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REPORT OF THE INDEPENDENT REVIEW PANEL

MR GRO-B (DECEASED)

Held at Parklands Hospital, Basingstoke, Hampshire
On Wednesday 29 November and Wednesday 6 December 2000

Lay Chairman - Mr David F Brown

Report of the Independent Review re Mr GRO-B **(deceased)**

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Report of the Independent Review re Mr GRO-B (deceased)

INTRODUCTION

Factual error - it was 21st June

On 31 May 1999, Mrs GRO-B (Widow of Mr GRO-B) requested an Independent Review of her complaints against the North Hampshire Hospitals NHS Trust.

This request followed a considerable number of communications that had sought to achieve Local Resolution.

She asked for an Independent Review of all the clinical issues relating to her husbands' consent for treatment, and his treatment, communication between all the disciplines of staff and the removal of body tissue samples by medical staff at The North Hampshire Hospitals NHS Trust, Basingstoke, Hampshire.

Untrue - I never accepted the terms of reference see correspondence on file.

These concerns form the basis of the Terms of Reference drawn up by the Trust's Convenor and accepted by Mrs GRO-B

All time limits for every stage were exceeded

There have been some delays in this review, which centre on the availability of the clinical assessors and obtaining independent pre-convening advice. The hearing was arranged for and took place on 29 November, and 6 December 2000, in the Boardroom of Parklands Hospital.

Mrs GRO-B requested that the review report should not be sent to her before mid January 2001.

My request was not to receive the report on the anniversary of my husbands death at Christmas. It did not arrive until 21st Feb despite asking for it.

Five assessors were appointed due to the complexity of the issues. Regrettably one of the assessors was unable to confirm his participation and asked to be omitted from the review.

The Panel consisted of:

Mr D F Brown	Chairman
Ms A Rushmere	Non-Executive Director and Convenor, North Hampshire NHS Trust
Ms J Kelly	North and Mid Hampshire Health Authority

Evidence was given to the panel by:

Mrs GRO-B who was supported by a friend.	
Dr J K Ramage	Consultant Physician (Gastroenterology)
Dr Sheen	Specialist Registrar
Sister J Cairns	
Staff Nurse H Bull	
Ms J Brown	Haemophilia Social Worker
Sister Y Stebbings	Haemophilia Unit
Dr T Nokes	Consultant Haematologist
Dr S Fowler	

I was told the pathologist would give evidence.

The panel was disappointed that Mrs GRO-B had been unable to give her evidence at the commencement of proceedings at 9.00 am. Mrs GRO-B had stated that due to the distance from her home in GRO-B and travel difficulties that she was not prepared to attend before 11.00 am.

This is a dismissal of the facts and serves to put me in a bad light.

It was noted that the Trust had offered to arrange and pay for overnight accommodation at a local hotel and that Mrs GRO-B had declined the offer. She was therefore asked to attend the review at 2.00 pm.

Whilst the panel accepted that some of the points Mrs GRO-B may have wished to raise might be overlooked, they were satisfied that the wealth of written documentation previously circulated to all members and assessors was sufficient to form the basis of questions to witnesses.

The panel considered that proceedings would not be disadvantaged if Mrs GRO-B gave her evidence later in the day and that to delay matters would be unreasonable.

TERMS OF REFERENCE

1. Whether the level of consent obtained for the paracentesis was appropriate.
2. Whether Mr GRO-B treatment for abdominal ascites by paracentesis was appropriate following his admission to The North Hampshire Hospitals NHS Trust in GRO-B 1998.
3. Whether the communication between all the disciplines of staff was appropriate.
4. The issues concerning the consent for samples being removed Mr GRO-B body after his death.

BACKGROUND

Mr GRO-B was a haemophiliac who suffered from HIV, Hepatitis C and Cirrhosis. He was also in remission following treatment for Lymphoma. Treatments had been managed at a number of centres over a long period of time.

Dr Ramage, Consultant at the North Hampshire Hospitals NHS Trust provided the treatment for Mr GRO-B ascites. Dr Nokes, Consultant, provided treatment for the haemophilia.

He provided the Rx not just for ascites but for liver disease as per his letter saying he could find no sign of chronic liver disease was not examine

Mr GRO-B was not a well man, and his prognosis had worsened since being seen in August 1998. His liver was rapidly deteriorating and was considered to be a life threatening condition. Transplantation had been considered but discounted. No it hadn't.

This conflicts with what we were told on GRO-B 98

Numerous telephone conversations took place between staff at the North Hampshire Hospitals NHS Trust and Mr & Mrs GRO-B on Friday GRO-B GRO-B 1998. Mr GRO-B 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 However, Mrs GRO-B was against this course of action as she felt that it would spoil Christmas.

This is not true and the manner of my husbands admission was disputed, I was told by the trauma that only from GRO-B 98 would be a Tx & but OLTx issues would be explored Despite this true disputed issue appears in to guise of background fear.

unsubstantiated allegation

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

Five litres of ascitic 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'.

