Health Service Commissioners Act 1993

Report by the Health Service Ombudsman

for England

of an investigation into a complaint made by

Mrs GRO-B

THE HEALTH SERVICE
OMBUDSMAN

E.2446/00-01

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Mrs GRO-B
GRO-B
GRO-B
Hampshire
GRO-B

Complaint against: North Hampshire Hospitals NHS Trust
(the Trust)

The complaint as put by Mrs GRO-B

1. The account of the complaint provided by Mrs GRO-B was that on GRO-B GRO-B 1998 her husband, Mr GRO-B was admitted to the North Hampshire Hospital (the hospital), which is managed by the Trust. He underwent treatment for abdominal ascites (a build up of fluid) by paracentesis (drainage through a tube inserted into the abdomen). Between GRO-B and GRO-B GRO-B when Mr GRO-B died, over 15 litres of ascitic fluid were drained. In March 1999 Mrs GRO-B discussed concerns which she had about her husband's treatment with a Consultant Physician (the Consultant) at the hospital. The consultant undertook to look into certain matters and write to Mrs GRO-B On 31 May 1999, having heard nothing further from the Consultant, Mrs GRO-B complained to the Chief Executive of the Trust. A few days later she received a letter dated 20 May 1999 from the Consultant and, on 13 July 1999, the Chief Executive wrote to her with the results of his investigations. Mrs GRO-B was not satisfied by either response and after further correspondence and an unsatisfactory meeting, when many of her questions could not be answered because there was no one present who was medically qualified, she asked for an independent review (IR) panel to be established. Her request was granted and she met the panel on 29 November 2000. The IR panel's report upheld some aspects of Mrs GRO-B complaint and was sent to her on 20 February 2001. In a covering letter the Chief Executive told Mrs GRO-B that he would write again shortly with details of the action that the Trust would be taking to address the IR panel's findings.

2. Mrs GRO-B heard nothing further from the Trust until their acting complaints manager wrote on 18 April 2001 enclosing an action plan. Neither the Chief Executive's letter, nor the letter from the acting complaints manager, contained any expression of regret for the shortcomings identified by the IR panel.

3. The matters investigated were that:

(a) staff failed to manage adequately Mr GRO-B paracentesis and maintain a satisfactory fluid balance;

(b) after Mr GRO-B died, tissue was removed from his body without staff having first obtained Mrs GRO-B consent;

(c) although Mr GRO-B was known to be a vegetarian he was not consulted about the use of an animal-based infusion; and

(d) the Trust's handling of the complaint after the IR panel was unsatisfactory.

Investigation

4. The statement of complaint for the investigation was issued on 10 August 2001. The Trust's comments were obtained, relevant documents, including Mr GRO-B clinical records, were examined and the Ombudsman's investigating officers took evidence from Mrs GRO-B. Two professional assessors were appointed to advise on the clinical issues in this case, a Consultant Physician and Hepatologist, and a Consultant Physician and Gastroenterologist. Their report is included at paragraphs 12, 19 and 23. I have not included in this report every detail investigated, but I am satisfied that no matter of significance has been overlooked.

(a) Inadequate management of Mr GRO-B paracentesis and fluid balance

Mrs GRO-B evidence

5. **Mrs** GRO-B told one of the Ombudsman's investigators that Trust staff had totally misunderstood her husband's wishes in the days prior to his admission on GRO-B 1998. He had wanted to know the results of some tests that had been done and which he had been told would be available by the end of the week. Around that time he also asked how he might be referred to a specialist in

liver disease at another Trust. Somehow, those two factors were interpreted as him asking to be admitted for treatment of his ascites. The Consultant's secretary telephoned to say that he would be admitted on GRO-B Mr GRO-B was not happy with that and asked to speak to the Consultant. When the Consultant called back Mrs GRO-B spoke to him. She asked for more information about the reasons for the change in her husband's treatment. Mrs GRO-B had not been opposed to the admission and she had never doubted that paracentesis was appropriate treatment for her husband. Her concerns centred on how it was carried out and the amount of fluid that was drained. She was also concerned that paracentesis continued after Mr GRO-B asked for it to be stopped and had been told that it would be.

6. Mrs GRO-B said that, reading the letters about her husband in the clinical records, it was clear that he was not considered to be close to death from advanced liver disease when he was admitted; yet the Trust's responses to her complaint, and the IR panel's report, had suggested otherwise. She did not accept that analysis. On 16 December 1998 a consultant oncologist wrote that he would see Mr GRO-B again in four weeks time. Even on GRO-B 1998, when the Consultant wrote to the liver disease specialist for a second opinion, two days before Mr GRO-B died, he was talking about him going home the next day and about the cause of the ascites being difficult to identify. That letter spoke only of symptoms that were 'suggestive' of cirrhosis.

7. The IR panel's report implied that drainage ceased altogether when the drain was clamped but that was not the case as, even with the clamp in use, leakage continued. The social worker had sent a letter to the Trust in June 1999, confirming that she had witnessed heavy leakage on Tuesday GRO-B 1998. Mrs GRO-B said that when she spoke to her husband on Tuesday evening he was expecting the drain to be removed, having been promised that it would be. In the event it was left, still clamped but leaking continuously. Mr GRO-B was unable to reach the buzzer in his room to call the nurses. As a result he was powerless to object. The drain was not removed until the next morning. When Mrs GRO-B spoke to her husband that evening he was feeling very miserable about having been left to stay in hospital and not having the results of the tests for his lymphoma. He was not told that the results were clear until the afternoon of GRO-B although they could have been made known to him much earlier. Mrs GRO-B herself had told him, after the Consultant Haematologist

had found out the results and told her. No one on the ward had told Mr GRO-B the results of the tests.

