From: Rebecca Faulkner Code A
Sent: 09 August 2007 15:41
To: Juliet StBernard Code A
Subject: RE: GMC : Dr Barton, Case Management Procedure (Old Rules)

Thank you Juliet - should I contact Defence with this update ?

Rebecca

From: Juliet StBernard Code A
Sent: 09 August 2007 15:05
To: Rebecca Faulkner Code A
Subject: RE: GMC : Dr Barton, Case Management Procedure (Old Rules)

Rebecca,

I have consulted FFW and we hope to make disclosure by the end of August and we should also be in a position to let the MDU know which cases we are proceeding with by then. It thus would be prudent to have the telecon sometime in September depending upon all parties availability.

Juliet

From: Rebecca Faulkner Code A
Sent: 08 Aug 2007 10:14
To: Juliet StBernard Code A
Subject: FW: GMC : Dr Barton, Case Management Procedure (Old Rules)

Hi Juliet,

Can you help me out on the below ? Not sure how to respond on the disclosure issues she raises - is this necessary before the telecon ?

Thanks,
Rebecca

From: Mason, Sara [mailto:MasonS@The-MDU.com]
Sent: 07 August 2007 18:49
To: Rebecca Faulkner Code A
Cc: Eke, Debbie
Subject: RE: GMC : Dr Barton, Case Management Procedure (Old Rules)

Dear Rebecca

Thank you for your email. Ian has not have received the emails below; the email address used is incorrect. He would have responded to you if he had. Although this is an old rules case, I confirm that we would wish Dr Barton represented at any case management meeting arranged. I understand however that Ian still does not even know with which cases the GMC plan to proceed to a hearing, and is also still waiting for further disclosure, in particular of expert evidence, from the GMC Solicitors. It would be helpful to have this information and

documentation before any meeting is arranged, as without it neither Ian or I are likely to be able to make any meaningful contribution. As far as arranging the meeting is concerned, it would make more sense for it to be held after Ian's return (not least because I am myself away for two weeks on annual leave the week after next). If you email me some dates this week, I will check his diary and ensure that it is fixed on a date that he can do so there is no further delay.

I look forward to hearing from you.

Regards,

Sara Mason
Solic

-----Original Message-----
From: Rebecca Faulkner (Code A
Sent: 07 August 2007 14:02
To: Rebecca Faulkner (Code A barkeri@the-mdu.com; Mason, Sara
Cc: Code A
Code A
Subject: RE: GMC : Dr Barton, Case Management Procedure (Old Rules)

Dear Sarah,

I understand that Mr Barker is now on leave until 28 August. Are you able to offer some assistance on the below correspondence ?

Kind regards,

Rebecca

From: Rebecca Faulkner Code A
Sent: 24 July 2007 13:43
To: Rebecca Faulkner Code A ; 'barkeri@the-mdu.com'
Cc: Code A
Code A
Subject: RE: GMC : Dr Barton, Case Management Procedure (Old Rules)

Good afternoon,

As I do not yet appear to have received a response to my below email, I would therefore, like to offer you an additional 7 days to consider this matter further. I would be grateful to receive your confirmation by **2 August 2007** if you wish to participate in the two-stage pre-adjudication case management procedure. If you are no longer representing Dr Barton, I would be very grateful if you could let me know.

I look forward to hearing from you. In the meantime, if you would like any further information, or if you would like to discuss any practical arrangements, please do not hesitate to contact me.

Kind regards,
Rebecca

From: Rebecca Faulkner (Code A
Sent: 09 July 2007 15:13
To: Code A
Cc: Tamsin Tomlinson; Code A
Code A
Subject: GMC : Dr Barton, Case Management Procedure (Old Rules)

Dear All,

We have been requested to contact you, inviting you to participate in Case Management Procedure for the hearing of Dr J A Barton.

This has been referred under Old Rules (as opposed to New Rules listing procedure that we have followed since 2004) and I would be grateful if you could indicate if you wish to take part .

The protocol requires two telephone conferences between the following parties :

GMC Adjudication Sections's listings officer (Chair)
The doctors representative
The GMC Solicitor
The GMC Caseworker

The first telephone conference called, called a Stage 3, is fixed to set a timetable for the case, including a provisional listing date, time estimate and location. The second telephone conference - called a Stage 5, is to confirm the listing date and time estimate and to resolve any outstanding procedural or legal issues.

For your reference I attach proformas of the Stage 3 and Stage 5 and also the BT Meet Me guide for assistance in dialling in to a telecon.

I would be very grateful if you could indicate to me, no later than 23 July 2007, if you wish to take part in the protocol.

If you need any further information please do not hesitate to contact me.

Yours sincerely,

Rebecca
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Rebecca Faulkner
Adjudication Co-ordinator
General Medical Council
Manchester DDI Code A

you have received this email in error please notify gmc@gmc-uk.org

General Medical Council

St James Building, 79 Oxford Street Manchester. M1 6FQ

Regents Place, 350 Euston Road, London. NW1 3JN

The Tun, 4 Jacksons Entry, Holyrood Road, Edinburgh. EH8 8AE

Regus House, Falcon Drive, Cardiff Bay. CF10 4RU

20 Adelaide Street, Belfast. BT2 8GD

Tel: 0845 357 8001
Fax: 0845 357 9001

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From: Rebecca Faulkner Code A
Sent: 09 August 2007 16:02
To: 'Mason, Sara'
Cc: Eke, Debbie; Juliet StBernard Code A
Subject: RE: GMC : Dr Barton, Case Management Procedure (Old Rules)

Dear Sarah,

Thank you for your below email. I am advised that Field Fisher Waterhouse hope to make disclosure by the end of August. - by which time they also anticipate being in a position to advise on which cases they will be proceeding with.

With this in mind, I would suggest organizing the first telephone conference for early in September (when Ian should be available) ?

I would like to propose the below dates and would be grateful if parties could indicate the most suitable :

6 September 10 am / 11 am / 2pm
7 September 2pm
10 September 11am / 2pm
11 September 10am/ 11am/ 2pm

I look forward to hearing from you .

Regards,

Rebecca

From: Mason, Sara [mailto: Code A
Sent: 07 August 2007 18:49
To: Rebecca Faulkner (Code A
Cc: Eke, Debbie
Subject: RE: GMC : Dr Barton, Case Management Procedure (Old Rules)

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Solic

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Kind regards,
Rebecca

From: Rebecca Faulkner (0161 923 6398)
Sent: 09 July 2007 15:13
To: [Code A]
Cc: Tamsin Tomlinso[Code A]
Subject: GMC : Dr Barton, Case Management Procedure (Old Rules)

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Yours sincerely,

Rebecca
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Rebecca Faulkner
Adjudication Co-ordinator
General Medical Council
Manchester DDI : Code A

The Tun, 4 Jacksons Entry, Holyrood Road, Edinburgh. EH8 8AE

Regus House, Falcon Drive, Cardiff Bay. CF10 4RU

20 Adelaide Street, Belfast. BT2 8GD

Tel: 0845 357 8001
Fax: 0845 357 9001

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Field Fisher Waterhouse

Case Report

[redacted]

Field Fisher Waterhouse

00066905

GENERAL MEDICAL COUNCIL

-AND-

DR BARTON

MEDICAL REPORTS

GENERAL MEDICAL COUNCIL

DR BARTON

Index to Medical Records

File 1

1. Elsie Devine, Dr Andrew Wilcock, 10 December 2004.
2. Elsie Devine, Dr D A Black, 4 January 2005.
3. Elsie Devine, Dr C R K Dudley, 20 March 2005.
4. Gladys Richards, Professor G A Ford, 12 December 2001.
5. Gladys Richards, Professor Brian Livesley, 10 July 2001.
6. Helena Service, Dr D A Black, 6 November 2004.
7. Helena Service, Dr M C Petch, March 2006.
8. Helena Service, Dr Andrew Wilcock, 19 June 2006.
9. Sheila Gregory, Dr D A Black, 1 November 2005.
10. Sheila Gregory, Dr Andrew Wilcock, 22 December 2005.
11. Arthur Cunningham, Dr D A Black, 11 July 2005.
12. Arthur Cunningham, Dr Andrew Wilcock, 27 September 2005.
13. Geoffrey Packman, Dr J Marshall, 1 April 2005.
14. Geoffrey Packman, Dr D A Black, 30 October 2005.
15. Geoffrey Packman, Dr Andrew Wilcock, 28 March 2006.

File 2

16. Alice Wilkie, Dr K I Mundy, 18 October 2001.

17. Alice Wilkie, Professor G A Ford, 12 December 2001.

18. Eva Page, Dr K I Mundy, 18 October 2001.

19. Eva Page, Professor G A Ford, 12 December 2001.

20. Ruby Lake, Dr Andrew Wilcock, 10 July 2005.

21. Ruby Lake, Dr D A Black 29 August 2005.

22. Ruby Lake, Dr Andrew Wilcock, 5 September 2005.

23. Leslie Pittock, Dr D A Black 31 January 2005.

24. Leslie Pittock, Dr Andrew Wilcock, 25 April 2005.

25. Leslie Pittock, Dr Andrew Wilcock, 26 April 2005.

26. Robert Wilson, Dr Andrew Wilcock, 21 May 2006.

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29. Robert Wilson, Dr J Marshall 28 April 2006.

30. Elsie Lavender, Dr D A Black, 19 March 2005.

31. Elsie Lavender, Dr Andrew Wilcock, 1 May 2005.

32. Enid Spurgin, Daniel Redfearn 22 January 2006.

33. Enid Spurgin, Dr D A Black 27 June 2005.

34. Enid Spurgin, Dr Andrew Wilcock, 5 March 2006.

REPORT

regarding

ELSIE DEVINE (BJC/16)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mrs. Devine was a frail 88 year old with significant medical problems. She was admitted with an episode of confusion to the Queen Alexander Hospital and diagnosed as having multi-infarct dementia. An infection may have contributed to her confusion. She improved somewhat and was referred to the geriatricians. The overall care given to Mrs Devine whilst at the Queen Alexandra Hospital does not appear suboptimal.

Mrs Devine was transferred to Gosport War Memorial Hospital, Dryad Continuing Care Ward for rehabilitation. During this admission, she became more confused. A fentanyl transdermal patch was commenced for an unspecified reason. The following day Mrs Devine became more confused and agitated. An injection of chlorpromazine was given and a syringe driver started one hour later containing diamorphine and midazolam. Mrs Devine died two days later.

The medical care provided by Dr Barton on Dryad ward is suboptimal: there was a failure to keep clear, accurate, and contemporaneous patient records; there was inadequate assessment of Mrs Devine's condition; treatments were prescribed that appeared excessive for Mrs Devine's needs. In particular, the prescription of a fentanyl transdermal patch and of diamorphine appear unjustified and/or excessive for Mrs Devine's needs. The use of chlorpromazine and midazolam appears justifiable on the grounds of Mrs Devine's confusion, but the doses used appear excessive for her needs.

If it were that Mrs Devine had naturally entered the terminal phase of her life, at best Dr Barton could be seen as a doctor who whilst failing to keep clear, accurate, and contemporaneous patient records had in good faith been attempting to allow Mrs Devine a peaceful death, albeit with what appears to be an inappropriate and excessive use of medication due to a lack of sufficient knowledge. However, in my opinion, based on the medical and nursing records, there is reasonable doubt that she had definitely entered her terminal

stage. Given this doubt, at worst, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Devine by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Devine by unnecessarily exposing her to inappropriate and excessive doses of medications as with the fentanyl transdermal patch, which could have resulted in a worsening of her agitation and confusion. Dr Barton's response to this was to further expose Mrs Devine to inappropriate and/or excessive doses of midazolam and diamorphine that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

2. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be suboptimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

3. ISSUES

3.1 Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day?

3.2 If the care is found to be suboptimal what treatment should normally have been proffered in this case?

3.3 If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

4. BRIEF CURRICULUM VITAE

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Code A

5. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Elsie Devine, including the death certificate.

[2] Full set of medical records of Elsie Devine on CD-ROM.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] *Hampshire Constabulary Operation Rochester Guidance for* Medical Experts.

[5] Hampshire Constabulary Summary of Care of Elsie Devine.

[6] Commission for Health Improvement Investigation Report on *Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital* (July 2002).

[7] Palliative Care Handbook Guidelines on Clinical Management Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

[8] Portsmouth Health Care NHS Trust Policies:

i) Control of Administration of Medicines by Nursing Staff Policy (January 1997).

ii) Prescription Writing Policy (July 2000).

iii) Policy for Assessment and Management of Pain (May 2001).

iv) Compendium of Drug Therapy Guidelines, Adult Patients (1998).

v) Draft Protocol for Prescription Administration of Diamorphine by Subcutaneous Infusion, Medical Director (December 1999).

vi) Medicines Audit carried out by the Trust referred to as Document 54 on page 52 in the Chi Report (reference 6).

[9] General Medical Council, Good Medical Practice (July 1998 and May 2001).

[10] Royal College of Physicians, London, Good Medical Practice Statement (March 2000).

[11] British National Formulary (BNF). Section on Prescribing in Palliative Care (September 1999).

[12] British National Formulary (BNF). Section on Prescribing in the Elderly (September 1999).

[13] Palliative Care Formualry (PCF). Twycross R, Wilcock A and Thorp S. Radcliffe Medical Press, Abingdon, Oxon (1998).

[14] Data sheet for Durogesic, fentanyl transdermal system; guidelines for use leaflet and laminated card (1994, 1995).

6. CHRONOLOGY/CASE ABSTRACT

Events at the Queen Alexander Hospital

Mrs Elsie Devine, an 88 year old widow who lived with her daughter, was admitted to the Queen Alexander Hospital on the 9th October 1999 under the care of Dr Duncan. The referral letter from her general practitioner, Dr Smith reported her to be confused '++' for two days, aggressive and wandering (page 38). Her medication consisted of thyroxine 100microgram, frusemide 120milligram and amiloride 5milligram all once a day (page 38). On admission she was noted to be frail, confused, pain free and hard of hearing (page 246).

She had previously been diagnosed with an underactive thyroid (treated with thyroxine), impaired kidney function that had most likely resulted from longstanding glomerulonephritis (inflammation damaging a particular part of the kidney) leading to nephrotic syndrome (page 60). This causes an

excessive loss of protein in the urine and can lead to fluid retention, for example, in the tissues of the legs. For this she was receiving frusemide and amiloride, both diuretics or 'water tablets'. She also had excess production of immunoglobulin A, a condition known as IgA paraproteinaemia. It can be associated with serious conditions such as myeloma or lymphoma but investigations had excluded these (pages 64, 303). However, Mrs Devine is incorrectly labelled as having myeloma in several entries in her medical notes (pages 28, 29, 154, 245, 395, 411, 412). Congestive cardiac failure and osteoarthritis of both knees were also noted.

An examination confirmed impaired cognitive function with a low score (3/10) on the short version of the mini-mental test. She did not have a raised temperature and there were no other particular findings of note (page 245). Investigations revealed a normal chest x-ray and electrical tracing of her heart (ECG). She had impaired kidney function with raised levels of urea and creatinine; a slightly reduced haemoglobin (11.5g/dl) and normal white cell and platelet counts (pages 247). A working diagnosis was made of 'confusion - cause to be determined' (page 245). She was treated with intravenous fluids and the dose of frusemide was reduced. Infection is a common cause of confusion of sudden onset in the elderly and she was given an antibiotic, trimethoprim (page 245), for a presumed urinary tract infection. No infection was found in a specimen of urine subsequently obtained (page 367) although this may have been after the antibiotic had been commenced.

On the 12th October 1999 she was still very confused and aggressive requiring an injection of haloperidol, an antipsychotic drug (page 160). On

the 13th October it was noted that her white cell count had increased (page 162). Her antibiotic was switched to a different one (cefaclor) in case she had an infection that was not responding to the trimethoprim (page 162). She was referred to Dr Lusznat for a psychogeriatric assessment.

On the 14th October Mrs Devine was seen by Dr Taylor, Clinical Assistant in Old Age Psychiatry who elicited a history of a slow decline in Mrs Devine's functional abilities since January 1999 and concluded that she was likely to have dementia and to have had an acute episode of confusion secondary to a urinary tract infection. She noted a score of 9/30 on a mini-mental state examination (page 163; a score less than 17 suggests definite cognitive impairment). Dr Taylor provided a more detailed report in a letter typed on 18th October but refers incorrectly to Mrs Devine having myeloma (page 28). She also notes that Mrs Devine was very deaf and that she may not have heard or understood a lot of what was being said because of this.

Entries on the 15th–18th October, around one week after her admission report Mrs Devine to be much more settled, not aggressive, more orientated and less confused (page 166). A CT (computerised tomography) scan of the head revealed changes in keeping with areas of the brain becoming starved of oxygen due to blockage of small blood vessels with no other obvious cause of her confusion. A final diagnosis was made of multi-infarct dementia (MID) (page 171).

Mrs Devine was unable to return to Code A ill health and various placement options were discussed. A referral was made to the geriatricians and she was assessed Dr Jayawardena, who thought her

suitable for rehabilitation at Gosport War Memorial Hospital (pages 26 and 171).

Events at Gosport War Memorial Hospital

On the 21st October 1999, Mrs Devine was transferred to Gosport War Memorial Hospital, Dryad Continuing Care Ward, under the care of Dr Reid. The initial plan was for the team to get to know her, assess her for rehabilitation potential and probably place in a rest home in due course (page 154). On the day of her transfer, the only analgesic prescribed to Mrs Devine was morphine solution (10mg/5ml) to be taken as required (page 277). No reason for this was given in the notes. She was not administered this or any other analgesic until 19th November (page 279). Infrequent entries in the medical notes make it difficult to closely follow Mrs Devine's progress. Those on 25th October and 1st November note her to be physically independent and continent but requiring supervision with washing and dressing, quite confused and disorientated and that she wandered during the day (pages 154, 155).

On the 15th November 1999 she was reported to be very aggressive and restless at times (page 155), requiring the use of thioridazine, an antipsychotic (see technical background). According to the drug chart, this was first prescribed on the 11th November 1999, on an 'as required' basis (page 277). There is no corresponding entry in the notes relating to its prescription. Mrs Devine received one to two doses of 10mg each day until 17th November 1999. On the 11th November 1999 she was also prescribed trimethoprim for a presumed urinary tract infection, although the entry on the 15th November 1999 noted that the urine specimen had revealed no

growth (pages 155, 363). Her white cell count rose from $10.1x10^9$/L on 22nd October 1999 to $12.6x10^9$/L on 9th November 1999 (pages 289, 291). As a result of her worsening confusion, she was referred back to Dr Lusznat on 16th November, with the entry noting that her renal function was deteriorating (page 155); between 22nd October and 16th November 1999 her urea had increased from 14.3 to 19.8mmol/L and creatinine from 187 to 360micromol/L (page 349). Her potassium on the 16th November was 5.6mmol/L (page 349).

She was seen on the 18th November 1999, at an unspecified time, by Dr Taylor, who had seen her previously, who agreed that her mental health state had deteriorated with her being more restless and aggressive again. She reported that Mrs Devine did not seem to be depressed and that her physical condition was stable. She was placed on the waiting list for Mulberry Ward. No changes in medication were recommended by Dr Taylor (page 156). In a separate entry in the Elderly Mental Health notes relating to this assessment, Dr Taylor noted 'reviewed on ward - happy, no complaints, waiting for her daughter, not obviously paranoid, says tablets make her mouth sore' (page 405).

The drug chart shows that on the 18th November 1999 at 9.30am a fentanyl transdermal patch (strength 25microgram per hour) was applied to Mrs Devine (pages 275, 277). There are no entries in the medical or nursing notes to explain why this was commenced.

On the 19th November 1999, an entry by Dr Barton in the medical notes reads 'marked deterioration overnight. Confused, aggressive, creatinine 360 (micromols/L), fentanyl patch commenced yesterday. Today further deterioration in general condition. Needs SC (subcutaneous) analgesia

with midazolam. Son seen and aware of condition and diagnosis. (It is not clear in the notes what diagnosis Dr Barton is referring to, or if this is an error and if she intended it to read prognosis.) Please make comfortable. I am happy for nursing staff to certify death' (page 156).

The summary nursing notes on the 19th November comment 'marked deterioration over past 24 hours. Extremely aggressive this am refusing all help from all staff. Chlorpromazine 50mg given IM (intramuscularly) at 08.30 - taken 2 staff to special.. Syringe driver commenced at 09.25 with diamorphine 40mg and midazolam 40mg. Fentanyl patch removed (pages 222, 223). Code A seen by Dr Barton at 13.00 and situation explained to him. Code A will contact Code A and inform Code A of Elsie's poor condition.' The drug chart records that the intramuscular injection of chlorpromazine 50mg had been given to Mrs Devine at 8.30am, a syringe driver containing diamorphine 40mg and midazolam 40mg commenced at 9.25am and the removal of the fentanyl patch at 12.30pm. All had been prescribed by Dr Barton (pages 275, 277, 279).

There is one further entry in the medical notes on the 21st November confirming Mrs Devine's death. The remaining six entries in the summary nursing notes suggest that Mrs Devine remained 'peaceful' until her death, pronounced at 20.30pm on the 21st November 1999.

The drug chart shows that the doses of diamorphine and midazolam remained unchanged and that no additional medication for agitation was required (page 277, 279).

On the death certificate, the cause of death was stated as 1a Renal failure and 2 Chronic glomerulonephritis.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Multi-infarct dementia

This form of dementia is due to multiple small strokes that starve the brain of oxygen resulting in damage. Patients often experience sudden losses in cognitive and functional ability and hence deterioration over time often occurs in a stepwise fashion.

ii) Multiple myeloma

Multiple myeloma is a form of cancer characterised by an increased production of particular sorts of cells (plasma cells) in the bone marrow, lytic bone lesions (areas of thinned bone, visible on X-ray), a paraproteinaemia (usually IgG, IgA, or IgM) and immunoparesis (reduced levels of other immunoglobulins). Treatment can consist of chemotherapy, radiotherapy and bisphosphonates, drugs that strengthen the bone. Half the patients survive 3–4 years or less.

It is because of Mrs Devines IgA paraproteinaemia that she was investigated for the possibility of multiple myeloma with blood tests, X-rays and a bone marrow biopsy. The results of these tests excluded multiple myeloma.

iii) Delirium (confusion) in the elderly

Delirium is common in the elderly with many possible causes. Dementia is a risk factor for delirium as, for example, are infection, drugs (including

opioid analgesics), depression, multiple co-existing medical conditions and poor hearing. In an elderly patient presenting with delirium, the history and examination together with appropriate investigation should identify or exclude the commonest causes and guide further management (as stressed by Portsmouth Hospitals and Portsmouth Healthcare Compendium of Drug Therapy Guidelines, Adult Patients, 1998; Management of acute confusion in the elderly, pages 38–41). This generally consists of treating the underlying cause when possible and appropriate, non-drug and drug approaches. Non-drug measures may include a well lit environment, ensuring the patient can see and hear well, familiar nursing staff etc. Drug measures generally include the use of antipsychotic drugs. The aim is to reduce the level of the patient's distress due to their disturbed thinking without inducing drowsiness. Haloperidol is a commonly used antipsychotic as it is least likely to induce drowsiness. It is the treatment of choice for aggressive confused patients in the Portsmouth Hospitals and Portsmouth Healthcare Compendium of Drug Therapy Guidelines, Adult Patients, 1998; Management of acute confusion in the elderly, pages 38–41. When severe thought disturbance or abnormal behaviour is present, inducing drowsiness may become necessary and antipsychotics such as thioridazine or chlorpromazine are used. The dose is titrated to improve the patient's thoughts and behaviour with the least level of drowsiness. If the cause of the delirium is considered reversible and the situation improves, the dose of antipsychotic can be gradually reduced and discontinued. This is less likely when the cause of the delirium is irreversible.

Typical starting doses in adults would be:

- haloperidol – 1.5–3mg by mouth every 8-12 hours
- thioridazine – 25mg by mouth every 12 hours
- chlorpromazine – 25–50mg by mouth (or intramuscular injection) every 8 hours.

In the elderly, lower doses, a third to one half of the above are advised (British National Formulary, BNF).

iv) Fentanyl transdermal patches

Fentanyl is a 'strong' opioid analgesic similar to morphine. In 1999, fentanyl transdermal patches were only licensed for the relief of chronic intractable pain due to cancer. Company produced prescribing advice anticipates that if used as a first line strong opioid, it would be in patients who had failed to get adequate relief from regular 'weak' opioids (see appendix). This was a safety consideration, as the lowest patch strength (25microgram per hour) can deliver the equivalent of up to 135mg of morphine a day. This exceeds the typically recommended starting dose of morphine in adults (e.g. 60mg of morphine a day (BNF, Palliative Care Formulary, PCF); 20–40mg (Wessex protocol)) and far exceeds that advised in the frail elderly (30mg of morphine a day or less). The risk of it being an excessive dose would be greatest in opioid-naïve patients. The PCF advised a minimum dose of previous weak opioid, e.g. at least 240mg of codeine a day. This was based upon the entry criteria used by the company in their initial trials with fentanyl.

After application of the patch it can take 3–23 hours to reach an effective plasma concentration and 36–48 hours to reach a stable level of fentanyl (PCF). This makes rapid titration difficult and the patch is not

recommended when there is a need for rapid titration of strong opioid medication for severe pain.

v) Syringe drivers, diamorphine and midazolam

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously via a syringe, over 24hours. Indications for its use include swallowing difficulties or a comatose patient. In the United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control of other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF, prescribing in *palliative care, 1999); others sometimes suggested dividing by 2 or* 3 depending on circumstance (as in the Wessex protocol). Based on the typically recommended starting doses of morphine quoted above this equates to 20-30mg of diamorphine a day in adults and at most 10-15mg diamorphine a day in the frail elderly. The Wessex protocol suggests a range with the lowest dose of 10mg of diamorphine a day. The regular dose would then be titrated upwards every 24–48 hours if pain relief is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients pain and need

for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for diamorphine 30mg in a syringe driver over 24hours, the 'as required' dose would be diamorphine 5mg given as a stat subcutaneous injection. The duration of effect should be in the order of 4 hours, but it may need to be given more frequently. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in their terminal phase would generally aim to find a dose that improves the patients symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive.

A typical starting dose of midazolam for an adult is 30mg a day. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated upwards every 24 hours if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24hours, the 'as required' dose would be

midazolam 5mg given as a stat subcutaneous injection. The duration of effect is generally no more than 4 hours, and it may need to be given more frequently. As an active metabolite of midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

8. OPINION

Events at Queen Alexandra Hospital

The medical notes reveal Mrs Devine to be a frail 88 year old with significant medical problems, most notably chronic renal failure and nephrotic syndrome. On the background of a gradual deterioration in her cognitive abilities she was admitted with an episode of acute confusion that from the history, examination, investigation and subsequent progress at the Queen Alexander Hospital, was in keeping with a diagnosis of multi-infarct dementia.

An infection may have been a possible contributing cause of the confusion. No specific source of infection was found, but her white cell count increased despite the antibiotic, trimethoprim. Following the change to another antibiotic, cefaclor, her mental state did appear to improve.

She was referred to the psychogeriatricians and seen by Dr Taylor, clinical assistant in old age psychiatry, who agreed with a diagnosis of dementia. She did however incorrectly refer to Mrs Devine as having multiple myeloma. The concerns of Mrs Devine's daughter relating to the care of her Mother were documented in the notes (pages 159, 167) partly relating to plans for placement of Mrs Devine. On each occasion these appear to have been satisfactorily resolved.

Events at Gosport War Memorial Hospital

Infrequent entries in the medical notes make it difficult to closely follow Mrs Devine's progress over the last month of her life. Although her physical condition appeared to change little, her level of confusion increased,

resulting in the prescription of thioridazine, an antipsychotic on an 'as required' basis on 11th November and a referral back to Dr Lusznat on 16th November 1999. Around this time, her white cell count had increased and her renal function deteriorated and she had received trimethoprim for a presumed urinary tract infection. She was seen on the 18th November 1999, again by Dr Taylor, who agreed that her mental health state had deteriorated and commented that her physical condition was stable. On this same day, without a documented reason, a fentanyl transdermal patch (strength 25microgram per hour) was applied to Mrs Devine (pages 275, 277). On the following day she was confused and aggressive to the point of requiring two nurses to 'special' her. This generally indicates that active containment is necessary to prevent the confused patient causing harm to themselves or to others and that they have sufficient physical strength to do this. She was given chlorpromazine by intramuscular injection and one hour later a syringe driver with diamorphine and midazolam was commenced. She died two days later. Her cause of death was registered as chronic renal failure secondary to chronic glomerulonephritis. The approximate interval between onset of the chronic renal failure and death was stated as 3 days. This is incorrect as it had been identified as a problem for several months (pages 42 and 52). My experience is limited in caring for patients dying from renal failure alone (most patients I look after will have cancer in addition to renal failure) but Mrs Devine's death was not typical of patients dying from chronic renal failure in my experience. It is generally more gradual in onset associated with progressively worsening renal failure, increasing weakness and drowsiness. A rapid worsening of Mrs Devine's mental state would be more suggestive of an underlying

aggravating factor, for example an infection, a cerebrovascular event ('stroke') or a drug. The latter is particularly relevant given the newly prescribed fentanyl transdermal patch the day before.

Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day?

The overall care given to Mrs Devine whilst at the Queen Alexandra Hospital was not substandard.

The medical care provided by Dr Barton to Mrs Devine following her transfer to Gosport War Memorial Hospital, Dryad Continuing Care Ward is suboptimal when compared to the good standard of practice and care expected of a doctor outlined by the General Medical Council (Good Medical Practice, General Medical Council, July 1998, pages 2–3) with particular reference to:

- good clinical care must include an adequate assessment of the patients condition, based on the history and clinical signs and, if necessary, an appropriate examination
- in providing care you must keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs or appliances that serve the patient's needs.

Specifically:

i) The cause of the acute confusion that led to Mrs Devine's admission is not noted. A diagnosis of multi-infarct dementia, possibly aggravated by infection, not responding to trimethoprim, would be important to note, as this information could influence the management of a similar deterioration in the future. This

knowledge should allow a doctor to consider the possibility that even sudden deteriorations in the future may represent a potentially temporary decline. Further, that it could be appropriate to use an alternative antibiotic to trimethoprim first line or, to have a low threshold for switching from trimethoprim to another antibiotic if clinical benefit is not obtained. Lack of this knowledge could lead a doctor to consider any future decline as an irreversible event or to fail to use an effective antibiotic.

ii) Failure to carefully read Mrs Devine's notes resulted in Mrs Devine being incorrectly labelled as having myeloma in the admission notes on transfer to Dryad ward (page 154). The fact that Mrs Devine did not have myeloma is clear from the information available in clinic letters from the haematologist Dr Cranfield (page 64). This mistake is important if it influenced how she was managed. For example, deterioration could be incorrectly considered an 'expected' irreversible terminal event due to her cancer-like condition and other possible reversible causes of her deterioration may not be considered.

iii) There is no entry in the medical notes that explains the reason for prescribing the morphine, as required, on the day of transfer, or the fentanyl transdermal patch on the 18th November 1999. Pain had not been recorded as a problem in the notes, nor had she received any other kind of analgesic, e.g. paracetamol or codeine. Without clear and accurate information in the notes that justifies the use of a fentanyl transdermal patch, it is difficult to endorse this prescribing action that results in the use of an above average dose of a strong opioid as a first line analgesic in a frail elderly patient, particularly as it goes against the company's prescribing advice (see appendix). In this regard good clinical practice is not adhered to as the treatment appears excessive to Mrs Devine's needs.

iv) In the medical notes entry of the 19th November 1999, although a marked deterioration was recorded, a lack of clear and accurate information means that it is impossible to know if there had been a sufficient consideration of the possible reversible causes of Mrs Devine's deterioration (page 156). For example, could the dose of strong opioid delivered by the fentanyl patch have resulted in a worsening of her delirium? If her deterioration was being attributed to her worsening renal function, what were the possible cause(s) of this? For example, was Mrs Devine becoming increasingly dehydrated due to her diuretic therapy combined with a reduced fluid intake?

v) The medication, detailed below, used in response to Mrs Devine's worsening confusion appears excessive for her needs, even if it were considered that she was dying from natural causes. Medication to control symptoms is usually commenced at a starting dose appropriate to the patient (e.g. considering age and frailty) and their particular symptom control needs and titrated upwards aiming to control these symptoms without necessarily rendering the patient unresponsive. Although the use of chlorpromazine, an antipsychotic, could be justified (see technical background), the dose of 50mg was double that recommended for an elderly, frail patient by the BNF and in this regard excessive to Mrs Devine's needs. This would likely to have caused prolonged drowsiness. There was no opportunity given to assess the long-term effect of this dose; it is possible that Mrs Devine's thoughts and behaviours would have improved as the peak effects of the chlorpromazine wore off and she became less drowsy. Instead, within one hour a syringe driver was commenced with diamorphine and midazolam. The diamorphine is referred to as an 'analgesic' in the medical notes (page 156), but there is no indication or assessment of what pain this is required for. The daily dose of 40mg (with scope to increase the dose to 80mg a day) is not justified at all in the notes. It is likely to be excessive for Mrs Devine's needs and to cause drowsiness. Increasing doses of opioids excessive to a patient's needs are also associated with an

increasing risk of delirium, nausea and vomiting and respiratory depression. Once unresponsive and not drinking, Mrs Devine's renal function would decline further, with increasing retention of the active metabolites of morphine, resulting in an increased overall effect, even though the dose was unchanged. There are no clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing a drug as a range, particularly a wide range, is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. It is not usual in my experience for such decisions to be left for nurses to make alone.

The daily dose of midazolam was prescribed as 20–80mg. Although many doctors would use midazolam in patients with agitation, it was commenced at a daily dose of 40mg, with no indication of why 20mg was not considered appropriate. This dose is likely to lead to drowsiness in a frail elderly patient. Again, there are no prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. In short, these drugs appear to have been prescribed without sufficient safeguard in relation to altering the dosage and in a way that exceeded the patient's needs. In regard to the latter, the notes do not report that Mrs Devine was able to respond after the chlorpromazine was given and the syringe driver commenced. The dose of diamorphine and midazolam did not alter and no additional doses of either drug were required.

If the care is found to be suboptimal what treatment should normally have been proffered in this case?

In relation to the above:

Issues i and ii (failure to read medical notes thoroughly)

There should have been an adequate assessment of the patients condition, including the history obtainable from careful reading of her medical records.

Issue iii (failure to document pain/inappropriate use of transdermal fentanyl patch)

There should have been an adequate assessment of the patients condition. If Mrs Devine directly reported pain, this should have been noted and attempts made to assess as a minimum the site, severity, aggravating/relieving factors and likely cause of the pain. If Mrs Devine was not capable of directly reporting pain, but it was the view of the staff that she was in pain, the reasons for this deduction should have been documented (e.g. her facial expressions, mood, behaviour). Whether or not Mrs Devine was capable of directly or only indirectly reporting pain, if analgesic drugs were considered appropriate, these should have been given in a proportional way. This would generally entail commencing with regular simple analgesics (e.g. paracetamol), progressing to weak opioids (e.g. codeine, dihydrocodeine) and if these were found inadequate, strong opioids such as morphine. Sometimes it is necessary to deviate from this general approach (e.g. for a patient in severe pain) and go straight to strong opioids. Nevertheless, the dose of strong opioid would still have to be individually determined and in my view for an elderly, frail patient with renal impairment, a safe starting dose would be morphine solution 2.5mg given every 6 hours and 'as required'. The regular dose would then be titrated upwards every 48 hours if pain relief is inadequate. The increment would be based upon the patients number of 'as required' doses needed and may generally be in the region of a 33–50% increase in total dose. A transdermal fentanyl patch would not in my view be appropriate in this situation (leaving aside the issue of pain not being documented as a problem) as even the lowest strength patch is likely to deliver too high a dose of strong opioid for an

elderly, frail, opioid naïve patient and it is less flexible than morphine solution in dose titration (see technical issues).