Mr GRO-B then developed multi organ failure and on GRO-B 1998, Mr GRO-B succumbed to his illness.

How can this be background information when it is the very point at issue?

Mrs GRO-B is concerned that although she knew that her husband was very ill she did not expect him to die on GRO-B 1998, and believes that his death was as a result of mismanagement of his treatment, which accelerated his death.

First Term of Reference.

Whether the level of consent obtained for the paracentesis was appropriate.

F1. Evidence was given to the panel that Mr GRO-B had sought admission to hospital because of the problems with his ascites, which was worsening. He sought paracentesis in order to make him feel better.

F2. The panel was surprised to learn that the method of consent for paracentesis was not written but a verbal consent. However the panel were satisfied that Mr GRO-B was able to make a proper judgement about his continuing treatment, and had given his consent for the procedure to be carried out.

F3. There is no evidence to support Mrs GRO-B complaint that her husband had withdrawn consent, although it is documented that Mrs GRO-B was seeking to withdraw consent on her husband's behalf.

See P3 of Dr Black report and P2 of unnamed report under communication rather than consent

Second Term of Reference.

Whether Mr GRO-B s treatment for abdominal ascites was appropriate following his admission to The North Hampshire Hospitals NHS Trust in GRO-B 1998

change to phrasing of term of reference

F4. Mr GRO-B had suffered from ascites since May 1998 and this was recognised to be probably due to his cirrhosis. The ascites had initially responded to therapy but had become more difficult to control.

F5. The ascites recurred in October 1998 and paracentesis was undertaken.

F6. By GRO-B 1998 Mr GRO-B has become uncomfortable and unwell with the ascites and his weight had increased.

F7. Mr GRO-B admission to hospital was precipitated by a combination of factors including a realisation that the ascites was not being controlled by medical treatment alone. A request by Mr GRO-B for a further hepatological opinion was seen as an indicator that he was unhappy and uncomfortable with the ascites. It is quite clear that Mr GRO-B was seriously ill at this time and that he was seeking intervention to deal with his ascites.

Why? + by whom?

F8. Compelling evidence was presented which satisfied the panel that Mr GRO-B was aware of the treatment and procedure to be carried out. Unfortunately Mrs GRO-B did not support treatment at this time.

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

F10. The panel was told that the treatment 'to drain to dryness' was in line with recognised practice. In this case, the treatment was relatively cautious in that the drainage was carried out over a period exceeding 40 hours. Look not monitored

F11. The choice of Gelofusine for intravenous administration to a vegetarian was a subject that had never been called into question in the experience of either medical staff or the advisors. It was recognised that many oral medications are administered in gelatine capsules.

F12. The panel was told that there was little experience held by nursing staff for this type of treatment, which was regarded as requiring a high degree of dependency. Staffing levels were low and inadequate.

See conclusion Term 1 in Fiona Cornelius report.

F13. Untrained health care support workers undertook some tasks without proper supervision. (It is pleasing to note that Sister Cairns has now put into place additional induction training for staff and a nursing standard has been devised).

F14. Evidence was presented to the panel that the recording of fluid balance charts was poorly performed without adequate supervision. However, this breakdown in recognised practice had no bearing on the outcome of Mr GRO-B treatment.

F15. The panel was impressed with the knowledge and openness of the evidence given by Sister Stebbings who was clearly an underused resource. Her skills and expertise in dealing with difficult patients and her knowledge of this case were not used to their full advantage.

F16. The panel was disappointed to learn that separate notes are maintained by each discipline, a single set of notes would allow medical and nursing staff to see an overview of the patient's history.

F17. The panel heard evidence from Mrs GRO-B that she thought that the treatment provided by Dr Ramage had killed her husband. Expert evidence refutes this statement. It is clear that Mr GRO-B was extremely ill with a poor prognosis at the time of his admission, and at risk of death at any time.

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

F19. The panel find that Mr GRO-B treatment of abdominal ascites at The North Hampshire Hospitals NHS Trust in GRO-B 1998 was totally appropriate.

Third Term of Reference

Whether the communication between all the disciplines of staff was appropriate.

F20. Medical and Nursing notes were commended for their completeness; there is however concern that comprehensive multi-disciplinary patient notes are not maintained. Such notes may have contributed to better communication and understanding of this case.

F21. Junior medical staff had been informed appropriately regarding changes in Mr GRO-B s condition by nurses and had responded judiciously.

F22. The panel was surprised that communications between Sister Stebbings (Haemophilia Unit) and Jane Brown (Social Worker) were not documented in the notes despite them having visited Mr GRO-B.

F23. The panel has concerns about the failure of healthcare workers to communicate significant clinical information necessary for fluid balance charts.

F24. The concerns that Mrs GRO-B felt about inaccurate reporting by Staff Nurse Bull of a telephone conversation that she had on the evening of GRO-B were explored. The panel established that matters were discussed with medical staff and the right course of action was pursued.