8. At 8.50am on the morning of GRO-B, Mrs GRO-B spoke to a nurse and asked her to record that Mr GRO-B no longer consented to paracentesis. Mrs GRO-B asked for the drain to be removed but was told that it could not be. The nurse made no record of Mrs GRO-B request and Mrs GRO-B thought that the drain was not removed until 10am, following her call to a ward sister, who subsequently went to the ward with the Consultant Haematologist. Her husband told Mrs GRO-B on the morning of GRO-B that he had had a dreadful night and had been sick. He said that an observant nurse noticed a drop in his blood pressure to 70/40 and had called the duty doctor. Mrs GRO-B said that, on GRO-B, after Mr GRO-B died, she was told by a Senior House Officer (SHO), in the presence of a witness, that paracentesis was allowed to continue after Mr GRO-B had asked for the drain to be removed. The SHO told her they carried on draining a bit after Mr GRO-B said they must stop.

9. Mrs GRO-B considered that, in stating that Mr GRO-B 'succumbed to his illness' the IR panel had effectively disregarded the whole basis of the complaint, which was that her husband would not have died in hospital if paracentesis had been carried out properly. She emphasised that she knew and accepted that her husband had not long to live and that it was unlikely he would survive more than another year. Her concern was that, with better management, he should not have died when he did. While he was in hospital he suffered from coldness, repeated vomiting, and breathing difficulties, all of which were drawn to the attention of nurses. He also became very confused and his blood pressure fell to 69/29. Mrs GRO-B considered that, by the morning of GRO-B he was showing classic signs of shock, but that the staff failed to react promptly. She also told staff that she suspected cerebral oedema, as her husband's symptoms were very similar to those exhibited when that had happened before. Action was taken when the Consultant attended, but that was only an hour or so before her husband died. No consideration seemed to have been given to transferring her husband to an intensive care unit.

10. Mrs GRO-B 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 1.00am on GRO-B

GRO-B when the Specialist Registrar said it was perfectly safe for Mrs GRO-B to leave the hospital, was witnessed by Mrs GRO-B daughter and by a nurse. Mrs GRO-B considered that the Specialist Registrar should have contacted the Consultant much sooner and should have been asked to account for his actions.

Trust evidence

11. At the start of the investigation the Trust's Chief Executive (the **Chief Executive**) provided a formal response to the complaint. That was in the form of a grid showing how the Trust had responded to Mrs GRO-B at each stage of the complaint and included details of actions taken as a result of the IR panel. For ease of reference I summarise below the main actions taken by the Trust as a result of Mrs GRO-B complaint:

- In a letter to Mrs GRO-B dated 9 December 1999 the Chief Executive agreed the importance of maintaining fluid balance charts and said he had asked ward sisters to re-emphasise this point strongly to all staff.

- At a meeting with Mrs GRO-B on 16 June 2000 it was agreed that the Trust would seek a second opinion from an external expert to review the clinical management of Mr GRO-B. Mrs GRO-B subsequently decided she did not want that but instead preferred to proceed to independent review.

- The IR panel concluded that fluid balance recording was poorly performed, although it had no bearing on the outcome of Mr GRO-B treatment. The IR panel also concluded that staff did not have the expertise to competently care for patients undergoing paracentesis. As a result of that the Trust developed an action plan (copy provided) and introduced training sessions to reinforce the need for good note keeping. In addition, guidelines for paracentesis have been introduced (copy provided).

Professional Assessors' Report

12. I set out below the report provided by the professional assessors on Mrs GRO-B complaint:

Report by the Professional Assessors to the Health Service Ombudsman for England of the clinical judgements of the staff involved in the complaint by Mrs GRO-B

Professional Assessors

First assessor: Dr A K Burroughs, MB ChB Hons FRCP, Consultant Physician & Hepatologist

Second assessor:Dr M Ashton, MB ChB FRCP, Consultant Physician & Gastroenterologist

Basis of Report

i. This report has been compiled from documents that were made available to us by the Ombudsman's office, including the statement of complaint; notes of an interview and subsequent telephone conversations with Mrs GRO-B *the Trust's formal response to the complaint and supporting papers; copies of key correspondence about the complaint including the IR report; and a copy of Mr* GRO-B *medical records.*

Background

ii. The complaint made by Mrs GRO-B *is based on her belief that her husband, the late Mr* GRO-B *died as a consequence of the drainage of his abdominal fluid (ascites), which is called therapeutic paracentesis. This was performed over a period of 39 hours and stopped 17 hours before his death. An IR panel subsequently investigated the complaint and concluded that Mr* GRO-B *died as a consequence of one or more of his medical conditions.*

iii. The matters considered by the professional assessors concern the issues in paragraph 4(a) to (c) of the statement of complaint:

- *That staff did not manage Mr* GRO-B *therapeutic paracentesis in an adequate fashion and failed to maintain a satisfactory fluid balance;*
- *That tissue was removed from his body following death without Mrs* GRO-B *s consent; and*
- *That although Mr* GRO-B *was known to be a vegetarian he was not consulted about the use of an animal based infusion.*