Issue iv (lack of adequate assessment of Mrs Devine's marked deterioration)

There should have been an adequate assessment of the patients condition, based on the history and clinical signs and an appropriate examination, with the common causes of delirium in elderly patients actively considered. Based upon this assessment it is usual to document a working diagnosis of the likely cause or causes (differential diagnoses) in the notes that helps to illustrate that this process has been undertaken. An appropriate management plan would be documented including any need for further investigation. The common causes of confusion that are reasonably simple to reverse should almost always be excluded/pursued as a minimum, e.g. faecal impaction, urinary retention, withdrawal of offending medication. Even in the situation where the cause of the confusion may be known but it is deemed impossible or inappropriate to pursue its treatment (e.g. due to the burden outweighing the benefit, the patients existing psychological or physical state, quality of life and likely prognosis) there should still be clear, accurate, and contemporaneous patient records that document how these decisions are made.

Issue v (excessive/inappropriate use of chlorpromazine, diamorphine and midazolam)

An antipsychotic is an appropriate treatment for someone who is agitated and confused (see technical background). Although haloperidol is often used, the selection of an antipsychotic that has a greater sedative effect such as chlorpromazine could be seen as reasonable when someone is particularly agitated. A much smaller dose, 12.5mg or at most 25mg, would have been preferable in an elderly, frail patient. It would be seen as reasonable practice to allow sufficient time to elapse to assess the longterm effect of the chlorpromazine as it may be sufficient to get a patient through an acute

episode of worsening confusion. Patients may emerge with an improved mental state and better able to co-operate, allowing a small dose of an antipsychotic, e.g. thioridazine, to be given regularly by mouth to maintain the improvement.

Benzodiazepines can be combined with antipsychotics when someone is agitated and confused. If the use of midazolam was deemed necessary, it would in my view have been more appropriate to give small doses (2.5mg-5mg) by intermittent subcutaneous injection as required. It would not be usual practice to commence a syringe driver in order to deliver midazolam with the express purpose of keeping Mrs Devine sedated and drowsy to the point of being unresponsive when the cause of her confusion is unclear. In my view, it can only be justified if it was considered without reasonable doubt that Mrs Devine was experiencing agitated confusion as a terminal event and was actively dying. The decision to take such an approach generally rests with the doctor after taking into account the clinical assessment of the patient, known wishes of the patient, the views of the family and other members of staff. Although some practitioners would use a dose designed to render the patient unresponsive, most would use a dose that improves symptoms without necessarily rendering the patient unresponsive; for Mrs Devine, a starting dose of midazolam 10mg over 24 hours would have been reasonable.

In the absence of pain, shortness of breath or cough, in my view there is no justification for the use of diamorphine in the syringe driver. If there was evidence or concern that Mrs Devine was in pain to a degree that warranted strong opioids and she was unable to take medication by mouth, it would have been more appropriate to offer her small doses of diamorphine (2.5mg) by intermittent subcutaneous injection. If on review, more than 1–2 doses were required a day, the equivalent amount could then be added into the syringe driver. If for whatever reason, it was felt preferable to give her a regular amount of diamorphine, in my view a starting dose of 5–10mg per day would have been more appropriate.

Generally, the doses of drugs to be given in a syringe driver should be prescribed as a fixed dose rather than as a range of doses. Any alterations in the dose are generally prescribed by a doctor, following a reassessment of the patient, number of additional as required doses used of analgesics/sedatives etc. A range is sometimes written in settings where doctors as less readily available on-site to change a prescription. If this is accepted practice within an organisation, it should ideally be covered by a policy.

If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

Dr Barton does not appear to have provided Mrs Devine with a good standard of clinical care as defined by the GMC (Good Medical Practice, General Medical Council, July 1998 pages 2–3).

Whether Mrs Devine was dying 'naturally' or not, the prescription of the fentanyl transdermal patch appears unjustified and/or excessive for Mrs Devine's needs. Further, the possibility that this action may have in itself led to a worsening of Mrs Devine's condition does not appear to have been considered or acted upon. Dr Barton's prescription of diamorphine also appears unjustified and/or excessive for Mrs Devine's needs. Dr Barton's use of chlorpromazine and midazolam appears justified on the grounds of Mrs Devine's agitation and confusion, but could be seen as excessive for her needs.

Although it is possible that Mrs Devine was dying 'naturally', it is also possible that her mental state had deteriorated in a temporary or reversible way and that she was not in her terminal phase. Mrs Devine's deterioration as documented in the medical notes appears to have been relatively rapid and mainly in her mental state. This contrasts with the gradual physical decline over days or weeks more typical of the terminal stage of many chronic illnesses. In this regard, there should have been a more thorough assessment

and clearer documentation of the possible contributing factors to Mrs Devine's deteriorating mental state. When there is such doubt, a more measured approach to the management of her confusion that did not render her unresponsive would have been particularly appropriate.

In patients with cancer, the use of diamorphine and midazolam when appropriate for the patients needs, does not appear to hasten the dying process. This has not been examined in patients dying from other illnesses to my knowledge, but one would have no reason to suppose it would be any different. The key issue is whether the use and the dose of diamorphine and midazolam are *appropriate* to the patients needs. In situations where they are inappropriate or excessive to the patients needs, it would be difficult to exclude with any certainty that they did not contribute more than minimally, negligibly or trivially to the death of the patient.

If it were that Mrs Devine had naturally entered the terminal phase of her life, at best, Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mrs Devine a peaceful death, albeit with what appears to be an inappropriate and excessive use of medication due to a lack of sufficient knowledge. However, in my opinion, based on the medical and nursing records, there is reasonable doubt that she had definitely entered her terminal stage. Given this doubt, at worst, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Devine by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Devine by unnecessarily exposing her to inappropriate and excessive doses of medications such as the fentanyl transdermal patch that could have resulted in a worsening of her agitation and confusion. Dr Barton's response to this was to further expose Mrs Devine to inappropriate and/or excessive doses of midazolam and diamorphine that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

9. LITERATURE/REFERENCES

British National Formulary 38 September 1999, Prescribing in Palliative Care, pages 11–14.

British National Formulary 38 September 1999, Prescribing for the Elderly, pages 15–16.

British National Formulary 47, March 2004.

Good Medical Practice, General Medical Council, July 1998, pages 2–3

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition 'Wessex Protocol' Salisbury Palliative Care Services May 1995, pages 3–4, 30–31.

Portsmouth Hospitals and Portsmouth Healthcare Compendium of Drug Therapy Guidelines, Adult Patients, 1998, Management of acute confusion in the elderly, pages 38–41.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: Code A Date: 16.12.04

APPENDICIES

Attachment A. Data sheet for Durogesic, fentanyl transdermal system, 1995.

Attachment B. Guidelines for use leaflet, 1994.

Attachment C. Guidelines for use laminated card, 1996.

C

PRESCRIBING DUROGESIC™▼

For patients previously on weak opioids

Start with a 25µg/h patch Titrate dosage for optimum pain relief

Short acting opioids can be added p.r.n.

For patients previously on strong opioids

Calculate the correct patch size using the conversion chart

It will take 6-12 hours to reach therapeutic plasma levels[12]

For this reason, continue to give the previously used strong opioid as indicated below

DOSE CONVERSION

24 HOURLY ORAL MORPHINE (mg)	<20	25-40	45-55	60-70	75-85	90-100	105-115	120-130	135-145	150-160	165-175
DUROGESIC PATCH STRENGTH (µg/h)	25	25	25	50	75	75	100	100	125	125	150

CONVERTING FROM

4 HOURLY ORAL MORPHINE	Continue to give 4 hourly morphine for the next 6-12 hours
10 mg	25µg/h
15 mg	25µg/h
20 mg	25µg/h
30 mg	50µg/h
40 mg	75µg/h
50 mg	75µg/h
60 mg	100µg/h
70 mg	100µg/h
80 mg	125µg/h
90 mg	125µg/h
100 mg	150µg/h

YOU SHOULD ENCOURAGE PATIENTS TO USE AS MUCH RESCUE ANALGESIA AS THEY NEED[1]

IF PATIENTS ARE NEEDING TO USE A LOT OF RESCUE ANALGESIA IN THE FIRST 24 HOURS THIS MAY BE A SIGN THAT THEY ARE A SLOW ABSORBER OF FENTANYL[1]

IF THEY ARE STILL NEEDING TO TAKE SEVERAL DOSES OF RESCUE ANALGESIA THE 2ND OR 3RD DAY THIS SUGGESTS THAT THE DOSE FOR DUROGESIC IS NOT STRONG ENOUGH[1]

How to continue with Durogesic

Review analgesic requirements after 72 hours

Titrate up in 25ug/h intervals* if necessary

When subsequent patches are started there is no need to wait 6-12 hours for analgesic levels

*Refer to the data sheet before prescribing

ALWAYS ENSURE THAT SHORT-ACTING MORPHINE IS AVAILABLE P.R.N. FOR BREAKTHROUGH PAIN

C

Durogesic™

FENTANYL TRANSDERMAL SYSTEM

1. Gourlay GK *et al.* Anesth Analg 1988: 67: 329-337. 2. Broome IJ, Wright BM, Bower S, *Anaesthesia 1995; 50: 300-3.* 3. *Brooks D. The National Association of Fundholding Practices* Annual Official Yearbook 1996.

ABBREVIATED PRESCRIBING INFORMATION – DUROGESIC ™ (fentanyl transdermal system) Please read Data Sheet before prescribing Presentation: Durogesic is a transparent self adhesive patch containing fentanyl and is available in four strengths (see below). Uses: Management of *chronic intractable pain due to cancer. Dosage: Adults: Initial dose;* In strong opioid naive patients the initial dose should be 25mcg/h patch. In opioid tolerant patients the dose should be converted from the previous 24 hour opioid requirement (see Data Sheet). *Titration and maintenance:* The patches should be changed every three days and titrated to analgesic efficacy. The new patch should be applied to a *different site. Elderly:* Serum levels tend to be higher. Elderly, cachectic or debilitated patients should be *observed for signs of toxicity and the dose reduced if necessary. Children:* Not recommended. Contraindications: Treatment of acute pain. Hypersensitivity to fentanyl or the silicone medical adhesive. Warnings and Precautions: Patients with serious adverse events should be monitored for up to 24 hours after patch removal as concentrations decline gradually. Durogesic should be kept out of reach of children before and after use. See pack insert for safe disposal instructions. As with all potent *opioids, respiratory depression may occur and is dose related. Care should be taken in patients with chronic obstructive or other pulmonary disease. Tolerance and dependence may occur but iatrogenic* addiction is rare. Use with care in patients with raised intracranial pressure, brain tumours and brady-arrhythmias. Patients with hepatic and renal disease should be observed carefully for toxicity and the dose reduced if necessary. Fentanyl metabolites are inactive. Patients who develop fever should be *monitored for opioid side effects since significant increases in body temperature can potentially* increase fentanyl delivery rate. Exposing the application site to direct external heat sources should be avoided. Durogesic may affect the ability to drive or use machinery. Pregnancy and lactation: Safety has not been established in pregnancy. Durogesic should not be used in women who are breast feeding. Interactions: Use of concomitant CNS depressants including alcohol requires special care and *observation as the effects may be additive. Side Effects: As with other potent opioids, the most serious* side effect is hypoventilation. Other side effects include nausea, vomiting, constipation, hypotension, somnolence, confusion, hallucinations, euphoria, pruritus and urinary retention. Local skin reactions such as rash, erythema and itching have occasionally been reported. These usually resolve within 24 hours of patch removal. Overdosage: The most serious side effect is respiratory depression. Treatment should include removing the patch and physically and verbally stimulating the patient. A patent airway should be maintained and respiration assisted if necessary. An opioid antagonist such as naloxone can be administered and repeated doses or continuous infusion may be required. Severe or persistent hypotension may be managed using parenteral fluids. Pharmaceutical Precautions: Store below 25°C. Legal Category: CD (Sch 2) POM. Pack Sizes, Product Licence/Authorisation Numbers and Cost: *All strengths are supplied in packs of 5.* Durogesic 25 (delivers approximately 25mcg/h of fentanyl): PL/0242/0192; £28.97 – PA 748/2/1; IR£28.95. Durogesic 50 (delivers approximately 50mcg/h): PL/0242/0193; £54.11 – PA 748/2/2; IR£54.08. Durogesic 75 (delivers approximately 75mcg/h): PL/0242/0194; £75.43 – PA 748/2/3; IR£75.38. Durogesic 100 (delivers approximately 100mcg/h): PL/0242/0195; £92.97 – PA 748/2/4; IR£92.92. Product Licence and Authorisation holder: Janssen-Cilag Ltd, Saunderton, High Wycombe, Bucks HP14 4HJ. Further Information: available from Janssen-Cilag Ltd, Saunderton, High Wycombe, Bucks HP14 4HJ. Date of Preparation: November 1996.

JANSSEN-CILAG ltd

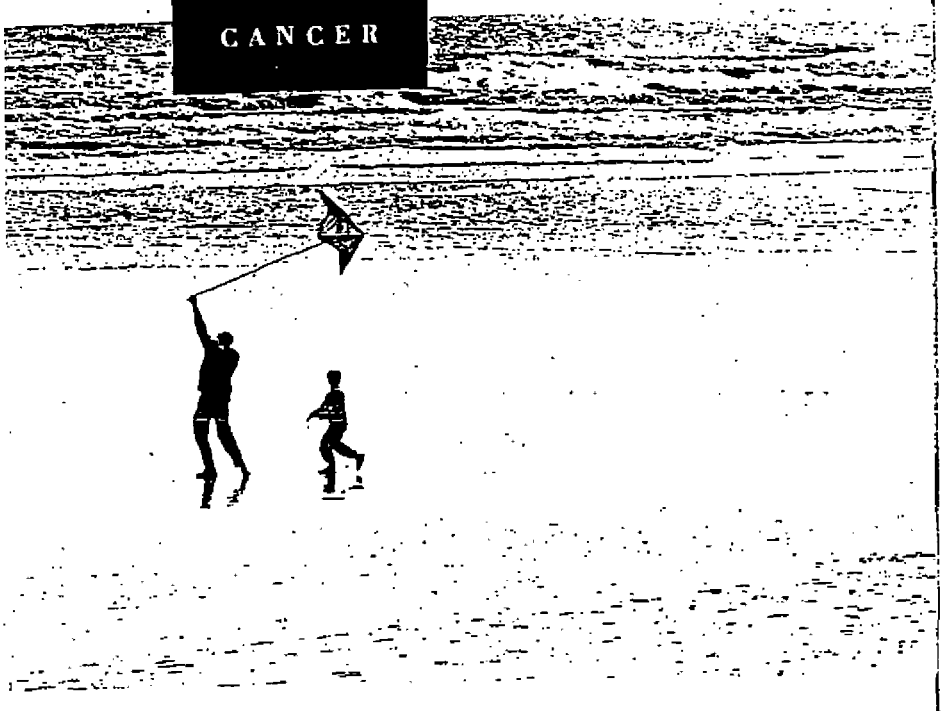
For technical information on Durogesic, please call the linkline free on

LINKLINE 0800 716 973

600966

B

LIVING LIFE WITH CANCER



GUIDELINES

FOR USE

Durogesic™

FENTANYL TRANSDERMAL SYSTEM

For prescribing information please see reverse.

A NEW FOUND FREEDOM IN CANCER PAIN

CONTINUOUS CONTROL OF CANCER PAIN

- Analgesic levels can be expected 6-12 hours following initial application[1,2]
- Three days' pain relief from each patch
- Plasma levels remain steady after patch changes[3]

FOLLOWING A SWITCH FROM MORPHINE TO DUROGESIC:

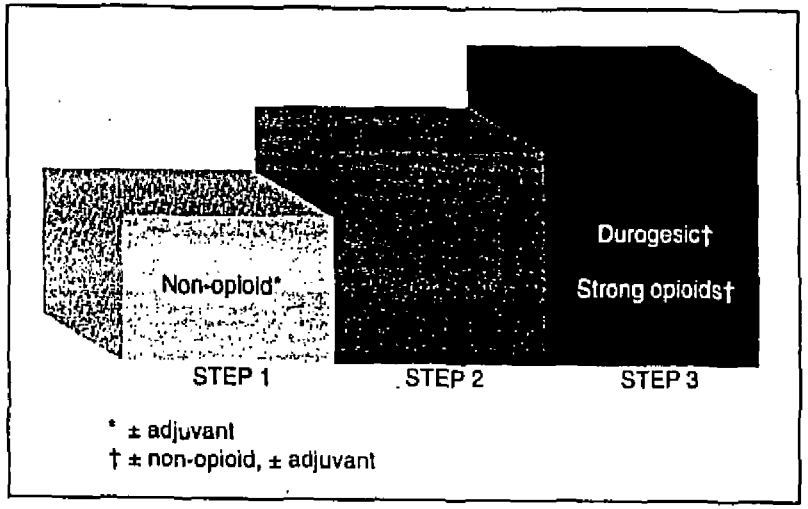
- Improved quality of pain control[4]
- Improved quality of sleep[5]
- *Improved morning alertness*[5]

AN ESTABLISHED ANALGESIC

- Over 20 million patient days' experience in the USA[6]
- Used successfully in individual patients for up to 1 year[7]

WHEN TO PRESCRIBE DUROGESIC

THE STEP-WISE APPROACH



Durogesic™
FENTANYL TRANSDERMAL SYSTEM

DOSE CONVERSION FROM ORAL MORPHINE TO DUROGESIC

4 HOURLY MORPHINE DOSE	DUROGESIC PATCH SIZE
5-20mg	25µg/h
25-35mg	50µg/h
40-50mg	75µg/h
55-65mg	100µg/h

LINKLINE

FOR TECHNICAL INFORMATION ON DUROGESIC PLEASE CALL THE MEDICAL INFORMATION DEPT. FREE ON 0800 716 973.

Durogesic™

FENTANYL TRANSDERMAL SYSTEM

Prescribing Information

DUROGESIC (fentanyl transdermal system)

Presentation Durogesic is a transparent self adhesive patch containing fentanyl and is available in four strengths (see below).

Uses Management of chronic intractable pain due to cancer.

Dosage *Adults: Initial dose;* In strong opioid naive patients the initial dose should be 25 mcg/h patch. In opioid tolerant patients the dose should be converted *from the previous 24 hour opioid requirement* (see data sheet).

Titration and maintenance; The patches should be changed every three days and titrated to analgesic efficacy. The new patch should be applied to a different site.

Elderly; Serum levels tend to be higher. Elderly, cachectic or debilitated patients should be observed for signs of toxicity and the dose reduced if necessary.

Children: Not recommended.

Contraindications Treatment of acute pain. Hypersensitivity to fentanyl or the silicone medical adhesive.

Warnings and precautions Patients with serious adverse events should be monitored for up to 24 hours after patch removal as concentrations decline gradually. Durogesic should be kept out of reach of children before and after use. *See pack insert for safe disposal instructions.*

As with all potent opioids, respiratory depression may occur and is dose related. Care should be taken in patients with chronic obstructive or other pulmonary disease.

Tolerance and dependence may occur but iatrogenic addiction is rare. Use with care in *patients with* raised intracranial pressure, brain tumours and brady-arrhythmias. Patients with hepatic and renal *disease should* be observed carefully for toxicity and the dose reduced if necessary. Fentanyl metabolites are inactive. Patients who develop fever should be monitored for opioid side effects since significant increases in body temperature can potentially increase fentanyl delivery rate. Exposing the application site to direct external *heat sources should* be avoided.

Durogesic may affect the ability to drive or use machinery.

Pregnancy and lactation; Safety has not been established in pregnancy. Durogesic should not be used in women who are breast feeding.

Interactions; Use of concomitant CNS depressants including alcohol requires special care and observation as *the effects may be additive.*

Side effects: As with other potent opioids, the most serious side effect is hypoventilation. Other side effects include nausea, vomiting, constipation, hypotension, somnolence, confusion, hallucinations, euphoria, pruritus and urinary retention.

Local skin reactions such as rash, erythema and itching have occasionally been reported. These usually resolve within 24 hours of patch removal.

Overdosage: The most serious effect is respiratory depression. Treatment should include removing the patch and physically and verbally stimulating the patient. A patent airway should be maintained and respiration assisted if necessary. An opioid antagonist such as *naloxone can be administered* and repeated doses or continuous infusion may be required. Severe or persistent hypotension may be managed using parenteral fluids.

Pharmaceutical Precautions Store below 25°C.

Legal Category CD (Sch 2) POM

Pack Sizes, Product Licence Numbers and Basic NHS Cost *All strengths are supplied* in packs of 5. DUROGESIC 25, £28.97, PL 0242/0192 delivers approximately 25 mcg/h of fentanyl. DUROGESIC 50, £54.11, PL 0242/0193 delivers approximately 50 mcg/h. DUROGESIC 75, £75.43, PL 0242/0194 delivers approximately 75 mcg/h. DUROGESIC 100, £92.97, PL 0242/0195 delivers approximately 100 mcg/h.

Product Licence Holder Janssen Pharmaceutical Limited, Grove, Wantage, Oxon OX12 0DQ.

References 1. Data on file, Janssen Pharmaceutical Limited. (Reilly, 1993). N91170 [Abstracts: 7th World Congress on Pain. Reilly CS, Broome IJ, Wright B, Bower S: Abstract 841]. 2. Gourlay GK, Kowalski SR, Plummer JL, Cousins MJ, Armstrong PJ. Anesth Analg 1988; 67: 329-337. 3. Data on file, Janssen Pharmaceutical Limited. (Portenoy, 1993) N73867 [*Portenoy RK, et al. Anaesthesiology* 78: 36-43 1993]. 4. Data on file, Janssen Pharmaceutical Limited. (Payne, 1989). N73859. 5. The TTS *Fentanyl Multi-Centre Study Group.* J. Drug Dev 1994; 6 (3): 93-97. 6. Data on file, Janssen Pharmaceutical Limited. (1994). [TAC 4/94]. 7. Simmonds MA, Richenbacher J. J. Pain Symptom Manage 1992; 7: S36-39.

Date of preparation: September 1994

JANSSEN PHARMACEUTICAL LTD

DATA SHEET

Durogesic™
FENTANYL TRANSDERMAL SYSTEM

Presentation

DUROGESIC is a transdermal drug delivery system comprising a transparent, self-adhesive patch containing a drug reservoir of fentanyl. Each system is designed to release fentanyl into the systemic circulation over a period of 72 hours. There are four different strengths:

DUROGESIC 25, with a delivery rate of approximately 25 micrograms/hour fentanyl (active surface area 10cm², fentanyl content 2.5mg, and printed "DUROGESIC 25µg fentanyl/h" in pink)

DUROGESIC 50, with a delivery rate of approximately 50 micrograms/hour fentanyl (active surface area 20cm², fentanyl content 5mg, and printed "DUROGESIC 50µg fentanyl/h" in green)

DUROGESIC 75, with a delivery rate of approximately 75 micrograms/hour fentanyl (active surface area 30cm², fentanyl content 7.5mg, and printed "DUROGESIC 75µg fentanyl/h" in blue)

DUROGESIC 100, with a delivery rate of approximately 100 micrograms/hour fentanyl (active surface area 40cm², fentanyl content 10mg, and printed "DUROGESIC 100µg fentanyl/h" in grey)

The drug reservoir also contains Ethanol BP, Hydroxyethylcellulose Ph.Eur and Purified Water Ph Eur. The contact adhesive is silicone medical adhesive.

Uses

Indications:
DUROGESIC is indicated in the management of chronic intractable pain due to cancer.

Properties:
Fentanyl is an opioid analgesic with a high affinity for the µ-opioid receptor.

DUROGESIC provides continuous systemic delivery of fentanyl over the 72 hour administration period. After the first DUROGESIC application, serum fentanyl concentrations increase gradually, generally levelling off

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between 12 and 24 hours and remaining relatively constant for the remainder of the 72 hour application period. Peak serum levels of fentanyl generally occur between 24 and 72 hours after the first application. The serum fentanyl concentrations attained are proportional to the DUROGESIC patch size. For all practical purposes by the second 72 hour application, a steady state serum concentration is reached and is maintained during subsequent applications of a patch of the same size.

After DUROGESIC is removed, serum fentanyl concentrations decline gradually, falling approximately 50% in 17 (range 13-22) hours. Continued absorption of fentanyl from the skin accounts for a slower disappearance of the drug from the serum than is seen after an iv infusion. Fentanyl is metabolised primarily in the liver. Around 75% of fentanyl is excreted into the urine, mostly as metabolites, with less than 10% as unchanged drug. About 9% of the dose is recovered in the faeces, primarily as metabolites. The major metabolite, norfentanyl, is inactive. Mean values for unbound fractions of fentanyl in plasma are estimated to be between 13 and 21%.

Dosage and Administration

DUROGESIC should be applied to non-irritated and non-irradiated skin on a flat surface of the torso or upper arm. A non-hairy area should be selected. If the site of DUROGESIC application requires to be cleansed prior to application of the system, this should be done with water. Soaps, oils, lotions or any other agent that might irritate the skin or alter its characteristics should not be used. The skin should be completely dry before the system is applied.

DUROGESIC should be applied immediately after removal from the sealed pouch. Following removal of the protective layer, the transdermal system should be pressed firmly in place with the palm of the hand for approximately 30 seconds, making sure the contact is complete, especially around the edges.

DUROGESIC should be worn continuously for 72 hours. A new system should then be applied to a different skin site after removal of the previous transdermal system. Several days should elapse before a new patch is applied to the same area of skin.

Adults:

Initial dose selection

The initial DUROGESIC dose should be based on the patient's opioid history, including the degree of opioid tolerance, if any, as well as on the current general condition and medical status of the patient.

In strong opioid-naive patients the lowest DUROGESIC dose, 25 micrograms/h, should be used as the initial dose.

In opioid-tolerant patients the initial dose of DUROGESIC should be based on the previous 24 hour opioid analgesic requirement. A recommended conversion scheme from oral morphine to DUROGESIC is given below:

Oral 24 hour morphine (mg/day)	DUROGESIC (micrograms/h)
<135	25
135-224	50
225-314	75
315-404	100
405-494	125
495-584	150
585-674	175
675-764	200
765-854	225
855-944	250
945-1034	275
1035-1124	300

For both strong opioid-naive and opioid-tolerant patients, the initial evaluation of the analgesic effect of DUROGESIC should not be made before the system has been worn for 24 hours due to the gradual increase in serum fentanyl concentrations up to this time. Previous analgesic therapy should therefore be phased out gradually from the time of the first patch application until efficacy with DUROGESIC is attained.

Dose titration and maintenance therapy

The DUROGESIC patch should be replaced every 72 hours. The dose should be titrated individually until analgesic efficacy is attained. If analgesia is insufficient at the end of the initial application period the dose may be increased. Dose adjustment, when necessary, should normally be performed in 25 micrograms/h increments, although the supplementary analgesic requirements (oral morphine 90mg/day ≈ DUROGESIC 25 micrograms/h) and pain status of the patient should be taken into account. More than one DUROGESIC system may be used for doses greater than 100 micrograms/h. Patients may require periodic supplemental doses of a short-acting analgesic for "breakthrough" pain. Additional or alternative methods of analgesia should be considered when the DUROGESIC dose exceeds 300 micrograms/h.

Discontinuation of DUROGESIC

If discontinuation of DUROGESIC is necessary, any replacement with other opioids should be gradual, starting at a low dose and increasing slowly. This is because fentanyl levels fall gradually after DUROGESIC is removed; it may take 17 hours or more for the fentanyl serum concentration to decrease by 50%. As a general rule, the discontinuation of opioid analgesia should be gradual.

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Use in elderly patients
Data from intravenous studies with fentanyl suggest that elderly patients may have reduced clearance, a prolonged half-life and they may be more sensitive to the drug than younger patients. Studies of DUROGESIC in elderly patients demonstrated fentanyl pharmacokinetics which did not differ significantly from young patients although serum concentrations tended to be higher. Elderly, cachectic, or debilitated patients should be observed carefully for signs of fentanyl toxicity and the dose reduced if necessary.

Use in children
The safety and efficacy of DUROGESIC in children has not been established and is therefore not recommended.

Contraindications, Warnings, etc.

Contraindications:
DUROGESIC is contraindicated in patients with known hypersensitivity to fentanyl or to the adhesive in the system.

DUROGESIC is a sustained-release preparation indicated for the treatment of chronic intractable cancer pain and is contraindicated in acute pain because of the lack of opportunity for dosage titration in the short term and the resultant possibility of significant respiratory depression.

Warnings and Precautions:
Patients who have experienced serious adverse events should be monitored for up to 24 hours after DUROGESIC removal since serum fentanyl concentrations decline gradually and are reduced by about 50% in approximately 17 (range 13-22) hours.

DUROGESIC should be kept out of the reach of children at all times before and after use.

Respiratory depression
As with all potent opioids, some patients may experience significant respiratory depression with DUROGESIC; patients must be observed for these effects. Respiratory depression may persist beyond the removal of the DUROGESIC system. The incidence of respiratory depression increases as the DUROGESIC dose is increased. See also 'Overdosage' concerning respiratory depression. CNS active drugs may increase the respiratory depression (see 'Interactions').

Chronic pulmonary disease
Fentanyl, like other opioids, may have more severe adverse effects in patients with chronic obstructive or other pulmonary disease. In such patients, they may decrease respiratory drive and increase airway resistance.

Drug dependence
Tolerance and physical and psychological dependence may develop upon repeated administration of opioids such as fentanyl. Iatrogenic addiction following opioid administration is rare.

Increased intracranial pressure
DUROGESIC should be used with caution in patients who may be particularly susceptible to the intracranial effects of CO_2 retention such as those with evidence of increased intracranial pressure, impaired consciousness or coma. DUROGESIC should be used with caution in patients with brain tumours.

Cardiac disease
Fentanyl may produce bradycardia and DUROGESIC should therefore be administered with caution to patients with bradyarrhythmias.

Hepatic disease
Because fentanyl is metabolised to inactive metabolites in the liver, hepatic disease might delay its elimination. In patients with hepatic cirrhosis, the pharmacokinetics of a single application of DUROGESIC were not altered although serum concentrations tended to be higher in these patients. Patients with hepatic impairment should be observed carefully for signs of fentanyl toxicity and the dose of DUROGESIC reduced if necessary.

Renal disease
Less than 10% of fentanyl is excreted unchanged by the kidney and, unlike morphine, there are no known active metabolites eliminated by the kidney. Data obtained with intravenous fentanyl in patients with renal failure suggest that the volume of distribution of fentanyl may be changed by dialysis. This may affect serum concentrations. If patients with renal impairment receive DUROGESIC, they should be observed carefully for signs of fentanyl toxicity and the dose reduced if necessary.

Patients with fever/external heat
Patients who develop fever should be monitored for opioid side effects since significant increases in body temperature can potentially increase fentanyl delivery rate.

Patients should also be advised to avoid exposing the Durogesic application site to direct external heat sources such as heating pads, hot water bottles, electric blankets, heat lamps, saunas or hot whirlpool spa baths while wearing the system, since there is potential for temperature dependent increases in release of fentanyl from the system.

Pregnancy and lactation
The safety of fentanyl in pregnancy has not been established. DUROGESIC should not be used in women of child-bearing potential without adequate contraception unless in the judgement of the doctor the potential benefits outweigh the possible hazards.

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Fentanyl is excreted into breast milk hence DUROGESIC should not be used by women who are breast-feeding.

Effects on driving and operating machinery
DUROGESIC may impair the mental or physical ability required to perform potentially hazardous tasks such as driving or operating machinery.

Drug interactions
The concomitant use of other CNS depressants, including opioids, anxiolytics, hypnotics, general anaesthetics, antipsychotics, skeletal muscle relaxants, sedating antihistamines and alcoholic beverages may produce additive depressant effects; hypoventilation, hypotension and profound sedation or coma may occur. Therefore, the use of concomitant CNS active drugs requires special care and observation.

Patch disposal
Used patches may contain significant residues of active substance. After removal, therefore, used patches should be folded firmly in half, adhesive side inwards, so that the release membrane is not exposed, and then discarded safely and out of the reach of children according to the instructions in the pack.

Side effects
The most serious adverse reaction, as with all potent opioids, is hypoventilation. Other opioid-related adverse reactions include: nausea; vomiting; constipation; hypotension; somnolence; confusion; hallucinations; euphoria; pruritus and urinary retention.

Local skin reactions such as rash, erythema and itching have occasionally been reported. These reactions usually resolve within 24 hours of removal of the patch.

Overdosage
Symptoms:
The symptoms of fentanyl overdosage are an extension of its pharmacological actions, the most serious effect being respiratory depression.

Treatment:
For management of respiratory depression, immediate countermeasures include removing DUROGESIC and physically or verbally stimulating the patient. These actions can be followed by administration of a specific opioid antagonist such as naloxone. The interval between iv opioid antagonist doses should be carefully chosen and repeated administration or a continuous infusion of naloxone may be necessary because of continued absorption of fentanyl from the skin after patch removal, which may result in prolonged respiratory depression. Reversal of the narcotic effect may result in acute onset of pain and release of catecholamines.

A patent airway should be established and maintained. An oropharyngeal airway or endotracheal tube and oxygen should be administered and respiration assisted or controlled, as appropriate. Adequate body temperature and fluid intake should be maintained.

If severe or persistent hypotension occurs, hypovolaemia should be considered, and the condition should be managed with appropriate parenteral fluid therapy.

Pharmaceutical Precautions
Store below 25°C.

Legal Category
CD (Schedule 2) POM

Package Quantities
DUROGESIC 25, 50, 75, 100:
Cartons of 5 patches individually packaged in pouches

Further Information
None.

Product Licence Number

DUROGESIC 25	PL 0242/0192
DUROGESIC 50	PL 0242/0193
DUROGESIC 75	PL 0242/0194
DUROGESIC 100	PL 0242/0195

Product Licence Holder

Janssen-Cilag Ltd

Saunderton, High Wycombe, Bucks HP14 4HJ

Date of preparation: January 1995

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SUMMARY OF CONCLUSIONS

Mrs Elsie Devine was an 89-year-old lady admitted to the Queen Alexandra Hospital following a crisis at home on the 21st October 1999. She has symptoms of confusion and aggression on a background of known chronic renal failure IgA Paraproteinaemia, Hypothyroidism and a dementing illness. There was little improvement in the Queen Alexandra Hospital and she was transferred to the Gosport War Memorial Hospital on 21st October for continuing care.

In the Gosport War Memorial Hospital she deteriorates over the first two weeks in November and by 19th November is terminally ill. She receives palliation including subcutaneous Diamorphine and Midazolam and dies 21st November 1999.