— wrong conversation

F25. The panel was disappointed to learn that the decision not to resuscitate was reached without reference to or discussion with either Mr or Mrs GRO-B. This should have been anticipated in a patient with several life threatening diagnoses, in particular his deteriorating liver disease.

immediate as from as no prology

F26. The panel heard of difficulties in communication with Mrs GRO-B junior staff found her style to be aggressive, anxious and at times intimidating. Senior staff found the demands placed upon them by Mrs GRO-B to be wearing. They clearly avoided her when they could.

— how can this be appropriate communication?

Fourth Term of Reference

The issue concerning the consent for samples being removed from Mr GRO-B s body after his death.

F27. Dr Nokes 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.

THE PANEL'S RECOMMENDATIONS

R1. The Trust should introduce a written form of consent for all paracentesis and similar procedures that are carried out. There should be a policy setting out which procedures require written consent.

R2. The Trust should ensure that a comprehensive information leaflet is provided to all patients for such procedures.

R3. The Trust should review its systems of communication between clinical teams to ensure proper and expeditious continuity of care. This should include clear documentation of records that are timed, dated and signed, in a written and legible form.

R4 The Trust should implement the use of inter-disciplinary notes as a method of enhancing communication between all staff.

R5 The Trust is asked to consider whether the expertise of the Clinical Nurse Specialist should be utilised more effectively with availability of advice and teaching.

R6 The Trust should review its arrangements for staffing on wards where high dependency nursing is required and ensure that staffing levels match the levels of demand. There should be a contingency plan, known to ward staff, to ensure that nurse staffing levels correlate with patient dependency.
[the panel understands that the Trust is currently undergoing a nursing staffing review]

R7 The Trust should ensure that adequate training is provided for all staff who are required to keep and maintain written records and that untrained staff are not allowed to work unsupervised.

R8 The Trust should review arrangements for treating patients requiring high dependency nursing for uncommon procedures, to provide a concentration of clinical expertise. The Trust should consider the creation of a properly staffed high dependency area.
[The panel understands that the Trust now has the facility for High Dependency nursing care]

R9 The Trust should ensure that informed consent from relatives is obtained for the removal of body tissues from the dead.

R10 The Trust should provide assertiveness training for staff to enable them to deal effectively with difficult and demanding patients and relatives.

R11 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 and for the unfortunate incident when her daughter walked into her step father's room shortly before his death.

The panel submits the foregoing Report to the Chief Executive of the North Hampshire Hospitals NHS Trust and those designated to receive the \report in accordance with the requirements of EL (96) 19.

Signed..... GRO-C .....Date..... 16-2-07

David F Brown
Independent Lay Chair

Signed GRO-C Date..... 19/2/01.....

Jo Kelly
North and Mid Hampshire Health Authority

Signed.. GRO-C .Date..... 19th February 07

Annette Rushmere
Convenor, North Hampshire NHS Trust

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KING'S COLLEGE HOSPITAL

14th December 2000

JO'G/cg

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Dear Mrs Robinson

Independent Review – Mr GRO-B

I am pleased to furnish my final report. This follows detailed examination of the hospital notes and consideration of the oral evidence given. but not the correspondence

Clinical Summary

Mr GRO-B was a known Hepatitis C carrier and this is the main determinant of his liver disease. He first developed ascites in May 1998 and this responded to diuretic therapy. The ascites recurred in October 1998 and by early November 1998 was described as severe. A 2 litre paracentesis with intravenous albumin cover was undertaken around that time. His maintenance treatment was with Spironolactone 100 mgms (relatively low dose). This dose was increased to 200 mgms on the 13th November 1998. By the 24th November 1998 his weight had decreased by 2.2 kilograms which is an appropriate response to the increase in the dose of diuretic. By the 15th December 1998 the weight had increased by 1 kilogram. However, the Potassium had increased to 6.0 mmol/l. This is a recognised side effect of Spironolactone and the dose was decreased to 100 mgms daily.

On the GRO-B 1998 the ascites was described as tense. A decision was taken to undertake paracentesis. The protocol outlined in his notes indicated an initial drainage of 5 litres with an intravenous infusion of 1 litre of plasma expander (using Gelofusine in this instance). On the GRO-B 1998 it was decided to continue the drainage of ascites with further Gelofusine cover. The input/output chart over the next 24 hours indicates that 9.9 litres of ascites was removed and 1.5 litres of Gelofusine was transfused.

/Cont....

Re: Mr GRO-B

Specific Comments

1. There are no national guidelines as yet for the management of ascites. These are being developed by the British Society of Gastroenterology but they have not yet been published.

2. The cause of the ascites was appropriately investigated. Lymphoma was considered and discounted. Cirrhosis related Hepatitis C was considered to be the most likely cause. The possibility of veno occlusive disease (a complication of chemotherapy) was entertained. The diagnostic investigation, a liver biopsy, was inappropriate and was not undertaken.