Summary of medical history prior to admission to hospital on GRO-B *98*

iv. Mr GRO-B *was a 40 year old man at the time of his death, who had a diagnosis of haemophilia at age 11. In 1980, as a complication of the treatment that he had received as a haemophiliac, he developed both retroviral associated disease, and chronic hepatitis C virus infection leading to cirrhosis of the liver. This latter condition had first caused accumulation of fluid in the abdomen (ascites) in May 1998. This responded to treatment with spironolactone, a diuretic, which increases the amount of water and salt passed in the urine.*

v. In July 1998 Mr GRO-B *was found to have a lymph node tumour (lymphoma) at the back of his throat and had been treated with chemotherapy and radiotherapy. He subsequently remained on a reducing dose of prednisolone as this had been an original part of the treatment regime of the lymphoma and cannot be stopped abruptly. The lymphoma had responded to treatment and there was no evidence nor record from the oncologists looking after him, that recurrence was present (letter from the Consultant Oncologist dated 16 December 1998).*

vi. Mr GRO-B *was also taking anti-retroviral therapy, Nevirapine Stavudine, and Didanosine, to suppress viral activity as well as an antibiotic, cotrimoxazole (Septrin) for the prevention of pneumocystis infection, and Isoniazid for the prevention of tuberculosis and atypical mycobacterial infections. (These are unusual infections related to tuberculosis, to which Mr* GRO-B *would have been particularly vulnerable due to the immune deficiency caused by the retroviral infection.)*

vii. Mr GRO-B *was referred for a second opinion to the Consultant (a Gastroenterologist) by the Clinical Haematologist, and was first seen on 11 August 1998. There were clear clinical signs of hepatic decompensation (such as a low albumin of 28g/l (grams per litre), which suggested that he might have cirrhosis. Although a subsequent ultrasound report on 9 September did not document cirrhosis, this was incorrect. Cirrhosis of this type might not be detectable by ultrasound as the scarring is of a fine type which does not cause a gross disturbance of the contour or substance of the liver as with other types of cirrhosis. Importantly, the autopsy findings confirmed a micronodular cirrhosis compatible with hepatitis C infection (specific scarring of the liver following hepatitis C infection).*

viii. Following chemotherapy the ascites (fluid in the abdominal cavity) worsened in November 1998, making Mr GRO-B *uncomfortable. The return of ascites is a manifestation of the increasing malfunction of the liver which would have implied that Mr* GRO-B *had cirhosis, as there was no suggestion that it was caused by the lymphoma or its treatment. The fluid accumulated to such a degree that it was drained (paracentesis) at the Royal South Hants Hospital, as it had not responded to first line medical therapy (low salt diet and diuretic - spironolactone) On 4/5 November two litres of ascites was drained without complications. Comment: Written consent for this procedure was not obtained for this first paracentesis (nor was it required in our opinion). On this occasion there was only a small amount of ascites to drain and the procedure was therefore of relatively short duration.*

ix. Mr GRO-B *was seen again by the Consultant on 13 November (clinic letter 16 November 1998); the ascites had returned. The spironolactone diuretic dose was increased to 200mg/day, prednisolone dosage was 5 mg on alternate days. He was due to be seen again in 2 weeks, following a specialised ultrasound examination (Doppler) to exclude any liver abnormality other than cirrhosis. He was seen again on 24 November (clinic letter 25 November 1998) when the ascites had slightly improved. Arrangements were made to review him on 15 December.*

x. On 15 December Mr GRO-B *had again developed severe ascites, although his body weight was recorded as 62.45kg, which was similar to the 63.5kg recorded on 13 November. A note was made to telephone Mr* GRO-B *with his blood test results, and there is a further hand written note to confirm the patient was telephoned, but there was no reply. The note (undated), but presumably made on 18 December, asks for Mr* GRO-B *to be telephoned to ask him to reduce his Spironolactone to 100mgs daily and to come into hospital. A bed had been booked for Monday* GRO-B *for a therapeutic paracentesis. A signature, presumably of a doctor, is present, but not decipherable to us.*

xi. Comment: This is a brief resume of what is a very complex medical history which, more importantly, reflects Mr GRO-B *decline in health, in particular his liver function, with an anticipated continuing irreversible decline.*

Medical events on GRO-B *98 (admission) and thereafter, with assessors' comments*

xii. On GRO-B *1998 Mr* GRO-B *was firstly and appropriately seen by the Clinical Haematologist, to arrange for Factor VIII (the missing blood factor in haemophilia) to be given to prevent bleeding during and following the paracentesis. A note of the blood electrolyte levels (of substances such as sodium and potassium) in blood from the 15 December (outpatient visit) were made: the sodium was lower at 126 mmol/l, (normal range 134-147) the potassium higher at 6.0 mmol/l (normal range 3.6-5.0), than in earlier November 1998. These results suggested that Mr* GRO-B *was receiving too much diuretic therapy as a possible cause of these findings. It was reasonable, therefore, to have reduced the dose of the diuretic therapy and to review him as soon as possible.*

xiii. The therapeutic paracentesis was planned (clinical note on GRO-B *1998), using colloid (to prevent low blood pressure and consequent kidney dysfunction) in the form of Gelofusin (a bovine product) 1 unit at the start, and 1 unit at the end of the paracentesis. It was anticipated that Mr* GRO-B *would be able to return home following an overnight stay, as detailed in the Consultant's letter of* GRO-B *1998.*

xiv. The therapeutic paracentesis took place at 7pm on GRO-B *1998 after the administration of Factor VIII. Precise instructions are recorded in the notes, regarding clamping of the drainage tube after 5 litres had been removed, and the requirement to give 500mls Gelofusin at the start of the drainage, and for a further unit of Gelofusin to be given after removal of the 5 litres. Comment: When 5 litres of ascites are drained, any colloid can be used as replacement, but when total drainage is planned to exceed 5 litres (in one continuous session), albumin is the preferred replacement colloid.*