The expert opinion is:

> Mrs Elsie Devine presents an example of the most complex and challenging problems in geriatric medicine. This included progressive medical and physical problems causing major clinical and behavioural management problems to all the care staff she comes into contact with.
>
> The major problem in deciding whether this lady's care was sub- optimal is the lack of documentation. Good medical practice (GMC, 2001) states that "good clinical care must included an adequate assessment of the patient's condition, based on the history and symptoms and, if necessary, an appropriate examination"... "in providing care you must, keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed". The major gaps in the written notes, as documented in my report, represent poor clinical practice to the standards set by the General Medical Council. However, by itself it does not prove that the care actually received by Mrs Devine was sub-optimal, negligent or criminally culpable.
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> In my view the drug management at Gosport was sub-optimal. There was no apparent justification for the Diamorphine to be written up prn on admission to Gosport. The logic for the prescription of Fentanyl is not explained, there was a three hour overlap between the prescription for the subcutaneous Diamorphine and Midazolam and the removal of the Fentanyl patch, the starting doses of both Midazolam and Diamorphine were higher than conventional guidance. The effect of higher than standard dosage of Diamorphine and Midazolam may have shortened her life by a short period of time. This would have been no more than hours to days. However, she was already terminally ill and appeared to receive good palliation of her symptoms. While her care was sub-optimal I cannot prove it negligent or criminally culpable.

1. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be sub-optimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

2. ISSUES

2.1. Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day.

2.2. If the care is found to be suboptimal what treatment should normally have been proffered in this case.

2.3. If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups.

3. CURRICULUM VITAE

Code A

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Version 2 of complete report 4th January 2005 – Elsie Devine

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4. DOCUMENTATION

This Report is based on the following documents:

[1] *Full paper set of medical records of Elsie Devine.*

[2] *Full set of medical records of Elsie Devine on CD-ROM.*

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Hampshire Constabulary Summary of Care of Elsie Devine.

[6] Commission for Health Improvement Investigation Report on Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital (July 2002).

[7] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

5 CHRONOLOGY/CASE ABSTRACT. (The numbers in brackets refer to the page of evidence)

5.1. In March 1998 (120) she was seen in a geriatric outpatient department with cellulitis, mild hypothyroidism, mild CCF, haemoglobin of 13 (317) and a creatinine of 90 (337).

5.2. In December 1998 she was seen in an orthopaedic clinic (102) and was found to be clinically fit for a knee replacement.

5.3. In March 1999 her haemoglobin was 12.8 (311) and her creatinine in February was 143 (325).

5.4. In April she was seen by a consultant geriatrician where she was found to be "moderately frail" although also noted to be "bright mentally" (84). Her weight was 58.8 kgs (144), her haemoglobin 11.5 (307) and a creatinine 151 (84).

5.5. She was referred to a renal physician and was also seen by a haematologist between June 1999 and September 1999. In June 1999 (60) her creatinine was 160, her haemoglobin 11.2 (297), her weight was 55.4 kgs (151). In July 1991 (50) the haematologist found 6% plasma cells and an albumen of 22 (52), immune paresis (70) and suggested a watch and wait approach. In September 1999 her renal physician noted that she had chronic renal failure with small kidneys and nephrotic syndrome with marked oedema. It was thought likely that this was on a background of progressive glumerulonenephritis (60) and she had an incidental IgA paraproteinaemia. Her Creatinine was 192 and her haemoglobin 10.5 (295).

5.6. On 9th October, she was admitted to the Queen Alexandra Hospital following a social crisis at home as Mrs Devine lived with Code A

Code A

Code A There was a story of confusion and aggression, which was suggested, had become worse prior to her admission. The clinical diagnosis was of a possible urinary tract infection, with an underlying dementing illness. However, Mrs Devine was never documented to be pyrexial (256) and the mid-stream urine sample had no growth (367). There is no full blood count available in the notes for the 9th October. The admission clerking, which would be expected to be available, either before page 31 or around pages 157 and 158 also appears to be missing from the notes.

5.7. On the 12th October (31) she is noted to be distressed and agitated and undergoes a CT scan of her head, which shows involutional changes only (24). She receives a single dose of Haloperidol (160) (267). On the 13th October her haemoglobin is 10.8 with a white cell count of 14.5 (293).

5.8. On the 15th October she is noted to be wandering (166) on the same day she is assessed by Dr Taylor, Clinical Assistant for the Mental Health Team who noted the history of confusion and disorientation and a 10 months history of mental deterioration (28). She was confused and disorientated but no longer aggressive. She was now mostly co-operative and friendly but tended to get lost, he also noted she was deaf. Her Mini Mental Test Score was 9/30, indicating moderate to severe dementia and he suggested that she would need ongoing institutional care. On the 18th October her creatinine was 201 (171).

5.9. On 20th October, there is a letter of an assessment from a locum consultant geriatrician (20). Who notes that she can stand, may have had a urinary tract infection on top of her chronic renal failure and that she was quite alert.

5.10. She is then transferred to the Gosport War Memorial Hospital with a discharge summary (24) that states she has chronic renal failure, paraproteinaemia, multiple infarct disease and an Abbreviated Mental Test Score of 3/10.

5.11. On 21st October she is received to the Gosport War Memorial Hospital and is transferred for "continuing care" (154). Her Barthel dependency is noted to be 8 and her Mini Mental Score is 9/30. Dr Barton incorrectly writes that she has 'Myeloma' (154) in the notes.

5.12. On 25th October she is mobile unaided, washes with supervision, remains confused.

5.13. On the 1st November she is quite confused (155) and is wandering. On the 9th November investigations show haemoglobin of 9.9, white cell count of 12.6 (289) and a creatinine of 200 (349). An M.S.U reported on 11th November (363) shows no growth.

5.14. 15th November she is noted to be very aggressive, very restless (155) and "is on treatment for a urinary tract infection". However, it is noted that the MSU from 11th November showed no growth. The medical note for the 15th is unsigned, I presume to be Dr Reid.

5.15. 18th November (156) she has rapidly deteriorated, become more restless and aggressive and is refusing medication. She is seen by the mental

health team who note that in their view that there was no new physical problem ongoing and put her on the waiting list for Mulberry Ward. Creatinine on 16th November is 360 and a potassium 5.6 (349).

5.16. 19th November there has been marked deterioration over night. The notes state "confused, aggressive, Creatinine 360, Fentanyl patch commences yesterday, today further deterioration in general condition needs subcut analgesia with Midazolam. Son seen and aware of condition and diagnosis, hence make comfortable. I am happy for nursing staff to confirm death" (156). The nursing notes (222) confirm marked deterioration over last 24 hours. "Chlorpromazine given IM. 9.25. Subcut syringe commenced Diamorphine 40 mgs and Midazolam 40 mgs, Fentanyl patch removed. Son seen by Dr Barton at 13.00 and situation explained to him. He will contact his sister regarding and inform her of Elsie's poor condition. 20.00 daughter visited and seen by Dr Barton. Nocte: peaceful night syringe driver recharged at 07.25."

5.17. 20th November the nursing notes (223) state, "condition remains poor, family have visited and are aware of poorly condition. Seen by Pastor Mary. Nocte: peaceful night extremities remain oedematous, skin mottling, syringe driver changed at 07.15. Dose of Diamorphine 40 mgs. Midazolam 40."

5.18. 21st November. Nursing notes (223), "condition continues to deteriorate slowly. Asked to see at 20.30 hours patient died peacefully"

5.19. Barthel scores are recorded on 21st October 8; 31st October 16, 17th November 10; 14th November 10; 21st November 1 (202) Her weight on 21st October was 52.5 kgs (200).

Drug Chart analysis: 1 dose of Haloperidol was given in the Queen Elizabeth hospital on the 13th October (269). Drug chart at Gosport showed a single dose of Chlorpromazine given at 08.30 on 19th November (277) confirming the nurses' cardex.

The patient had received regular doses of Thioridazine (often given for confused behaviour) from the 11th November up unto 17th November (277). A small dose of prn 2.5 – 5 mgs Diamorphine had been written up on admission to Gosport but had never been prescribed. Hyoscine had also been written up and not prescribed.

Trimethoprim (for a presumed urinary tract infection) is prescribed on 11th November (277 & 276) and continued until 15th November. A 25-microgram patch per hour of Fentanyl is written up on the 18th November and a single patch is prescribed at 9.15 on 18th November (276). The evidence from the nursing cardex is that the Fentanyl patch is removed

on the morning of the 19th (223) at 12.30 (275) 3 hours after the time the subcutaneous infusion was started.

A new drug chart is written up on 19th November for Diamorphine 40 – 80 mgs subcut in 24 hours and Midazolam 20 – 80 mgs subcut in 24 hours. The drug card (279) confirms that 40 mgs is put into the syringe driver at 09.25 19th, 7.35 on 20th and 7.15 on 21st and 40 mgs of Midazolam at each of those times. All other drugs had been stopped.

6 TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

6.1. This section will consider whether there were any actions so serious that they might amount to gross negligence or any unlawful acts, or deliberate unlawful killing in the care of Elsie Devine. Also whether there were any actions or omissions by the medical team, nursing staff or attendant GP's that contributed to the demise of Mrs Devine, in particular, whether beyond reasonable doubt, the actions or omissions more than minimally, negligibly or trivially contributed to death.

6.2. In particular I will discuss:
a) whether it was appropriate to decide on 19th November that Mrs Devine was terminally ill and if so whether symptomatic treatment was appropriate
and
b) whether the treatment that was provided was then appropriate.

6.3. Mrs Devine had progressive mental and physical deterioration starting in January 1999. Before that she had had relatively minor medical problems, a normal haemoglobin and creatinine and was put on a waiting list for a knee replacement at the end of 1998. Orthopaedic surgeons do not generally list people for knee replacements if they look or are significantly frail. Such patients tend to make poor functional recoveries.

6.4. Mrs Devine's physical deterioration can be marked by her slowly falling haemoglobin from 13 in 1998 (317) to 9.9 (289) in November 1999. Her albumin also falls and is documented at 22 in July 1999 (52) then extremely low at 18 (349) on admission to Gosport. At the same time her creatinine rises over the course of the year from 90 in 1998 to 160 in June 1999 and around 200 on admission to the Queen Alexandra Hospital in October 1999. The physicians, including the renal physician and the haematologist that she saw, all conclude this was a progressive problem with no easily treatable or remedial cause. The small kidneys shown on ultrasound usually suggest irreversible kidney pathology. I

would agree with that assessment.

6.5. The history taken by the mental health team from her daughter, also describe mental deterioration and increasing confusion over the course of the year. Such confusion is often missed in hospital appointments, although the comment that she did not bring her drugs or know what drugs she was taking in September 1999 (40) is a marker of probable mental impairment. The notes fail to come to any definitive diagnosis as to whether this is Alzheimer's disease or vascular dementia. This is difficult and cannot be criticised. It is probably more likely to be vascular dementia on its basis of its rapid progression, and that she had another systematic illness going on identified by the renal physician as probable glomerulonenephritis.

6.6. When admitted to the Queen Alexandra Hospital with significant behavioural problems the original working assumption was that this was an acute event, caused by a probable underlying infection. However, no infection was ever demonstrated on the investigations ordered, and no pyrexia was identified, although the admission notes are missing. It is likely that her behaviour had gradually been deteriorating, the crisis then occurred with the social crisis in her family. Admitting patients acutely to hospital will often exacerbate confusion in an already underlying dementing illness.

6.7. The natural history of most dementia's is of some fluctuation on a downward course, both in terms of symptoms and progression of the underlying disease. When seen by the mental health team on 15th October (28), though her behaviour was not seriously disturbed at that time, they documented a mini-mental state examination of 9/30 indicating moderate to severe underlying dementia. The mental decline had been rapidly progressive over the same year, as had her physical decline. Although she received Haloperidol at Queen Alexandra, and Thioridazine at Gosport I think it is unlikely that any therapeutic intervention significantly altered the progression of either her mental or her physical deterioration.

6.8. On admission to Gosport Dr Barton writes in the notes that the patient has Myeloma (a malignant disease) rather than the Paraproteinaemia (a pre-malignant condition) that has actually been diagnosed. She may have mistakenly believed that she had a progressive cancer as well as her dementia and renal failure. This (not uncommon mistake in non-specialists) might have influenced the management of care.

When transferred to the Gosport Hospital on 21st October, probably to await nursing home placement, she had a number of markers suggesting a very high risk of in-hospital death. She had been in

hospital over two weeks, the longer you are in hospital the more likely you are to die in hospital. She had a possibility of delirium on top of a rapidly progressive dementing illness, again a marker of high in-hospital mortality and finally, she had an extremely low albumin of 18, probably one of the strongest markers of a poor outcome. Serum albumin is an indirect marker of nutritional status, in particular a marker of protein metabolism. A low albumin and poor nutritional status makes a patient highly susceptible to infection, pressure sores and an inability to cope with the physiological stresses.

6.9. On 25th October she appears to be stable in the ward environment at Gosport, however, by the 1st November there has been a deterioration and she is noted to have become quite confused and is wandering again.

6.10. On admission under the routine drugs that were prescribed, it is noted that both Hyoscine and a small dose of Diamorphine were written up prn. It is often common practice in hospitals where there are non-resident staff or great shortage of medical staff to try and write up all possible drugs that might need to be prescribed as prn drugs, so that if a crisis occurs a needed drug can be prescribed by a nurse without a doctor having to immediately attend. In my experience it is unusual though for a patient who has no known causes of severe pain, nor had an underlying cardiac condition to write up Diamorphine prn and indeed, Hyoscine is normally written up for treating upper airway secretions in dying patients.

A possible interpretation is that actually many of the patients transferred to this ward for "continuing care" or "slow-stream rehabilitation" were actually patients who it was expected were unlikely to leave hospital. A group of patients who are not immediately dying but who are either too ill to be put through the trauma of applying and moving to a nursing home, only to die shortly after, or is not clear what their outcome will be, certainly exists in all hospitals. It may be that as it was not unusual for patients to actually become (appropriately and expectedly) terminally ill, it had become normal practice to write up drugs that might be needed. In my view this is poor clinical practice, even if it might appear pragmatic practice.

6.11. There are no medical notes between the 1st November and the 15th November at which time she is noted to be very aggressive and very restless, there must have been clinical deterioration over that period of time. Blood tests are sent on 9th November (289) and an MSU has also been sent and reported on 11th November (363) although this is normal. It is unlikely that these tests would have been done if there had not been a significant change in her condition. Indeed, it appears that she was

put on antibiotics for a presumed (subsequently proved mistakenly) urinary tract infection.

The drug chart analysis also demonstrates she was now receiving regular Thioridazine, an anti-psychotic medication which is often prescribed for significantly disturbed behaviour in older patients. The change in behaviour noted, the new medication started, the antibiotics prescribed (277,276) and the blood and urine tests carried out (289,363) all suggest a major change in condition. Yet the lack of medical notes makes a proper assessment of the situation difficult and is poor clinical practice.

6.12. The simple investigations and pragmatic management does not work though. By 18th November she has deteriorated further, is very restless and confused and is now refusing medication. Further blood tests have been carried out on 16th November that now show that creatinine has almost doubled to 360 and her potassium is 5.6. She is now in established acute on chronic renal failure. A patient who is already frail and running with a creatinine of 200 can extremely rapidly decompensate and become seriously ill. On 19th November there is further marked deterioration overnight.

6.13. There is no doubt this lady is now very seriously ill. The question that would have to be answered by the doctors (she was seen by both Dr Reid and Dr Barton) on the 15th and 19th was this a further acute event that could be easily reversed. The straightforward investigations had been performed and the decision would presumably be to have to return the lady to the District General Hospital for further investigation and management, possibly even on a high dependency unit. The other possible decision to be made was that this was a progression of a number of incurable problems and actually she was terminally ill. In these circumstances the decision would then be to decide what form of symptomatic or palliative care was most appropriate.

Mrs Devine was seen by Dr Reid on 15th and Dr Barton may have seen her on the on 18th: the day Fentanyl was started. This should be clarified as no clinical note is made. This is poor practice. Dr Barton is a Clinical Assistant and I am not currently aware of the status of Dr Reid. It is not clear from the notes whether any further advice was obtained from the consultant legally responsible for the care of this patient or whether Drs Barton and Reid were highly experience and knowledgeable clinicians working with a considerable degree of clinical freedom based on a long-standing relationship with their clinical consultant.

6.14. It was presumably in the mind of the doctor who (probably) saw her on 18th that she probably was terminally ill. Evidence for this is that she

started her on a Fentanyl patch on top of the regular Thioridazine, which she was already receiving. However, the logic of starting the Fentanyl patch is not explained in the notes. This is an opioid analgesic usually reserved for severe pain, but it is possible that it was prescribed for severe restlessness in a terminally ill patient (see paragraph 2.20). The lack of explanation is poor clinical practice.

6.15. It is my opinion, certainly by the 19th November, this lady was terminally ill and it was a reasonable decision to come to this conclusion. Equally not all clinicians would come to exactly the same conclusion and some might have referred her back to the DGH when a creatinine of 360 was noted on 16th November. However, on balance I believe that many clinicians would come to the same conclusion after a month in hospital.

6.16. Having made the decision that the lady was terminally ill, the next decision was whether or not to offer palliative care. Mrs Devine was reported as extremely restless and aggressive and in some distress. In my view it would now be inappropriate not to provide high quality palliative care.

6.17. She is then written up for Diamorphine and Midazolam by subcutaneous infusion and the Fentanyl patch prescribed the previous day is removed. There was a three-hour overlap in the prescription of these drugs but this is unlikely to have had a major clinical effect. There is also a discussion regarding her status with a member of her family. There appears to be no dissent as to the appropriateness of her proposed care with either the nurses or the family.

6.18. A pharmacist's opinion should be obtained on the actual way the drug was prescribed. I am not certain the prescription of Diamorphine follows national guidance in writing dosages in words and figures as well as the total dosages. It is also written in a way that leaves some discretion to the dosage to be used to the nursing staff.

6.19. Two drugs are used, Diamorphine and Midazolam intravenous infusion pump. The main reason for using both was terminal restlessness. There is no doubt that Midazolam is widely used subcutaneously in doses from 5 – 80 mgs per 24 hours. The dose of Midazolam used was 40 mgs per 24 hours, which is within current guidance although many believe that elderly patients may need a slightly lower dose of 5 – 20 mgs per 24 hours (Palliative Care. Chapter 23 in Brocklehurst's Text Book of Geriatric Medicine 6th Edition 2003).

6.20. The addition of Diamorphine is more contentious. Although there was serious restlessness and agitation in this lady, no pain was definitively documented and Diamorphine is particularly used for pain in terminal

care. Diamorphine is compatible with Midazolam and can be mixed in the same syringe driver. However, despite the lack of pain Diamorphine is widely used, and believed to be a useful drug, in supporting patients in the terminal phase of restlessness. One study of patients on a long stay ward (Wilson J.A et al Palliative Medicine 1987; 149 – 153) found that 56% of terminally ill patients on a long-stay ward received opiate analgesia. The dose of Diamorphine actually prescribed was 40 mgs. The normal starting dose for pain, of morphine, is 30 – 60 mgs and Diamorphine subcutaneously is usually given at a ratio of 1:2 (i.e. 15 – 30 mgs). It could therefore be argued that Mrs Devine was prescribed up to twice the usual starting dose of Diamorphine. There is no exact science to judging the dose of Diamorphine to give, although it is normal clinical practice to start low and increase the doses rapidly to obtain symptom control.

6.21. In my view the death certificate would appropriately say:
1a: Acute on-chronic renal failure
1b: Chronic Glomerulonephritis

2a: IgA Paraproteinaemia
2b: Dementia

At the time of writing I have not seen the death certificate.

6.22. 24 hours later Mrs Devine is reported to be comfortable and without distress, she finally dies approximately 58 hours after starting the mixture of Diamorphine and Midazolam, and as far as can be deciphered from the notes, without distress.

6.23. The prediction how long a terminally ill patient will live is virtually impossible and even palliative care experts show enormous variation (Higginson I.J. and Costantini M. Accuracy of Prognosis Estimates by 4 Palliative Care teams: A Prospective Cohort Study. BMC Palliative Care 2002 1:1.) I believe that it is certainly possible; it may even have been probable that without any treatment, considering her creatinine of 360 on 16th November, she would have been dead on the 21st November.

6.24. It is also apparent that the doses of drugs used to relieve her symptoms were high considering her age of 89 years and her previous lack of use of either of medications. It is possible that the medication did shorten her life by a short period of time but she was also out of distress for the last 58 hours.

6.25. I am therefore not able to say that the use of Fentanyl, Diamorphine and Midazolam were prescribed with the intention of deliberately shortening her life or indeed, nor that they had the definite effect of shortening her

life in more than a minor fashion.

7. OPINION

7.1 Mrs Elsie Devine presents an example of the most complex and challenging problems in geriatric medicine. This incluluded progressive medical and physical problems causing major clinical and behavioural management problems to all the care staff she comes into contact with.

7.3 The major problem in deciding whether this lady's care was sub-optimal is the lack of documentation. Good medical practice (GMC, 2001) states that "good clinical care must included an adequate assessment of the patient's condition, based on the history and symptoms and, if necessary, an appropriate examination"... "in providing care you must, keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed". The major gaps in the written notes, as documented in my report, represent poor clinical practice to the standards set by the General Medical Council. However, by itself it does not prove that the care actually received by Mrs Devine was sub-optimal, negligent or criminally culpable.

7.3 In my view the drug management at Gosport was sub-optimal. There was no apparent justification for the Diamorphine to be written up prn on admission to Gosport. The logic for the prescription of Fentanyl is not explained, there was a three hour overlap between the prescription for the subcutaneous Diamorphine and Midazolam and the removal of the Fentanyl patch, the starting doses of both Midazolam and Diamorphine were higher than conventional guidance. The effect of higher than standard dosage of Diamorphine and Midazolam may have shortened her life by a short period of time. This would have been no more than hours to days. However, she was already terminally ill and appeared to receive good palliation of her symptoms. While her care was sub-optimal, I can not prove it negligent or criminally culpable.

8 LITERATURE/REFERENCES

1. Good Medical Practice, General Medical Council 2002
2. Withholding withdrawing life, prolonging treatments: Good Practice and decision making. General Medical Council 2002.

3. Palliative Care, Welsh J, Fallon M, Keeley PW. Brocklehurst Text Book of Geriatric Medicine, 6th Edition, 2003, Chapter 23 pages 257-270.
4. The treatment of Terminally Ill Geriatric Patients, Wilson JA, Lawson, PM, Smith RG. Palliative Medicine 1987; 1:149-153.
5. Accuracy of Prognosis, Estimates by 4 Palliative Care Teams: A Prospective Cohort Study. Higginson IJ, Costantini M. BMC Palliative Care 2002:1:129

9. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

10. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Version 2 of complete report 4th January 2005 – Elsie Devine

Signature: _____ Date: _____

CONTENTS

1. INSTRUCTIONS

To examine and comment upon the statement of Dr Jane Barton re Elsie Devine. In particular, it raises issues that would impact upon any expert witness report prepared.

2. DOCUMENTATION

This report is based on the following document:

2.1 Job Description for Clinical Assistant Post to the Geriatric Division in Gosport as provided to me by the Hampshire Constabulary (February 2005).

2.2 Statement of Dr Jane Barton re Elsie Devine as provided to me by Hampshire Constabulary (February 2005). Appendix 1

2.3 Statement of Dr Jane Barton as provided to me by Hampshire Constabulary (February 2005). Appendix 2

2.4 Report regarding Elsie Devine (BJC/16) Dr D Black 2004.

3. COMMENTS

3.1 Comments on Job Description (2.1)

3.1.1 This confirms the Clinical Assistant is responsible for a maximum of 46 patients and confirms that all patients are under the care of a named Consultant Physician who would take overall responsibility for their medical management. A Clinical Assistant should take part in the weekly consultant ward rounds.

3.1.2 A specific responsibility is the writing up of the original case notes and ensuring the follow up notes are kept up to date and reviewed regularly.

3.1.3 The post is for five sessions a week i.e. is half what a full time doctor would commit to the post. However, the time to be spent in the unit is not specified as the time is allowed to be "worked flexibly".

3.1.4 There appears to be some confusion between the

statements in the job summary, that "patients are slow stream or slow stream for rehabilitation but holiday relief and shared care patients are admitted" and the statement in the previous sentence "to provide 24 hour medical care to the long stay patients in Gosport". The job description appears to be confusing patients for rehabilitation with long stay patients (see discussion paragraph 6.2 of Elsie Devine Report).

3.1.5 There is no comment on the medical cover to be provided when the post holder is unavailable for out of hours or longer period of leave such as holidays. Lack of explicit cover might explain some gaps in the notes.

3.2 Report on the statement of Dr Jane Barton re Elsie Devine (2.2).

The comments refer by page and paragraph to the report. Any numbers in brackets refer to the pages of the photocopies of the notes of Elsie Devine.

3.2.1 Page 1 paragraph 2: Dr Barton again states that Mrs Devine had multiple myeloma. As recorded in my report I believe she did not have multiple myeloma but a separate condition called IgA paraproteinaemia.

3.2.2 Page 1 paragraph 2: States that Mrs Devine had chronic renal failure and nephrotic syndrome. Nephrotic syndrome is a triad of proteinuria, hypoalbuminaemia and oedema, it does not cause chronic renal failure, although, the two may coexist. Page 3 paragraph 1: Dementia is a clinical diagnosis and cannot be "confirmed by CT scan". CT scan is sometimes undertaken to exclude other potential treatable causes that might mimic a clinical syndrome of dementia. Dementia is most commonly caused by Alzheimer's disease. The point of commenting on these two statements is that although they may seem minor misunderstandings, they might also indicate a doctor who did not have a full understanding of the medical conditions that they were managing in a patient with complex medical problems.

3.2.3 Page 3 paragraph 1: Dr Barton states that the CT scan showed "ischaemic changes". The only report that I have been able to find is one that states, "involutional changes only" (24). If the police or other authority can provide further information in relation to this point, I will reconsider my views.

3.2.4 Page 4 paragraph 1: A dose of Oramorphine is prescribed prn. I have been unable to find evidence in the notes that she complained to pain up until that date and the drug charts in

Portsmouth appear to show that she only receive Paracetamol on one occasion on 10th October (269)

Having reviewed page 277 of the photocopies, I agree that the patient was prescribed Oramorphine and not Diamorphine as written in paragraphs 5.19, 6.10, 7.3 or my report and the summary on page 1. This in no way changes or invalidates any of the opinions in my report.

3.2.5 Page 5 paragraphs 1 and 3: These confirm a consultant Dr Reid has seen her on two wards and written appropriate comments in the notes on both 25th October and 1st November. Page 6 paragraphs 2 and 3 confirm that changes in clinical condition did occur from around 9th November and confirm the investigations and management changes could be inferred from the notes. Despite this, nothing is written in the patients' notes until the next consultant ward round on 15th November.

3.2.6 Page 9 paragraph 2: "The hanging on the bars in the main corridor of the ward" has not been recorded in the medical notes (156) and appears to be new and unrecorded clinical information.

3.3 Report on the Statement of Dr Jane Barton as provided to me by the Hampshire Constabulary (2.3):

3.3.1Page 1 paragraph 3: States that she works eight general practice surgery sessions. It is my understanding that most full time General Practitioners work eight or nine sessions. This suggests to me that she is undertaking a full time General Practitioner job and a half time community hospital job. Despite the fact the job description says that the job can be worked flexibly, an opinion should be obtained from an experience General Practitioner as to whether this workload is actually deliverable within a reasonable working week.

3.3.2 Page 1 paragraph 4: The job description states 46 beds, Dr Barton states 48 beds. The CHI report says 44 beds (20 on Dryad and 24 on Daedalus) Dr Barton uses the phrase "continuing care for long stay elderly patients". The job description also referred to slow stream or slow stream rehabilitation as well as holiday relief and shared care patients. There may have been confusion between staff in terms of the objectives of individual patient management (see paragraph 6.2. Devine Report).

3.3.3 Page 1 paragraph 5: This statement is incorrect as the post of Clinical Assistant is not a training post but a service post in the NHS. The only medical training grade posts are pre-registration house officers, senior house officers, specialist

registrars and GP registrars.

3.3.4 Page 1 paragraph 5: States that she and her partners had decided to allocate come of the sessions to "out of hours aspects of the post". This would appear to be a local arrangement of the contractual responsibilities: it needs to be clarified if this was agreed with the Portsmouth and South East Hampshire Health Authority. This would influence how much time was expected to be provided for the patients and influence the pressure on Dr Barton to deliver the aspects of care provided.

3.3.5 Page 2 paragraph 3: This does confirm that there were consultants responsible for all the patients under the care of Dr. Barton. Thus a consultant should always have been available for discussing complex or difficult management decisions. However,(page 3 paragraph 1) , in my view it would be completely unacceptable of the Trust to have left Dr Barton with continuing medical responsibilities for the inpatients of Gosport Hospital without consultant supervision and regular ward rounds. This would be a serious failure of responsibility by the Trust in its governance of patients and in particular failings and in my view the Trust would need to take part of the responsibility for any clinical failings.

3.3.6 Page 3 paragraph 3: This again suggests that Dr Barton was trying to provide her half time responsibilities by fitting the work around her full time responsibilities as a General Practitioner. She suggests 5 patients were admitted each week, implying approximately 250 admissions and discharges a year. With a bed occupancy around 80%, this would suggest an average length of stay of 5 – 6 weeks. However, CHI state the actual figures were somewhat less, 1997/98 were 169 FCE's for Dryad and Daedalus and 197 FCE's in 1998/99. A new patient assessment including history and examination, writing up the notes, drug charts, talking to the nurses, talking to any relatives present and undertaking blood tests if these had to be taken by a doctor rather than any other staff, would take a maximum of 60 minutes.

Page 5 paragraph 2: The patients who were genuinely long stay or continuing care do not need to be reviewed medically every day, nor would a medical record be made daily. Indeed with average length of stay of six or more weeks, it is clear that many patients were genuinely long-stay patients and one would expect them to be medically reviewed no more than once a week and any medical comments to be no more than once a week.. However, whenever patients' physical or mental state has changed and they are reviewed by a doctor, it would be normal practice to always make a comment in the notes.

Patients who are in rehabilitation and making a good progress, then review and comments in the notes once or twice a week would also be the norm.

It is my view that with less than 200 FCE's and a total of 44 inpatients, then this should be satisfactorily managed by somebody working half time as a Clinical Assistant with regular consultant supervision.

3.3.7 Page 4 paragraph 2: This suggests that Dr Barton is stating that she takes personal responsibility for most changes in medication, rather than it being a nursing decision.

3.3.8 Page 9 paragraph 2: An individual doctor must take responsibility for their prescribing however I would agree that consultants should also take responsibility for ensuring patients under their care were having appropriate medical management. It does appear that there was a consultant responsible for all patients in both Dryad and Daedalus Ward.

4. CONCLUSION

4.1 Having read all the documents above provided by Hampshire Constabulary, the only change I would wish to make to my export report is in paragraphs 5.19, 6.10, 7.3 in the summary on page 1, the patient was prescribed Oramorphine and not Diamorphine as written in the report.

Devine/ Barton statements Version 5 16 April 2005

APPENDIX 1

Devine/ Barton statements Version 5 16 April 2005

APPENDIX 2

3

FINAL REPORT

regarding

Elsie DEVINE (Ref No. BJC/16)

PREPARED BY

Dr C.R.K. Dudley

Consultant Nephrologist and Senior Clinical Lecturer

The Richard Bright Renal Unit, Southmead Hospital, North Bristol NHS Trust,

Westbury-on-Trym, Bristol BS10 5NB

AT THE REQUEST OF

Hampshire Constabulary

Date of report

20 March 2005

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1. SUMMARY OF CONCLUSIONS

Mrs DEVINE was an elderly, "frail" lady who had a plasma cell dyscrasia manifested by the presence of an IgA lambda paraprotein and amyloidosis. In addition, she had the nephrotic syndrome and progressively deteriorating renal function probably as a consequence of renal amyloid. In the 9-12 months prior to her final hospital admission, she had suffered with chronic memory loss and had become unable to look after herself. She was admitted as an emergency to hospital with an acute confusional state for which no cause other than multi-infarct dementia and severe renal impairment could be found. After a period of stabilisation, her clinical condition worsened with severe renal failure and worsening agitation and restlessness. Although it may have been possible to stabilise her condition with relatively simple measures, this would not have materially changed her prognosis as death was inevitable. She was treated appropriately in the terminal phase of her illness with strong opioids to ensure comfort and calm, to enable nursing care and to maintain her dignity.

2. INSTRUCTIONS

I was asked to prepare this report on the instructions of Detective Sergeant Dave GROCOTT of Hampshire Constabulary based at Fareham Police Station, Quay Street, Fareham, Hampshire PO16 0NA.

3. ISSUES

I was asked to consider the following issues:

3.1 Beyond all reasonable doubt, was Mrs Devine dying due to her failing renal condition?

3.2 If Mrs Devine was beyond all reasonable doubt dying of renal failure, would any simple measures that were available and appropriate have had any reasonable chance of making a difference?

3.3 Would the acute confusional state that Mrs Devine developed be in keeping with dying from renal failure?

3.4 At the time when Mrs Devine's renal function declined, would a better assessment have identified appropriate treatment options that would have had a reasonable chance of stabilising or improving her situation?

3.5 Would the acute confusional state be untypical of someone dying of renal failure?

3.6 A comment on the use of strong opioids to "calm, keep comfortable and enable nursing care" in someone dying of renal failure who is not in obvious pain.

4. BRIEF CURRICULUM VITAE

Code A

5. DOCUMENTATION

This Report is based on the following documents:

(1) A copy of Mrs Elsie DEVINE'S medical records

(2) A copy of a statement made by Dr Judith STEVENS (statement number S237), Consultant Nephrologist, Portsmouth Hospitals National Health Service Trust

(3) A copy of a statement made by Dr. Tanya CRANFIELD (statement number S254), Consultant Haematologist, Haematology Department, Michael Darmady Laboratory, Queen Alexandra Hospital, Cosham, Portsmouth

(4) A copy of a statement made by Dr Jane BARTON (no statement number), General Practitioner, Forton Medical Centre, White's Place, Gosport, Hampshire and Clinical Assistant at Gosport War Memorial Hospital from 1988 to 2000

Detective Sergeant GROCOTT provided all these records in a single lever arch file. The quality of some of the photocopied medical records was poor and difficult to read and in places was unreadable. Similarly, the size and quality of the copy of the drug treatment charts is such that these could not be read clearly (e.g. page 277).

The copy of the medical records has been paginated. In my report reference to the relevant page number from the medical records is given in parenthesis.

6. CHRONOLOGY/CASE ABSTRACT

SEQUENCE OF EVENTS PRIOR TO ADMISSION TO HOSPITAL

Mrs DEVINE an 87 year old lady, was referred to Dr LOGAN (Consultant Physician in Geriatrics) on the 9th March 1999 because of increasing ankle swelling and abnormal blood tests including a creatinine of 130 µmol/l (normal laboratory range for females given as 45 – 90 µmol/l). In the past a diagnosis of mild to moderate congestive cardiac failure and hypothyroidism (under-active thyroid gland) had been made. At the time of referral she was taking a combination of a "water tablet" (diuretic) known as Co-amilofruse 5/40 one or two a day and Thyroxine 100 micrograms a day. She was seen on the 1st April 1999 in the Elderly Medicine Clinic by Dr RAVINDRANE, Specialist Registrar to Dr LOGAN. A number of investigations were performed which revealed the nephrotic syndrome which is a condition whereby excessive amounts of the blood protein albumin leak through the kidney into the urine resulting in a low blood albumin level. As a consequence fluid retention occurs, characterised by swelling of the ankles as in Mrs DEVINE'S case. Her kidney function had also deteriorated with her creatinine rising to 151 µmol/l. An ultrasound of the kidneys had been performed (page 375) and was reported as showing both kidneys to be slightly small, the right measuring 8.7 cm and the left 8.4 cm. No other abnormality was identified and a chest x-ray was normal. Blood tests also revealed the presence of an IgA lambda paraprotein quantified at 5.9 g/l. Her urine however tested negative for Bence Jones protein (often found in a condition known as myeloma).