3. The principal clinical manifestation of the liver disease was ascites. On the GRO-B this was clearly severe. In excess of 15 litres was present and this accounted for over 25% of his body weight.

4. It is not clear from the notes what degree of salt and fluid restriction had been imposed as the initial component for treatment of ascites. Evidence from Mrs GRO-B indicates that the need for salt restriction was well appreciated but no formal fluid restriction was in place. However, it is clear that the maximum dose of diuretics had been utilised. The increased Potassium necessitated a reduction in the dose of Spironolactone and the low serum Sodium precluded the use of Frusemide. This combination of events is termed intractable ascites.

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

6. The liver function was deteriorating quite rapidly over the 10 weeks prior to admission. This is best illustrated by the rapid fall in the serum Albumin from 28 g/l to 22 g/l over this period. A significant increase in the AST was noted on the 13th November 1998 and it was postulated that this may reflect a surge in activity of the Hepatitis C. This is a plausible explanation for the deterioration. The prognosis of his liver disease was poor and he was unlikely to survive more than 3 months.

/Cont....

Re: Mr GRO-B

Opinion

1. The decision to undertake a paracentesis was appropriate and no other feasible therapy was available.

2. The management of fluid balance during the conduct of the paracentesis was appropriate.

3. The risk of infection complicating the paracentesis was increased by the cannula remaining in situ for approximately 48 hours. However, there is no evidence that sepsis did develop.

4. There is no evidence that the cannula caused bowel perforation or other complications to implicate it in the causation of the terminal illness.

5. The severity of the liver disease was sufficiently severe to put Mr GRO-B at risk of death at any time and independent of the paracentesis.

6. The temporal relationship between the paracentesis and death does not establish a direct relationship between the two events in this case.

7. The rapidly changing prognosis from the point of view of the liver disease appears to have been lost in the complexity of this case. An appreciation of the poor prognosis and communication of this to Mr and Mrs GRO-B may have averted some of the subsequent difficulties that arose.

Yours sincerely

GRO-C

Dr John O'Grady, MD FRCPI
Consultant Hepatologist

GRO-B

Herts. GRO-B

4th December 2000

Your ref. JCP\AR\ GRO-B

Re: Mr GRO-B

Dear GRO-B

Please find enclosed a copy of my final report in relation to the terms of reference after the independent review of the complaints regarding Mr GRO-B. Do not hesitate to contact me if you require clarification of the report.

Yours sincerely,

GRO-C

M Gary Brook,
Consultant Physician

08 DEC 2000

Report for the Independent Review Panel

Opinion on the treatment of Mr [GRO-B] with respect to the four terms of reference.

Author: Dr M Gary Brook Written 01/12/2000

Background

This report is written following detailed examination of the case-notes, clinical letters and written evidence relating to the case and having heard evidence given to the Independent Review Panel at Parklands Hospital on the 29th of November 2000. What is not in dispute is that Mr. [GRO-B] was infected with HIV and Hepatitis C virus following previous treatment for his haemophilia. He had a lymphoma of the naso-pharynx treated with chemotherapy and radiotherapy in mid to late 1998 and had developed abdominal ascites in the May 1998.

The picture gained from the various witnesses interviewed is that of Mr [GRO-B] as an increasingly ill man visiting many specialists for their opinions in the hope that his condition could be improved. It is clear that both Mr. and Mrs [GRO-B] felt, understandably, that the NHS was responsible for Mr [GRO-B] ill health as a result of the HIV and hepatitis C acquired through treatment of his haemophilia.

I will now examine the four terms of reference.

1. Whether Mr. [GRO-B] treatment for abdominal ascites by paracentesis was appropriate following admission to The North Hampshire NHS Trust in [GRO-B] 1998

Mr. [GRO-B] had suffered from ascites from May 1998 and this had been recognised to be probably due to cirrhosis from the onset by Dr Mark Nelson at the Chelsea and Westminster Hospital. It had initially responded to therapy with spironolactone accompanied by fluid and salt restriction. However, it became increasingly difficult to control in the Autumn of 1998 despite increasing doses of spironolactone and appropriate dietry advice. Several witnesses independently reported that Mr. [GRO-B] had become uncomfortable with the ascites in [GRO-B] 1998. It seems that his admission to hospital was precipitated by a combination of factors including a realisation that the ascites was not being controlled by medical treatment alone and a request by Mr. [GRO-B] for a further hepatological opinion which was seen as an indicator that he was unhappy and uncomfortable with the ascites.

The high serum potassium and low serum sodium excluded treatment with means other than paracentesis. The decision to "drain to dryness" with intravenous fluid and colloid replacement is a normal treatment under the circumstances seen here of diuretic-resistant ascites.

Conclusions:

- Paracentesis was appropriate treatment.

Whether the communication between all the disciplines of staff was appropriate?