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 when there is massive ascites under pressure requiring to be drained, which then leaked out around the tube.

xvi. The nursing notes record the patient's refusal to have his sheets changed. A fever of 37.7°C was recorded at 1am. The patient was reviewed on the morning of 22 December, when the 5 litres had drained overnight.

xvii. It was noted that the patient was more comfortable. As the urea, electrolytes and creatinine were stable (annotation next to clinic notes for both blood tests on GRO-B *1998), further drainage was planned (by unclamping the tube) and with more Gelofusin replacement. This was discussed with the Consultant as noted by the Registrar's note of* GRO-B *1998. It was decided to keep Mr* GRO-B *in overnight (of* GRO-B *), to re-check blood tests the next morning. Comment: This was a reasonable course of action.*

xviii. There is a nursing note at 8am on GRO-B *1998 detailing Mrs* GRO-B *telephone call about her concerns about her husband's treatment. A similar telephone call was recorded at 8pm. The on call team were made aware of this.*

xix. Mr GRO-B *was seen on* GRO-B *1998 (the entry date is not visible) by the Consultant Physician and a plan was made to remove the drain, observe the urine output and blood pressure and then to discharge him, possibly in the evening of* GRO-B *Comment: We assume the Consultant would have discussed his plans with Mr* GRO-B *but there is no written confirmation of this in the clinical records. On* GRO-B *at 9.10pm there is a note in the medical records that the patient was angry about still being in hospital. The SHO (a locum) explained the Consultant's plan and suggested further or repeated questions could be answered best by him on the following morning. This was a reasonable course of action and in line with current medical practice.*

xx. There is a note on GRO-B *from the haematologists, who reported that Mr* GRO-B *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 Mr* GRO-B *was a haemophiliac (and, therefore, likely to bleed). It was specifically noted that Mr* GRO-B *'seemed to understand'. There is no mention of concern about the origin of Gelofusin.*

xxi. Blood results from GRO-B *1998 show that the urea, creatinine and potassium had risen and the sodium had fallen slightly. Comment: This represents a minor change of renal function which in retrospect was not indicative of significant or progressive renal failure.*

xxii. The white cell count in the blood at this point had increased to 15.5 $x10^9$/l (it was 11.9 $x10^9$/l on admission). The analysis of the ascitic fluid is recorded – there was no increase in LDH or reduction in sugar level in the fluid (LDH is a marker of white blood cells whose presence would indicate infection, as would a fall in the sugar level in the ascitic fluid). A further white cell count was requested but no result was filed. Bacterial cultures were negative. Comment: These results indicate that the fluid was thus not infected, but there was a suggestion of infection elsewhere in the body.

xxiii. On GRO-B *at 2.45pm Mr* GRO-B *was reviewed by the medical team as he had become drowsy and unwell, with a low blood pressure and evidence of a postural drop in blood pressure. Comment: This was further evidence of deterioration, which could be due to further loss of fluid, or the effects of bacterial infection. However, in retrospect, it is our view that this was not due to excess fluid loss but, in the clinical context at that time, it was reasonable to interpret that Mr* GRO-B *could be either suffering from dehydration due to fluid loss or from infection. (Spontaneous bacterial peritonitis is an infection of the ascitic fluid.)*

xxiv. Mr GRO-B *was then treated appropriately with intravenous antibiotics, the diuretic therapy was discontinued and intravenous colloid was replaced as before. It is at this point that there is a note regarding Mrs* GRO-B *expressing concern over the use of Gelofusin as Mr* GRO-B *was a vegetarian. Replacement colloid for the Gelofusin, a litre of dextran 70, was ordered. Comment: This was appropriate action. In our view it would not be usual procedure to consult a patient as ill as Mr* GRO-B *then was, about the change of infusion.*

xxv. There is a further, extensive note at 6pm on GRO-B *by the Specialist Registrar regarding a discussion with Mrs* GRO-B *about her husband's deteriorating condition. It is specifically stated that he apologised if it had not been made clear to Mr* GRO-B *that the paracentesis drain needed to be left in*

overnight. The use of colloid replacement was also explained. It is recorded that Mrs GRO-B *wished to be informed of every single treatment or action taken regarding her husband and why it was being done. The reply was that 'we will endeavour to explain everything, but time is limited'. A record of a further apology regarding communication with her and her husband was made. Comment: These were entirely reasonable actions under the circumstances and we do not think the staff could have done more.*

xxvi. Mr GRO-B *was reviewed again at 7.45pm on* GRO-B *It was noted that he said he felt better, but that his respiratory rate was rapid. The abdomen was distended, but there was less fluid, and bowel sounds were present. The blood pressure, measured in the lying position, had improved to 110/70, but the pulse rate was 110 beats per minute (high). Comment: These signs suggest active infection, which was already being treated with appropriate antibiotics. It is recorded that the patient asked his wife to leave as she was 'overloading him with information'.*