Following a clinic visit on the 15th April 1999, Dr LOGAN referred Mrs DEVINE to Dr TANYA CRANFIELD for a further opinion on whether the paraprotein was associated with a haematological malignancy such as myeloma with the nephrotic syndrome related. In his referral letter he noted that Mrs DEVINE was *"moderately frail but very bright mentally"*.

Dr CRANFIELD assessed Mrs DEVINE in the clinic on the 13th May 1999. She went onto perform a bone marrow biopsy and aspirate which revealed no evidence of myeloma and although plasma cells were prominent they made up only 6% of the nucleated cells present. There were no lytic lesions on a skeletal survey although this did show generalised osteoporosis. On the basis of these investigations Dr CRANFIELD felt that there was insufficient evidence for a diagnosis of myeloma to be made (page 70). She referred the patient to Dr JUDITH STEVENS, Consultant Renal Physician in view of Mrs DEVINE'S deteriorating renal function and for an opinion on the cause of the nephrotic syndrome.

Dr JUDITH STEVENS reviewed the patient in a clinic on the 8th June 1999 (page 60). Dr STEVENS' opinion was that *"in view of the small kidneys this is likely to be long-standing glomerulonephritis rather than a new problem"*. Glomerulonephritis is a condition resulting in damage to the filtering units of the kidneys usually associated with blood and protein loss in the urine. A modification in Mrs DEVINE'S diuretic tablets was suggested. In her letter she noted, *"she is a rather frail old lady"*.

The patient was further reviewed by Dr CRANFIELD in a clinic on the 28th July 1999 (page 50). In that letter she noted that Mrs DEVINE'S leg swelling was much better controlled on the increased dose of diuretic tablets. She noted that further laboratory staining of the bone marrow biopsy revealed the presence of amyloid. She also noted that the patient's kidney function had worsened further with her creatinine rising to 192 µmol/l.

Mrs DEVINE was reviewed again by Dr STEVENS in a clinic on the 7th September 1999 when Dr STEVENS noted that the oedema (swelling) extended up to the patient's knee. A further increase in the dose of diuretic medication was recommended.

SEQUENCE OF EVENTS FOLLOWING ADMISSION TO QUEEN ALEXANDRA HOSPITAL

Mrs DEVINE was admitted to the Queen Alexander Hospital, Cosham, Portsmouth on the 9th October 1999. The referral letter from Dr P. SMITH, a general practitioner at the Health Centre, Osborne Road, Fareham, reported that for 2 days she had been confused, aggressive and wandering (page 38). The copy of the medical records provided to me from the day of her admission are illegible but from the discharge summary (page 24) and the remainder of the medical records (from page 158) I can determine that she was treated for a possible urinary tract infection and given intravenous fluids. She remained very confused and aggressive and had a mental test score of 3/10 reflecting significant cognitive impairment. A creatinine of 201 µmol/l was noted. This indicates advanced renal failure (calculated creatinine clearance of 14 mls/min; chronic kidney disease stage 5).

Because she continued confused and aggressive, refusing medication and physically harming staff, she was treated with Haloperidol, an anti-psychotic sedating drug (page 160).

On the 14th October she was seen by Dr TAYLOR, Clinical Assistant in Old Age Psychiatry, who recorded that since January of that year Mrs DEVINE'S family had noticed a decline in

her memory and was no longer able to look after herself (page 28). She concluded that it was likely Mrs DEVINE had dementia with an acute episode of confusion secondary to urinary tract infection. Mrs DEVINE scored 9/30 on a mini-mental state examination reflecting definite cognitive impairment. Code A

Code A A recommendation that she be referred to the social services for residential care in a home that had experience in dealing with memory problems was made (page 29). A CT scan of the head was performed with sedation on the 18th October and was recorded as showing involutional and ischaemic changes only (signs of atrophy and impaired blood supply due to blockage of small arteries) (page 168). The patient was assessed by Dr JAYAWARDENA, Locum Consultant Physician in Geriatrics on the 19th October who thought her suitable for a rehabilitation programme and made arrangements for her care to be transferred to Gosport War Memorial Hospital (pages 26 and 171). On the 18th October her creatinine is recorded as 201 µmol/l (page 171).

SEQUENCE OF EVENTS FOLLOWING ADMISSION TO GOSPORT WAR MEMORIAL HOSPITAL

On the 21st October 1999, Mrs DEVINE was transferred to Dryad Ward, Gosport War Memorial Hospital under the care of Dr REID, consultant-in-charge. The plan recorded in the notes by Dr BARTON at that time was for the team to get to know Mrs DEVINE, assess her for rehabilitation potential and probably place her in a rest home in due course (page 154). She was noted to be mildly confused, mobile, able to wash with supervision and dress herself as well as being continent (page 154). A mini-mental state examination of 9/30 was recorded. Elsewhere in the notes it is recorded that Mrs DEVINE was quite confused and disorientated (P155). I am not able to identify from the signature in the notes by whom this entry and others elsewhere were made. However, Dr BARTON identifies these entries in her statement as being made by Dr REID. Mrs DEVINE'S creatinine is recorded as 187 µmol/l on the 22nd October and as 200 µmol/l on the 9 November 1999 (page 349). By the 15th November, the patient's condition had apparently deteriorated and Dr REID notes that she had become very aggressive at times and very restless requiring the use of thioridazine, an antipsychotic drug used to calm restless patients (page 155). The patient was receiving treatment for a suspected urinary tract infection although a mid-stream urine sample (MSU) had revealed no growth. A referral back to Dr LUSZNAT was requested and made the following day (page 155). On that date (16 November 1999) laboratory results revealed a marked deterioration in Mrs DEVINE'S kidney function as demonstrated by a rise in creatinine to 360 µmol/l (page 349).

She was seen on 18th November 1999 by a locum staff psychiatrist who noted that the patient had deteriorated and had become more restless and aggressive again (page 156). She was placed on the waiting list for Mulberry ward.

On the 19th November, Dr BARTON'S entry in the notes records *"Marked deterioration overnight. Confused and aggressive. Creatinine 360. Fentanyl patch commenced yesterday. Today further deterioration in general condition, needs sc analgesia with midazolam. Son seen and aware of condition and diagnosis. Please make comfortable. I am happy for nursing staff to confirm death"*(page 156). The nursing notes on 19th November record that the patient's condition had deteriorated markedly over the previous 24 hours and that she had become extremely aggressive refusing all help. Chlorpromazine had been given intramuscularly (an antipsychotic drug used to calm restless patients) and a syringe driver consisting of 40 mg diamorphine and 40 mg midazolam had been commenced at 09.25 (page 222 and 223). Mrs DEVINE died on the 21st November 1999.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

Mrs DEVINE had progressive renal failure and the presence of the nephrotic syndrome would indicate that there was damage to the filtering units within the kidney. It is possible that this was due to an unrelated glomerulonephritis (non-specific term for "inflammation" within the glomeruli or sieving units) as suggested by Dr STEVENS. However, it is more likely that it was directly related to the underlying IgA lambda paraprotein.

IgA is one of 5 classes of antibody protein (immunoglobulin) produced by plasma cells within the bone marrow and lymph glands. Different plasma cells produce different types of IgA antibodies resulting in a mixture within the blood referred to as polyclonal (derived from many different clones of plasma cells).

Occasionally for reasons that are poorly understood, a plasma cell divides and multiplies to an aberrant degree resulting in an abnormal collection of identical plasma cells producing the identical antibody type (in this case IgA lambda). Using biochemical techniques, the excessive amount of anomalous identical antibody type can be identified in the blood. As this protein is derived from one individual clone of plasma cells it is referred to as a monoclonal immunoglobulin or paraprotein.

Such an expansion of monoclonal plasma cells is abnormal. At one extreme, the number of abnormal plasma cells proliferating in the bone marrow is excessive (> 10%) and suppresses

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Such an expansion of monoclonal plasma cells is abnormal. At one extreme, the number of abnormal plasma cells proliferating in the bone marrow is excessive (> 10%) and suppresses

the other normal plasma cells as well as destroying the bone itself (lytic lesions), causing an elevated plasma calcium level. This is a malignant condition known as multiple myeloma and untreated results in death. At the other extreme, the number of abnormal plasma cells is low, the number of normal plasma cells is maintained and the bone is not destroyed. The significance of the abnormal clone is uncertain and the patient remains well without treatment for many years. This condition is known as a monoclonal gammopathy of uncertain significance (MGUS). Between these two extremes is the condition of smouldering multiple myeloma, which has some but not all the features of multiple myeloma but probably represents an early stage of this condition. This group of conditions is known as plasma cell dyscrasia (reference 1).

A component of the monoclonal immunoglobulin known as the light chain may "join together" and become deposited particularly in the walls of blood vessels. This condition is known as amyloidosis and can be identified from a biopsy of an affected tissue or organ. In the setting of a paraprotein, amyloid can be thought of as a malignant condition with a prognosis similar to that of multiple myeloma (reference 2). Within the kidney, amyloid is deposited in the sieving units (glomeruli) damaging them resulting in protein leaking into the urine and kidney dysfunction.

Further examination of Mrs DEVINE'S bone marrow biopsy demonstrated the presence of amyloid (page 50). It is more likely than not that the cause of Mrs DEVINE'S nephrotic syndrome and renal impairment was due to the deposition of amyloid within the kidney rather than a *"long-standing glomerulonephritis"*.

On the 20th January 1999, Mrs DEVINE'S creatinine was 130 µmol/l (page 96) with a normal laboratory range for females given as 45 – 90 µmol/l. Using the Cockcroft and Gault formula her calculated creatinine clearance, a measure of glomerular filtration rate, was 22.3 mls/min (normal range usually 80-120 mls/min). This value reflects moderate to severe renal impairment (DOQI Stage 4 reference 3). Over the course of the year there was a progressive rise in her creatinine reflecting a progressive deterioration in renal function. By the 7th September 1999 it had risen to 203 µmol/l (creatinine clearance 14 mls/min) (page 357). During her admission to Queen Alexandra her creatinine varied between 161 and 201 µmol/l (page 349). During her admission to Gosport War Memorial Hospital it varied between 187-200 µmol/l. On the 16th November her creatinine had risen to 360 µmol/l reflecting a marked deterioration in renal function (creatinine clearance 7.8 mls/min) signifying severe renal

failure. It is probable that an unidentified infection was responsible for the deterioration in the patient's general condition and renal function. Intravascular volume depletion ("dehydration") associated with inappropriate diuretic use is less likely given the stability in the patient's weight (see weight chart page 250). Fluctuation in weight over a short period of time is a good indicator of changes in body fluid status.

Mrs DEVINE was admitted as an emergency to hospital with an acute confusional state for which no cause other than multi-infarct dementia and severe renal impairment could be found.

8. OPINION

8.1 Beyond all reasonable doubt, was Mrs Devine dying due to her failing renal condition?

In my opinion, beyond all reasonable doubt, Mrs DEVINE was dying from a combination of amyloidosis, progressive renal failure and dementia. It is probable that the acute deterioration in her condition noted on the 15th November was precipitated by an unidentified infection.

8.2 If Mrs Devine was beyond all reasonable doubt dying of renal failure, would any simple measures that were available and appropriate have had any reasonable chance of making a difference?

It is difficult for me to comment on her diuretic therapy as I cannot read her drug chart clearly. However, the patient's weight chart shows no marked change in weight to suggest significant fluid depletion. In my opinion, any simple measures such as stopping diuretics, the use of intravenous fluids and/or antibiotics were unlikely to have had any significant effect on the eventual outcome. Although her clinical condition may have improved or stabilised for a few days, a further deterioration culminating in her death was inevitable.

8.3 Would the acute confusional state that Mrs Devine developed be in keeping with dying from renal failure?

Mrs Devine appeared to have a chronic confusional state (dementia) which had acutely worsened, resulting in her admission to the Queen Alexandra Hospital. During this admission and after her transfer to Gosport War

Memorial Hospital, her confusional state fluctuated. This chronic confusional state with episodes of exacerbation was likely to be due to a number of factors including progressive renal failure on a background of multi-infarct dementia.

8.4 **At the time when Mrs Devine's renal function declined, would a better assessment have identified appropriate treatment options that would have had a reasonable chance of stabilising or improving her situation?**

Mrs Devine's renal function declined progressively over the course of 1999 with a further acute deterioration in the final phase of her illness. As stated above, although simple measures such as stopping diuretics, the use of intravenous fluids and/or antibiotics may have improved or stabilised her clinical condition for a few days, further deterioration culminating in her death was inevitable. Treatment options such as dialysis would not have been appropriate given her age, frailty and general medical condition.

8.5 **Would the acute confusional state be untypical of someone dying of renal failure?**

Death from renal failure is usually characterised by increasing drowsiness leading to coma. However, in a proportion of patients, renal failure is characterised by an acute confusional state (reference 4) and such an observation would not be untypical in a patient with terminal renal failure particularly when a previous chronic confusional state exists.

8.6 **Comment on the use of strong opioids to "calm, keep comfortable and enable nursing care" in someone dying of renal failure who is not in obvious pain.**

Strong opioids are commonly used in the terminal care of patients dying with renal failure who are agitated and restless to ensure comfort and calm, to enable nursing care and to maintain dignity.

9. LITERATURE/REFERENCES

Reference 1 Kyle RA. Diagnosis and differential diagnosis of multiple myeloma. UpToDate Version 13.1 2005 http://www.uptodate.com/

Reference 2 Kyle RA. Primary (AL) amyloidosis and light and heavy chain deposition diseases. UpToDate Version 13.1 2005 http://www.uptodate.com/

Reference 3 Table 10 Stages of Chronic Kidney Disease from Part 4 Clinical Practice Guidelines; DOQI, National Kidney Foundation http://www.kidney.org/professionals/kdoqi/guidelines_ckd/toc.htm

Reference 4 Cohen, LM, Germain, M, Poppel, DM, et al. Dialysis discontinuation and palliative care. Am J Kidney Dis 2000; 36:140.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: Code A Date: 20/3/05

Appendix 1: Brief Curriculum Vitae

Code A

Code A

Appendix 2: References

Reference 1 Kyle RA. Diagnosis and differential diagnosis of multiple myeloma. UpToDate Version 13.1 2005 http://www.uptodate.com/

Reference 2 Kyle RA. Primary (AL) amyloidosis and light and heavy chain deposition diseases. UpToDate Version 13.1 2005 http://www.uptodate.com/

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Reference 4 Cohen, LM, Germain, M, Poppel, DM, et al. Dialysis discontinuation and palliative care. Am J Kidney Dis 2000; 36:140.

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MEDICO-LEGAL REPORT

Re: **Gladys Mabel RICHARDS**
Arthur "Brian" CUNNINGHAM
Alice WILKE
Robert WILSON
Eva PAGE

Prepared by:
Professor G A Ford, MA, FRCP
Consultant Physician, Freeman Hospital
Newcastle upon Tyne
Professor of Pharmacology of Old Age, University of Newcastle upon Tyne

For: **Hampshire Constabulary**

Date: **12th December 2001**

Contents

Introduction and Remit of the Report

8.1 I am Professor of Pharmacology of Old Age in the Wolfson Unit of Clinical Pharmacology at the University of Newcastle upon Tyne, and a Consultant Physician in Clinical Pharmacology at Freeman Hospital. I am a Doctor of Medicine and care for patients with acute medical problems, acute poisoning and stroke. I have trained and am accredited on the Specialist Register in Geriatric Medicine, Clinical Pharmacology and Therapeutics and General Internal Medicine. I provide medical advice and support to the Regional Drugs and Therapeutics Centre Regional National Poisons Information Service. I was previously clinical head of the Freeman Hospital Care of the Elderly Service and have headed the Freeman Hospital Stroke Service since 1993. I undertake research into the effects of drugs in older people. I am co-editor of the book 'Drugs and the Older Population' and in 2000 was awarded the William B Abrams award for outstanding contributions to Geriatric Clinical Pharmacology by the American Society of Clinical Pharmacology and Therapeutics. I am a Fellow of the Royal College of Physicians and have practised as a Consultant Physician for nine years.

8.2 I have been asked by Detective Superintendent John James of Hampshire Constabulary to examine the clinical notes of five patients (Gladys Mabel Richards, Arthur "Brian" Cunningham, Alice Wilkie, Robert Wilson, Eva Page) treated at the Gosport War Memorial Hospital and to apply my professional judgement to the following:

- The gamut of patient management and clinical practices exercised at the hospital
- Articulation of the leadership, roles, responsibilities and communication in respect of the clinicians involved
- The accuracy of diagnosis and prognosis including risk assessments
- An evaluation of drugs prescribed and the administration regimes
- The quality and sufficiency of the medical records
- The appropriateness and justification of the decisions that were made
- Comment on the recorded causes of death
- Articulate the duty of care issues and highlight any failures

1.3 I have prepared individual reports on each case and an additional report commenting on general aspects of care at Gosport War Hospital from a consideration of all five cases.

1.4 I have been provided with the following documents by Hampshire Constabulary, which I have reviewed in preparing this report:

- Comment on the recorded causes of death
- Letter DS J James dated 15th August 2001
- Terms of Reference document
- Hospital Medical Records of Gladys Richards, Brian Cunningham, Alice Wilkie, Robert Wilson and Eva Page
- Witness statements by Leslie France Lack, and Gillian MacKenzie
- Report of Professor Brian Livesley
- Transcripts of police interviews with Gosport War Memorial staff Dr Barton, Mr Beed, Ms Couchman, Ms Joice

- Transcript of police interviews with Royal Hospital Haslar staff Dr Reid and Flt. Lt. Edmondson
- Transcript of interviews with patient transfer staff Mr Warren and Mr Tanner
- Transcript of police interviews with or statements from following medical and nursing staff: Dr Lord, LM Baldacchino, M Berry, JM Brewer, J Cook, E Dalton, W Edgar, A Fletcher, J Florio and A Funnell.

Gladys Mabel RICHARDS

Course of Events

2.1 Gladys Richards was 91 years old when admitted as an emergency via the Accident & Emergency Department to Haslar Hospital on 29Th July 1998. She had fallen onto her right hip and developed pain. At this time she lived in a nursing home and was diagnosed as having dementia. She had experienced a number of falls in the previous 6 months and the admission notes comments "*quality of life has ↓↓ markedly last 6/12*". She was found to have a fracture of the right neck of femur. An entry in the medical notes by Surgeon Commander Malcom Pott, Consultant orthopaedic surgeon dated 30 July 1998 states '*After discussion with the patient's daughters in the event of this patient having a cardiac arrest she is NOT for cardiopulmonary resuscitation. However she is to be kept pain free, hydrated and nourished.*' Surgery (right hemiarthroplasty) was performed on 30 July 1998.

2.2 On 3rd August she was referred for a geriatric opinion and seen by Dr Reid, Consultant Physician in Geriatrics on 3rd August 1998. In his letter dated 5th August 1998 he notes she had been on treatment with haloperidol and trazadone and that her daughters thought she had been 'knocked off' by this medication for months, and had not spoken to then for 6-7 months. Her mobility had deteriorated. Her daughters commented to Dr Reid that she had spoken to them and had been brighter mentally since the trazadone had been omitted following admission. Dr Reid found Mrs Richards to be confused but pleasant and cooperative, unable to actively lift her right leg from the bed but appeared to have little discomfort on passive movement of the right hip. He commented '*I understand she has been sitting out in a chair and I think that despite her dementia, she should be afforded the opportunity to try to re-mobilise her.* He arranged for her transfer to Gosport War Memorial Hospital.

2.3 Following Dr Reid's entry in the notes on 3rd August two further entries are made in the medical notes by the on call house officer (Dr Coales?) on 8th August 1998. Dr Coales was asked to see Mrs Richards who was agitated on the ward. She had been given 2mg haloperidol and was asleep when first seen at 0045h. At 02130 hr a further entry records Mrs Richards was '*noisy and disturbing other patients n ward. Unable to reason with patient. Prescribed 25mg thioridazine'*. A transfer letter for Sergeant Curran, staff nurse to the Sister in Charge dated 10th August 1998 describes Mrs Richards status immediately prior to transfer and notes *'Is now fully weight bearing, walking with the aid of two nurses and a zimmer frame. Gladys needs total care with washing and dressing eating and drinking. Gladys is continent, when she becomes fidgety and agitated it means she wants the toilet. Occasionally incontinent at night, but usually wakes.*

2.4 On 11th August 1998 Mrs Richards was transferred to Daedalus ward. Dr Barton writes *in the medical notes "Impression frail demented lady, not obviously in pain, please make comfortable. Transfers with hoist, usually continent, needs help with ADL Barthel 2. I am happy for nursing staff to confirm death".* The summary admitting nursing notes record *"now fully weight bearing and walking with the aid of two nurses and a Zimmer frame"*. On 12th August the nursing notes record "*Haloperidol given at 2330 as woke from sleep. Very agitated, shaking and crying. Didn't settle for more than a few*

minutes at a time. Did not seem to be in pain" .On 13th August nursing notes record "*found on floor at 1330h. Checked for injury none apparent at time. Hoisted into safer chair. 1930 pain Rt hip internally rotated, Dr Brigg contacted advised Xray am and analgesia during the night. Inappropriate to transfer for Xray this pm."*

2.5 On 14th August 1998 Dr Barton wrote '*sedation/pain relief has been a problem. Screaming not controlled by haloperidol 1g ? but very sensitive to Oramorph. Fell out of chair last night. R hip shorter and internally rotated, Daughter nurse and not happy. Plan Xray . Is this lady well enough for another surgical procedure?"* A further entry the same day states "*Dear Cdr Spalding, further to our telephone conversation thank you for seeing this unfortunate lady who slipped from her chair and appears to have dislocated her R hip. Hemiarthroplasty was done on 30-8-98. I am sending Xrays. She has had 2.5ml of 10mg/5ml oramoroph at midday. Many thanks".*

2.6 Following readmission to Haslar hospital Mrs Richards underwent manipulation of R hip under iv sedation (2 mg midazolam) at 1400h. At 2215h the same day she was not responding to verbal stimulation but observations of blood pressure, pulse, respiration and temperature were all in the normal range. A further entry on 17th August by Dr Hamlin (House Officer) states "*fit for discharge today (Gosport War Mem) To remain in straight knee splint for 4/52. For pillow between legs (abduction) at night."* A transfer letter to the nurse in charge at Daedalus ward states "*Thank you for taking Mrs Richards back under your care... was decided to pass an indwelling catheter which still remains in situ. She has been given a canvas knee immobilising splint to discourage any further dislocation and this must stay in situ for 4 weeks. When in bed it is advisable to encourage abduction by using pillows or abduction wedge. She can however mobilise fully weight bearing".*

2.7 Nursing notes record on 17th August " 1148h *returned from R.N.Haslar patient very distressed appears to be in pain. No canvas under patient – transferred on sheet by crew."* Later that day at 1305h "*in pain and distress, agreed with daughter to give her mother Oramorph 2.5mg in 5ml*". A further hip Xray was performed which demonstrated no fracture. Dr Barton writes on 17th August 1998 *"readmission to Daedalus ward. Closed reduction under iv sedation. Remained unresponsive for some hours. Now appears peaceful. Can continue haloperidol, only for Oramorph if in severe pain. See daughter again"* and on 18th August "*still in great pain, nursing a problem, I suggest sc diamorphine/ haloperidol/midazolam. I will see daughters today. Please make comfortable".* Nursing notes record "*reviewed by Dr Barton for pain control via syringe driver".* At 2000h "*patient remained peaceful and sleeping. Reacted to pain when being moved – this was pain in both legs".* On 19th August the nursing notes record "*Mrs Richards comfortable*" and in a separate entry "*apparently pain free*". There are no nursing entries I can find on 20th August. I can find no entries in the nursing notes describing fluid or food intake following admission on 17th August.

2.8 The next entry in the medical notes is on 21st August by Dr Barton "*much more peaceful. Needs hyoscine for rattly chest*". The nursing notes record "*patient's overall condition deteriorating. Medication keeping her comfortable*". A staff

nurse records Mrs Richards's death in the notes at 2120h later that day. The cause of death was recorded as bronchopneumonia.

2.9 Medication charts record the following administration of opiate, analgesic and sedative drugs during Mrs Richards's first admission to Haslar Hospital.

29 July 2000h Trazadone 100mg (then discontinued)
29 July to 11th August. Haloperidol 1mg twice daily
30 July 0230h Morphine iv 2.5mg
31 July 0150h morphine iv 2.5mg
1905h morphine iv 2.5 mg
1 Aug 1920h morphine iv 2.5mg
2 Aug 0720h morphine iv 2.5mg
Cocodamol two tablets as required taken on 16 occasions at varying times between 1-9th August

2.10 Medication charts record the following administration of opiate, analgesic and sedative drugs during Mrs Richards second admission to Haslar Hospital

14 Aug 1410h midazolam 2mg iv
15 Aug 0325h cocodamol two tablets orally
16 Aug 0410h haloperidol 2mg orally
0800h haloperidol 1mg orally
1800h haloperidol 1mg orally
2310h haloperidol 2mg orally
17 Aug 0800h haloperidol 1mg orally

2.11 Medication charts record the following administration of opiate and sedative drugs on Daedalus ward:

11 Aug	1115h	5mg/5ml Oramorph
	1145h	10 mg Oramorph
	1800h	1 mg haloperidol
12 Aug	0615h	10 mg Oramorph
		haloperidol
13 Aug	2050h	10mg Oramorph
14 Aug	1150h	10mg Oramorph
17 Aug	1300h	5mg Oramorph
	?	5 mg Oramorph
	1645h	5mg Oramorph
	2030h	10mg Oramorph
18 Aug	0230h	10mg Oramorph
	?	10mg Oramorph
	1145h	diamorphine 40mg/24hr, haloperidol 5mg/24hr midazolam 20mg/24hrby
19 Aug	1120h	diamorphine 40mg/24hr, haloperidol 5mg/24hr midazolam 20mg/24hr, hyoscine 400microg/24hr
20 Aug	1045h	diamorphine 40mg/24hr, haloperidol 5mg/24hr midazolam 20mg/24hr, hyoscine 400microg/24hr
21 Aug	1155h	diamorphine 40mg/24h, haloperidol 5mg/24hr midazolam 20mg/24hr, hyoscine 400microg/24hr

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

2.12 Primary responsibility for the medical care of Mrs Richards during her two admissions to Gosport Hospital lay with Dr Lord, as the consultant responsible for his care. My understanding is that day-to-day medical care was delegated to the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital (statement of Dr Lord in interview with DC Colvin and DC McNally). Primary responsibility for the medical care of Mrs Richards during her two admissions to Queen Alexandra Hospital lay with Surgeon Commander Scott, Consultant Orthopaedic Surgeon. Junior medical staff were responsible for day-to-day medical care of Mrs Richards whilst at Queen Alexandra Hospital. Ward nursing staff were responsible for assessing and monitoring Mrs Richards and informing medical staff of any significant deterioration.

2.13 Dr Reid, Consultant Geriatrician was responsible for assessing Mrs Richards and making recommendations concerning her future care following her orthopaedic surgery, and arranged transfer to Gosport Hospital for rehabilitation.

Accuracy of diagnosis and prognosis including risk assessments

2.14 The initial assessment by the orthopaedic team was in my opinion competent and the admitting medical team obtained a good history of her decline in the previous six months. Surgeon Commander Pott discussed management options with the family and a decision was made to proceed with surgery but for Mrs Richards to not undergo cardiopulmonary resuscitation if she sustained a cardiac arrest, with a clear decision to keep Mrs Richards pain free, hydrated and nourished. There are good reasons to offer surgery for a fractured neck of femur to very frail patients with dementia even when a high risk of peri-operative death or complications is present. This is because without surgery patients continue to be in pain, remain immobile and nearly invariably develop serious complications such as pneumonia and pressure sores, which are usually fatal. From the information I have seen I would, as a consultant physician/geriatrician recommended the initial management undertaken. I consider it good management that the trazadone as discontinued when the history from the daughters suggested this might have been responsible for decline in the recent past.

2.15 After Mrs Richards was stable a few days following surgery it was appropriate to refer her for a geriatric opinion, and Dr Reid rapidly provided this. Dr Reid's assessment was in my opinion thorough and competent. He identified the potential for her to benefit from rehabilitation. I would consider his decision to refer her for rehabilitation despite her dementia to be appropriate. An elderly care rehabilitation, rather than an acute orthopaedic ward is in general a preferable environment to undertake such rehabilitation. It is implicit in his decision to transfer her to Gosport War Memorial Hospital that she would receive rehabilitation there and not care on a continuing care ward without input from a rehabilitation team. Dr Lord in an interview with DC McNally and DC Colvin describes Daedalus ward as "*Back in '98 .. Daedalus was a continuing care ward with 24 beds of which 8 beds were for slow stream stroke*

rehabilitation". Although Mrs Richards had a fractured neck of femur and not stroke as her primary problem requiring rehabilitation I would assume, in the light of Dr Reid's letter that she was transferred to one of the 8 slow stream rehabilitation beds on Daedalus ward.

2.16 The transfer letter from Sergeant Curran provides a clear description of Mrs Richards's status at the time of transfer. The observation that she was walking with the aid of two nurses and a zimmer frame, and the usual cause of agitation was when she needed to use the toilet are relevant to subsequent events following transfer to Gosport Hospital. The use of a Barthel Index score as a measure of disability is good practice and demonstrates that Mrs Richards was severely dependent at the time of her transfer to Gosport Hospital.

2.17 The initial entry by Dr Barton following Mrs Richards' transfer to Daedalus ward does not mention that she has been transferred for rehabilitation, and focuses on keeping her 'comfortable' despite recording that she is "*not obviously in pain*". The statement '*I am happy for nursing staff to confirm death*" also suggests that Dr Barton's assessment was that Mrs Richards might die in the near future. Dr Barton in her statement to DS Sackman and DC Colvin, confirms this when she states "*I appreciated that there was a possibility that she might die sooner rather than later*". Dr Barton refers to her admission as a "*holding manoeuvre*" and her statement suggests a much more negative view of the potential for rehabilitation. She does not describe any rehabilitation team or focus on the ward and suggests her transfer was necessary because she was not appropriate for an acute bed, rather than her being appropriate for rehabilitation- "*.her condition was not appropriate for an acute bed. ....seen whether she would recover and mobilise after surgery. If as was more likely she would deteriorate due to her age, her dementia, her frail condition and the shock of the fall followed by the major surgery, then she was to be nursed in a clam environment away from the stresses of an acute ward*". In my opinion this initial note entry and the statement by Dr Baron indicate a much less proactive view of rehabilitation, less appreciation than Dr Reid of the potential for Mrs Richards to recover to her previous level of functioning, and probably a failure to appreciate the potential benefits of appropriate multidisciplinary rehabilitation to Mrs Richards. This leads me to believe that Dr Barton's approach to Mrs Richards was in the context of considering her as a continuing care patient who was likely to die on the ward. It was not wrong or incorrect of Dr Barton to believe Mrs Richards might die on the ward, but I would consider her apparent failure to recognise Mrs Barton's rehabilitation needs may have led to subsequent sub-optimal care.

2.18 There are a number of explanations and contributory factors that may have led to Dr Barton possibly not recognising Mrs Richard's rehabilitation needs in addition to her nursing and analgesic needs. First she may have not clearly understood Dr Reid's assessment that she needed rehabilitation. In her statement Dr Barton states " *Dr Reid was of the view that, despite her dementia, she should be given the opportunity to try to remobilise*" which suggests Dr Barton may not have considered the necessity for Mrs Richards to receive Physiotherapy as a necessary part of her opportunity to remobilise. Second the ward had both continuing care and rehabilitation beds and these patients may require very different care. It is not uncommon for "slow stream" rehabilitation beds to be in the same ward as continuing care beds, but it does

require much broader range of care to meet the medical and social needs of these patients. I would anticipate that some patients would move from the slow stream rehabilitation to continuing care category. Dr Lord describes the existence of fortnightly multidisciplinary ward case conference suggesting there was a structured team approach that would have made Dr Barton and nursing staff aware of rehabilitation needs of patients. In Mrs Richards's case no such case conference took place because she became too unwell in a short period. Third Dr Barton may not have received sufficient training or gained adequate experience of rehabilitation or geriatrics despite working under the supervision of Dr Lord. Dr Lord states that Dr Barton was "*an experienced GP*" who had rights of admission to a GP ward and that Dr Lord had admitted patients "*under her care say for palliative care*". Experience in palliative care may possibly have influenced her understanding and expectations of rehabilitating older patients.

2.19 The assessment of Mrs Richard's agitation the following day on 12th August was in my opinion sub-optimal. The nursing records state that she did not appear to be in pain. There is no entry from Dr Barton this day but in her statement she states which I have some difficulty in interpreting: "*When I assessed Mrs Richards on her arrival she was clearly confused and unable to give any history. She was pleasant and co-operative on arrival and did not appear to be in pain. Later her pain relief and sedation became a problem. She was screaming. This can be a symptom of dementia but could also be caused by pain. In my opinion it was caused by pain as it was not controlled by Haloperidol alone. Screaming caused by dementia is frequently controlled by this sedative. Given my assessment that she was in pain I wrote a prescription for a number of drugs on 11th August, including Oramorph and Diamorphine. This allowed nursing staff to respond to their clinical assessment of her needs rather than wait until my next visit the following day. This is an integral part of team management. It was not in fact necessary to give diamorphine over the first few days following her admission but a limited number of small doses of Oramorph were given totalling 20mg over the first 24 hours and 10mg daily thereafter. This would be an appropriate level of pain relief after such a major orthopaedic procedure*".

2.20 I am unable establish from the notes and Dr Barton's statement whether she saw Mrs Richards in pain after she wrote in the notes and then wrote up the opiate drugs later on the 11th August, or if she wrote up these drugs after seeing her when she was not in pain, because she considered she might develop pain and agitation. In either case there is no evidence that the previous information provided by Sergeant Curran that Mrs Richards usually required the toilet when she was agitated was considered by Dr Barton. Screaming is a well-described behavioural disturbance in dementia (Dr Barton was clearly aware of this), which can be due to pain but is often not. In some cases it is not possible to identify a clear precipitating cause although a move to a new ward could precipitate such a behavioural disturbance. I would consider the assumption by Dr Barton that Mrs Richards screaming was due to pain was not supported by her own recorded observations. There is no evidence from the notes that Dr Barton examined Mrs Richards in the first two days to find any evidence on clinical examination that pain from her hip was the cause of her screaming. If the screaming had been worse on weight bearing or movement of the hip this would have provided supportive evidence that her screaming was

due to hip pain. Staff Nurse Jennifer Brewer in her interview with DC Colvin and DC McNally states that the nursing staff had considered the need for toileting and other potential causes of Mrs Richards screaming.