Communication seems on the whole to have been good. There are comprehensive medical and nursing notes which document Mr GRO-B s treatment and the discussions between staff and Mr. and Mrs. GRO-B It seems that Mr. and Mrs. GRO-B had concerns and misconceptions about this admission. Mr. GRO-B quite clearly expected to stay in hospital for only a day, as reported by Jane Brown, but it is also apparent that the need for a longer stay was communicated to him subsequently. It also seems that Mrs GRO-B had disagreed with her husband about the need for admission just before Christmas and did not initially accompany him to the hospital. Staff did keep her informed of her husbands progress as appropriate.

Conclusion:
Communication was appropriate.

Whether the level of consent obtained for paracentesis was appropriate.

There is no clear distinction between an operation and a non-operative procedure. Whilst many doctors ask for written consent for procedures other than blood tests, this practice is not widespread and a large proportion of doctors do not obtain written consent for procedures such as abdominal paracentesis. There is evidence that Mr. GRO-B gave verbal consent in as much as the paracentesis was the reason for this admission, that he did not object to the procedure and the further discussion with Mr. and Mrs. GRO-B was around whether the drain should have been subsequently left in overnight.

Although Mr. GRO-B was apparently under the misconception that he was to leave hospital on the GRO-B it is clear that the decision to continue in-patient treatment was subsequently explained to him. Although in the case-notes Mr. GRO-B is reported to have stated to Dr Nokes on GRO-B 98 that he had not consented to overnight drainage, he is also reported to have "seemed to understand" the need for draining the ascites "all off at once". Several witnesses reported that Mr. GRO-B remained clear minded until the afternoon of the GRO-B GRO-B

Conclusion

- The level of consent obtained for the paracentesis was appropriate although cases like this highlight the need for Trusts to form policy about which procedures require written consent.
- It seems that consent for overnight drainage was withdrawn by the patient although he subsequently accepted the need for this procedure when it was explained to him.

The issues concerning the consent for samples being removed from Mr. GRO-B GRO-B s body after his death.

Dr. Nokes obtained permission of the coroner to send tissue samples from Mr. GRO-B s body to Dr Ironside in Edinburgh for research purposes. Therefore, legally, Dr. Nokes was entitled to do this. However I feel that there was a moral

responsibility to discuss this with Mrs. GRO-B , irrespective of her state of anguish, as enshrined in the Declaration of Helsinki.

Dr. Nokes informed the panel that only recently has this research been referred for ethics committee approval via the Multi-centre Research Ethics committee (MREC). I think that if this situation should arise again, before MREC approval, at the very least the local ethics committee should be involved.

Conclusions.

- Dr Nokes was technically entitled to send samples of Mr. GRO-B body for research.
- I personally believe that samples of Mr. GRO-B body should not have been taken for research purposes without Mrs GRO-B 's consent.
- This case raises significant moral issues regarding informed consent by relatives to research on dead people, which need to be resolved through the ethics committee and guidance should be stated through the Trust's research governance procedures.

Other issues arising from this review

Several issues arose that the Trust need to address, although I do not believe that the significantly affected this case.

1. There were only two nurses on the ward after midnight of the GRO-B This is inadequate as both were heavily involved in Mr. GRO-B s care essentially leaving the other twenty one patients without nursing care. It is also likely that the unfortunate incident of the teenage daughter walking into her step-fathers room could have been avoided.
2. The fluid balance charts relating to Mr. GRO-B are incomplete, It seems that part of the task of completing fluid balance charts is left to Health Care Support workers (HCSW) who are not trained for this. In any case the trained nurses were too reliant on the HCSWs when it was ultimately their responsibility to ensure accurate record keeping. I understand that this issue is being addressed.
3. Paracentesis is an uncommon procedure on the medical wards and of the two nurses interviewed, one had never seen this procedure before and the other had only done it once. There is therefore a strong case for a high dependency area were such procedures can be performed, thus concentrating experience and providing a higher level of nursing support. I understand that this is planned by the Trust and that the nurses are improving protocols.
4. Research on the dead should be treated exactly as with the living. The same high standards of informed consent (from relatives) should pertain. The Trust should provide a directive to all members of staff, in consultation with the local ethics committee, supporting this concept.
5. The clinical governance department should provide guidelines on when to obtain written consent for procedures, such as paracentesis.

Concluding Remarks

Mrs GRO-B understandably feels aggrieved with the NHS as she has lost her husband to complications of infections that he caught through treatment of his haemophilia. It is also clear that she didn't want her husband to be admitted to hospital just before Christmas, possibly as she recognised that he had little time left to live and wanted to

spend the holiday with him, and therefore his death at that time was especially distressing.

In GRO-B 1998 Mr GRO-B was seriously ill and coming to the end of his life and so all medical decisions were difficult, trying to balance the potential benefits of any treatment with the discomfort they might cause. I can find no evidence of any serious mistakes in his medical management and the decisions taken would have been made by most doctors. That Mr. GRO-B died during admission for paracentesis does not mean the decision was necessarily wrong neither was it performed negligently. It reflects the fact that the patient was very ill and although most patients would have benefited, this unfortunately was not the case here.