xxvii. Mr GRO-B *was reviewed again at 10pm when it was noted that he complained of nausea and was drowsy. The clinical findings were unchanged, his pulse rate was still rapid at 110 beats per minute, and blood pressure was 110/70. Due to his continued abdominal distension and rapid respiratory rate of 28 per min, chest and abdominal x-rays were ordered as well as further blood tests. The x-rays did not show any specific features. However, the blood tests showed that his renal function had worsened: urea 12.4 mmol/l, potassium 5.4 mmol/l, creatinine 199 µmol/l and the white cell count (indicative of infection) was still raised at 16.4 $x10^9$/l. A further medical note correctly identifies the renal impairment issue, and appropriate observations were instituted. Comment: The renal impairment was a reflection of his deterioration rather than the cause of it and the cause of the raised white cell count is likely to have been infection, notwithstanding the lack of evidence as to its origin.*

xxviii. Mr GRO-B *drowsiness was attributed to hepatic encephalopathy, a reversible confusion which occurs in cirrhotic patients who develop infection, renal failure or other complications. In view of Mrs* GRO-B *concern about it, the Registrar made a note to discuss this with the Consultant Physician the following morning. No further action was taken in this regard on medical grounds that evening. Comment: This was reasonable given the other actions that had already been taken.*

xxix. At 0.30am on GRO-B *Mr* GRO-B *became more confused and, in view of this, his clinical condition was discussed with the Consultant, who decided to come to hospital to review him. It was considered necessary to put in a special line (central venous pressure line - CVP) to measure the venous pressure to allow the amount of fluid to be replaced intravenously to be more accurately assessed. The risk of bleeding during a central venous line insertion (despite Factor VIII cover) was discussed with the Clinical Haematologist. Factor VIII was therefore given to cover this procedure. A urinary catheter was inserted but only 20mls residual urine was drained from the bladder, indicating renal shutdown as a result of his deterioration. Mr* GRO-B *was seen at 2am by the Consultant. Action taken, included assessment of blood gases and treatment of possible cerebral oedema. The Consultant spoke to Mrs* GRO-B *stating that Mr* GRO-B *was seriously ill and could die that same evening. Comment: These actions were reasonable and appropriate.*

xxx. The CVP line was inserted at 2am following Factor VIII administration. There were no complications following this, and the CVP recordings did not show depletion of the circulatory volume. The blood gases, which require arterial blood (and, therefore, could only be sampled after Factor VIII administration) revealed severe acidosis (pH 6.772) compatible with severe sepsis, hypotension (low blood pressure) and/or liver failure. (Normal pH is 7.4, with pH below 7 being indicative of severe retention of acid products and generally associated with a fatal condition unless quickly reversed.) The clinical situation was such that cardiopulmonary resuscitation was not thought to be appropriate should a cardiac arrest occur, as it would be unlikely to succeed in such circumstances.

xxxi. Mr GRO-B *death was certified at 3.40am on* GRO-B *In a note timed 9.05am by the Consultant, Mrs* GRO-B *voiced her concerns regarding the continued drainage of ascites. The signature is not legible, but it is stated that a verbal consent for the continued drainage of ascites had been obtained from Mr* GRO-B *on the morning of* GRO-B

Summary of fluid balance (including ascites drained)

xxxii. The nursing fluid charts in Mr GRO-B *case were not well documented and there were no records on some days. The 24 hour period from 2pm to 2pm made the charts difficult to interpret. This is not in line with good medical*

practice. The data below is a 'reconstruction' from the fluid charts, nursing notes and medical notes.

GRO-B *1998*

Therapeutic paracentesis at 7pm
5 litres drained, drain clamped over night
3 units of Gelofusin given over 90 minutes immediately after Factor VIII which was given just before the parancetesis
nurses were not asked to record urine output for GRO-B *1998 – none recorded*

GRO-B *1998*

11am – 5 litres ascites drained after unclamping the tube, 2 units of Gelofusin given
6pm – 1800mls drained
10pm – 1600mls drained, 2 units of Gelofusin given, – first at 2pm, last one at 7pm
700mls urine output over 24 hours is recorded

GRO-B *1998*

6am – 1500mls drained
9am – drain removed
3 units Gelofusin given before 6pm first at 5.45am
6am – only 100mls urine documented from 10pm the day before
Dextran 70 given after 3pm after Mrs GRO-B *voiced concerns about gelofusion*
3 units albumin given when patient deteriorated in the evening and into GRO-B GRO-B

Conclusions- paracentesis management and fluid balance

xxxiii. The ascitic fluid was drained in the volumes recommended by current guidelines which are based on the results of randomised clinical trials and according to usual clinical practice. The drainage took place over a relatively longer period such that there is no question of too rapid a removal. The volumes of colloid replaced were at the level and slightly above what is recommended, (ie, 8gm of albumin for every litre of ascites drained), but this does not put a patient at risk. This is again in line with current recommendations and clinical practice. The initial clamping of the drain after 5 litres and leaving the drain in situ until further review, and then draining some more, was a very reasonable

treatment schedule. We do not think that formal written consent was required for the paracenteses and the normal explanation of the procedure and its purposes is all that is required. (A patient information leaflet on ascites and its treatment might be worth consideration.)