2.21 Mrs Richards pain following surgery had been controlled at Haslar hospital by intermittent doses of intravenous morphine and then intermittent doses of cocodamol (paracetamol and codeine phosphate). Dr Barton did not prescribe cocodamol or another mild or moderate analgesic to Mrs Richards to take on a prn basis when she was transferred. This makes me consider it probable that Dr Barton prescribed prn Oramorph, diamorphine, hyoscine and midazolam when she first saw Mrs Richards and she was not in pain. If this is the case it is highly unusual practice in a patient who has been transferred for rehabilitation, was not taking any regular or intermittent analgesics for 36 hours prior to transfer, and had last taken two tablets of cocodamol. In a rehabilitation or continuing care ward without resident medical staff I would consider it reasonable and usual practice to prescribe a mild or moderate analgesic to take on an as required basis in case further pain developed. In Mrs Richards's case a reasonable choice would have been cocodamol since she had been taking this a few days earlier without problems. I do not consider it was appropriate to administer intermittent doses of oramorph to Mrs Richards before first prescribing paracetamol, non-steroidal anti-inflammatory drugs or mild opiate. It is not appropriate to prescribe powerful opiate drugs as a first line treatment for pain not clearly due to a fracture or dislocation to a patient such as Mrs Richards 12 days following surgery. Dr Barton's statement that diamorphine and oramorph were appropriate analgesics at this stage following surgery when she had been pain free is incorrect and in my opinion would not be a view held by the vast majority of practising general practitioners and geriatricians.

2.22 The management of Mrs Richards when sustained a dislocation of her hip on 13th August was in my opinion sub-optimal. The hip dislocation most likely occurred following the fall from her chair at 1330h. The nursing notes suggest signs of a dislocation were noted at 1930h. If there was a delay in recognising the dislocation I would not consider this indicates poor care, as hip fractures and dislocations can be difficult to detect in patients who have dementia and communication difficulties. Mrs Richards suspected dislocation or fracture was discussed with the on-call doctor, Dr Briggs, who I would assume is a medical house officer. Given the concern about a fracture or dislocation I would judge it would have been preferable for her to b transferred to the orthopaedic ward that evening and be assessed by the orthopaedic team. I certainly consider the case should have been discussed with either the on call consultant geriatrician or the orthopaedic team. The benefits of transfer that evening in a patient where it was highly probable a fracture or dislocation were present would have been Mrs Richards could have received manipulation earlier the following morning and possibly that same evening, and that traction could have been applied even if reduction was not attempted.

2.23 Mrs Richards was found to have a dislocation of her right hip and this was manipulated under intravenous sedation the same day. Although she was initially unresponsive, most probably due to prolonged effects of the intravenous midazolam, 3 days later on 17th August she was mobilising and fully weight bearing and not requiring any analgesia. Although there are few medical note entries, the management at Haslar hospital during this period

appears to be appropriate and competent. Shortly after transfer back to Daedalus ward Mrs Richards again became very distressed. The nursing notes indicate there was an incorrect transfer by the ambulance staff of Mrs Richards onto her bed. Repeat dislocation of the right hip was reasonably suspected but not found on a repeat Xray. My impression is that this transfer may have precipitated hip or other musculoskeletal pain in Mrs Richards but that other causes of screaming were possible.

2.24 Intermittent doses of oral morphine were first administered to Mrs Richards, again without first determining whether less powerful analgesics would have been helpful. On 18th August Dr Barton suggested commencing subcutaneous diamorphine, haloperidol and midazolam. The diamorphine and midazolam had been prescribed 7 days earlier. An infusion of the three drugs was commenced later that morning and hyoscine was added on 19th August. Both Dr Barton's notes and the nursing notes indicate Mrs Richards was in pain, although it is not clear what they considered was the cause of the pain at this stage, having excluded a fracture or dislocation of the right hip. Dr Barton states in her prepared statement "*... it was my assessment that she had developed a haematoma or large collection of bruising around the area where the prosthesis had been lying while dislocated*".

2.25 Although there are no clear descriptions of Mrs Richard's conscious level in the last few days, her level of alertness appears to have deteriorated once the subcutaneous infusion of diamorphine, haloperidol and midazolam was commenced. It also seems that she was not offered fluids or food and intravenous or subcutaneous fluids were not considered as an alternative. My interpretation is that this was most probably because medical and nursing staff were of the opinion that Mrs Richards were dying and that provision of fluids or nutrition would not change this outcome. In her prepared statement Dr Barton states "*As their mother was not eating or drinking or able to swallow, subcutaneous infusion of pain killers was the best way to control her pain.*" and "*I was aware that Mrs Richards was not taking food or water by mouth*". She then goes on to say "*I believe I would have explained to the daughters that subcutaneous fluids were not appropriate*".

Evaluation of drugs prescribed and the administration regimens

2.26 The decision to prescribe oral opiates and subcutaneous diamorphine to Mrs Richards initial admission to Daedalus ward was in my opinion inappropriate and placed Mrs Richards at significant risk of developing adverse effects of excessive sedation and respiratory depression. The prescription of oral paracetamol, mild opiates such as codeine or non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen would have been appropriate oral and preferable with a better risk/benefit ratio. The prescription of subcutaneous diamorphine, haloperidol and midazolam infusions to be taken if required was inappropriate even if she was experiencing pain. Subcutaneous opiate infusions should be used only in patients whose pain is not controlled by oral analgesia and who cannot swallow oral opiates. The prescription by Dr Barton on 11th August of three sedative drugs by subcutaneous infusion was in my opinion reckless and inappropriate and placed Mrs Richards at serious risk of developing coma and respiratory depression had these been administered by the nursing staff. It is exceptionally unusual to prescribe subcutaneous infusion of these three drugs with powerful effects on conscious level and respiration to

frail elderly patients with non-malignant conditions in a continuing care or slow stream rehabilitation ward and I have not personally used, seen or heard of this practice in other care of the elderly rehabilitation or continuing care wards. The prescription of three sedative drugs is potentially hazardous in any patient but particularly so in a frail older patient with dementia and would be expected to carry a high risk of producing respiratory depression or coma.

2.27 I consider the statement by Dr Barton "*my use of midazolam in the dose of 20mg over 24 hours was as a muscle relaxant, to assist movement of Mrs Richards for nursing procedures in the hope that she could be as comfortable as possible. I felt it appropriate to prescribe an equivalence of haloperidol to that which she had been having orally since her first admission.*" Indicates poor knowledge of the indications for and appropriate use of midazolam administered by subcutaneous infusion to older people. Midazolam is primarily used for sedation and is not licensed for use as a muscle relaxant. Doses of benzodiazepine that produce significant muscle relaxation in general produce unacceptable depression of conscious level, and it is not usual practice amongst continuing care and rehabilitation wards to administer subcutaneous midazolam to assist moving patients.

Quality and sufficiency of the medical records

2.28 The medical and nursing records relating to Mrs Richards admissions to Daedalus ward are in my opinion not of an adequate standard. The medical notes fail to adequately account for the reasons why oramorph and then infusions of diamorphine and haloperidol were used. The nursing records do not adequately document hydration and nutritional needs of Mrs Richards during her admissions to Daedalus ward.

Appropriateness and justification of the decisions that were made

2.29 There are a number of decisions made in the care of Mrs Richards that I consider to be inappropriate. The initial management of her dislocated hip prosthesis was sub-optimal. The decision to prescribe oral morphine without first observing the response to milder opiate or other analgesic drugs was inappropriate. The decision to prescribe diamorphine, haloperidol and midazolam by subcutaneous infusion was, in my opinion, highly inappropriate.

Recorded cause of death

2.30 The recorded cause of death was bronchopneumonia. I understand that the cause of death was discussed with the coroner. A post mortem was not obtained and the recorded cause was certainly a possible cause of Mrs Richards's death. I am surprised the death certificate makes no mention of Mrs Richards's fractured neck of femur or her dementia. It is possible that Mrs Richards died from drug induced respiratory depression without bronchopneumonia present or from the combined effects of bronchopneumonia and drug-induced respiratory depression. Mrs Richards was at high risk of developing pneumonia because of the immobility that resulted following her transfer back to Daedalus ward even if she had not received sedative and opiate drugs. Bronchopneumonia can also occur as a secondary complication of opiate and sedative induced respiratory depression. In the absence of post-mortem, radiological data (chest Xray) or recordings of Mr Cunningham's respiratory rate I would consider the recorded cause of death of bronchopneumonia was possible. However given the rapid decline in

conscious level that preceded the development of respiratory symptoms (rattly chest) I would consider it more likely that Mrs Richards became unconscious because of the sedative and opiate drugs she received by subcutaneous infusion, that these drugs caused respiratory depression and that Mrs Richards died from drug induced respiratory depression and/or without bronchopneumonia resulting from immobility or drug induced respiratory depression. There are no accurate records of Mrs Richards respiratory rate but with the doses used and her previous marked sedative response to intravenous midazolam it is highly probable that respiratory depression was present.

Duty of care issues

2.31 Medical and nursing staff on Daedalus ward had a duty of care to deliver medical and nursing care to attempt to monitor Mrs Richards and to document the effects of drugs prescribed. In my opinion this duty of care was not adequately met. The prescription of diamorphine, midazolam and haloperidol was extremely hazardous and Mrs Richards was inadequately monitored. The duty of care of the medical and nursing staff to meet Mrs Richard's hydration and nutritional needs was also in my opinion probably not met.

Summary

2.32 Gladys Richards was a frail older lady with dementia who sustained a fractured neck of femur, successfully surgically treated with a hemiarthroplasty, and then complicated by dislocation. During her two admissions to Daedalus ward there was inappropriate prescribing of opiates and sedative drugs by Dr Baron. These drugs in combination are highly likely to have produced respiratory depression and/or the development of bronchopneumonia that led to her death. In my opinion it is likely the administration of the drugs hastened her death. There is some evidence that Mrs Richards was in pain during the three days prior to her heath and the administration of opiates can be justified on these grounds. However Mrs Richards was at high risk of developing pneumonia and it possible she would have died from pneumonia even if she had not been administered the subcutaneous sedative and opiate drugs.

Arthur "Brian" CUNNINGHAM

Course of Events

3.1 Mr Cunningham was 79 years old when admitted to Dryad ward, Gosport Hospital under the care of Dr Lord. Dr Lord had assessed him on a number of occasions in the previous 4 years. A letter dated 2nd December 1994 from Dr Bell, Clinical Assistant, indicates Parkinson's disease had been diagnosed in the mid 1980s and that he was having difficulties walking at this time. In 1998 it was noted he had experienced visual hallucinations and had moved into Merlin Park Rest Home. His weight was 69Kg in August 1998. In July 1998 he was admitted under the care of Dr Banks, Consultant in Old Age Psychiatry to Mulberry Ward A and discharged after 6 weeks to Thalassa Nursing Home. He was assessed to have Parkinson's disease and dementia, depression and myelodysplasia. Dr Lord in a letter dated 1 September 1998 summarises her assessment of Mr Cunningham when she saw him on Mulberry Ward A on 27 August 1998 before he was discharged to Thalassa Nursing Home. At this time he required 1-2 people to transfer and was unable to wheel himself around in his wheelchair. She commented that more levodopa might be required but was concerned it would upset his mental state. She arranged to review him at the Dolphin Day Hospital.

3.2 On 21st September 1998 he was seen at the Dolphin Day Hospital by Dr Lord who recorded *'very frail, tablets found in mouth, offensive large necrotic sacral sore with thick black scar. PD - no worse. Diagnoses listed as sacral sore (in N/H), PD, old back injury, depression and element of dementia, diabetes mellitus –diet, catheterised for retention. Plan – stop codanthramer and metronidazole. looks fine. TCI Dyad today –aserbine for sacral ulcer – nurse on side – high protein diet – oramorph prn if pain. N/Home to keep bed open for next 3/52 at least. Pt informed of admission agrees. Inform N/Home Dr Banks and social worker. Analgesics prn.'* He was admitted to Dyad ward. An entry by Dr Baron on 21 September states *'make comfortable, give adequate analgesia. Am happy for nursing staff to confirm death.'* On 24th September Dr Lord has written *'remains unwell. Son has ??? again today and is aware of how unwell he is. sc analgesia is controlling pain just. I am happy for nursing staff to confirm death.'* The next entry by Dr Brook is on 25th September *'remains very poorly. On syringe driver. For TLC'.*

3.3 Medication charts record the following administration of opiate and sedative drugs:

21 Sep 1415h Oramorph 5mg
1800h Coproxamol two tablets
(subsequent regular doses not administered)
2015h Oramorph10mg
21 Sep 2310h Diamorphine 20mg/24hr, midazolam 20mg/24hr infusion sc
22 Sep 2020h Diamorphine 20mg/24hr, midazolam 20mg/24hr infusion sc
23 Sep 0925h Diamorphine 20mg/24hr, hyoscine 200microg/24hr
midazolam 20 mg/24hr infusion sc
2000h Diamorphine 20mg/24hr, hyoscine 200microg/24hr
midazolam 60mg/24hr infusion sc
24 Sep 1055h Diamorphine 20mg/24hr, hyoscine 800microg/24hr
midazolam 80mg/24hr infusion sc
25 Sep 1015h Diamorphine 60mg/24hr, hyoscine 1200mg/24hr

midazolam 80mg/24hr infusion
26 Sep 1150h Diamorphine 80mg/24hr, hyoscine 1200mg/24hr
midazolam 100mg/24hr infusion
Sinemet 110 5 times/day was discontinued on 23rd September

3.4 The nursing notes relating to the admission to Dyad ward record on 21st Sept *'remained agitated until approx 2030h. Syringe driver commenced as requested* (unclear who made this request) *diamorphine 20mg, midazolam 20mg at 2300. Peaceful following".* On 22nd Sep *'explained that a syringe driver contains diamorphine and midazolam was commenced yesterday evening for pain relief and to allay his anxiety following an episode where Arthur tried to wipe sputum on a nurse saying he had HIV and going to give it to her. He also tried to remove his catheter and empty the bag and removed his sacral dressing throwing it across the room. Finally he took off his covers and exposed himself.'*

3.5 On 23rd Sep *'Has become chesty overnight to have hyoscine added to driver. Stepson contacted and informed of deterioration. Mr Farthing asked is this was due to the commencement of the syringe driver and informed that Mr Cunningham was on a small dosage which he needed.'* A later entry *'now fully aware that Brian is dying and needs to be made comfortable. Became a little agitated at 2300h, syringe driver adjusted with effect. Seems in some discomfort when moved, driver boosted prior to position change'.* On 24th Sept *'report from night staff that Brian was in pain when attended to, also in pain with day staff – especially his knees. Syringe driver renewed at 1055".* On 25th Sept *'All care given this am. Driver recharged at 1015 –diamorphine 60mg, midazolam 80mg and hyoscine 1200mcg at a rate of 50mmols/hr. Peaceful night - unchanged, still doesn't like being moved.'* On 26th September *'condition appears to be deteriorating slowly'.*

3.6 On 26th September staff nurse Tubbritt records death at 2315h. Cause of death was recorded on the death certificate as bronchopneumonia with contributory causes of Parkinson's disease and Sacral Ulcer.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

3.7 Primary responsibility for the medical care of Mr Cunningham during his last admission lay with Dr Lord, as the consultant responsible for his care. She saw Mr Cunningham 5 days before his death in the Dolphin Day Hospital, and 2 days before his death on Dyad ward. My understanding is that day-to-day medical care was the responsibility of the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital. Ward nursing staff were responsible for assessing and monitoring Mr Cunningham and informing medical staff of any significant deterioration.

Accuracy of diagnosis and prognosis including risk assessments

3.8 Initial assessment by Dr Lord was comprehensive and appropriate with a clear management plan described. The nursing staff record Mr Cunningham was agitated following admission on 21st September. Dr Lord had prescribed prn (intermittent as required) oramorph for pain. Nursing staff made the decision to administer oramorph but there is no clear recording in the nursing notes that he

was in pain or the site of pain. The nursing entry on 22nd Sept indicates a syringe driver was commenced for 'pain relief and to allay anxiety. Again the site of pain is not states. My interpretation of the records is that the nursing staff considered his agitation was due to pain from his sacral ulcer. The medical and nursing teams view on the cause of Mr Cunningham's deterioration on 23rd September when he became 'chesty' are not explicitly stated, but would seem to have been thought to be due to bronchopneumonia since this was the cause of death later entered on the death certificate. The medical and nursing staff may not have considered the possibility that Mr Cunningham's respiratory symptoms and deterioration may have been due to opiate and benzodiazepine induced respiratory depression. The nursing staff filed to appreciate that the agitation Mr Cunningham experienced on 23rd Sept at 2300h may have been due to the midazolam and diamorphine. It was appropriate for nursing staff to discuss Mr Cunningham's condition with medical staff at this stage.

3.9 When Dr Lord reviewed Mr Cunningham on 24th September the notes imply that he was much worse that when she had seen him 3 days earlier. There is clear recording by Dr Lord that Mr Cunningham was in pain. The following day the diamorphine dose was increased three fold from 20mg/24hr to 60mg/24hr and the dose was further increased on 26th September to 80mg/24hr although the nursing and medical notes do not record the reason for this. The notes suggest that the nursing and medical staff may have failed to consider causes of agitation other than pain in Mr Cunningham or to recognise the adverse consequences of opiates and sedative drugs on respiratory function in frail older individuals.

Evaluation of drugs prescribed and the administration regimens

3.10 The prescription of oramorph to be taken 4 hourly as required by Mr Cunningham was reasonable if his pain was uncontrolled from cocodamol. I consider the decision by Dr Barton to prescribe and administer diamorphine and midazolam by subcutaneous infusion the same evening he was admitted was highly inappropriate, particularly when there was a clear instruction by Dr Lord that he should be prescribed intermittent (underlined instruction) doses of oramorph earlier in the day. I consider the undated prescription by Dr Baron of subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr to be poor practice and potentially very hazardous. In my opinion it is poor management to initially commence both diamorphine and midazolam in a frail elderly underweight patient such as Mr Cunningham. The combination could result in profound respiratory depression and it would have been more appropriate to review the response to diamorphine alone before commencing midazolam, had it been appropriate to commence subcutaneous analgesia, which as I have stated before was not the case.

3.11 In my opinion it is doubtful the nursing and medical staff understood that when a syringe infusion pump rate is increased it takes an often appreciable effect of time before the maximum effect of the increased dose rate becomes evident. Typically the time period would be 5 drug half-lives. In the case of diamorphine this would be between 15 and 25 hours in an older frail individual.

Quality and sufficiency of the medical records

3.12 In my opinion the medical and nursing records are inadequate following Mr Cunningham's admission to Dryad ward. The initial assessment by Dr Lord on 21st September is in my opinion competent and appropriate. The medical notes following this are inadequate and do not explain why he was commenced on subcutaneous infusions of diamorphine and midazolam. The nursing notes are variable and at times inadequate.

Appropriateness and justification of the decisions that were made

3.13 An inappropriately high dose of diamorphine and midazolam was first prescribed. There was a failure to recognise or respond to drug induced problems. Inappropriate dose escalation of diamorphine and midazolam and poor assessment by Dr Lord. The assessment by Dr Lord on 21st September 1998 was thorough and competent and a clear plan of management was outlined. There is a clear note by Dr Lord that oramorph was to be given intermittently (PRN) for pain and not regularly. It is not clear from the medical and nursing notes why Mr Cunningham was not administered the regular cocodamol he was prescribed following the initial dose he received at 1800h. following admission. It is good practice to provide regular oral analgesia, with paracetamol and a mild opiate, particularly when a patient has been already taking this medication and to use prn morphine for breakthrough pain. I consider the prescription by Dr Barton on admission of prn subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr to be unjustified, poor practice and potentially very hazardous. It is particularly notable that only hours earlier Dr Lord had written that oramorph was to be given intermittently and this had been underlined in the medical notes. There is no clear justification in the notes for the commencement of subcutaneous diamorphine and midazolam on the evening following admission. If increased opiate analgesia was required increasing the oramorph dose and frequency could have provided this. I would judge it poor management to initially commence both diamorphine and midazolam. The combination could result in profound respiratory depression and it would have been more appropriate to review the response to diamorphine alone before commencing midazolam.

3.14 I am concerned by the initial note entry by Dr Barton on 21st September 1998 that she was happy for nursing staff to confirm death. There was no indication by Dr Lord that Mr Barton was expected to die, and Dr Barton does not list the reason she would have cause to consider Mr Cunningham would die within the next 24 hours before he was reviewed the following day by medical staff. In my opinion it is of concern that the nursing notes suggest the diamorphine and midazolam infusions were commenced because of Mr Cunningham's behaviour recorded in the nursing entry on 22nd September.

3.15 Hyoscine was commenced on 23rd September after Mr Cunningham had become 'chesty' overnight. I consider it very poor practice that there is no record of Mr Cunningham being examined by a doctor following admission on 21st September, and a decision to treat this symptomatically with hyoscine appears to have been made by the medical staff. At this stage Mr Cunningham's respiratory signs are likely to have been due to bronchopneumonia or respiratory depression resulting in depressed clearance of bronchial secretions. A medical assessment was very necessary at this

stage to diagnose the cause of symptoms and to consider treatment with antibiotics or reduction in the dose of diamorphine and midazolam.

3.16 Again I consider it very poor practice that the midazolam was increased from 20mg/24hr to 60mg/24 hr at 2000h on 23rd September. There is no entry in the medical notes to explain this dose increase. The decision to triple the midazolam dose appears to have been made by a member of nursing staff as the nursing notes record *"agitated at 2300h, syringe driver boosted with effect"*.

3.17 A medical assessment should have been obtained before the decision to increase the midazolam dose was made. At the very least Mr Cunningham's problems should have been discussed with on call medical staff. Mr Cunningham's agitation may have been due to pain, where increasing analgesia would have been appropriate, or hypoxia (lack of oxygen). If Mr Cunningham's agitation was due to hypoxia a number of interventions may have been indicated. Reducing the diamorphine and midazolam dose would have been appropriate if hypoxia was due to respiratory depression. Commencement of oxygen therapy and possibly antibiotics would have been appropriate if hypoxia was due to pneumonia. Reducing the dose diamorphine or midazolam would have been indicated if hypoxia was due to drug-induced respiratory depression. The decision to increase the midazolam dose was not appropriately made by the ward nursing staff without discussion with medical staff.

3.18 When Mr Cunningham was reviewed by Dr Lord on 24th September he was very unwell but there is not a clear description of his respiratory status or whether he had signs of pneumonia. At this stage Dr Lord notes Mr *Cunningham is in pain, but does not state the site of his pain. It is not clear to* me whether the subsequent alteration in infusion rate of diamorphine, hyoscine and midazolam was discussed with and sanctioned by Dr Lord or Dr Barton. I consider the increase in midazolam from 60mg/24 hr to 80mg/24 hr was inappropriate as a response to the observation that Mr Cunningham was in pain. It would have been more appropriate to increase the diamorphine dose or even consider treatment with a non-steroidal anti-inflammatory drug. The increase in midazolam dose to 80mg/24 hr would simply make Mr Cunningham less conscious than he already appears to have been (there is not a clear description of his conscious level at this stage).

3.19 The increase in hyoscine dose to 800microg/24 hr is also difficult to justify when there is no record that the management of bronchial secretions was a problem. The subsequent threefold increase in diamorphine dose later that day to 60mg/24 hr is in my view very poor practice. Such an increase was highly likely to result in respiratory depression and marked depression of conscious level, both of which could lead to premature death. The description of Mr Cunningham, was that analgesia was 'just' controlling pain and a more cautious increase in diamorphine dose, certainly no more than two fold, was indicated with careful review of respiratory status and conscious level after steady state levels of diamorphine would have been obtained about 20 hours later. A more appropriate response to deal with any acute breakthrough pain is to administer a single prn (intermittent) dose of opiate by the oral or intramuscular route, depending on whether Mr Cunningham was unable to swallow at this time.

3.20 The increase in both diamorphine dose and midazolam dose on 26th September is difficult to justify when there is no record in the medical or nursing notes that Mr Cunningham's pain was uncontrolled. Although it is possible to accept the increase in diamorphine dose may have been appropriate if Mr Cunningham was observed to be in pain, I find the further increase in midazolam dose to 100mg/24hr of great concern. I would anticipate that this dose of midazolam administered with 80mg/24hr of diamorphine would be virtually certain to produce respiratory depression and severe depression of conscious level. This would be expected to result in death in a frail individual such as Mr Cunningham. I would expect to see very clear reasons for the use of such doses recorded in the medical notes.

3.21 I can find no record of Mr Cunningham receiving food or fluids following his admission on 21st September despite a note from Dr Lord that Mr Cunningham was to receive a 'high protein diet'. There is no indication in the medical or nursing notes as to whether this had been discussed, but given that Mr Cunningham was admitted with the intention of returning to his Nursing Home (it was to be held open for 3 weeks) I would expect the notes to record a clear discussion and decision making process involving senior medical staff accounting for the decision to not administer subcutaneous fluids and/or nasogastric nutrition once Mr Cunningham was commenced on drugs which may have made him unable to swallow fluids or food.

Recorded causes of death

3.22 The recorded cause of death was bronchopneumonia with contributory causes of Parkinson's disease and sacral ulcer. A post mortem was not obtained and the recorded causes were in my opinion reasonable. It is possible that Mr Cunningham died from drug induced respiratory depression without bronchopneumonia present or from the combined effects of bronchopneumonia and drug-induced respiratory depression. Mr Cunningham was at high risk of developing pneumonia even if he had not received sedative or opiate drugs, bronchopneumonia can occur as a secondary complication of opiate and sedative induced respiratory depression. In the absence of post-mortem, radiological data (chest Xray) or recordings of Mr Cunningham's respiratory rate I would consider the recorded cause of death of bronchopneumonia as reasonable. Even if the staff had considered Mr Cunningham had drug-induced respiratory depression as a contributory factor, it would not be usual medical practice to enter this as a contributory cause of death where the administration of such drugs was considered appropriate for symptom relief.

Duty of care issues

3.23 Medical and nursing staff on Dryad ward had a duty of care to deliver medical and nursing care to attempt to heal Mr Cunningham's sacral ulcer and to document the effects of drugs prescribed. In my opinion this duty of are was not adequately met and the denial of fluid and diet and prescription of high doses of diamorphine and midazolam was poor practice and may have contributed to Mr Cunningham's death.

Summary

3.24 In summary although Mr Cunningham was admitted for medical and nursing care to attempt to heal and control pain from his sacral ulcer, Dr Barton and the ward staff appear to have considered Mr Cunningham was dying and had been admitted for terminal care. The medical and nursing records are inadequate in documenting his clinical state at this time. The initial prescription of subcutaneous diamorphine, midazolam and hyoscine by Dr Barton was in my view reckless. The dose increases undertaken by nursing staff were inappropriate if not undertaken after medical assessment and review of Mr Cunningham. I consider it highly likely that Mr Cunningham experienced respiratory depression and profound depression of conscious level due to the infusion of diamorphine and midazolam. I consider the doses of these drugs prescribed and administered were inappropriate and that these drugs most likely contributed to his death through pneumonia and/or respiratory depression.

ALICE WILKIE

Course of Events

4.1 Alice Wilkie was 81 years old when admitted under the care of Dr Lord, by her general practitioner on 31st July 1998 from Addenbrooke Rest Home to Phillip Ward, Department of Medicine for Elderly People, at the Queen Alexandra Hospital, Portsmouth. The general practitioner referral letter states "*This demented lady has been in this psychogeriatric care home for a year. She had a UTI early this week and has not responded to trimethoprim. Having fallen last night, she is not refusing fluids and is becoming a little dry*". The medical admitting notes record she was taking prozac (fluoxetine) syrup 20 mg once daily, codanthramer 5-10ml nocte, lactulose 10ml once daily zopiclone 1.875 or 3.75mg nocte and promazine syrup 25mg as required. On examination she had a fever and bilateral conjunctivitis but no other significant findings. The admitting doctor diagnosed a urinary tract infection and commenced intravenous antibiotics to be administered after a blood culture and catheter specimen of urine had been obtained. The following day DNR (do not resuscitate) is recorded in the notes. On 3rd August 1998 the medical notes record the fever had settled, that she was taking some fluids orally, was taking the antibiotic Augmentin elixir orally and receiving subcutaneous fluids. The notes then record (date not clear) that her Mental Test Score was 0/10 and Barthel 1/20 (indicating severe dependency). Mrs Wilkie was to be transferred to Daedalus NHS continuing care ward on 6th August 1998 with a note that her bed was to be kept at Addenbrooke Rest Home.

4.2 Following transfer on 6th August an entry in the medical notes states "*Transferred from Phillips Ward. For 4-6/52 only. On Augmentin for UTI*". Dr Lord writes on 10th August 1998 '*Barthel 2/20. Eating and drinking better. Confused and slow. Give up place at Addenbrooke's. R/V* (review) *in 1/12* (one month) *–if no specialist medical or nursing problems D* (discharge) *to a N/Home. Stop fluoxetine*'. The next entry is by Dr Barton on 21st August "*Marked deterioration over last few days. sc analgesia commenced yesterday. Family aware and happy*". The final entry is on the same day at 1830h where death is confirmed. The most recent record of the patient's weight I can find is 56Kg in April 1994.

4.3 The nursing notes, which have daily entries during her one week stay on Phillip ward note she was catheterised, was confused at times and was sleeping well prior to transfer. The nursing notes on Daedalus ward record "6/8/98 *Transferred from Philip ward QAH for 4-6 weeks assessment and observation and then decide on placement. Medical history of advanced dementia, urinary tract infection and dehydration*" and that she was seen by Dr Peters. The nursing assessment sheet notes *"does have pain at times unable to ascertain where"*. The nutrition care plan states on 6th August 1998 "*Due to dementia patient has a poor dietary intake*". And dietary intake is recorded between 12th August and 18th August but not before or following these dates. Nursing entries in the contact record state on 17th August 1998 "*Condition has generally deteriorated over the weekend Daughter seen- aware that mums condition is worsening, agrees active treatment not appropriate and to use of syringe driver if Mrs Wilkie is in pain*". There is no entry in the notes on 20th August or preceding few days indicating Mrs Wilkie was in pain.

4.4 A nursing entry on 21st August 1998 at 1255h states "*Condition deteriorating during morning. Daughter and granddaughters visited and stayed. Patient comfortable and pain free*". There are a number of routine entries in the period 6th August 1998 to death on 21st August 1998 in nutrition, pressure area care, constipation, catheter care, and personal hygiene. The nursing care plan records no significant deterioration until 21st August where it is noted death was pronounced at 2120h by staff nurse Sylvia Roberts. Cause of death was recorded as bronchopneumonia.

4.5 The drug charts records that Dr Barton prescribed as a regular daily review (not intermittent as required) prescription diamorphine 20-200mg/24hr, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr all to be administered subcutaneously. The prescription is not dated. Drugs were first administered on 20th August, diamorphine at 30mg/24hr and midazolam 20mg/24hr from 1350h and then again on 21st August. Mrs Wilkie had not been prescribed or administered any analgesic drugs during her admission to Daedalus ward prior to administration of the diamorphine and midazolam infusions. During the period 16th-18th August she was prescribed and received zopiclone (a sedative hypnotic) 3.75mg nocte and co-danthramer 5-10ml (a laxative) orally.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

4.6 Primary responsibility for the medical care of Mrs Wilkie during her admission to Daedalus ward lay with Dr Lord, as the consultant responsible for her care. She saw Mrs Wilkie on 10th August 1998, 11 days prior to her death. My understanding is that day-to-day medical care was the responsibility of the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital. Ward nursing staff were responsible for assessing and monitoring Mrs Wilkie and informing medical staff of any significant deterioration.

Accuracy of diagnosis and prognosis including risk assessments

4.7 The initial diagnosis of a urinary tract infection and dehydration was reasonable and appears correct. Mrs Wilkie had a diagnosis of dementia, which there was clear evidence for. The entry by Dr Lord on 10th August 1998 provides a reasonable assessment of her functional level at this time, and a plan to review appropriate placement in one month's time. No diagnosis was made to explain the deterioration Mrs Wilkie is reported to have experienced around 15th August. There is no medical assessment in the notes following 10th August except documentation on 21st August 1998 of a marked deterioration. There is no clear evidence that Mrs Wilkie was in pain although she was commenced on opiate analgesics.

Evaluation of drugs prescribed and the administration regimens

4.8 No information is recorded in the medical or nursing notes to explain why Mrs Wilkie was commenced on diamorphine and hyoscine infusions. In my opinion there was no indication for the use of diamorphine and hyoscine in Mrs Wilkie. Other oral analgesics, such as paracetamol and mild opiate drugs could and should first have been tried, if Mrs Wilkie was in pain, although there is no evidence that she was. If these were inadequate oral morphine would have

been the next appropriate choice. From the information I have seen in the notes it appears the diamorphine and midazolam may have been commenced for non-specific reasons, perhaps as a non-defined palliative reasons as it was judged she was likely to die in the near future.

4.9 I consider the undated prescription by Dr Barton of subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr to be poor practice and potentially very hazardous. I consider it poor and hazardous management to initially commence both diamorphine and midazolam in a frail elderly underweight patient with dementia such as Mrs Wilkie. The combination could result in profound respiratory depression and it would have been more appropriate to review the response to diamorphine alone before commencing midazolam, had it been appropriate to commence subcutaneous analgesia, which as I have stated before was not the case.

Quality and sufficiency of the medical records

4.10 The medical and nursing records during her stay on Daedalus ward are inadequate not sufficiently detailed, and do not provide a clear picture of Mrs Wilkie's condition. In my opinion the standard of the notes falls below the expected level of documentation on a continuing care or rehabilitation ward. The assessment by Dr Lord on 10th August 1998 is the only satisfactory medical note entry during her 15 day stay on Daedalus ward.

Appropriateness and justification of the decisions that were made

4.11 As discussed above I do not consider the decision to commence diamorphine and hyoscine was appropriate on the basis of the information recorded in the clinical notes.

Recorded causes of death

4.12 There was no specific evidence that bronchopneumonia was present, although this is a common pre-terminal event in frail older people, and is often entered as the final cause of death in frail older patients. I am surprised the death certificate did not apparently refer to Mrs Wilkie's dementia as a contributory cause. It is possible Mrs Wilkie's death was due at least in part to respiratory depression from the diamorphine she received, or that the diamorphine led to the development of bronchopneumonia. However since there are no clear observations of Mrs Wilkie's respiratory observations it is difficult to know whether respiratory depression was present Mrs Wilkie deteriorated prior to administration of diamorphine and midazolam infusion, and in view of this, my opinion would be that although the opiate and sedative drugs administered may have hastened death, and these drugs were not indicated, Mrs Wilkie may well have died at the time she did even if she had not received the diamorphine and midazolam infusions.

Duty of care issues

4.13 Medical and nursing staff on Daedalus ward had a duty of care to deliver medical and nursing care, to monitor, and to document the effects of drugs prescribed to Mrs Wilkie. In my opinion this duty of care was not adequately met, the prescription of diamorphine and midazolam was poor practice and this may have contributed to Mrs Wilkie's death.

Summary

4.14 In my opinion the prescription of subcutaneous diamorphine and midazolam was inappropriate, and probably resulted in depressed conscious level and respiratory depression, which may have hastened her death. However Mrs Wilkie was a frail very dependent lady with dementia who was at high risk of developing pneumonia. It is possible she would have died from pneumonia even if she had not been administered the subcutaneous sedative and opiate drugs.

Robert WILSON

5.1 Mr Wilson was 75 years old man when he was admitted to Queen Alexandra Hospital on 22nd September 1998 after he sustained a proximal fracture of the left humerus. He was treated with morphine, initially administered intravenously and then subcutaneously. He developed vomiting. On 24th September he was given 5mg diamorphine and lost sensation in the left hand. On 29th September an entry in the medical notes states "*ref to social worker, review resus status. Not for resuscitation in view of quality of life and poor prognosis*".