There were clearly tensions created, especially between Mrs GRO-B and various staff members. It also seems that Mr. and Mrs. GRO-B had different expectations and wishes. On the one hand, staff tried very hard to keep Mrs. GRO-B informed, but on the other it is likely that these tensions at times led to difficult discussions being delayed or avoided. It is difficult to legislate for this but health care workers have to continue to communicate with relatives, no matter how difficult.

The death of Mr. GRO-B and the subsequent enquiry has been a difficult time for many people, none more so than Mrs. GRO-B. I believe that the review process has been fair and should now allow everyone to move on with the knowledge that everything that should have been done, has been done.

MEDICAL REPORT

INDEPENDENT REVIEW PANEL - MR GRO-B

1. **Whether Mr GRO-B treatment for abdominal ascites by paracentesis was appropriate following his admission to The North Hampshire Hospital NHS Trust in GRO-B 1998.**

It had been recognised for some months that Mr GRO-B had ascites and this had been appropriately investigated as to the underlying cause. It was concluded that the ascites was due to his hepatitis C-induced cirrhosis of the liver. In November 1998 paracentesis had been performed at Southampton General Hospital with considerable clinical relief of symptoms. During the year appropriate medical treatment with diuretic drugs and dietary salt restriction had been given, but these measures were no longer achieving control of his ascites and his serum albumin level had significantly fallen during the 2 months prior to his admission. Drainage of ascitic fluid during his admission on GRO-B 1998 was appropriate management.

It was established that the Trust protocol for paracentesis was followed and understood well by the medical staff, although the nursing staff had little experience of this procedure. Expert evidence was heard that the protocol was professionally acceptable and in line with specialist practice in other similar units. The appropriateness of "a draining to dryness" was discussed and expert evidence given that drainage in excess of 10 litres of ascitic fluid during a 36 to 48 hour period was a common practice. Discussion took place regarding length of time that the paracentesis cannula was left in situ, providing as it did potential portal for sepsis to which Mr GRO-B was substantially at risk. There was no evidence that sepsis occurred, and the haemorrhagic risk of repeatedly removing and reintroducing the cannula because of his haemophilia was recognised as a counterbalancing factor when taking this decision. The volume and type of fluid replacement was agreed to have been appropriate. The choice of gelofusion for administration to a vegetarian was a subject that had never been called into question in anyone's experience. It was recognised that many oral medications are administered in gelatin capsules.

It was the conclusion of the Panel that treatment of Mr GRO-B ascites by paracentesis was appropriate, that the local protocols were professionally acceptable and had been properly followed.

2. **Whether the communication between all the disciplines of staff was appropriate.**

(a) Communication with Tertiary Centre:
Dr Mark Nelson, Dr Graham Moyle, Chelsea and Westminster Hospitals.
Dr John Sweetenham, Southampton General Hospital.

It was agreed by Dr Ramage and Dr Nokes that there was good communication regarding management of Mr GRO-B HIV and lymphoma from the Tertiary Centres. Mrs GRO-B was also satisfied with communication with these Centres.
A factor mentioned in the decision to remove Mr GRO-B haemophiliac care to North Hampshire Hospital from the Oxford Centre was that communication with staff at Basingstoke was more patient-centred.

(b) Communication between medical and nursing staff during his admission GRO-B 1998.

Both medical and nursing notes were commended for their completeness. Junior medical staff had been informed appropriately regarding changes in Mr GRO-B condition by nurses and had responded appropriately. Concern was expressed regarding the failure of healthcare workers to communicate significant clinical information necessary for fluid balance charts and also possibly of Mr GRO-B vomiting. It was recognised that healthcare workers on the ward had not been trained in recording urine output which they removed from patients' bedsides. This had been due to absence of a training programme and also to the levels of staffing which were probably inadequate for the number and complexity of the caseload on the ward. Sister Cairns was commended for the introduction of healthcare workers' training programme following the evidence brought to light in this case.

Mrs GRO-B was very concerned regarding what she felt to be an inaccurate reporting by Staff Nurse Bull of the telephone conversation which she had with her on the evening of GRO-B, in that the record made no comment that Mr GRO-B had said he wanted his drain removed. Staff Nurse Bull, however, reports discussing the conversation with the on-call medical SHO Dr Cullishall, who discussed the problem with Mr GRO-B and recommended that he raised his concerns with Dr Ramage's team in the morning.

Communication between the staff of the Haemophilia Centre, Sister Stebbings and Jane Brown, with the nursing and medical teams was not documented in the notes, and there was no record of their visits. Jane Brown gave evidence that Mr GRO-B wanted his drain to be removed on GRO-B and to go home that evening. She stated, however, that Mr GRO-B did not withdraw his consent for continued paracentesis. This information did not appear to have been recognised by medical or nursing staff who all stated that Mr GRO-B did not ask for his drain to be removed. It was felt that multi-disciplinary notes, particularly including notes from the Haemophilia Sister, would have contributed to better communication and understanding of the case.