xxxiv. It is our opinion, judged from the clinical events, that superadded sepsis led to the circulatory collapse, oliguria (small amounts of urine passed) and then death. Any sepsis in Mr GRO-B *situation would be enough to cause these severe consequences, due to his inability to deal with the toxic products produced by infection. There is no evidence that this was due to infected ascitic fluid or due to the procedure itself causing circulatory collapse and subsequent oliguria. The presence of infection cannot be completely proven, but a raised white cell count before the paracentesis is suggestive of the presence of sepsis. The paracentesis therefore was* ***not*** *the precipitating cause of death.*

xxxv. We have also considered the possibility that some of the anti-retroviral drugs Mr GRO-B *was receiving could have contributed to his terminal acidosis. There are reports in the literature and warning in the British National Formulary (BNF vol 47, September 2001) of potentially fatal lactic acidosis occurring with some of these agents, especially in the presence of liver impairment. Lactic acid accumulates in the cells when they are starved of oxygen from a variety of causes although lactic acidosis is inevitable in death from whatever cause and thus the specific cause cannot be identified at autopsy. This information was not available in* GRO-B *1998. The liver is the major organ that deals with lactic acid excess so liver failure itself is frequently associated with lactic acidosis.*

xxxvi. With the anti-retroviral drugs, lactic acid may also accumulate in the absence of the usual causes and can thus produce severe disturbance to cellular, tissue and body functions as they all require a normal acid environment (pH around 7.4) to work effectively. One important biochemical sign might be a low serum bicarbonate or to calculate the anion gap (the difference between measured electrolytes which indicates the presence of another substance such as lactate). However, bicarbonate and chloride were not routinely available in the hospital's standard "u&e" (urea and electrolytes) profile. The attending staff did not consider this possibility. Only the blood gas analysis performed shortly before Mr GRO-B *death gave an indication of this acidosis possibility.*

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 Mr GRO-B *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.*

xxxviii. The sub-optimal part of Mr GRO-B *therapeutic paracentesis was the poor recording of the fluid balance (notes after* GRO-B *to 1pm on* GRO-B *). After this the urine output was scheduled to be recorded. 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 Mr* GRO-B *further deterioration and eventual death.*

xxxix. Precise record of fluid balance is not usually an issue in therapeutic paracentesis, when it is done rapidly over a few hours, as routine observations of the pulse and blood pressure, and careful observation of the patient will show adverse events. However, the longer the duration of the paracentesis the more there is a need to be precise about the fluid balance. Regular blood estimations of urea and electrolytes (and ideally bicarbonate and chloride) would also be required to give a more accurate detection of adverse renal events. In addition, if IV fluids are administered or the patient had other signs of liver decompensation, input of fluids needs to be monitored as well as output. Appropriate measures were taken in relation to the low blood pressure, and poor urine output when it was detected, and suspected infection was treated immediately once Mr GRO-B *condition had deteriorated.*

Findings (a)

13. Mrs GRO-B knew that her husband's long term prognosis was poor but she believed that his last paracentesis was not well managed and lead to him dying prematurely. She felt there had been confusion over the reasons for his admission on GRO-B 1998 and that Trust staff had been slow to react to her husband's wish to have the paracentesis stopped in order that he could go home. She was also concerned about the leakage of ascites and what she had been told about that and the staff's reactions to her husband's apparent sudden

deterioration. The Ombudsman's Professional Assessors have examined Mr GRO-B medical and nursing records very carefully. Their report (paragraph 12) addresses Mrs GRO-B concerns. They have noted that signs of problems with Mr GRO-B liver were first noted in August 1998 and that his ascites worsened following chemotherapy in November. 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 I note that the Trust have asked ward sisters to remind staff about the importance of maintaining fluid balance charts. The Assessors are satisfied that the paracentesis was not the precipitating cause of Mr GRO-B death and have suggested other possible reasons for his sudden deterioration and death. For example, it could have been the result of infection, leading to sepsis and the inability of his body to cope with that due to his immune deficiency. Another reason relates to the possible terminal acidosis explained in detail in paragraphs *xxxv-xxxvi* of their report. On the basis of their advice I do not uphold this complaint. However, I **recommend** that the Trust remind all staff of the importance of accurately recording fluid balance levels, particularly in the case of patients like Mr GRO-B and consider the assessors' suggestion of introducing a patient information leaflet on ascites and its treatment.

(b) Removal of tissue from Mr GRO-B body without Mrs GRO-B consent

Legal position

14. The legal position relating to the removal of tissue after death for the purpose of medical research is governed by the **Human Tissue Act 1961** (the Act). Section 1, subsection (1) of the Act provides that a deceased's body, or part of it, can be used for, amongst other things, the purpose of medical research, if the deceased has so requested, either in writing or orally in the presence of two or more witnesses. Subsections 1(2) and (7) of the Act allow for the person having control or management of the hospital, or somebody designated by them, to give authority for the removal of tissue for medical research. That authority is dependent on reasonable enquiries having been made to ensure that the deceased had not expressed an objection to their body being so dealt with or that the surviving spouse or relative does not object to the removal of tissue. Subsection 1(5) specifies that, where the coroner is involved, or is likely to be involved, no authority can be given for the removal of tissue under the foregoing provisions except with the consent of the coroner.