5.2 On 7th October the notes record he was "*not keen on residential home and wished to return to his own home*". Dr Lusznat, Consultant in Old Age Psychiatry on 8th October 1998, saw him. Dr Lusznat's letter on 8th October notes that Mr Wilson had been sleepy and withdrawn and low in mood but was now eating and drinking well and appeared brighter in mood. His Barthel score was 5/20. Dr Lusznat noted he had a heavy alcohol intake during the last 5 years. At the time he was seen by Dr Lusznat her was prescribed thiamine 100 mg daily, multivitamins two tablets daily, senna two tablets daily, magnesium hydroxide 10 mls twice daily and paracetamol 1g four time daily. On examination he had mildly impaired cognitive function (Mini Mental State Examination 24/30). Dr Lusznat considered Mr Wilson might have developed an early dementia, which could have been alcohol related, Alzheimer's disease or vascular dementia. An antidepressant trazadone 50mg nocte was commenced. Dr Lusznat states at the end of her letter "*On the practical side he may well require nursing home care though at the moment he is strongly opposed to that idea I shall be happy to arrange follow up by our team once we know when and where he is going to be discharged*". On 13th October the medical notes record a ward round took place, that he required both nursing and medical care, was at risk of falling and that a short spell in long-term NHS care would be appropriate. Reviewing the drug charts Mr Wilson was taking regular soluble paracetamol (1g four times daily) and codeine phosphate 30mg as required for pain. Between 8th and 13th October Mr Wilson was administered four doses of 30mg codeine. Mr Wilson's weight in March 1997 was 93Kg

5.3 On the 14th October Mr Wilson was transferred to Dryad Ward. An entry in the medical notes by Dr Barton reads "*Transfer to Dryad ward continuing care. HPC fracture humerus. needs help with ADL (*activities of Daily Living*), hoisting, continent, Barthel 7. Lives with wife. Plan further mobilisation*". On 16th November the notes record; '*Decline overnight with S.O.B. o/e ? weak pulse. Unresponsive to spoken work. Oedema ++ in arms and legs. Diagnosis ?silent MI, ? decreased __ function. ↑frusemide to 2 x 40mg om* '. On 17th October the notes record '*comfortable but rapid deterioration*'. On 18th October staff nurse Collins records death at 2340h. Cause of death is recorded as congestive cardiac failure.

5.4 Nursing notes state in the summary section on 14th October "*History of left humerus fracture, arm in collar and cuff. Long history of heavy drinking. LVF chronic oedematous legs. S/B Dr Barton. Oramorph 10mg/5ml given. Continent of urine – uses bottles*". On 15th October "*Commenced oramorph 10mg/5ml 4 hrly for pain in L arm. Wife seen by sis. Hamblin who explained Robert's condition is poor*". An earlier note states "*settled and slept well*". On 16th October "*seen by Dr Knapman an as deteriorated over night. Increase*

frusemide to 80mgdaily. For A.N.C (active nursing care)". Later that day a further entry states "*Patient very bubbly chest this pm. Syringe driver commenced 20mg diamorphine, 400mcgs hyoscine. Explained to family reason for driver*". A separate note on 16th October in the nursing care plan states "*More secretions – pharyngeal – during the night, but Robert hasn't been distressed. Appears comfortable*". On 17th October 0515h "*Hyoscine increased to 600mcgs as oro-pharyngeal secretions increasing. Diamorphine 20mg.*" Later that day a further entry states "*Slow deterioration in already poor condition. Requiring suction very regularly – copious amounts suctioned. Syringe driver reviewed at 15.50 s/c diamorphine 40mg, midazolam 20mcgs, hyoscine 800 mcgs*". A later note states "*night: noisy secretions but not distressing Robert. Suction given as required during night. Appears comfortable*". On 18th October "*further deterioration in already poor condition. Syringe driver reviewed at 14:40 s/c diamorphine 60mg, midazolam 40mg, hyoscine 1200mcg. Continues to require regular suction*".

5.5 *The medication charts record administration of the following drugs:*

14 Sep 1445h oramorph 10mg
2345h oramorph 10mg
16 Sep 1610h diamorphine 20mg/24 hr, hyoscine 400 microg/24hr subcutaneous infusion
17 Sep 0515h diamorphine 20mg/24hr; hyoscine 600 microg/24hr
1550h diamorphine 40mg/24hr, hyoscine 800 microg/24hr midazolam 20mg/24hr
18 Sep 1450h diamorphine 60mg/24hr, hyoscine 1200 microg/24hr midazolam 40mg/24hr

Frusemide was administered at a dose of 80mg daily at 0900h on 15th and 16th October. An additional 80 mg oral dose was administered at an unstated time on 16th October.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

5.6 Responsibility for the care of Mr Wilson during his admission to Dryad ward lay with Dr Lord as the consultant responsible for his care. My understanding is that day to day medical care was delegated to the clinical assistant Dr Barton and during the out of hours responsibility was with the on call doctor based at Queen Alexandra Hospital. Ward nursing staff were responsible for assessing and monitoring Mr Wilson and informing medical staff of any significant deterioration.

5.7 Dr Lusznat was responsible for assessing Mr Wilson and making further recommendations concerning his future care when he was seen at Queen Alexandra Hospital.

Accuracy of diagnosis and prognosis including risk assessments

5.8 Dr Barton assessed Mr Wilson on 14th October the day he was transferred to Dyad ward. There was a plan to attempt to improve his mobilisation through rehabilitation. There is no record of any significant symptomatic medical problems, in particular any record that Mr Wilson was in pain in the medical

notes. The nursing notes suggest Mr Wilson was prescribed oramorph for pain in his arm following his admission to Dryad Ward. He was prescribed paracetamol to take as required but did not receive any paracetamol whilst on Dryad Ward.

5.9 Mr Wilson deteriorated on 15th September when he became short of breath. The working diagnosis was of heart failure due to a myocardial infarct. I do not consider the assessment by the on call doctor of Mr Wilson was adequate or competent. There is no record of his blood pressure, clinical examination findings in the chest (which might have indicated whether he had signs of pulmonary oedema or pneumonia). In my opinion an ECG should have been obtained that night, and a Chest Xray obtained the following morning to provide supporting evidence for the diagnosis. Mr Wilson was admitted for rehabilitation not terminal care and it was necessary and appropriate to perform reasonable clinical assessments and investigations to make a correct diagnosis.

5.10 Following treatment Mr Wilson was noted to have had a rapid deterioration. The medical and nursing teams appear to have failed to consider that Mr Wilson's deterioration may have been due to the diamorphine infusion. In my opinion when Mr Wilson was unconscious the diamorphine infusion should have been reduced or discontinued. The nursing and medical staff failed to record Mr Wilson's respiratory rate, which was likely to have been reduced, because of respiratory depressant effects of the diamorphine. The diamorphine and hyoscine infusion should have been discontinued to determine whether this was contributing to his deteriorating state. There is no record of the reason for the prescribing of the midazolam infusion commenced the day before his death. At this time the nursing notes record he was comfortable. Mr Wilson did not improve. The medical and nursing teams did not appear to consider that the diamorphine, hyoscine and midazolam infusion could be a major contributory factor in Mr Wilson's subsequent decline. The infusion should have been discontinued and the need for this treatment, in my opinion unnecessary at the time of commencement, reviewed.

Evaluation of drugs prescribed and the administration regimens

5.11 The initial prescription and administration of oramorph to Mr Wilson following his transfer to Dryad ward was in my opinion inappropriate. His pain had been controlled with regular paracetamol and as required codeine phosphate (a mild opiate) prior to his transfer, and in the first instance these should have been discontinued.

5.12 I am unable to establish when Dr Barton wrote the prescription for subcutaneous diamorphine 20-200mg/24hr, hyoscine 200-800microg/24hr, and midazolam 20-80mg/24hr as these are undated. The administration of diamorphine and hyoscine by subcutaneous infusion as a treatment for the diagnosis of a silent myocardial infarction was in my opinion inappropriate. The prescription of a single dose of intravenous opiate is standard treatment for a patient with chest pain following myocardial infarction is appropriate standard practice but was not indicated in Mr Wilson's case as he did not have pain. The prescription of an initial single dose of diamorphine is appropriate as a treatment for pulmonary oedema if a patient fails to respond to intravenous diuretics such as frusemide. Mr Wilson was not administered intravenous

frusemide or another loop diuretic. Instead only a single additional oral dose of frusemide was administered. In my opinion this was an inadequate response to Mr Wilson's deterioration. The prescription of continuous subcutaneous infusion of diamorphine and hyoscine is not appropriate treatment for a patient who is pain free with a diagnosis of a myocardial infarction and heart failure. When opiates are used to treat heart failure, close monitoring of blood pressure and respiratory rate, preferably with monitoring of oxygen saturation is required. This was not undertaken.

5.13 The increase in diamorphine dose to 40mg/24hr and then 60mg/24 hr in the following 48 hours is not appropriate when the nursing and medical notes record no evidence that Mr Wilson was in pain or distressed at this time. This was poor practice and potentially very hazardous. Similarly the addition of midazolam and subsequent increase in dose to 40mg/24hr was in my opinion highly inappropriate and would be expected to carry a high risk of producing profound depression of conscious level and respiratory drive.

Quality and sufficiency of the medical records

5.14 The initial entry in the medical records by Dr Barton on 14th October is reasonable and sufficient. The subsequent entries relating to Mr Wilson's deterioration are in my opinion inadequate, and greater detail and the results of examination findings should have been recorded. No justification for the increases in diamorphine, midazolam and hyoscine dose are written in the medical notes. The nursing notes are generally of adequate quality but I can find no record of fluid and food intake by Mr Wilson.

Appropriateness and justification of the decisions that were made

5.15 I consider the prescription of oramorph was inappropriate. The subsequent prescription and administration of diamorphine, hyoscine and midazolam was highly inappropriate, not justified by information presented in the notes and could be expected to result in profound depression of conscious level and respiratory depression in a frail elderly man such as Mr Wilson.

Recorded causes of death

5.16 The recorded cause of death was congestive cardiac failure. The limited clinical information recorded in the absence of a chest Xray result or post-mortem findings, suggest this may have been the cause of Mr Wilson's death. However in my opinion it is highly likely that the diamorphine, hyoscine and midazolam infusion led to respiratory depression and/or bronchopneumonia and it is possible that Mr Wilson died from drug induced respiratory depression.

Duty of care issues

5.17 Medical and nursing staff on Dryad ward had a duty of care to deliver appropriate medical and nursing care to Mr Wilson, and to monitor the effects of drugs prescribed. In my opinion this duty of care was not adequate. The administration of high doses of diamorphine and midazolam was poor practice and may have contributed to Mr Wilson's death.

Summary

5.18 Mr Wilson was a frail elderly man with early dementia who was physically dependent. Following his admission to Dryad ward he was, in my opinion, inappropriately treated with high doses of opiate and sedative drugs. These drugs are likely to have produced respiratory depression and/or the development of bronchopneumonia and may have contributed to his death.

Eva PAGE

6.1 Eva Page was 87 years old when admitted as an emergency on 6th February 1998 to the Department of Medicine for Elderly People at Queen Alexandra Hospital. The medical notes record that she had experienced a general deterioration over the last 5 days was complaining of nausea and reduced appetite and was dehydrated. She had felt 'depressed' during the last few weeks. On admission she was taking ramipril 5mg once daily (a treatment for heart failure and hypertension), frusemide 40mg once daily (treatment for fluid retention), digoxin 125microg once daily (to control irregular heart rate), sotalol 40 mg twice daily (to control irregular heart rate), aspirin 75 mg once daily (to prevent stroke and myocardial infarction) and sertraline 50mg once daily (an antidepressant commenced by her general practitioner on 26th January 1998). A discharge summary and medical notes relating to an admission in May 1997 states that she was admitted with acute confusion, had reduced movement on the right side and was discharged back to her residential home on aspirin. No admitting diagnosis is recorded in the clerking notes written by Dr Harris on 6th February 1998 but they record that *"patient refuses iv fluids and is willing to accept increased oral fluids"*.

6.2 On 7th February 1998 the medical notes record an opacity seen on the chest Xray and sate *"mood low. Feels frightened – doesn't know why. Nausea and ??. Little else. Nil clinically."* An increased white cell count is noted (13.0) and antibiotics commenced. A subsequent chest Xray report (undated) states there is a 5cm mass superimposed on the left hilum highly suspicious of malignancy. The medical notes on 11 February 1998 record this at the Xray meeting. On 12th February 1998 the notes record (? Dr Shain) *'In view of advanced age aim in the management should be palliative care. Charles Ward is suitable. Not for CPR'.* On 13th February the notes record *'remains v low Appears to have 'given up' d/w son re probably diagnosis d/w RH (residential home) re ability to cope'.* The notes record *'son agrees not suitable for invasive Tx* (treatment)*. Matron from RH visiting today will check on ability to cope.'*

6.3 On 19th February the notes record she fell on the ward and experienced minor cuts. On 16th February *'gradual deterioration, no pain, confused. For Charles Ward she could be discharged to community from Charles Ward'.* On 19th February the notes summarise her problems *'probable Carcinoma of the bronchus, previous left ventricular failure, atrial fibrillation, digoxin toxicity and a transient ischaemic attack, that she was sleepy but responsive, states that she is frightened but doesn't know why. Says she has forgotten things, not possible to elicit what she can't remember, low MTS (mental test score). Plan encourage oral fluids, s/c fluid over night if tolerated. Continue antidepressants'*. On 18th February the medical notes state *"No change. Awaiting Charles Ward bed"*.

6.4 The nursing notes record she was confused but mobilised independently. On 19th February she was transferred to Charles Ward instead of the preferred option of a bed at Gosport Hospital, which the notes record was full ('no beds'). The Queen Alexandra Hospital medical notes record a summary of her problems on 19th February prior to transfer as follows " *Diagnosis CA bronchus probable [no histology] Diag based on CXR. PMH 95 LVF + AF 95 Digoxin toxicity 97 TIA. Admitted 6.2.98 general deterioration CXR ? Ca Bronchus:*

Well defined O lesion. Exam: sleepy but responsive answers appropriately. States that she is frightened but doesn't know why. Says she has forgotten things. Not possible to elicit what she can't remember. Low MTS" and *"Feels in general tired and very thirsty. Plan encourage oral fluids, s/c fluid overnight is tolerated continue antidepressants".*

6.5 The medical notes on 23rd February record diagnoses of depression, dementia, ? Ca bronchus, ischaemic heart disease and congestive heart failure. On 25th February Dr Lord records in the medical notes "*confused and some agitation towards afternoon – evening try tds* (three times daily) *thioridazine, son in Gosport, transfer to Gosport 27/2, heminevrin prn nocte'.* A further entry states *'All other drugs stopped by Dr Lord'.*

6.6 Mrs Page was transferred to Dryad ward at Gosport War Memorial Hospital on 27th February 1998. Dr Barton writes in the medical notes "*Transfer to Dryad ward continuing care, Diagnosis of Ca Bronchus on CXR on admission. Generally unwell off legs, not eating, bronchoscopy not done, catheterised, needs help with eating and drinking, needs hoisting, Barthel 0. Family seen and well aware of prognosis. Opiates commenced. I'm happy for nursing staff to confirm death".* The nursing notes state she was admitted for *'palliative care'*, that she had a urinary catheter (inserted on 22nd February 1998) was incontinent of faeces, and was dependent for washing and dressing but could hold a beaker and pick up small amounts of food. Barthel Index was 2/20. The nursing action plan states '*encourage adequate fluid intake'.* On 28th February an entry in the medical notes by Dr Laing (duty GP) record '*asked to see: confused. Feels 'lost' agitated esp. night/evening, not in pain, to give thioridazine 25mg tds regular, heminevrin noct.* The nursing notes record she was very distressed and that she was administered thioridazine and Oramorph 2.5ml.

6.7 On 2nd March Dr Barton records *'no improvement on major tranquillisers. I suggest adequate opioids to control fear and pain; Son to be seen by Dr Lord today'.* A subsequent entry by Dr Lord on the same day states ' *spitting out thioridazine, quieter on prn sc diamorphine. Fentanyl patch started today. Agitated and calling out even when staff present (diagnoses) 1) Ca Bronchus 2) ? Cerebral metastases. -ct* (continue) *fentanyl patches.*' A further entry by Dr Lord that day records '*son seen. Concerned about deterioration today. Explained about agitation and that drowsiness was probably due in part to diamorphine. He accepts that his mother is dying and agrees we continue present plan of Mx* (management)".

6.8 On 2nd March the nursing notes record "*commenced on Fentanyl 25mcg this am. Very distressed this morning seen by Dr Barton to have and diamorphine 5mg i/m (intramuscular) same given 0810h by a syringe driver.* A further entry the same day states *"S/B Dr Lord. Diamorphine 5mg i/m given for syringe driver with diamorphine loaded".* On 3rd March a rapid deterioration in Mrs Page's condition is recorded *'Neck and left side of body rigid – right side rigid,* At 1050h diamorphine and midazolam were commenced by syringe driver. Death is recorded later that day at 2130h, 4 days following admission to Dyad ward.

6.9 The prescription charts (which are incompletely copied in notes made available to me) indicate she received the following drugs during this admission Two doses of intramuscular diamorphine 5 mg were administered at 0800 and 1500h (date not visible)

28 Feb 1998	1300h thioridazine 25mg
	1620h oramorph 5mg
	2200h heminevrin 250mg in 5ml
1 Mar 1998	0700h thioridazine 25 mg
	1300h thioridazine 25 mg
	2200h heminevrin 250mg
2 Mar 1998	0700h thioridazine 25mg
	0800h fentanyl 25microg
3 Mar 1998	1050h diamorphine 20mg/24hr, midazolam 20 mg/24hr by subcutaneous infusion

On 27th February Dr Barton prescribed thioridazine 25mg (prn tds) and Oramorph (10mg/5ml) 4hrly prn. On 2nd March Dr Barton prescribed fentanyl 25microg patch (x3 days) to take as required (prn). On 3rd March Dr Barton prescribed diamorphine 20-200mg/24hr, hyoscine 200-800ucg/24hr and midazolam 20-80mg/24hr by subcutaneous infusion.
The notes do not indicate that the fentanyl patch was removed and I would assume this was continued when the diamorphine and midazolam infusion was commenced.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

6.10 Primary responsibility for the medical care of Mrs Page during her admission to Dryad Ward lay with Dr Lord, as the consultant responsible for his care. She saw Mrs Page 2 days before her transfer to Dryad ward and two days following her admission, the day before she died. My understanding is that day-to-day medical care was the responsibility of the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital. Ward nursing staff were responsible for assessing and monitoring Mrs Page and informing medical staff of any significant deterioration.

Accuracy of diagnosis and prognosis including risk assessments

6.11 The assessment and management of Mrs Page at Alexandra Hospital was in my opinion competent and considered. From the information in the clinical notes I would agree with the diagnosis of probable carcinoma of bronchus. The decision to prescribe an antidepressant was in my opinion appropriate. Prior to transfer to Dryad ward she was not in pain but was transferred for palliative care. Although Mrs Page was clearly very dependent and unwell, it is not clear why Dr Barton prescribed opiates to Mrs Page on admission to Dryad ward when there is no evidence she was in pain. I suspect the reason was to provide relief for Mrs Page's anxiety and agitation. This is a reasonable indication for opiates in the palliative care of a patient with known inoperable carcinoma. Mrs Page was noted to be severely dependent, Barthel Index 0, and in conjunction with a probable carcinoma of the bronchus the assessment that she required palliative care and was likely to die in the near future was appropriate.

Evaluation of drugs prescribed and the administration regimens

6.12 The prescription of the major tranquilliser thioridazine for anxiety was reasonable and appropriate. The prescribing of the sedative/hypnotic drug heminevrin was similarly reasonable although potential problems of sedation from the combination need to be considered. Mrs Page was not in pain but I consider the prescription of oramorph on 28th February to attempt to improve her distress was reasonable. By 2nd March Mrs Page remained very distressed despite prescription of Oramorph, thioridazine and heminevrin. Since the notes reported she was more settled following intramuscular diamorphine and she had been spitting out her oral medication, I would consider it appropriate to prescribe a transdermal fentanyl patch to provide continuing opioid drugs to Mrs Page. The lowest dose patch was administered but it would have been important to be aware of the potential for depression of respiration and/or conscious level that could occur.

6.13 I do not understand why subcutaneous diamorphine and midazolam infusions were commenced on 3rd March when Mrs Page had deteriorated whilst on the fentanyl patch. There is no indication in the notes that Mrs Page was in pain or distressed. The notes describe her as having undergone a rapid deterioration, which could have been due to a number of different causes, including a stroke or an adverse effect of the fentanyl patch. In my opinion the prescription by Dr Barton of subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr was poor practice and potentially very hazardous. I would judge it poor management to initially commence both diamorphine and midazolam in a frail elderly underweight patient such as Mrs Page who was already receiving transdermal fentanyl. I would expect very clear reasons to support the use of the drugs to be recorded in the medical notes. The combination could result in profound respiratory depression and there are no symptoms recorded which suggest the administration of either drug was appropriate.

Quality and sufficiency of the medical records

6.14 The medical and nursing records relating to Mrs Page's admission to Dryad ward are in my view of adequate quality, although as stated above the reasons for the use of midazolam and diamorphine are not recorded in either the medical or nursing notes.

Appropriateness and justification of the decisions that were made

6.15 In my opinion the majority of management and prescribing decisions made by medical and nursing staff were appropriate. The exception is the prescription of diamorphine and midazolam on the day of Mrs Page's death. From the information I have seen in the notes it appears that Dr Barton may have commenced the diamorphine and midazolam infusion for non-specific reasons or for non-defined palliative reasons when it was judged she was likely to die in the near future.

Recorded causes of death

6.16 In the absence of a post-mortem the recorded cause of death is reasonable. Mrs Page had a probable carcinoma of the bronchus and experienced a slow deterioration in her general health and functional abilities. It is possible that Mrs Page died from drug induced respiratory depression. However Mrs Page was at high risk of dying from the effects of her probable carcinoma of the bronchus even if she had not received sedative and opiate drugs. Bronchopneumonia

can also occur as a complication of opiate and sedative induced respiratory depression but also in patients deteriorating from malignancy. In the absence of post-mortem, radiological data (chest Xray) or recordings of Mrs Page's respiratory rate I would consider the recorded cause of death was possible. The deterioration on between the 2nd March and 3rd March could have been secondary to the fentanyl patch she received but again could have occurred in the absence of receiving this drug. There are no accurate records of Mrs Page's respiratory rate but significant potentially fatal respiratory depression was likely to have resulted could have resulted from the combination of diamorphine, midazolam and fentanyl.

Duty of care issues

6.17 Medical and nursing staff on Dryad ward had a duty of care to deliver medical and nursing care, to monitor Mrs Page and to document the effects of drugs prescribed. In my opinion this duty of care was adequately met except during the last day of her life when the prescription of diamorphine and midazolam was poor practice and may have contributed to Mrs Wilkie's death.

Summary

6.18 Mrs Page was a frail elderly lady with probable carcinoma of the bronchus who had been deteriorating during the two weeks prior to admission to Dryad ward. In general I consider the medical and nursing care she received was appropriate and of adequate quality. However I cannot identify a reason for the prescription of subcutaneous diamorphine, midazolam and hyoscine by Dr Barton on the 3rd March. In my view this was an inappropriate, potentially hazardous prescription. I would consider it highly likely that Mrs Page experienced respiratory depression and profound depression of conscious level from the combination of these two drugs and fentanyl but I cannot exclude other causes for her deterioration and death at this time such as stroke or pneumonia.

Opinion on clinical management at Gosport War Memorial Hospital *based on review of five cases presented by Hampshire Police*

7.1 My opinion on the five cases I have been asked to review at Gosport War Memorial Hospital must be considered in context. My understanding is that the five cases have been selected by Hampshire Police because of concerns expressed relating to the management of these patients. Therefore my comments should not be interpreted as an opinion on the quality of care in general at Gosport War Memorial Hospital or of the general quality of care by the clinicians involved. My comments also relate to a period 2-4 years ago and the current clinical practice at the hospital may be very different today. An opinion on the quality of care in general at the hospital or of the clinicians would require a systematic review of cases, selected at random or with pre-defined patient characteristics. Examination of selected cases is not an appropriate *mechanism to comment on the general quality of care of an institution or* individual practitioners.

7.2 However having reviewed the five cases I would consider they raise a number of concerns that merit further examination by independent enquiry. Such enquiries could be made through further police interviews or perhaps more appropriately through mechanisms within the National Health Service, such as the Commission for Health Improvement, and professional medical and nursing bodies such as the General Medical Council or United Kingdom Central Council for Nursery, Midwifery and Health Visiting.

7.3 My principle concerns relate to the following three areas of practice: prescription and administration of subcutaneous infusions of opiate and sedative drugs in patients with non-malignant disease, lack of training and appropriate medical supervision of decisions made by nursing staff, and the level of nursing and non-consultant medical skills on the wards in relation to the management of older people with rehabilitation needs.

7.4 In all five cases subcutaneous infusions of diamorphine and in combination with sedative drugs were administered to older people who were mostly admitted for rehabilitation. One patient with carcinoma of the bronchus was admitted for palliative care. Although intravenous infusion of these drugs are used frequently in intensive care settings, very close monitoring of patients is undertaken to ensure respiratory depression does not occur. Subcutaneous infusion of these drugs is also used in palliative care, but the British National Formulary indicates this route should be used only when the patient is unable to take medicines by mouth, has malignant bowel obstruction or where the patient does not wish to take regular medication (Appendix 2). In only one case were these criteria clearly fulfilled i.e. in Mrs Page who was refusing to take oral medication. Opiate and sedative drugs used were frequently used at excessive doses and in combination with often no indication for dose escalation that took place. There was a failure by medical and nursing staff to recognise or respond to severe adverse effects of depressed respiratory function and conscious level that seemed to have occurred in all five patients. Nursing and medical staff appeared to have little knowledge of the adverse effects of these drugs in older people.

7.5 Review of the cases suggested that the decision to commence and increase the dose of diamorphine and sedative drugs might have been made by nursing staff without appropriate consultation with medical staff. There is a possibility that prescriptions of subcutaneous infusions of diamorphine, midazolam and hyoscine may have been routinely written up for many older frail patients admitted to Daedalus and Dryad wards, which nurses then had the discretion to commence. This practice if present was highly inappropriate, hazardous to patients and suggests failure of the senior hospital medical and managerial staff to monitor and supervise care on the ward. Routine use of opiate and sedative drug infusions without clear indications for their use would raise concerns that a culture of "involuntary euthanasia" existed on the ward. Closer enquiry into the ward practice, philosophy and individual staff's understanding of these practices would be necessary to establish whether this was the case. Any problems may have been due to inadequate training in management of older patients. It would be important to examine levels of staffing in relation to patient need during this period, as the failure to keep adequate nursing records could have resulted from under-staffing of the ward. Similarly there may have been inadequate senior medical staff input into the wards, and it would be important to examine this in detail, both in terms of weekly patient contact and in time available to lead practice development on the wards. My review of Dr Lord's medical notes and her statement leads me to conclude she is a competent, thoughtful geriatrician who had a considerable clinical workload during the period the above cases took place.

7.6 I consider the five cases raise serious concerns about the general management of older people admitted for rehabilitation on Daedalus and Dryad wards and that the level of skills of nursing and non-consultant medical staff, particularly Dr Barton, were not adequate at the time these patients were admitted.

7.7 Having reviewed the five cases presented to me by Hampshire Police, I consider they raise serious concerns about nursing and medical practice on Daedalus and Dryad wards at Gosport War Memorial Hospital. In my opinion a review of practice at the institution is necessary, if this has not already taken place. I would recommend that if criminal proceedings do not take place, that these cases are brought to the attention of the General Medical Council and United Kingdom Central Council for Nursery, Midwifery and Health Visiting, in relation to the professional competence of the medical and nursing staff, and the Commission for Health Improvement, in relation to the quality of service provided to older people in the Trust.

APPENDIX 1

Pharmacology of Opiate and Sedative Drugs

Morphine

8.1 Morphine is a potent opiate analgesic considered by many to the 'drug of choice' for the control of acute pain (Therapeutic Drugs Dollery). Recommended starting dosage regimens for a fit adult of 70Kg are for intravenous bolus dosing 2.5mg every 5 min until analgesia achieved with monitoring of the duration of pain and dosing interval, or a loading dose of 5-15mg over 30min than 2,5mg – 5mg every hour. A standard reference text recommends 'morphine doses should be reduced in elderly patients and titrated to provide optimal pain relief with minimal side effects'. Morphine can be used for sedation where sedation and pain relief are indicated, Dollery comments *'it should be noted that morphine is not indicated as a sedative drug for long-term use. Rather the use of morphine is indicated where the requirement for pain relief and sedation coexist such as in patients admitted to intensive care units and other high dependency areas, the morphine dose should be titrated to provide pain relief and an appropriate level of sedation. Frequently other pharmacological agents (e.g.: benzodiazepines) are added to this regimen to increase the level of sedation".*

8.2 Diamorphine

8.3

8.4 **Fentanyl**

8.5 Fentanyl is a transdermal opioid analgesic available as a transdermal patch. The '25' patch releases 25microg/hr.

8.6 The British National Formulary (copy of prescribing in palliative care attached Appendix 2) comments on the use of syringe drivers in prescribing in palliative care that drugs can usually be administered by mouth to control symptoms, and that indications for the parenteral route are: patient unable to take medicines by mouth, where there is malignant bowel obstruction, and where the patient does not wish to take regular medication by mouth, It comments that staff using syringe drivers should be adequately trained and that incorrect use of syringe drivers is a common cause of drug errors.

Heminevrin

Midazolam

8.1 Midazolam is a benzodiazepine sedative drug. It is used as a hypnotic, preoperative medication, sedation for procedures such as dentistry and GO endoscopy, long-term sedation and induction of general anaesthesia. Iot is not licensed for subcutaneous use, but is described in the British National Formulary prescribing in palliative care section as 'suitable for a very restless patient: it is given in a subcutaneous infusion dose of 20-100mg/24 hrs.

8.2 DA standard text describes the use of sedation with midazolam in the intensive care unit setting, and states, "*sedation is most commonly met by a combination of a benzodiazepine and an opioid, and midazolam has generally replaced diazepam in this respect*". It goes on to state, "in critically ill patients, prolonged sedation may follow the use of midazolam infusions as a result of delayed administration". Potentially life threatening adverse effects are described, "Midazolam can cause dose-related CNS depression, respiratory and

cardiovascular depression. There is a wide variation in susceptibility to its effects, the elderly being particularly sensitive. Respiratory depression, respiratory arrest, hypotension and even death have been reported following its use usually during conscious sedation. The elderly are listed as a high-risk group; the elderly are particularly sensitive to midazolam. The dose should be reduced and the drug given slowly intravenously in a diluted form until the desired response is achieved. In drug interactions the following is stated. *"midazolam will also potentiate the central depressant effects of opioids, barbituates, and other sedatives and anaesthetics, and profound and prolonged respiratory depression might result.*

8.3

Hyoscine

8.4 The British National Formulary describes hyoscine hydrobromide as an antagonist (blocking drug) of acetylcholine. It reduces salivary and respiratory secretions and provides a degree of amnesia, sedation and antiemesis (antinausea). IN some patients, especially the elderly, hyoscine may cause the central anticholinergic syndrome (excitement, ataxia, hallucinations, behavioural abnormalities, and drowsiness). The palliative care section describes it as being given in a subcutaneous infusion dose of 0.6-2.4mg/24 hours.

8.5.

Use of syringe drivers

8.1 The BNF states 'oral medication is usually satisfactory unless there is severe nausea and vomiting, dysphagia, weakness, or coma in which case parenteral medication may be necessary. In the pain section it comments the non-opioid analgesics aspirin or paracetamol given regularly will often make the use of opioids unnecessary. An opioid such as codeine or dextropropoxyphene alone or in combination with a non-opioid analgesic at adequate dosage may be helpful in the control of moderate pain id non-opioids are not sufficient. If these preparations are not controlling the pain, morphine is the most useful opioid analgesic. Alternatives to morphine are hydromoprhine, oxycodone and transdermal fentanyl. In prescribing morphine it states 'morphine is given as an oral solution or as standard tablets every 4 hour, the initial dose depending largely on the patient's previous treatment. A dose of 5-10mg is enough to replace a weaker analgesic. If the first dose of morphine is no more effective than the previous analgesic it should be increased by 50% the aim being to choose the lowest dose which prevents pain. The dose should be adjusted with careful assessment of the pain and the use of adjuvant analgesics (such as NSAIDs) should also be considered. Although morphine in a dose of 5-10mg is usually adequate there should be no hesitation in increasing it stepwise according to response to 100mg or occasionally up to 500mg or higher if necessary. The BNF comments on the parenteral route *'diamorphine is preferred for injection. The equivalent intramuscular or subcutaneous dose of diamorphine is approximately a third of the oral dose of morphine'.*

8.2 In the chapter on pain relief in 'Drugs and the Older Person' Crome writes on the treatment of acute pain ' *treat the underlying cause and give adequate pain relief. The nature of the painful condition, the response of the patient and the presence of comorbidity will dictate whether to start with a mild analgesic or to go immediately to a more potent drug. In order to avoid the situation that patients remain in pain, "starting low" must be followed by regular re-evaluation with, if necessary, frequent increases in drug dose. The usual method of*

prescribing morphine for chronic pain is to start with standard oral morphine in a dose of 5-10mg every four hours. The dose should be halved in frail older people.

Prescribing for the Elderly

The British National Formulary states in Prescribing for the Elderly section "*The ageing nervous system shows increased susceptibility to many commonly used drugs, such as opioid analgesics, benzodiazepines, antipsychotics and antiparkinsonian drugs, all of which must be used with caution*".

APPENDIX 2

BNF Prescribing in palliative care

5

Medical Report:
concerning the case of Gladys Mable Richards deceased

Prepared for:

Hampshire Constabulary
Major Crime Complex, Fratton Police Station, Kingston Crescent,
North End, Portsmouth, Hampshire PO2 8BU

by: Professor Brian Livesley MD FRCP
The University of London's Professor in the Care of the Elderly
Imperial College School of Science, Technology, & Medicine
The Chelsea and Westminster Hospital, London SW10 9NH

For the purpose of ... providing an independent view about treatment given to Mrs Gladys RICHARDS and the factor(s) associated with her death.

Synopsis

1. At the age of 91 years, Mrs Gladys RICHARDS was an in-patient in Daedalus ward at Gosport War Memorial Hospital.

1.1. A registered medical practitioner prescribed the drugs diamorphine, haloperidol, midazolam, and hyoscine for Mrs Gladys RICHARDS.

1.2. These drugs were to be administrated subcutaneously by a syringe driver over an undetermined number of days.

1.3. They were given continuously until Mrs RICHARDS became unconscious and died.

1.4. During this period there is no evidence that Mrs RICHARDS was given life sustaining fluids or food.

1.5. It is my opinion that as a result of being given these drugs, Mrs RICHARDS's death occurred earlier than it would have done from natural causes.

CONTENTS

The writer's declaration

1. This report consisting of thirty-four pages is true to the best of my knowledge and belief and I make it knowing that if tendered in evidence, I shall be liable for prosecution if I have wilfully stated in it anything that I know to be false or do not believe to be true.

Introduction

2. The documents with which I have been provided and the visits I have made to the hospitals involved in this enquiry are listed in the Appendix A.