(c) The communication with Mr and Mrs GRO-B

It appeared that there had been in general good communication with Mr and Mrs GRO-B and they had been given a detailed understanding of the severity of Mr GRO-B s illness and his prognosis. Sister Stebbings and Jane Brown of the Haemophilia Centre had been in close touch over the months since Mr GRO-B introduction to the Centre and were very actively involved with both before and after Mr GRO-B final admission. There appears to have been a breakdown in communication with Mr GRO-B during the ward round on the morning of GRO-B The medically recorded plan in the notes for further paracentesis and echocardiogram appeared not to have been completely discussed with Mr GRO-B as he expected to have his drain removed that day and to go home in the evening, as he told Jane Brown on the morning of GRO-B his wife in the telephone conversation on the evening of GRO-B, and Dr Nokes as he records on his ward round on the morning of GRO-B

Communication regarding decisions about resuscitation had plainly not taken place with Mr and Mrs GRO-B This should have been anticipated in a patient with several life-threatening diagnoses, in particular his deteriorating liver disease.

3. **Whether the level of consent obtained for the paracentesis was appropriate.**

Dr Ramage stated that, according to local protocol, "verbal consent after full and informed discussion" was current practice prior to paracentesis, and it was acknowledged that this was common practice in most units. Sister Stebbings gave evidence that Mr GRO-B sought admission to hospital because he wanted paracentesis in order to make him feel better for Christmas as had been his experience following paracentesis in November. The breakdown in communication with Mr GRO-B regarding the extent and duration of the drainage on the morning of GRO-B gave rise to his complaints as mentioned above. Jane Brown, however, states that he did not withdraw permission for paracentesis and this is borne out by the other medical and nursing notes.

The conclusion was drawn that Mr GRO-B gave full verbal consent for paracentesis in line with local protocol, and that while he expressed a wish for curtailment of drainage on both GRO-B he at no time withdrew consent.

It was recommended that Dr Ramage and other clinicians should consider introduction of a written form of consent for paracentesis and similar procedures. Introduction of patient information leaflets by the nursing staff about such procedures was welcomed.

4. **The issues concerning consent for samples to be removed from Mr GRO-B body after his death.**

Dr Nokes gave evidence regarding the importance of the Edinburgh study of analysis of post mortem tissue from haemophiliacs providing evidence of the transmissability of new variant CJD by blood products. This national study had been approved at the UK Haemophilia Centre Directors Organisation's annual meeting, but it is still awaiting MREC approval. Dr Nokes had not sought local ethical committee approval to take part in the study. He said that he had avoided asking Mrs GRO-B permission for samples to be taken because she was distraught and he feared that he would distress her further: he also thought that she might be incapable of a rational decision because of her grief. He discussed the problem with the Coroner who gave legal permission for the sampling to be done.

Although a legally correct procedure, it was felt that this decision was insensitive, particularly in the light of other recent national issues regarding retention of post mortem tissue. It was recognised that he had acted legally and from good scientific motives, but, unfortunately, by his decision he had worsened Mrs GRO-B distress.

REPORT FROM CLINICAL ASSESSOR
RE: MR GRO-B (deceased)

NAME: Fiona Cowdell RN, MA, PGCE, BA(Hons)

CURRENT POST: Sister Emergency Medical Unit /
Lecturer Practitioner Acute Medicine
West Dorset General Hospitals NHS Trust

TERMS OF REFERENCE

1. Whether Mr GRO-B 's treatment for abdominal ascites by paracentesis was appropriate following his admission to the North Hampshire Hospital NHS Trust in GRO-B 1998.

2. Whether the communication between all disciplines of staff was appropriate.

3. Whether the level of consent obtained for paracentesis was appropriate.

4. The issues concerning the consent for samples being removed from Mr GRO-B GRO-B body after his death.

REPORT

I have reviewed the case notes and other documentation concerning the above patient. On 29th November 2000 I met and questioned Mrs GRO-B and some members of the clinical staff involved in the care of Mr GRO-B

My conclusions about the nursing care received by Mr GRO-B in relation to the first three terms of reference are summarised below. The fourth term of reference is primarily a medical issue.

Background

Mr GRO-B was a forty year old man with known haemophilia, hepatitis C and HIV. He had developed ascites that was not responding to diuretics. He was admitted to the North Hampshire Hospital on GRO-B 98 for elective paracentesis. Mr GRO-B died on GRO-B 98.

Terms of Reference

1. Whether Mr GRO-B s treatment for abdominal ascites by paracentesis was appropriate following his admission to the North Hampshire Hospital NHS Trust in GRO-B 1998.

The choice of paracentesis as a course of treatment is clearly a medical decision. However having spoken to some of the staff caring for Mr GRO-B a number of nursing issues have been raised.

