nursing records timed at 23:00 on [GRO-B] 1998 records:

"Wife seen by Dr Fowler and Dr Sheen – who explained what blood tests are for and the results were given to wife."

Question 6

"At paragraph 61 of her statement witness 1303 states that her husband's doctors failed properly to record his Fluid Balance Chart after draining fluid from him. They also allegedly failed to notice that his abdomen was refilling."

55. There were shortcomings in the recording of the patient's fluid balance, which were acknowledged both by the Independent Review and in the report of the Health Service Ombudsman dated 27 June 2010. However these shortcomings did not adversely affect the

patient's treatment, or its outcome – again this was acknowledged by the Independent Review and by the Health Service Ombudsman. The Trust apologised to Witness 1303 in relation to this aspect of her complaint, and changes were implemented. Maintaining the Fluid Balance Chart is the responsibility of the nursing staff, and therefore concerns regarding resource and training deficiencies are a matter for the nursing and Trust management rather than for me as the patient's treating consultant.

56. The records do not assist in relation to the suggestion that the patient's abdomen was refilling, although I see that following the discontinuance of the paracentesis, Dr Sheen noted "*little*" or "*minimal ascites*".

Question 7

"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 bag after she died."

57. Again these are nursing issues in relation to which I can make only very limited comment. Had I seen anything to suggest that the patient was not being adequately cared for, I would have raised appropriate concerns. Leakage around the drainage site would be common and the nursing staff would assist with preventing this. Such leakage would not affect the infection risk, although can be unpleasant for the patient. The return of clothing to Witness 1303 following her husband's death would not be a matter with which I would be in any way involved and criticisms in this regard should be addressed to the Trust management.

58. I note a number of entries in the nursing records which are potentially relevant in this regard.

At 11:00 on GRO-B 1998 there an entry:

"To be changed overnight"

59. At 05:00 on GRO-B 1998 it is recorded:

"Refused to have sheet changed on bed where drain has leaked."

60. Untimed entry, overnight on GRO-B 1998 records:

"Paracenteses site leaking-bed changed"

Question 8

"At paragraph 62 of her statement witness W1303 asserts that her husband continued to be drained despite the fact that he had withdrawn consent for it."

61. Because medical treatment of the patient's ascites with diuretics had proved ineffective, drainage was the only possible treatment to provide him with relief. Patients with cirrhosis and diuretic-resistant ascites have a poor survival rate in the region of 50% in one year. The other complicating conditions of HIV, Hepatitis C and a history of recent lymphoma treated with chemotherapy and radiotherapy, rendered the patient's prognosis far worse.

62. The issue of consent is covered extensively in the hospital records, in documented discussions with both Witness 1303 and her husband. It was also explored during the Independent Review and by the Health Service Ombudsman.

63. It is clear from the records that the patient attended and was admitted specifically for paracentesis. My decision to drain the ascites to dryness with Gelofusin cover was appropriate and reasonable, and in line with accepted practice both then and now. A cautious approach was adopted with the paracentesis being performed in two stages over a rather

longer than usual period, and keeping the patient in for observations overnight, to avoid the complication of subsequent hypotension as a result of volume drop. It is clear that when seen by the on call Senior House Officer at 21:10 on the [GRO-B] the patient was unhappy about the fact that he was still in hospital. The on call SHO reiterated the intention to drain to dryness and advised the patient to raise his concerns with my team the following morning. As I have already indicated, it would not have been usual for an on call SHO to have revised the treatment plan and terminated the paracentesis on his own initiative overnight.

64. Dr Noakes' entry on the morning of [GRO-B] 1998 is of particular relevance in this regard. He records that the patient stated that he had not given permission for the drain to stay in overnight, in response to which Dr Noakes reassured him as to the appropriateness of the procedure and that the patient would have been informed of the intention. Five litres of fluid had been drained off initially on the first day of admission and it was then agreed that further fluid would be drawn off on the second day, given that partial paracentesis at the Royal Southampton Hospital in November had not produced any significant benefit. The draining of fluid on [GRO-B] had taken longer than anticipated and had continued overnight in the interests of patient safety.

65. Following Witness 1303's telephone call at 08:00 on [GRO-B] 1998 in which she expressed concerns (see above) Dr Fowler reviewed the patient and the drain was removed, at the first safe opportunity.

Question 9

"At paragraph 62 of her statement witness 1303 also 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 research to be conducted on him. When she protested she was allegedly told that "haemophiliacs make an excellent model for this kind of study".

66. I am not in a position to comment on this. Dr Noakes, the haematologist, dealt with the tissue retention issue, and I was completely unaware that tissue had been retained for vCJD purposes until I learned of this in Witness 1303's complaint to the Trust.

Question 10

“At paragraph 63 of her statement witness 1303 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.”

67. Again I cannot comment – see response to question 9 above.

Section 3: Other Issues

68. The criticisms raised by Witness 1303, together with a number of other concerns she had regarding her husband's care and treatment, have previously been the subject of full investigations by an Independent Review Panel and by the Health Service Ombudsman for England.

69. The Independent Review Panel heard evidence on 29 November and 6 December 2000. The Panel was assisted by independent expert reports from Dr John O'Grady, Consultant Hepatologist, Dr Gary Brook, Consultant Physician, Dr MG Semple, and Sister Fiona Cowdell. I attach a copy of the report which was published in February 2001. The Panel (and the experts advising it) concluded that the patient had given adequate consent for his treatment and that the management of his ascites was appropriate. It made no criticism of my actions, although shortcomings in communication were identified, and the Panel was of the view that the tissue retention issue had been poorly handled.

70. Witness 1303 also raised similar concerns with the Health Service Ombudsman for England.

The matter was rigorously investigated, resulting in the report by Mrs Ann Dougdale dated 27 June 2002. The Ombudsman was assisted by independent professional advisers – Dr AK Burrows, Consultant Physician and Hepatologist and Dr M Ashton, Consultant Physician and Gastroenterologist. The only aspect of the complaint that was upheld related to the fluid balance monitoring already discussed, although once again there were criticisms of the way in which the tissue retention issue was handled. Both the Ombudsman and the two assessors advising her concluded that the clinical management of the patient's ascites was entirely appropriate, and I was the subject of no criticism.

Statement of Truth

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

Signed

GRO-C

Dr John Ramage

Dated

4 / 7 / 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
Current	Dr John Ramage: Curriculum vitae	WITN4134002
27 June 2002	Parliamentary and Health Service Commissioner's Report: 27 June 2002	WITN4134003

29 November – 6 December 2000	Independent Review Panel Report	WITN4134004
11 August GRO-B GRO-B 1998	Extracts from Hospital Records	WITN4134005
GRO-B 1998	Extracts from Nursing Records	WITN4134006
12 August 1998	Letter: Dr Ramage to Dr GRO-B	WITN4134007
25 November 1998	Letter: Dr Ramage to Dr GRO-B	WITN4134008
GRO-B 1998	Letter: Dr Ramage to Dr Rosenberg	WITN4134009
Undated	File note by Dr Ramage	WITN4134010
25 July 1998	Paper: Human albumin administration in critically ill patients	WITN4134011
January 1990	Paper: Total paracentesis associated with intravenous albumin management of patients with cirrhosis and ascites	WITN4134012
February 1991	Paper: Paracentesis with Dextran 70 v paracentesis with albumin in cirrhosis with tense ascites	WITN4134013