2.1. Appendix B contains facts of the environment provided by the statements of Mrs Gillian MACKENZIE (the elder daughter of Mrs Gladys RICHARDS (deceased)) and Mrs Lesley Frances LACK (the younger daughter).

2.2. I have indicated any medical terms in **bold type**. I have defined these terms in a glossary in Appendix C.

2.3. I have included in Appendix D references to published material.

2.4. Appendix E contains details of my qualifications and experience.

2.5. This report has been presented on the basis of the information available to me—should additional information become available my opinions and conclusions may be subject to review and modification.

Information relating to Mrs Gladys Richards (deceased)

3. Mrs Gladys Mable RICHARDS (*née Beech*) was born on 13th April 1907 and died on 21st August 1998 aged 91 years.

3.1. Mrs Richards has two daughters. They are Mrs Gillian MACKENZIE (the elder daughter) and Mrs Lesley Frances LACK.

3.1.1. Mrs Lack is a retired Registered General Nurse. She retired during 1996 after 41 years continuously in the nursing profession. For 25 years prior to her retirement she was involved in the care of elderly people. For 20 years prior to retirement she held supervisory and managerial positions in this particular field of nursing.

3.2. The Glen Heathers Nursing Home is a private registered nursing and residential home at Lee on the Solent, Hampshire. Dr J BASSETT is a general practitioner who visits.

3.3. The Royal Hospital Haslar is an acute general hospital in Gosport, Hampshire serviced by the Armed Forces at the time of the incident but available as a National Health Service facility to local people.

3.4. Gosport War Memorial Hospital is part of the Portsmouth Healthcare NHS Trust.

3.4.1. Daedalus ward is a continuing care and rehabilitation ward at Gosport War Memorial Hospital.

3.5. Dr Jane Ann BARTON is a registered medical practitioner who in 1988 took up a part-time post as clinical assistant in elderly medicine. This post became centered at Gosport War Memorial Hospital. She retired from this part-time post in the year 2000.

3.6. Mr Philip James BEED is the clinical manager and charge nurse on Daedalus ward at Gosport War Memorial Hospital. Ms Margaret COUCHMAN and Ms Christine JOICE are registered general nurses who were working on Daedalus ward at the time of the incident.

3.7. Dr Anthea Everista Geredith LORD is a consultant physician, within the department of elderly medicine of Portsmouth Healthcare NHS Trust, who was usually responsible for the patients on Daedalus ward and who was on study leave on 17/18 August 1998.

3.7.1. Other consultant physicians from the department of elderly medicine provide on-call consultant physician cover when Dr LORD is absent from duty.

Relevant aspects of Mrs RICHARDS's medical history

4. Mrs RICHARDS became resident at the Glen Heathers Nursing Home on 5th August 1994 at the age of 87 years and although disorientated and confused she was able to wash and dress herself and able to go up and down stairs and walk well.

4.1. It is noted that she also had a past medical history of bilateral deafness for which she required hearing aids.

4.1.1. Unfortunately both of her hearing aids were lost by December 1997 while she was at the Glen Heathers Nursing Home and had not been replaced by July 1998 when she was admitted to Daedalus ward at Gosport War Memorial Hospital).

4.1.2. It is noted that on 8th July 1998 her general practitioner, Dr J BASSETT wrote to the audiologist at Queen Alexandra Hospital, Cosham requesting an '**URGENT** [sic]' domiciliary visit to Glen Heathers Nursing Home. This was '... with a view to supplying her [Mrs RICHARDS] with two new hearing aids.... Since her poor hearing probably contributes to her

confusional state I would be grateful if you would visit with a view to fitting of replacement aids as soon as possible please.'

4.2. It is also noted that Mrs RICHARDS had had operations for the removal of cataracts and required glasses.

4.2.1. Unfortunately her spectacles were also lost at the Glen Heathers Nursing Home and had not been replaced by August 1998 when she was admitted to Daedalus ward at Gosport War Memorial Hospital.

4.2.2. As Dr BASSETT had noted Mrs RICHARDS poor hearing probably contributed to her confusional state. The absence of her spectacles would also make it difficult for Mrs RICHARDS to be aware of what was going on around her, further aggravate her confusional state due to lack of sensory stimulation, and increase her dependency on others for her normal daily activities.

4.2.3. The absence of both her hearing aids and her spectacles would make the assessment of and communication with Mrs RICHARDS extremely difficult.

4.2.3.1. It is noted that such sensory deprivation can produce and aggravate confusional and disorientated states.

4.3. At the beginning of 1998, she had become increasingly forgetful and less able physically but was inclined to wander and she had about a six months' history of falls.

4.4. On 29th July 1998, at the Glen Heathers Nursing Home, Mrs RICHARDS developed a fracture of the neck of her right femur [thighbone] and she was transferred to the Royal Hospital Haslar, Gosport.

4.4.1. In the Accident & Emergency department she was given 2.5mg of **morphine** and 50 mg of **cyclizine** at 2300 hours to relieve her pain and distress. She was known to be taking **haloperidol** 1mg twice daily and **Tradazone** 100mg at night.

4.5. On 30th July 1998 Mrs RICHARDS had a right cemented hemiarthroplasty [an artificial hip joint inserted].

4.5.1. Post-operatively she was given 2.5 mg morphine intravenously on July 30th at 0230 hours, 31st at 0150 and 1905 hours, and on August 1st at 1920 hours and 2nd at 0720 hours. From August 1st –7th she was weaned over to two tablets of **co-codamol**, requiring these on average twice daily for pain relief.

4.5.2. On 3rd August 1998 it was noted 'All well. Sitting out early mobilization'.

4.6. On 5th August 1998, Dr REID, a consultant geriatrician, saw her. He stated in a letter that '... she appeared to have a little discomfort on passive movement of the right hip. I understand that she has been sitting out in a chair and I think that, despite her dementia, she should be given the opportunity to try to re-mobilise. I will arrange for her transfer to Gosport Memorial Hospital.'

4.6.1. Dr REID also noted that Mrs RICHARDS had continued on Haloperidol and '... her Trazodone has been omitted. According to her daughters it would seem that since her Tradozone has been omitted she has been much brighter mentally and has been speaking to them at times.'

4.7. A discharge letter, dated 10th August 1998, was sent by the sergeant staff nurse at the Royal Hospital Haslar and addressed to 'The Sister in Charge Ward [sic] Memorial Hospital, Bury Road, Gosport, Hants.' It contained the following information:-

4.7.1. After the operation Mrs RICHARDS became '...fully weight bearing, walking with the aid of two nurses and a **Zimmer frame**.' She was noted to require 'total care with washing and dressing, eating and drinking....' She was '... continent, when she become[s] fidgety and agitated it means she wants the toilet....' She 'Occasionally says recognisable words, but not very often.' Her wound 'Is healed, clean and and dry.'

4.8. On 11th August 1998, Mrs RICHARDS was transferred to Daedalus ward at the Gosport War Memorial Hospital. She was not in pain and had been fully weight bearing at the Royal Hospital Haslar walking with the aid of two nurses and a Zimmer frame.

4.8.1. At the Gosport War Memorial Hospital there was an unsigned 'Summary' record which is apparently a Nursing record and this states:-

4.8.1.1. '11-8-98 Addmitted [sic] from E6 Ward Royal Hospital Haslar, into a continuing care bed. Gladys had sustained a right fractured neck of Femur on 30th July 1998 in Glen Heathers Nursing Home. She has had a right cemented hemi-arthroplasty and she is now fully weight bearing, walking with the aid of two nurses and a Zimmer frame. Daughter visits regularly and feeds mother. She wishes to be informed Day or night of any deterioration in mothers condition....'

4.8.2. The contiguous 'Assessment Sheet' states, 'Patient has no apparent understanding of her circumstances due to her impaired mental condition ... Deaf in both ears ... Cataract operation to both eyes ... occasionally says recognisable words, but not very often ... soft diet. Enjoys a cup of tea ... requires feeding ... Dental/Oral status Full "Set" – keeps teeth in at night.'

4.8.3. The 'Patient Medication Information' states, '11.8.98 ... Haloperidol O[rally] 1 mcg [looks like 'mcg' but probably is 'mg' since this drug is not prescribed in single **microgram** doses] B.D. [twice daily]'

4.9. ??[initials]B [subsequently identified as Dr BARTON] has written in the medical case records '11-8-98 Transferred to Daedalus Ward Continuing Care.... O/E [on examination] Impression frail demented lady [paragraph] not obviously in pain [paragraph] Please make comfortable [paragraph] transfers with hoist Usually continent needs help with **ADL [activities of daily living]**.... I am happy for nursing staff to confirm death.'

4.10. At 1300 hours on the 13th August 1998 the Nursing Contact Record states 'Found on floor at 13.30hrs [sic]. Checked for injury none apparent at time hoisted into safer chair 20.00 [hours][altered on record to 19.30] pain Rt [right] hip internally rotated. Dr BRIGG contacted advised Xray AM [in the morning] & **analgesia** during the night. Inappropriate to transfer for Xray this PM [evening] [initialled signature (? by whom)] RGN [Registered General Nurse] [next line] Daughter informed.'

4.11. Dr BARTON has recorded '14-8-98 Sedation/pain relief has been a problem screaming not controlled by haloperidol 1 [illegible symbol or word] but very sensitive to **oramorph**. Fell out of chair last night ... Is this lady well enough for another surgical procedure?'

4.12. In her contiguous note Dr BARTON has recorded '14-8-98 Dear [?] Cdr [Commander] SPALDING Further to our telephone conversation thank you for taking this unfortunate lady who slipped from her chair at 1.30 pm yesterday and appears to have dislocated her R[ight] hip.... She has had 2.5ml of 10mg/5ml Oramorph at midday.'

4.12.1. According to the letter signed by Philip BEED, Mrs RICHARDS was given 10mgs of Oramorph at 1150 hours on 14th August 1998 prior to being transferred back to the Royal Hospital Haslar.

4.13. The Nursing Contact Record at Daedalus ward continues:-

4.13.1. '14/8/98 am [morning] R[ight] Hip Xrayed – Dislocated [paragraph] Daughter seen by Dr BARTON & informed of situation. For transfer to Haslar A&E [accident and emergency department] for reduction under sedation [initialled signature]'

4.13.2. 'pm [afternoon or evening of 14th August 1998] Notified that dislocation has been reduced. [Mrs RICHARDS] To stay in Haslar [hospital] for 48 hours then return to us [[initialled signature] Family aware.'

4.14. At the Royal Hospital Haslar (at 1400 hours) Xray having confirmed that the hemiarthroplasty had dislocated, intravenous sedation using 2 mgs of midazolam

allowed the dislocation to be corrected by traction. The procedure was described as 'Under sedation c [with] CVS/RS [cardiovascular and respiratory systems] monitoring. ... Easy reduction.' Mrs RICHARDS was noted to be 'rather unresponsive following the sedation. The [She] gradually became more responsive....' She was then admitted the Royal Hospital for 48 hours observation.

4.15. Apart from two tablets of co-codamol on the 15th August 1998, she did not need to be given any pain relief following the reduction of her hip dislocation.

4.15.1. Two days later, on 17th August 1998, it was recorded that 'She was fit for discharge that day and she was to remain in straight knee splint for four weeks. In the discharge letter from Haslar Hospital it was also recorded that Mrs RICHARDS was to return to Daedalus Ward. It was further stated that 'She has been given a canvas immobilising splint to discourage any further dislocation, and this must stay in situ for four weeks. When in bed it is advisable to encourage abduction by using pillows or abduction wedge. She can however mobilise fully weight bearing.'

4.16. On 17th August 1998 it was also recorded that she was 'Fit for discharge today (Gos[port] War Mem[orial hospital). To remain in straight knee splint for 4/52 [four weeks] ... No follow-up unless complications.'

4.17. She was returned to Daedalus ward in the Gosport War Memorial Hospital later that day but in a very distressed state. The Daedalus ward nursing record states 'Returned from R.N. Haslar, patient very distressed appears to be in pain. No canvas under patient – transferred on sheet by crew To remain in straight knee splint for 4/52 [four weeks] For pillow between legs at night (abduction) No follow-up unless complications.'

4.17.1. Mrs RICHARDS was given Oramorph 2.5 mg in 5mls. The nursing record for 17th August 1998 further states '1305 [hours] ... Daughter reports surgeon to say her mother must not be left in pain if dislocation occurs again. Dr Barton contacted and has ordered an Xray. M. COUCHMAN. [paragraph] pm Hip Xrayed at 1545 [hours] Films seen by Dr PETERS & radiologist & no dislocation seen. For pain control overnight & review by Dr BARTON mane [in the morning]. ?[illegible nurse signature]

4.17.1.1. This radiograph was reported by Dr. DOMJAN, Consultant Radiologist as showing 'RIGHT HIP: The right hemiarthroplasty is relocated in the **acetabulum**.'

4.18. On 17th August 1998, Dr BARTON noted 'Readmission to Daedalus from RHH [Royal Hospital Haslar] Closed reduction under iv [intravenous] sedation remained unresponsive for some hours now appears peaceful. Plan Continue haloperidol [paragraph] Only give oramorph if in severe pain See daughter again.'

4.19. On 18th August 1998, Dr BARTON recorded 'Still in great pain [paragraph] Nursing a problem. [paragraph] I suggest sc[subcutaneous] diamorphine/Haloperidol/midazolam [paragraph] I will see daughters today [paragraph] please make comfortable.'

4.20. The nursing Contact Record on Daedalus ward in the Gosport War Memorial Hospital continues:-

4.20.1. '18/8/98 am Reviewed by Dr Barton. For pain control via syringe driver. [paragraph] 1115 Treatment discussed with both daughters [Mrs LACK and Mrs MACKENZIE]. They agree to use of **syringe driver** to control pain [It is noted that Mrs LACK has disagreed with this statement] & allow nursing care to be given. [paragraph] 1145 Syringe driver diamorphine 40 mg. Haloperidol 5 mg, Medazolam [midazolam] 20 mg commenced'

4.20.2. '18/8/98 20.00 Patient remained peaceful and sleeping. Reacted to pain when being moved – this was pain in both legs. [paragraph] Daughter quite upset and angry about mother's condition, but appears happy that she is pain free at present. C JOICE.'

4.20.2.1. It is noted that a 'disturbance reaction' occurs in patients when they are moved that is easily mistaken for pain requiring specific treatment. It is noted here that Mrs RICHARDS was described as being 'pain free' at this time apart from when she was being moved.

4.20.3. The nursing Contact Record continues 'Daughter, Jill, stayed the night with Gladys [Mrs RICHARDS], grandson arrived in early hours of morning [initialled signature; dated '19/8/98'] [paragraph] He would like to discuss Grand mother's condition with someone – either Dr. Barton or Phillip Beed later today [initialled signature]' [paragraph] '19/8/98 am Mrs Richards comfortable. [paragraph] Daughters seen. Unhappy with various aspects of care, complain[t] to be handled officially by Mrs S Hutchings Nursing co-ordinator [initialled signature]'

4.20.4. It is noted that there is no continuing nursing Contact Record for the 20th August 1998.

4.20.5. The contiguous nursing Contact Record states '21/8/98 12.13 [hours] Patient's [Mrs RICHARDS] overall condition deteriorating, medication keeping her comfortable. Daughters visited during the morning. C JOICE'

4.21. Dr BARTON's next contiguous medical record was on 21st August 1998 when she wrote 'Much more peaceful [paragraph] needs Hyoscine for rattly chest'.

4.21.1. It is noted that Mrs RICHARDS was already being given hyoscine at this time and had been doing so continuously since 19th August 1998.

4.21.2. Nurse GRIFFIN made the next note in the medical records on 21st August 1998 stating that Mrs Richards was dead at 2120 hours.

4.22. The Nursing Care Plan records state:-

4.22.1. '12.8.98 Requires assistance to settle and sleep at night.... 12.8.98 Haloperidol given at 2330 [hours] as woke from sleep very agitated shaking and crying. Didn't settle for more than a few minutes at a time. Did not seem to be in pain.'

4.22.2. '13.8.98 oromorph at 2100 [hours] Slept well [initialled signature] [paragraph] For Xray tomorrow morning [initialled signature]'

4.22.3. '14.8.98 Same pain in rt[right] leg / ?[query] hip this am. [initialled signature]'

4.22.4. 'Re-admitted 17/8/98'

4.22.5. '17.8.98 Oromorph [Oramorph] 10mg/5ml at present.'

4.22.6. '18.8.98 Now has a syringe driver with 40mgs Diamorphine – comfortable. Daughters stayed. [initialled signature]'

4.22.7. 'Daughters stayed with Gladys [Mrs RICHARDS] overnight. [initialled signature]'

4.22.8. There is no record of continuance of the Nursing Care Plan for 20th and 21st August 1998.

4.22.9. After Mrs RICHARDS had been readmitted to Daedalus ward on 17th August 1998, there is no record between 17th and 21st August 1998 in the patient Nursing Care Plan for 'Nutrition'. On 21st August the record states 'no food taken [initialled signature]'.

4.22.9.1. There is no record that Mrs RICHARDS was offered any fluids.

4.22.10. Similarly, the Nursing Care Plan for 'Constipation' shows no record between 17th and 21st August1998. On 21st August the record states 'BNO [bowels not open] [initialled signature]'

4.22.11. The Nursing Care Plan for 'Personal Hygiene' states:-

4.22.11.1. '18.8.98 Complete Bed Bath given plus oral [Signature] Hygiene [second signature]'

4.22.11.2. '18.8.98 Night: oral care given frequently'

4.22.11.3. '19.8.98 Nightie changed & washed, repositioned. Apparently pain free during care [initialled signature]'

4.22.11.4. It is noted that there is no record of Mrs Richards being attended to for 'Personal Hygiene' on 20th August 1998.

4.22.11.5. '21.9.98 General care and oral hygiene given [initialled signature]'

4.23. The drugs prescribed for Mrs RICHARDS at Gosport War Memorial Hospital from the time of her admission there on 11th August 1998 are described below.

Drugs prescribed for Mrs RICHARDS at Gosport War Memorial Hospital

5. Dr BARTON wrote the following drug prescriptions for Mrs RICHARDS.

5.1. On 11th August 1998:-

5.1.1. Oramorph 10mgs in 5mls to be given orally four hourly. On the Administration Record these doses are recorded as being given—

5.1.1.1. twice on 11th August 1998 (10mg at 1015 [?1215] and 10mg at 1145 [?pm]);

5.1.1.2. once on 12th August (10mg at 0615);

5.1.1.3. once on 13th August (10mg at 2050);

5.1.1.4. once on 14th August (5ml [10mg] at 1150);

5.1.1.5. four times on 17th August (2.5ml [5mg] at 1300, 2.5ml [5mg] at ????[time illegible], 2.5ml [5mg] at1645, and 5ml [10mg] at 2030); and,

5.1.1.6. twice on 18th August 1998 5ml [10mg] at 01230[sic and ? meaning 0030 hours] and 5ml [10mg] at [?]0415).

5.1.2. Diamorphine at a dose range of 20 – 200 mg to be given subcutaneously in 24 hours.

5.1.2.1. None of this diamorphine prescription is recorded on the Administration Record as having been given between 11th – 14th August inclusive.

5.1.3. Hyoscine at a dose range of 200 – 800 mcg [micrograms] to be given subcutaneously in 24 hours.

5.1.3.1. None of this hyoscine prescription is recorded on the Administration Record as having been given between 11th – 14th August inclusive.

5.1.4. Midazolam at a dose range of 20-80 mgs to be given subcutaneously in 24 hours.

5.1.4.1. None of this midazolam prescription is recorded on the Administration Record as having been given between 11th – 14th August inclusive.

5.1.5. Haloperidol 1mg orally twice daily. It is noted that at the top of this prescription chart 'TAKES MEDICINE OFF A SPOON' [sic] is clearly written.

5.1.5.1. She was give 1mg of haloperidol at 1800 hours on 11th August 1998, at 0800 and 2330 hours on 12th August 1998, at 0800 and 1800 hours on 13th August 1998.

5.1.5.2. In addition, on 13th August 1998, Mrs RICHARDS was prescribed haloperidol 2mgs in 1ml to be administered orally as required at a dose of 2.5ml [this figure has been altered and also can be read as 0.5 ml] to be given 'IF NOISY' [sic]. She was given a dose [quantity not stated bearing in mind the altered prescription] at 1300 on 13th August 1998.

5.1.5.3. She was also given 1mg of haloperidol at 0800 hours on 14th and also at 1800 hours on 17 August 1998.

5.1.6. It is noted that, apart from 2330 hours on 12 August 1998, at the above times when Mrs RICHARDS was given haloperidol she was also give 10ml of **Lactulose** [a purgative].

5.2. On 12th August 1998:-

5.2.1. Oramorph 10mgs in 5mls to be given orally in a dose of 2.5 mls four hourly [equivalent to 5mgs of oramorph].

5.2.1.1. Although this drug was apparently not administered its prescription was written up on the 'Regular Prescription' chart but at the side in an ink-drawn box there are the letters PRN [meaning that the prescription is to be administered as required].

5.2.2. Oramorph 10mgs in 5mls to be given orally once at night.

5.2.2.1. Although this drug was apparently not administered its prescription was also written up on the 'Regular Prescription' chart but at the side in an ink-drawn box there are the letters PRN [meaning that the prescription is to be administered as required].

5.3. 18th August 1998:-

5.3.1. Diamorphine at a dose range of 40-200mg to be administered subcutaneously in 24 hours

5.3.2. Haloperidol a dose range of 5-10 mgs to be administered subcutaneously in 24 hours.

5.4. On 18th, 19th, 20th, and 21st August 1998, Mrs RICHARDS was given simultaneously and continuously subcutaneously diamorphine 40mgs, and haloperidol 5mgs, and midazolam 20mgs during each 24 hours.

5.4.1. These drugs are recorded as being administered at the same time of day on each of the four days they were given. They were administered at 1145, 1120, 1045, and 1155 for 18th, 19th, 20th, and 21st August 1998 respectively.

5.4.1.1. All these drugs were administered at the times stated and were signed off by initials as being co-administered by the same person each day. Over the four days of 18th, 19th, 20th, and 21st August 1998, at least three nurses were involved in administering these drugs.

5.4.1.2. According to the prescription charts these drugs were signed for as being administered to Mrs RICHARDS via the syringe driver by Mr Philip BEED on 18th and 19th August 1998, by Ms Margaret COUCHMAN on 20th August 1998, and by Ms Christine JOICE on 21st August 1998.

5.4.2. It is noted that on the 19th, 20th, and 21st August 1998 the drugs midazolam 20mgs, diamorphine 40mgs, and haloperidol 5mgs were also co-administered subcutaneously in 24 hours with 400mcg of hyoscine [this last drug had been

prescribed by Dr BARTON to be given as required on 11th August 1998 but its administration was not commenced until 19th August 1998].

5.4.3. It is also noted that all the drugs for subcutaneous administration were not prescribed at specific starting dosages but each was prescribed for a wide range of dosages and for continuous administration over 24-hour periods.

5.4.3.1. It is not known who selected the dosages to be given.

Death certification and cremation

6. The circumstances of Mrs RICHARDS death have been recorded as follows:

6.1. In a document [Case no. 1630/98] initialled by the Coroner on 24th August 1998 'Reported by Dr BARTON [sic]. Deceased had undergone surgery for a fractured neck of femur. Repaired. Death cert[ificate] issued. [paragraph] THOMAS [sic]

6.2. The cause of death was accepted by the Coroner on 24th August 1998 as being due to:-

6.2.1. '1(a) Bronchopneumonia'.

6.2.2. The death was certified as such by Dr J A BARTON and registered on 24th August 1998.

6.2.3. It is noted that the continuous subcutaneous administration of diamorphine, haloperidol, midazolam, and hyoscine to an elderly person can produce unconsciousness and death from respiratory failure associated with pneumonia.

6.3. The body was cremated.

Conclusions

7. Mrs Gladys Mable RICHARDS died on 21st August 1998 while receiving treatment on Daedalus ward at Gosport War Memorial Hospital.

7.1. Some fours years earlier, on 5th August 1994, Mrs RICHARDS had become resident at the Glen Heathers Nursing Home.

7.2. Mrs RICHARDS's had a confused state that after December 1997 had been aggravated by the loss at the Glen Heathers Nursing Home of her spectacles and both of her hearing aids.

7.3. On 29th July 1998, Mrs RICHARDS developed a fracture of the neck of her right femur [thighbone] and she was transferred from the Glen Heathers Nursing Home to the Royal Hospital Haslar, Gosport.

7.4. Despite her confused state, Mrs RICHARDS was considered by medical staff at the Royal Hospital Haslar to be suitable for implantation of an artificial hip joint. This took place on 30th July 1998.

7.5. On 11th August 1998, and having been seen by a consultant geriatrician, Mrs RICHARDS was transferred for rehabilitation to Daedalus ward at Gosport War Memorial Hospital.

7.6. At that time Dr BARTON recorded that Mrs RICHARDS was not obviously in pain but despite this Dr BARTON prescribed Oramorph [an oral morphine preparation] to be administered orally four hourly.

7.6.1. At that time also Dr BARTON prescribed for Mrs RICHARDS diamorphine, hyoscine, and midazolam. These drugs were to be given subcutaneously and continuously over periods of 24 hours for an undetermined number of days and the exact dosages were to be selected from wide dose ranges.

7.6.2. Also on 11th August 1998, at the end of a short case note, Dr BARTON wrote 'I am happy for nursing staff to confirm death'.

7.6.3. It is noted that although prescribed on the day of her admission to Daedalus ward at Gosport War Memorial Hospital these drugs (diamorphine, hyoscine, and midazolam) were not administered at that time.

7.7. On 13th August 1998, Mrs RICHARDS's artificial hip joint became dislocated.

7.8. The following day, 14th August 1998, although Dr BARTON had recorded 'Is this lady well enough for another surgical procedure?' she arranged for Mrs RICHARDS to be transferred back to Haslar Hospital where the dislocation of the hip was reduced.

7.8.1. It is noted that at the age of 91 years, and despite Dr Barton's comment about Mrs RICHARDS, and her confused mental state, Mrs RICHARDS was considered well enough by the staff at the Royal Hospital Haslar to have two operations on her right hip within about two weeks.

7.9. Three days later, on 17th August 1998, Mrs RICHARDS was returned to the Gosport War Memorial Hospital on a sheet and not on a stretcher. She was very distressed when she reached Daedalus ward.

7.10. There is no evidence that Mrs RICHARDS, although in pain, had any specific life-threatening and terminal illness that was not amenable to treatment and from which she could not be expected to recover.

7.11. Despite this, and on 18th August 1998, Dr BARTON, while knowing of Mrs RICHARDS's sensitivity to oral morphine and midazolam, prescribed diamorphine, midazolam, haloperidol, and hyoscine to be given (from wide dosages ranges) continuously subcutaneously and by a syringe driver over periods of 24 hours for an unlimited period.

7.11.1. Neither midazolam nor haloperidol is licensed for subcutaneous administration.

7.11.2. It is noted, however, that in clinical practice these drugs are administered subcutaneously in the management of distressing symptoms during end-of-life care for cancer.

7.11.3. It is also noted that Mrs RICHARDS was not receiving treatment for cancer.

7.12. There is no evidence that in fulfilling her duty of care Dr BARTON reviewed appropriately Mrs RICHARDS's clinical condition from 18th August 1998 to determine if any reduction in the drug treatment being given was indicated.

7.13. During this period when a syringe driver was being used to administer the subcutaneous drugs, there is no evidence that Mrs RICHARDS was given fluids or food in any appropriate manner.

7.14. There is no evidence that in fulfilling their duty of care Mr Philip BEED, Ms Margaret COUCHMAN and Ms Christine JOICE reviewed appropriately Mrs RICHARDS's clinical condition from 18th August 1998 to determine if any reduction in the drug treatment they were administering was indicated.

7.15. There is, however, indisputable evidence that the subcutaneous administration of drugs by syringe driver continued without modification and during every 24 hours from 18th August 1998 until Mrs RICHARDS died on 21st August 1998.

7.16. Dr Barton recorded that death was due to bronchopneumonia.

7.16.1. It is noted that the continuous subcutaneous administration of diamorphine, haloperidol, midazolam, and hyoscine to an elderly person can produce unconsciousness and death from respiratory failure associated with pneumonia.

My opinion

8. When Mrs RICHARDS was first admitted to Daedalus ward at Gosport War Memorial hospital on 11th August 1998 she was not in pain and had been fully weight bearing walking with the aid of two nurses and a Zimmer frame.

8.1. Despite recording that Mrs RICHARDS was not in pain, on 11th August 1998 Dr BARTON prescribed wide dosage ranges of opiate and sedative drugs to which Mrs RICHARDS was known to be sensitive.

8.1.1. Dr Barton also recorded that 'I am happy for nursing staff to confirm death.' when Mrs RICHARDS had been admitted for rehabilitation and her death was not obviously imminent.

8.2. When, at the age of 91 years, Mrs RICHARDS dislocated her operated hip and despite her confused mental state, she was considered well enough to have a second operation on her right hip within about two weeks of the first operation.

8.3. There is no evidence to show that after her second operation Mrs RICHARDS, although in pain, had any specific life-threatening and terminal illness that was not amenable to treatment and from which she could not be expected to recover.

8.4. It is my opinion, and there is evidence to show, that Mrs RICHARDS was capable of receiving oral medication for the relief of the pain she was experiencing on 17th August 1998.

8.5. Mrs RICHARDS was known by Dr BARTON to be very sensitive to Oramorph, an oral morphine preparation, and to have had a prolonged sedated response to intravenous midazolam.

8.6. Despite this, and from 18th August 1998 for an undetermined and unlimited number of days, Dr BARTON prescription led over 24-hours periods to the continuous subcutaneous administration to Mrs RICHARDS of diamorphine 40mgs, haloperidol 5mgs, and midazolam 20mgs to which was added hyoscine 400mcg from 19th August 1998.

8.7. The administration of these drugs continued on a 24-hours regime without their dosages being modified according to Mrs RICHARDS's response to them and until Mrs RICHARDS died on 21st August 1998.

8.8. There is no record that Mrs RICHARDS was given any food or fluids to sustain her from the 18th August 1998 until she died on 21st August 1998.

8.9. As a result of the continuous subcutaneous administration of the prescribed drugs diamorphine, haloperidol, midazolam, and hyoscine Mrs RICHARDS became unconsciousness and died on 21st August 1998.

8.10. No other event occurred to break the chain of causation and in my opinion Mrs RICHARDS's death was directly attributable to the administration of the drugs she continuously received by syringe driver from 18th August 1998 until her death on 21st August 1998.

8.11. It is my opinion that Mrs Gladys RICHARDS's death occurred earlier than it would have done from natural causes and was the result of the continuous administration of diamorphine, haloperidol, midazolam, and hyoscine which had been prescribed to be administered continuously by a syringe driver for an undetermined number of days.

APPENDIX A

14. I have received and read the following documents:-

14.1. The letter of DCI BURT dated 22nd November 1999 that gave an initial overview of the case.

14.2. The documents in the file DCI BURT presented at our meeting on 28th January 2000 as follows:-

14.2.1. 1) Draft (unsigned) statement (MG11) of Lesley HUMPHREY.
14.2.2. 2) Copy of PEC (NHS) T Health Record (LH/1/C).
14.2.3. 3) Copy of RHH Medical Record (AF/1/C).
14.2.4. 4) Draft (unsigned) statement (MG11) of Gillian MACKENZIE.
14.2.5. 5) Draft (unsigned) statement of Lesley LACK.

14.3. The documents in the file DCI BURT presented at our meeting on 8th March 2000 including those pursuant to my request of 28th January 2000 (documents WX1, WX2, and YZ were forward to me on 9 March 2000) as follows:-

14.3.1.	A	Typed copy of Notes prepared by Mrs LACK and given to Portsmouth Healthcare NHS Trust
14.3.2.	B	Typed copy of additional page of notes which was prepared by Mrs LACK but, apparently, not passed to Portsmouth Healthcare NHS Trust
14.3.3.	C	Typed copy of Notes prepared by Mrs LACK and given to Social Services
14.3.4.	D	Typed copy of comments made by Mrs LACK in respect of letter from Portsmouth Healthcare NHS Trust which represented a response to her Notes of complaint (A)

14.3.5.	E	Typed copy of comments made by Mrs LACK in respect of a Report prepared by Portsmouth Healthcare NHS Trust which resulted in the letter referred to above
14.3.6.	F	As D above but made by Mrs MACKENZIE
14.3.7.	G	As E above but made by Mrs MACKENZIE
14.3.8.	HI	Copy of letter written by Mrs MACKENZIE to DI MORGAN (OIC of initial investigation) plus 5 copies newspaper cuttings
14.3.9.	JK	Copy of Coroner's Officer's Form
14.3.10.	L	Copy of letter from Dr REID to S/Cdr SCOTT
14.3.11.	M	Copy of Report made by Dr LORD during original investigation
14.3.12.	N	Copy of additional newspaper cutting
14.3.13.	O (1)	Typed copy of signed statement of Anne FUNNELL (RHH)
14.3.14.	O (2)	Typed copy of signed statement of Lesley HUMPHREY (Portsmouth Healthcare NHS Trust)
14.3.15.	O (3)	Copy of signed statement of Lesley LACK
14.3.16.	O (4)	Copy of final draft of Gillian MACKENZIE's statement
14.3.17.	PQ	Copy of schedule of x-ray images (RHH)
14.3.18.	R	Copy of Risk Event Record (Portsmouth Healthcare NHS Trust)
14.3.19.	S (1)	Copy of letter which DCI BURT has sent to Lesley HUMPHREY (Portsmouth Healthcare NHS Trust) raising various issues
14.3.20.	S (2)	Copy of entries in medical directories 1998/1999 - Dr Jane Ann BARTON
14.3.21.	S (3)	Copy of letter from Mrs MACKENZIE to DCI BURT
14.3.22.	S (4)	Copy of documents which accompanied the two Portsmouth Healthcare NHS Trust x-ray images
14.3.23.	T	Copy of various documents which featured in a Social Services Case Conference stemming from receipt of Mrs LACK's Notes of complaint (C above)
14.3.24.	UV	Copy of Death Certificate - Mrs RICHARDS
14.3.25.	WX1	Witness Statement of Mrs Gillian MACKENZIE dated March 6 2000
14.3.26.	WX2	Copy of letter from DR J.H. BASSETT to Mrs MACKENZIE with an addendum of five pages being a photocopy from 'Toxic Psychiatry' a book by Dr Peter BREGGEN published by Harper Collins.
14.3.27.	YZ	Two extracts from 'Criminal Law. Diana Rowe. Hodder & Stoughton 1999.'

14.4. On 8th March 2000, in the presence of DCI BURT, I visited:-

14.4.1. the Gosport Memorial Hospital and followed the passageways along which Mrs Richards was conveyed and the ward areas in which she was treated; and,

14.4.2. the Royal Hospital Haslar and followed the passageways along which Mrs Richards was conveyed and the ward area in which she was treated.

14.4.2.1. At the Royal Hospital Haslar, on 8th March 2000, in the presence of DCI BURT, I was also shown twelve (12) radiographs relating to Mrs Richards' treatment there on 12th April 1998, 17th July 1998, 14th August 1998, 29th July 1998, and 31st July 1998.