The nursing staff interviewed both stated that paracentesis was a procedure that was rarely performed on the ward in which Mr GRO-B was a patient. One nurse had seen the procedure once, the other had never seen it. There were no clear guidelines on the nursing management of paracentesis although some have subsequently been produced.

This lack of nursing expertise is a cause of concern. The nurses clearly failed to comprehend the importance of accurate monitoring of fluid balance during paracentesis. The fluid balance charts show significant deficiencies, several charts lack the date and patient's name. It is difficult to determine how much replacement intravenous fluid was given at what times. Mr GRO-B s urine output is not recorded on some charts. There was a suggestion that not all vomiting was recorded.

It was notable that the nurses questioned suggested that the responsibility for completing fluid charts lay with the Health Care Assistants; they were slow to acknowledge the registered nurses accountability for the omissions. It was stated that training is now provided for HCA's in the maintenance of accurate fluid balance charts.

Conclusions

- The nursing staff did not have the expertise to competently care for a patient undergoing paracentesis. Although guidelines for paracentesis have now been produced these lack the required detail.

- The nurses did not appear to fully accept their own accountability for their practice.

2. Whether the communication between all disciplines of staff was appropriate.

This term of reference can be considered from two viewpoints: the communication between staff and the communication between the staff and Mr and Mrs GRO-B

Communication Between Staff

The medical notes set out a clear plan of care for Mr GRO-B this was reviewed at least daily and altered according to his condition. The nursing notes record that treatment for Mr GRO-B was delivered according to the plan.

It is evident that there was effective communication between medical and nursing staff. There are several entries which indicate that nursing staff contacted medical staff when they were concerned about the condition of Mr GRO-B The doctors were also kept informed of the concerns about treatment expressed by Mr and Mrs GRO-B The case notes indicate that the medical staff responded to requests to review Mr GRO-B

There is evidence in the correspondence that Yvonne Stebbings (Clinical Nurse Specialist) and Jane Brown (Social Worker) were involved in the care of Mr GRO-B during this period; I am unable to find documentary evidence of this in the case notes. On meeting both Sister Stebbings and Ms Brown it was evident that they had both been involved in the care of Mr GRO-B during this in-patient episode. They both had considerable insight into his previous history and had had extensive contact with Mr and Mrs GRO-B

The fact that Sister Stebbings and Ms Brown had both visited the ward but had had no contact with other clinical staff is a matter of concern. These practitioners both had a wealth of knowledge and expertise that could have been shared with the ward staff. This would have had the benefits of both offering support to clinical staff and in ensuring consistent and seamless communication between patient, relatives and staff.

Communication Between Staff and Mr and Mrs GRO-B

There are frequent entries in both medical and nursing notes indicating that both, but particularly Mrs GRO-B had been kept informed of Mr GRO-B treatment and condition.

The level of documentation in the case notes strongly implies that good communication occurred. The clinical staff may be complimented on the standard of their record keeping. The only exceptions to this are that not all sheets have the patient's name on, some entries are not timed and dated and many signatures are illegible.

Conclusions

- The level of communication was broadly very good
- The communication between 'specialist' staff and ward staff was not effective.

3. Whether the level of consent obtained for the paracentesis was appropriate.

In my experience the consent obtained for this type of procedure is verbal rather than written.

There is an implication that Mr GRO-B consented to having the paracentesis; if he did not it is highly unlikely that the procedure would have happened. There is a retrospective entry in the medical notes stating that Dr Ramage discussed continued drainage with Mr GRO-B on the morning of GRO-B 98 and that the patient gave his verbal consent for this to be done.

All the documentation regarding the length of time that the abdominal drain was in situ relate to concerns raised by Mrs GRO-B it is not clear whether Mr GRO-B asked for the drain to be removed at any point.

All the information given by the staff that were questioned indicate that Mr GRO-B himself did not at any time withdraw his consent for paracentesis.

Conclusion

- The level of consent obtained for paracentesis was appropriate although this case highlights the need to have a policy about which procedures require written consent.

Other Issues

The nursing staff stated that Mr GRO-B was a patient who required a high level of skilled nursing care. They stated that they did not have experience of paracentesis and that it was difficult to provide adequate care given the staffing levels on the ward at the time. The nursing staff did not seem aware of any contingency plan to alter staffing levels or to provide the expert care needed for patients with complex and specialist nursing needs.

Conclusions

- The levels of nurse staffing on the ward at the time were not sufficient to provide the care required.
- The nursing staff did not have the required expertise to care for a patient with such a complex condition.

RECOMMENDATIONS

- In order to provide high quality care there should be a concentration of clinical expertise to ensure that patients with specific complex needs are nursed in the same area.

- The expertise of the Clinical Nurse Specialist should be utilised more effectively with availability of advice and teaching.

- There should be a contingency plan, known to ward staff, to ensure that nurse staffing levels correlate with patient dependency.

- There should be a policy for which procedures require written consent.

- The use of inter-disciplinary notes would enhance communication between all staff.

GRO-C

Fiona Cowdell
10.12.00