The IR report

15. The IR panel's fourth term of reference was: 'The issues concerning the consent for samples being removed from Mr GRO-B body after his death.' The panel's findings under that term of reference were:

> 'F27. [The Consultant Haematologist] gave evidence to the panel that Mrs GRO-B was understandably very distraught following the death of her husband. He felt that to ask for her consent for the removal of samples from Mr GRO-B may have distressed her further. He accepted that by not asking for Mrs GRO-B 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 Mr GRO-B and that legally further consent from Mrs GRO-B was not required.
>
> 'F29. Whilst the panel appreciated the need for research for "the greater good", and the fact that Mr GRO-B was a "good subject", the decision to remove samples without the consent of Mrs GRO-B was not appropriate.'

16. The report included two recommendations relating to this term of reference:

> 'The Trust should ensure that informed consent from relatives is obtained for the removal of body tissues from the dead.
>
> 'The Trust should apologise to Mrs GRO-B and her family for the distress and unhappiness that has been caused as a result of the removal of body tissues …'

Mrs GRO-B evidence

17. **Mrs** GRO-B said that there had been a number of issues about which the Trust had failed to gain her consent, or failed to take enough notice of what she and her husband had said to staff. She said that after her husband had died the Consultant Haematologist had asked to speak to her. She had been very distressed at the time. She had gained the impression that he had wanted to ask her something but had changed his mind due to her distress. When she saw him during local resolution he agreed that he had considered speaking to her about removal of tissue samples but had not done so because of her distress. He had

told her that, in any case, her husband's body was by then the property of the Coroner who could make such decisions. Mrs GRO-B said she felt this was just another example of Trust staff going behind her back, knowing that she would probably have refused permission.

Trust evidence

18. In his formal response (paragraph 11) the action plan provided by the **Chief Executive** recorded that the Trust's policy for removal of body tissues was being updated to correspond with recent National guidelines and a consent form was to be implemented. In addition, the Trust had apologised again to Mrs GRO-B for the distress caused (see paragraph 26, letter dated 2 August 2001). Subsequently, the Chief Executive provided copies of the patient information leaflet and consent form for post mortem examinations, which had been updated in August 2001 to include reference to possible organ or tissue removal.

Professional Assessors' Report

19. The following conclusion was made by the Professional Assessors in respect of this aspect of Mrs GRO-B s complaint:

> *xl. Removal of Tissue*
> *Consent was obtained from the coroner, who was in charge of the post-mortem. It is regrettable that Mrs GRO-B was not informed, but the clinical staff looking after Mr GRO-B had no knowledge of this and could not have supplied her with this information. It would have been helpful if, for Coroner's post mortems, the Coroner's officers or those to whom they delegate, could have informed patients' relatives regarding tissues being removed for national research projects.*

Findings (b)

20. It is not disputed that tissue was removed or that Mrs GRO-B was not consulted about that. The Trust apologised again about that in the Chief Executive's letter of 2 August 2001. The legal position is that the Coroner had given consent for the removal of samples from Mr GRO-B body. This issue was included in the Ombudsman's investigation as a means of ensuring that the Trust had responded adequately to the recommendations of the IR panel (paragraph 16). I am satisfied that the actions described by the Chief Executive in paragraph 18 are satisfactory and, accordingly, I do not uphold this complaint.

(c) Failure to consult Mr GRO-B about the use of an animal-based infusion

Mrs GRO-B evidence

21. **Mrs** GRO-B said that her husband was not told he had been given Gelofusin. He was a strict vegetarian, and it was therefore akin to giving a Jehovah's Witness a blood transfusion. All that happened was that the staff changed him to Dextran 70, without consulting him. Mrs GRO-B doubted whether Dextran 70 was the most suitable substitute in her husband's case. She had not asked for Gelofusin to be stopped but for someone to discuss the matter with her husband. By failing to do that the staff had placed her in a most difficult position. She still had concerns as to whether, if she had not said anything about the Gelofusin, Mr GRO-B might have continued on that and lived longer.

Trust evidence

22. In a letter dated 1 May 2002 the **Chief Executive** wrote:

> 'The Trust has never denied that Gelofusin was used or that it is an animal based product.
>
> 'There are alternatives to Gelofusin available within the Trust – hydroxyethyl starch and human albumin solution. However, only a limited amount of the starch may be given to each patient, and the human albumin carries a risk of viral and prion infection. Clinicians have been made more aware of the need to consider the wishes of vegetarian patients when using Gelofusin, however this is frequently done at times of acute emergency and staff may not at that point be able to ascertain if someone is vegetarian.'

Professional Assessors' Report

23. The following conclusion was made by the Professional Assessors in respect of this aspect of Mrs GRO-B complaint:

Gelofusin being derived from animal plasma

xli. This is not a fair complaint. Firstly, the patient did not ask or make his wishes clear regarding the possible use of intravenous animal derived products. The patient knew hospitals and treatments well and had he wanted to make this known in our opinion he could have done so. Vegetarianism is commonly understood to relate to ingested food and drink, so that the nurses and doctors

would not be expected to apply lateral thinking in this case and consider intravenous fluids as a source of animal protein. However, immediately Mrs GRO-B *had raised this issue the staff responded appropriately and an alternative, Dextran 70, was given. This was totally appropriate in the circumstances. Although it might have been helpful if staff had discussed this change with Mr* GRO-B *in our view it would not have been appropriate to have done so at the time, bearing in mind how ill he had become.*

Findings (c)

24. Mrs GRO-B was concerned that her husband, a strict vegetarian, had been given a bovine product without consulting him about that. She was also concerned that, when she drew that to the attention of staff, they changed the infusion, again without consulting her husband, and that the replacement infusion (Dextran 70) might not have been the most suitable. The Chief Executive has explained (paragraph 22) that although alternatives are available, there are risks involved with those. He has also said that it is often not possible, for example in emergency situations, to ascertain whether a patient is vegetarian. Whilst I accept that is the case, that did not apply to Mr GRO-B as he was not admitted as an emergency and had been a patient before. It might have been more appropriate, once the problem had been highlighted by Mrs GRO-B if the staff had discussed the matter with Mr GRO-B However, the Ombudsman's Professional Assessors (paragraph 23) have said that staff responded appropriately in providing Dextran 70 as a replacement for Gelofusin and that it would not have been appropriate to discuss the matter with Mr GRO-B at that time. I do not uphold this complaint.

(d) Unsatisfactory handling of the complaint after the IR panel

Mrs GRO-B evidence

25. When **Mrs** GRO-B received the Trust's action plan, following the issue of the IR report, she wrote to the Ombudsman on 4 March 2001. Her letter included:

> 'I have enclosed the long awaited communication from [the Trust]. As I was not happy with the whole review process and believe the recommendations do not address many of the issues, I did not expect to be happy with the follow up plan. This is just to state I am not happy with it in case I was supposed to confirm this.

'Their description of it as a "Review Action Plan" is taking liberties with our language. Eight weeks after the report recommended they apologise over the taking of body tissues, they state under the heading of "Action Taken", "letter to be sent to Mrs GRO-B ."! The rest is little better and the more times you read it the more apparent it becomes [that] little has been done.'

Sequence of events

26. I set out below a summary of the Trust's actions following the IR panel:

20 February 2001 The Chief Executive sent a copy of the report to Mrs GRO-B which had been signed by the panel members on 19 February. His covering letter included: 'I will be writing to you again shortly detailing the action plan the hospital is going to initiate in view of the findings of the Independent Review'.

18 April The Trust's Acting Complaints Manager sent Mrs GRO-B a copy of the Trust's action plan.

2 August The Chief Executive wrote to Mrs GRO-B with an updated version of the plan:

'I am writing further to the April 2001 Review Action Plan. I have updated all action that has been reviewed and initiated since the document was first drawn up.

'This hospital has found the changes and introduction of new practices implemented since your Independent Review Panel of great benefit to the staff and also, more importantly to the patients.

'I hope that you will find the Review Action Plan to be as positive as the Trust has. I would greatly appreciate your thoughts and feedback on this document.

'I would also like to take this opportunity to say how sorry I am for the issues that arose whilst your husband was an inpatient at this hospital. It has been a reminder to staff of how concerns such as the removal of tissue

sample and unfortunate incidents, such as when your daughter saw your husband shortly before his death can cause effects that are long lived.

'In the meantime if I can be of further assistance please do not hesitate to contact me.'

Trust evidence

27. In his letter of 1 May 2002 (paragraph 22) the **Chief Executive** wrote:

'We believe the Action Plan was adequate in addressing the issues raised by Mrs GRO-B complaint. The Action Plan has been fully implemented.

'An apology was made in the first response to the complaint in December 1999 and in a further letter from the Chief Executive dated 2 August 2001, who also apologised to Mrs GRO-B at the [local resolution meeting]. However I do accept that the delay in responding to the Independent Review report was not reasonable. The report was delayed due to a request from Mrs GRO-B that it was not sent before 20 January and a delay in receiving the final report from the Convener. There was a further delay in producing the Action Plan due to a combination of staff sickness and staff changes in the complaints department for which we would wish to apologise.

'Since this complaint was made we have made substantial changes within the department. We have appointed a Director of Clinical Governance with responsibility for complaints on behalf of the Chief Executive and a Head of Customer Care to oversee complaints handling. We have also appointed a new Complaints Manager and have administrative support for the Customer Care department. These changes have enabled improvements to be made in the service and is ensuring the Trust develops a learning culture in respect of complaints.'

Findings (d)

28. Mrs GRO-B was dissatisfied with the Trust's action plan and felt that it showed that little had been done as a result of her complaint. The Chief Executive has accepted that the delays following the issue of the panel's report were unreasonable. He has explained that that was due to a combination of staff

sickness and staff changes in the complaints department and I note the actions taken since then to improve complaints handling. However, my own concern relates not only to the two month delay in sending Mrs GRO-B the action plan but the fact that it was sent by the Acting Complaints Manager and did not contain the apology recommended by the IR panel. Mrs GRO-B had to wait for that until the Chief Executive wrote to her on 2 August, five and a half months after the IR report was issued. I consider that was unacceptable. I uphold this aspect of Mrs GRO-B complaint.

Conclusions

29. I have set out my findings in paragraphs 13, 20, 24 and 28. The Trust have asked me to convey – as I do through my report – their apologies to Mrs GRO-B for the shortcomings I have identified and have agreed to implement the recommendation in paragraph 13.

GRO-C

Mrs Ann Dugdale
Senior Investigating Officer
duly authorised in accordance with
paragraph 12 of schedule 1 to the
Health Service Commissioners Act 1993

27 June 2002