14.5. In addition I have read the following the documents given to me by DCI BURT on 12th May 2000 consisting of the following which are numbered below as listed in the two containing ring binders:

14.5.1.	E 25	Copy of Glen Care Homes file Re: Gladys RICHARDS supplied by Glen Care Homes
14.5.2.	E 22	Copy of Hampshire County Council Social Services file Re: Gladys RICHARDS
14.5.3.	E23	Copy of Glen Care Homes file Re: Gladys RICHARDS supplied Nursing Homes Inspectorate
14.5.4.	E 24	Copy Portsmouth and South East Hampshire Health Authority GP Patient Records of Gladys RICHARDS
14.5.5.	D 63	Police letter 090300 to Miss CROSS, Haslar Hospital with further questions
14.5.6.	D 65	Letter 100400 from Miss CROSS at Haslar including Patient transfer order and further medical records
14.5.7.	D 104	Letter 080200 from Mrs. MACKENZIE with notes Re: draft statement
14.5.8.	D 108	Portsmouth NHS Trust Dept. of Diagnostic Imaging report folder
14.5.9.	D 110	Copy typed Gladys RICHARDS Death Certificate dated 240898

14.6. I have also read the documents given to me by DCI BURT on 19th July 2000, consisting of copies of the statements made by:-

14.6.1. JOICE Christine
14.6.2. GIFFIN Sylvia Roberta
14.6.3. PULFORD Monica Catherine
14.6.4. WALKER Fiona Lorraine
14.6.5. MARJORAM Catherine
14.6.6. BALDACCHINO Linda Mary
14.6.7. PERKINS Margaret Joan
14.6.8. TUBBRITT Anita
14.6.9. COUCHMAN Margaret
14.6.10. WALLINGTON Kathleen Mary
14.6.11. FLETCHER Anne
14.6.12. COOK Joanne
14.6.13. MOSS JEAN Kathleen
14.6.14. TYLER Christina Ann

14.7. I have also read statements, provided on 30th August 2000 by DCI BURT, made by:

14.7.1. Doctor Jane Ann BARTON
14.7.2. Phillip James BEED

14.8. I have also received from DCI BURT on 8th September 2000 and read copies of:-

14.8.1. A letter dated 18th August 2000 from Mrs Gillian MACKENZIE to DCI BURT.

14.8.1.1. Enclosed with this letter was a copy of a letter dated 9th August 2000 from Ms Jill BAKER to Mrs Gillian MACKENZIE to which had been added a petition form.

14.9. A letter dated 21st August 2000 from Mrs Gillian MACKENZIE to DCI BURT.

14.9.1. Enclosed with this letter was a copy of a letter dated 14th December 1998 from Ms Lesley HUMPHREY, Quality Manager at Portsmouth Healthcare NHS Trust Central Office to Mrs Gillian MACKENZIE. This had enclosed with it a copy of a letter dated 22nd September 1998 from Mr Max MILLETT, Chief Executive of Portsmouth Healthcare NHS Trust.

14.10: Copies of Witness Statements (taken by Mrs S.HUTCHINGS who led the initial Internal Inquiry as Investigating Officer of Portsmouth Healthcare NHS Trust) as follows:-

14.10.1. On 3rd September 1998 statement consisting of four pages from Mrs Jenny BREWER – Staff Nurse Daedalus Ward to which is attached an additional statement (three pages) by Staff Nurse Brewer (the first page of this three pages is headed Portsmouth Healthcare NHS Trust and has been signed on page three by S. N J Brewer RGN and dated 9-9-98 (Reference D142)).

14.10.2. On 8th September 1998 statement consisting of five pages from Mr Philip BEED – Clinical Manager Daedalus Ward (Reference D143).

14.10.3. On 9th September 1998 statement consisting of three pages from Ms Christine JOICE – Staff Nurse Daedalus Ward (Reference D144).

14.10.4. On 8th September 1998 statement consisting of two pages from Ms Monica PULFORD – Enrolled Nurse Daedalus Ward (Reference D145).

14.10.5. On 3rd September 1998 statement consisting of four pages from Ms Margaret COUCHMAN – Staff Nurse Daedalus Ward (Reference D146).

14.11. A copy of the National Council for Hospice and Specialist Palliative Care Services paper entitled 'Ethical decision-making in palliative care'.

14.12. On 5th and 6th October 2000 I received from Hampshire Constabulary and subsequently read:-

14.12.1. The records of the interviews conducted with Dr Anthea Everista Geredith LORD on 27th September 2000.

14.12.2. During these interviews Dr LORD produced as listed in the Officer's Report by DC McNally the following documents:-

14.12.2.1. Drug Therapy Guidelines for subcutaneous fluid replacement as approved by the Elderly Medicine and Formulary & Medicines Group of Portsmouth Hospitals and Portsmouth Healthcare updated for 1998.

14.12.2.2. Consultants' Rota for August 1998 of the Department of Medicine for Elderly People (Ref: CI/28.7.98).

14.12.2.3. Memorandum from Mrs. L HUMPHREY of Portsmouth Health Care NHS Trust to Dr. LORD dated 17th December 1998 and headed 'Mrs. Richards deceased, Gosport War Memorial Hospital, 21st August, 1998.'

14.12.2.4. Letter from Dr R I REID, Medical Director of Portsmouth Health Care NHS Trust giving approval of study leave for Dr. LORD for the dates of 17/18 August 1998.

14.12.2.5. Consultants' Timetable of the Department of Medicine for Elderly People from 4.5.98 – 8.2.99.

Appendix B

Facts of the environment - obtained from the statements of Mrs RICHARDS's daughters

15. Mrs MACKENZIE is the elder of Mrs RICHARDS's two daughters. It is noted that her sister, Mrs LACK, is a retired Registered General Nurse.

15.1. Mrs LACK retired in 1996 after 41 years continuously in the nursing profession. For 25 years prior to retirement she was involved in the care of elderly people. For 20 years prior to retiring she held supervisory and managerial positions in this field of nursing.

15.2. By July 1998, Mrs RICHARDS had been resident at the Glen Heathers Nursing Home for some four years. She had a past medical history of bilateral deafness for which she required two hearing aids (unfortunately these were lost while she was at the Glen Heathers Nursing Home). She had had operations for the removal of cataracts and required glasses (unfortunately these were also lost at the Glen Heathers Nursing Home).

15.3. Also by July 1998, Mrs RICHARDS had become increasingly forgetful and less able physically. She had had 17 falls documented at the Glen Heathers Nursing Home between 29th January 1998 and 29th July 1998.

15.3.1. During this period Mrs MACKENZIE decided to meet and question her mother's general practitioner, Dr BASSETT. Mrs MACKENZIE had formed the opinion that the drugs Dr BASSETT was prescribing could contribute to her mother's confused mental state and deterioration of her physical health. One drug was Trazodone and the other was haloperidol. Following this meeting she sent him a copy of a book entitled *Toxic Psychiatry*.

15.3.2. Dr BASSETT replied, in a hand-written letter, thanking Mrs MACKENZIE and stating '... I have a reputation in Lee [-on-Solent] of being somewhat sparing with 'mood' drugs and especially antibiotics. ... most drugs are prescribed with more caution these days. [paragraph] Hopefully we can continue to keep your Mother's drugs to a minimum!'

15.4. It is convenient to mention here that both Mrs MACKENZIE and Mrs LACK have registered serious concerns about the care given to their mother in the Glen Heathers Nursing Home.

15.4.1. Jane PAGE, Principal Nursing Home Inspector, Portsmouth & S.E. Hants Health Authority investigated these concerns formally. On 11th August 1998, she made an unannounced visit to the Glen Heathers Nursing Home. She reported, on 26th August 1998, that 'From the written records obtained and discussions held, I can find no evidence to substantiate that Mrs RICHARDS did not receive appropriate care and medication.'

15.4.2. These concerns were discussed further by the Social Services Department at a meeting held on 23rd November 1998 when Mrs LACK was present. The conclusion was that 'There was no evidence of deliberate abuse [of Mrs RICHARDS] although there seemed to be problems of complacency in some of the care practices which needed review.... However, there was no evidence of malpractice by the Home.'

15.5. On 29th July 1998, while in the Glen Heathers Nursing Home, Mrs RICHARDS sustained a fracture of the neck of her right femur (thighbone). According to Mrs

LACK her mother underwent a surgical operation on 30th July 1998 'following a discussion with the consultant who thought my mother should be given the chance to remain ambulant.'

15.6. Mrs LACK has also stated:-

15.6.1. 'My mother received a replacement hip, on her right side, and remained in the Haslar Hospital a further eleven days until Tuesday the 11th August 1998. [paragraph] I visited my mother every day during this period and, in my view, when taking into account the serious injury which she had sustained and the trauma she had suffered, my mother appeared to make a good recovery during this period.'

15.6.2. 'Prior to her discharge, and transfer to the Gosport War Memorial Hospital, my mother was responding to physiotherapy, able to walk a short distance with the aid of a zimmer frame and no longer required a catheter. Her medication had been reduced and she was able to recognise family members and make comments to us which made sense.'

15.6.3. 'She was with encouragement, eating and drinking naturally and as a result the drips, which had facilitated the provision of nourishment after the operation, had been removed.'

15.6.4. 'Significantly, my mother was no longer in need of pain relief. It was quite apparent, to me, that she was free of pain.'

15.6.5. 'Such was the extent of my mother's recovery that it was considered appropriate to discharge her and transfer her to the Gosport War Memorial Hospital where she was admitted to Daedalus Ward on Tuesday the 11th August 1998. This was the first occasion that my mother had been admitted to this particular hospital.'

15.7. On 12th August 1998, the day after her mother's admission to the Gosport War Memorial Hospital, Mrs LACK visited her mother there and has recorded '... I was rather surprised to discover that I could not rouse her [Mrs RICHARDS]. As she was unrousable she could not take nourishment or be kept hydrated. [paragraph] I enquired among the staff and I was told that my mother had been given the morphine based drug 'Oramorph' for pain. This also surprised me. When my mother had been discharged from the Haslar Hospital, the day before, she had not required pain relief for several days. [paragraph] I was distressed to observe my mother's deteriorated condition which significantly contrasted with the level of recovery which had been achieved following treatment at the Haslar hospital during the period after the surgical operation to replace her hip. [paragraph] I was told that my mother had been calling out, showing signs of being anxious, and it was believed that she was suffering pain. They did not investigate the possible cause. I consider it likely that she was in need of the toilet. ... One of the

consequences of being rendered unrousable, by the effects of 'Oramorph', was that no fluids could be given to my mother and this, together with the abandonment of other forms of rehabilitation, would have served to inhibit or prevent the recovery process which had begun prior to her admission to the Gosport War Memorial Hospital.'

15.8. Mrs RICHARDS had a fall on 13th August 1998 (as described above). On the following morning (14th August 1998), Mrs LACK noted that while her mother was being taken to the X-ray department at the Gosport War Memorial Hospital 'She was still deeply under the effects of the 'Oramorph' drug.'

15.9. As described above Mrs RICHARDS was then transferred to the Royal Hospital Haslar for the reduction of her dislocated artificial hip. She was returned to the Gosport War Memorial Hospital on 17th August 1998 having been noted the previous day (16th August) by Mrs LACK [a nurse experienced in the care of elderly people] to be 'easily manageable'.

15.9.1. In accepting that he would transfer Mrs RICHARDS to the Gosport War Memorial Hospital, Dr REID (consultant geriatrician) had stated that '... despite her dementia, she [Mrs RICHARDS] should be given the opportunity to try to re-mobilise.'

15.10. On visiting her mother at the Gosport War Memorial Hospital at about 1215 hours on 17th August 1998, Mrs LACK accompanied by her sister [Mrs MACKENZIE], found her mother to be screaming and in pain. The screaming ceased 'within minutes' when Mrs LACK and a registered general nurse repositioned Mrs Richards.

15.11. Subsequently, the X-ray at the Gosport War Memorial Hospital showed no fresh dislocation of the artificial hip.

15.12. Following this further X-ray, Mrs LACK told Dr BARTON that Haslar Hospital would be prepared to readmit her mother. Dr BARTON is reported to have '... felt that was inappropriate.' Mrs LACK '... considered this was essential so that the 'cause' of my mother's pain could be treated and not simply the pain itself.'

15.12.1. Dr BARTON is stated to have said to Mrs LACK that, '..."It was not appropriate for a 91 year old, who had been through two operations, to go back to Haslar Hospital where she would not survive further surgery." '

15.13. Mrs LACK states that, on 18th August 1998, the Ward Manager [Mr Philip BEED] explained to her and her sister that a syringe driver was going to be used. This was to ensure Mrs RICHARDS 'was pain free at all times' so that she would not suffer when washed, moved, or changed in the event she should become incontinent. Mrs LACK has also described in her contemporaneous notes (as well as in her Witness Statement, see below) that 'A little later Dr BARTON appeared and confirmed that a haematoma

was present and that this [the use of a syringe driver] was the kindest way to treat my mother. She [Dr BARTON] also stated "And the next thing will be a chest infection." '.

15.13.1. In her Witness Statement, Mrs LACK has recorded 'The outcome of the syringe driver was explained to my sister and I fully. Drawing on my experience as a nurse I [Mrs LACK] knew that the continuous use of morphine, as means of relieving her pain, could result in her death. She [Mrs RICHARDS] was, at the time, unconscious from the effects of previous doses of 'Oramorph'.... [paragraph] As result of seeing my mother in such great pain I was becoming quite distressed at this stage. My sister asked the Ward Manager, "Are we talking about euthanasia? It's illegal in this country you know." The Ward Manager replied, "Goodness, no, of course not." I was upset and said, "Just let her be pain free". [paragraph] The syringe driver was applied and my mother was catheterised to ease the nursing of her. She had not had anything by mouth since midday Monday 17th August 1998. [paragraph] A little later Dr BARTON [sic] appeared and confirmed that a haemetoma [sic] was present and that this was the kindest way to treat my mother. She also stated, "And the next thing will be a chest infection." .... [In her witness statement Mrs Mackenzie has stated that ' DR BARTON [sic] then said, "Well, of course, the next thing for you to expect is a chest infection".'][paragraph] I would like to clarify the issue of my 'agreement' to the syringe driver process. It was not a question, in my mind, of 'agreement'. [paragraph] I wanted my mother's pain to be relieved. I did not 'agree' to my mother being simply subjected to a course of pain relief treatment, at the Gosport War Memorial Hospital, which I knew would effectively prevent steps being taken to facilitate her recovery and would result in her death. [paragraph] I also wanted my mother to be transferred back to the Haslar Hospital where she had, on two occasions, undergone operations and recovered well. My mother was not, I knew, terminally ill and, with hindsight, perhaps I should have challenged Dr BARTON [sic] more strongly on this issue. [paragraph] In my severe distress I did not but I do believe that my failure to pursue the point more vigorously should not have prevented Dr BARTON [sic] from initiating an alternative course of action to that which was taken, namely a referral back to the Haslar Hospital where my mother's condition could have been treated and where an offer had already been made to do so. [paragraph] I accept that my mother was unwell and that her physical, reserves had been depleted. However, she had, during the preceding days and weeks, demonstrated great courage and strength. I believe that she should have been given a further chance of recovery especially in the light of the fact that her condition had, it would seem likely, been aggravated by poor quality service and avoidable delay experienced whilst in the hands of those whose responsibly [responsibility] it was to care for her. [paragraph] My mother's bodily strength allowed her to survive a further 4 days using her reserves. She suffered kidney failure on 19th August and no further urine was passed. The same catheter remained in place until

her death. [paragraph] Because the syringe driver was deemed to be essential following the night of several doses of pain relief my mother's condition gradually deteriorated during the next few days, as I knew it inevitably would, and she died on Friday the 21st August 1998.'

15.14. It is noted that Mrs LACK had made contemporaneous hand-written notes comprising five numbered pages. In her Witness Statement she records these '... are in the form of a basic chronology and I incorporated within them a series of questions which focused on particular areas of concern in respect of which I sought an explanation or clarification from the hospital authorities. Following presentation of my notes we were visited on the ward by Mrs Sue HUTCHINGS [sic] on 20.8.98.'

15.14.1. Mrs LACK also made a further one page of contemporaneous hand-written notes. In these she states she was so appalled about her mother's condition, discomfort and severe pain that she visited Haslar Hospital at about lunchtime on 17th August 1998 to ask questions about her mother's condition before she [Mrs RICHARDS] had left the Haslar Hospital ward for her second transfer to Gosport War Memorial Hospital. She learned that, prior to her discharge from Haslar Hospital on 17th August 1998, her mother had been eating, drinking, using a commode and able to stand if aided. Mrs LACK also states in this contemporaneous record that 'On leaving the ward [at Haslar Hospital at about lunchtime on 17th August 1998] I bumped into the Dr [doctor] who had been in casualty theatre for my mothers [sic] second [sic] operation. He was with consultant when all the procedures were explained to me on Friday 14th [August 1998] He said "How's your mother". I explained the current position to him in detail. I told him that she was in severe pain since the transfer which had been undertaken a short time earlier. He said "We've had no referral. Get them to refer her back. We'll see her."

15.15. It is noted that a Discharge Letter from the Royal Hospital Haslar describes Mrs RICHARDS' condition on discharge on 17th August 1998 as "She can, however, mobilise fully weight bearing."

15.16. It is also noted that Mrs LACK has stated that she and her sister were constantly at the Gosport War Memorial Hospital, day and night, from 17th August 1998 until the time their mother died.

15.16.1. Mrs MACKENZIE has stated that 'I stayed with my mother until very late that Tuesday night [18th August 1998]. it was past midnight, in fact, when my son arrived from London. As from the Wednesday night my sister also sat with me all night long and we both remained, continuously, until twenty past nine on the following Friday evening [21st August 1998] when my mother died. During that time Dr Barton [sic] did not visit my mother. I am quite certain about this because our mother was not left alone, in her room, at

any time apart from when she was washed by the nursing staff. Either my sister or I, [sic] was with her throughout.'

15.16.2. Mrs MACKENZIE has also stated that although she did not sign the contemporaneous notes made by Mrs LACK she '... was a party, at times, to the preparation process and where, on occasions, my sister has referred to 'I' in fact it could read 'we' as we were together when certain events occurred.'

15.16.3. Mrs MACKENZIE continues 'It seems to me that she [Mrs RICHARDS] must have had considerable reserves of strength to enable her to survive from Monday until Friday, five days, when all she had was a diet of Diamorphine and no hydration whatsoever, apart from porridge, scrambled eggs and a drink, at the Royal Hospital Haslar, before transfer to the Gosport War Memorial Hospital.'

Appendix C

Glossary

Acetabulum is the name given to the two deep socket into which the head of the thigh bone (femur) fits at the hip joint.

ADL [activities of daily living] are those physical activities of daily life necessary for normal human functioning and include getting up, washing, dressing, preparing a simple meal, etc.

Analgesia is the relief of pain. This can be achieved by physical means including warmth and comfortable positioning as well as by the use of drugs. The aim is to keep patients pain free with minimal side effects from medication.

Bronchopneumonia is inflammation of the lung usually caused by bacterial infection. Appropriate antibiotic therapy, based on the clinical situation and on microbiological studies, will result in complete recovery in the majority of patients. It can contribute to the cause of death in moribund patients.

Co-codamol is a drug mixture consisting of paracetamol and codeine phosphate, which is used for the relief of mild to moderate pain.

Cyclizine is a drug used to prevent nausea and vomiting, vertigo, and motion sickness.

Dementia is the name given to a condition associated with the acquired loss of intellect, memory, and social functioning.

Diamorphine, also known as heroin, is a powerful opioid analgesic.

Haematoma is an accumulation of blood within the tissues, which clots to form a solid swelling.

Haloperidol, a drug used in the treatment of psychoses including schizophrenia and mania and also for the short-term management of agitation, excitement, and violent or dangerously impulsive behaviour. Dosage for all indications should be individually determined and it is best initiated and titrated under close clinical supervision. For patients who are elderly the normal starting dose should be halved, followed by a gradual titration to achieve optimal response. It is not licensed for subcutaneous administration (see **licensed** below).

Hemiarthroplasty is the surgical remodelling of a part of the hip joint whereby the bone end of the femur is replaced by a metal or plastic device to create a functioning joint.

Hyoscine is a drug used to reduce secretions and it also provides a degree of amnesia and sedation, and has an anti-vomiting effect. Its side effects include drowsiness.

Lactulose is a preparation taken by mouth to relieve constipation.

A microgram is one millionth of a gram and is not to be confused with a milligram dosage of a drug, which is one thousand times larger.

Midazolam is a sedative drug about which there have been reports of respiratory depression. It has to be use with caution in elderly people. It is used for intravenous sedative cover for minor surgical procedures. It is also used for sedation by intravenous injection in critically ill patients in intensive care. It can be given intramuscularly. In the management of overdosage special attention should be paid to the respiratory and cardiovascular functions in intensive care. It is not licensed for subcutaneous administration (see **licensed** above).

Morphine is an opioid analgesic used to relieve severe pain.

Oramorph is a drug used in the treatment of chronic pain. It contains morphine and is in the form of a liquid. 10mls of Oramorph at a strength of 10mgs of morphine sulphate in 5mls of liquid is an appropriate first dose to give to a person in severe pain, which had not responded to other less potent, pain relieving drugs.

Respiratory depression is the impairment of breathing by drugs or mechanical means which leads to asphyxia and, if uncorrected, to death.

Subcutaneous means beneath the skin.

A **syringe driver** is a power driven device for pushing the plunger of a syringe forward at an accurately controlled rate. It is an aid to administering medicinal preparations in liquid form over much longer periods than could be achieved by injecting by hand. In this case the syringe driver used was a Sims Graseby MS 26 Daily rate syringe driver which operates over periods of 24-hours.

Tradazone is a drug used in the treatment of depressive illness, particularly when sedation is required.

Unlicensed medicines. In order to ensure that medicines are safe, effective and of suitable quality, they must have a product licence (now called a market authorisation) before being marketed in the United Kingdom. Unlicensed drugs are not licensed for use for any indication or age group. Licensing arrangements constrain pharmaceutical companies but not prescribers. The Medicines Act 1968 and European legislation make provision for doctors to use unlicensed medicines. Individual prescribers of unlicensed medicines, however, are always responsible for ensuring that there is adequate information to support the quality, efficacy, safety and intended use of a drug before using it.

A **Zimmer frame** is a lightweight, but sturdy, frame the patient can use for support to assist safe walking.

APPENDIX D

Texts used for reference have included:

1. Adam J. ABC of palliative care: The last 48 hours. *British Medical Journal* 1997; 315: 1600-1603.

   1.1. This paper is from the widely read, British Medical Journal which is published weekly and received by about 30,000 general practitioners and 45,000 hospital doctors in England and Wales. It records that treatment with opioids (viz. morphine and diamorphine) should be individually tailored, the effect reviewed, and the dose titrated accordingly.

2. *ABPI Compendium of data sheets and summaries of product characteristics 1998-99: with the code of practice for the Pharmaceutical Industry*. Datapharm Publications Limited, 12 Whitehall, London SW1A 2DY.

3. Breggin P R. *Toxic psychiatry. Drugs and electroconvulsive therapy: the truth and the better alternatives*. 1993. HarperCollins Publishers. London. pp. 578.

4. British Medical Association and the Royal Pharmaceutical Society of Great Britain. *British National Formulary*. Number 32 (September 1996). The Pharmaceutical Press. Oxford.

5. *Cecil Textbook of Medicine*. eds. J.C. Bennett & F. Plum. W.B. Saunders Co. 20th Edition. 1996.

6. Letter from Clive Ward-Able (Medical and Healthcare Director) and Lee Neubauer BSc (Hons) (New Product Specialist), Roche Pharmaceuticals.

   6.1. A copy of this letter has already been supplied to the Police and reports that the product licence does not cover the administration of Hypnovel® (midazolam) by subcutaneous injection.

7. Roche Pharmaceuticals. Hypnovel® [midazolam]. Summary of product characteristics.

8. Letter from Dr R J Donnelly, Medical Director of Janssen-Cilag Ltd.

   8.1. A copy of this letter has already been supplied to the Police and reports that Haldol™ decanoate (haloperidol) is not licensed for subcutaneous use.

9. Letter from Miss Jo Medlock, Manager of Medical Information and Pharmacovigilance, Norton Pharmaceuticals.

   9.1. A copy of this letter has already been supplied to the Police and reports that Serenace™ (haloperidol) ampoules are not licensed for subcutaneous administration.

10. MeReC. Pain control in palliative care. *MeReC Bulletin National Prescribing Centre*. 1996; 7 (7); 25-28.

    10.1. MeReC is the abbreviation for the 'Medicines Resource Centre'. This bulletin is sent free to all general practitioners in England and Wales and also to NHS Hospital and Community Pharmacists. The list of those who receive this bulletin is updated every few weeks.

11. Sims Graseby Limited. *MS 16A Syringe Driver. MS 26 Syringe Driver: Instruction manual*. Sims Graseby Limited. 1998.

Appendix E

The writer's qualifications and experience including the management of dying patients

Code A

Code A

Code A

Code A

signed .. Code A ... date 10th July 2001

6

Report on the Care and Death of
Helena Service
5th June 1997
Draft: 6th November 2004

This report has been provided by Dr David A Black, MA MB BChir (Cantab) FRCP, Consultant Physician at Queen Mary's Sidcup NHS trust. This report is in two parts, a factual summary of time line including important investigations and in the second part an opinion on the events that occurred. The numbers in brackets refer to the pages of evidence to support the statements.

1. Timeline

1.1. Mrs Service's hospital notes start in 1991 when she is investigated for difficulty in swallowing (102) this was initially thought to be a cancer (101). She is noted to be in atrial fibrillation (99) and eventually has a major abdominal operation (a partial gastrectomy) (99), which finds that she has benign gastric ulcer disease (no cancer). She has no complications following surgery.

1.2. In 1994 she is admitted with a stroke causing a left sided hemiplegia (weakness), she remains in atrial fibrillation has high blood pressure (94) and spends 4 weeks in hospital (86-87). Her heart is documented to be enlarged at that time (229). A home visit (92) shows that she is slow but independent, but her "memory is poor" (90).

1.3. 1987 progression of her profound deafness due to otosclerosis is documented (81).

1.4. In 1988 she presents with a high blood sugar (diabetes mellitus) unmarsked because she was started on steroid tablets for a presumed diagnosis of polymyalgia rheumatica. She has a week of inpatient care (79). Her mental test score is documented at 9/10 (79).

1.5. In 1992 she is admitted having been found on the floor with a new stroke and new left sided weakness (70). She is thought to be confused but her mental test score is again documented at 9/10. Albumin is 31; haemoglobin is 10.9 (70).

1.6. In January 1995 she has now moved into a residential home. A visit to the home finds that she is in congestive cardiac failure with mitral regurgitation and it is thought she is likely to need hospital admission (68 – 69). She is subsequently admitted to hospital for a week and is noted to be in quite severe congestive cardiac failure on admission (58-59)

1.7. After admission needs a week in hospital where her medication is altered and she returns to her residential care (56 – 57). She now has significant documented dependency with a Barthel of 10/20 (326).

1.8. In January 1996 she is admitted with a diagnosis of gout and dehydration. Her Barthel is 3/20 on admission and 6/10 on discharge (11). Her Waterlow score is 30 on 27th January (12) giving her a very high risk of pressure sores. Very poor mobility is documented (13) despite this, she returns to her residential care home (54).

1.9. The notes from her residential home show that she is declining in health in May 1997, for example, her bedsores have started bleeding in the residential care home notes (283).

1.10. On the 17th May 1997 at the age of 99 she is admitted at the request of her GP to hospital with confusion, disorientation and progressive failure for the rest home to be able to cope. (51 –52). She is now on Melleril (Thioridazine) a major tranquilliser often used for people who are confused and disorientated. She is thought to be dehydrated (156). Admission creatinine is raised 151 (157). She is found to be markedly hypoxic (PO2 of 6.7, PCO2 of 5.6 (157) and is diagnosed to have a combination of "dehydration and left ventricular failure" (158).

1.11. She is thought to make some progress. However on the 20th May she is sleeping in a chair. Her creatinine has fallen with, rehydration, to 114 (159).

1.12. On 26th May she is noted to have a possible new left sided weakness due to a new stroke (160). The nursing notes 26th May (296) she "remains confused". They also note (303) that after 26th May she remains totally dependent "transfers with two". Social Services assessment on 27th May (276) records a maximum Barthel of 4.

1.13. On 28th May she is referred to the geriatric team, her Barthel remains 4 (162). Dr Ashbal sees her on 29th May and records that she has had long standing congestive cardiac failure, is deaf and he is clear that she will not return to a level of function that will allow her to return to the residential home. He says that he will arrange transfer to the Gosport Memorial Hospital "with a view to considering continuing care" (39).

1.14. The medical notes at the Queen Alexander record no obvious change in function but the nursing notes for the 2nd June (296) note that she was "very demanding overnight , shouting out continuously". This suggests that she was acutely confused. Also on the 2nd June she remained continuously breathless and

needed to be "nursed upright all night" (298)

1.15. On 3rd June she is transferred to the Gosport War Memorial Hospital. The transfer note (164) states that she is confused, "off legs", has diabetes and heart failure. There is an examination recorded, which states that she is breathless and lethargic, there is a "gallop rhythm" with normal first and second heart sounds, chest was clear. Written underneath the examination record, the notes state "needs palliative care as necessary" and "happy for nursing staff to confirm death".

Barthel of 0/20 on admission to Gosport is documented. (24).

There were no further medical notes apart from a nursing note confirming that she had died peacefully at 3.45 am 5th June 1997.

1.16. The nursing cardex on admission to Gosport (22) documented "very pleasant lady" and a buttock bedsore.

1.17. At 02.00 on 4th June she was noted to be very restless and agitated and Midazolam 20 mgs over 24 hours is started by syringe driver.

1.18. On 4th June it is documented that she has deteriorated overnight and the syringe driver is replaced by Diamorphine 20 mgs and Midazolam 40 mgs. She continues to deteriorate and dies at 03.45 on 5th June (22).

1.19. Drug Chart Analysis:

1996 Drug Chart shows nothing unusual and the only drugs on the "as required" side are Temazepam and Metaclopamide (260). When she is admitted to the Queen Alexander Hospital (269-273) she is on Zestril, Bumetanide, Aspirin and Digoxin for her heart disease and atrial fibrillation, Allopurinol for her gout. On the "as required" side, Thioridazine (which is then given it each night as a sedative), and Paracetamol.

1.20. In 1997 on admission to Gosport: Bumetanide, Lisinopril, Lanoxin, Aspirin are all continued with Allopurinol and all these drugs are given to her on both 3rd and 4th June. (38). On the "as required" side Diamorphine 20 – 60 mgs subcutaneously in 24 hours is written up, also Hyoscine 200 – 400 micrograms and Midazolam 20 – 40 milligrams (37) all in 24 hours. Midazolam is started at 2.15 am on 4th June (37) 20 mgs for 24 hours and is then replaced with 20 mgs Diamorphine with 40 Midazolam at 9.20 am on 4th June.

A single dose of Diamorphine 5 – 10 mgs i/m is also signed for on the once only section of the drug chart, (37). It is not dated or timed and it is not clear if this was even given.

2. Expert Opinion:

2.1. This section will consider if there are any actions so serious they might amount to gross negligence or any unlawful acts or deliberate unlawful killing in the care of Mrs Helena Service. Also if the actions or omissions by the medical team, nursing staff or attendant GP's contributed to the demise of Mrs Service, in particular, whether beyond reasonable doubt, actions or admissions more than minimally, negligently or trivially contributed to death.

2.2. In particular, I will discuss a) whether Mrs Service had become terminally ill and if so whether symptomatic treatment was appropriate and b) whether the treatment provided was then appropriate.

Mrs Service's hospital notes go back for 16 years prior to her death. They document that she has heart disease with an irregular heartbeat (atrial fibrillation) in 1981 and heart enlargement in 1984 (229). She also has two previous strokes documented in both 1984 and 1992. (86 and 70). The natural history of heart disease is in general for progressive decline over time, with a very poor prognosis once serious heart failure has developed, as documented on this lady in 1995 (58-59).

2.3. She is also profoundly deaf which leads to communication difficulties and makes a patient more likely to get acute confusion. She suffers from Diabetes Mellitus, which is unmasked when she receives steroid treatment for polymyalgia rheumatica, she is also thought to have had an episode of gout and has been dehydrated with impaired kidney function on at least two occasions.

2.4. Despite her noted physical frailty she eventually makes a good recovery from a stroke in 1984, (92). By 1995 she has moved into a residential home. We do not know what precipitated this, however in 1995 her Barthel is documented at only 10/20 (326) meaning that she required considerable help with her routine activities of daily living.

2.5. In 1996 she is admitted with gout, and is found to be profoundly dependent on admission with a Barthel of 3/20 (11), which improves to 6/20 on discharge. Very poor mobility is noted and she has a Waterlow score which is a risk score for pressure sores (12) of 30 putting her into a very high-risk category. There is no doubt that this lady would normally be cared for in a nursing home, with this level of dependency, or even in NHS continuing care if she had not already been living in a residential home that was committed to

her care.

2.6. By the time she is admitted on 17th May 1997 she has been progressively failing in the residential home (283). It seems unlikely that this was a dramatic change in function, but the end point of a slow deterioration of her multiple illnesses, including her progressive heart disease, her cerebro-vascular disease and of course the physiological frailty of an age of 99 years,

2.7. When admitted to hospital she was found to be both dehydrated and in again heart failure. This is often a combination suggesting poor prognosis. She has acute confusion (delirium) and this does not resolve, although it does fluctuate, during all her time in the Queen Alexander Hospital. Investigations on admission found she is dehydrated with a raised creatinine of 151 (157) but she is also markedly hypoxic (low oxygen in the blood) with a PO2 of 6.7 kPa (normal range 12.7+0.7) with a PCO 5.6 kPa (normal range 5.3+0.3) She is now very unwell, and highly dependent with a Barthel at best 4/10 (162). On the basis of the nursing notes she makes very little improvement in her confusion or her breathlessness and indeed things take a turn for the worse when she probably has a new stroke on 26th May (116) (303). She remains totally dependent after this.

2.8. She is seen by a locum consultant geriatrician, Dr Ashbal on 29th May. His assessment is that she will not return to her residential home and that he is transferring her to Gosport "with a view to considering continuing care". By this he probably means an assessment as to whether this lady is dying or will improve enough to be discharged into a nursing home, or perhaps to simply remain in an NHS continuing care bed until she does die. However, this is not spelt out in the letter or the notes.

2.9. The medical notes make very little further comment on her clinical condition at the Queen Alexander Hospital, however, the nursing notes on the 2nd June comment she is very demanding overnight, shouting out continuously, suggesting that she is acutely delirious again and that she is so breathless that she has to sit up all night on the night of the 2nd June. I believe this lady is now physically deteriorating, but it is impossible to tell if this is progression of heart failure, a pulmonary embolus, or chest infection on top of her other problems. I have little doubt that she was entering a terminal phase of her illness.

2.10. On the 3rd June she is transferred to Gosport War Memorial hospital where she is noted to have a buttock bedsore (22). The recorded medical assessment is brief but does include an examination, which although it notes that she has a tachycardia and is very breathless, fails to give an overall impression of her status and whether this is acute, chronic or acute on chronic, and

fails to record her pulse and blood pressure. A thorough objective assessment of this lady's clinical status is not possible from the notes that are made on admission, and would appear to be below an acceptable standard of good medical practice.

2.11. It seems likely though that the doctor recognises that this lady was seriously ill as the only comment under the examination is "needs palliative care if necessary". There is no record in the notes of this being discussed at this stage with the nurses or the family.

2.12. The drug chart is written up with all the usual medication from Queen Alexander Hospital and this is given on both the 3rd and 4th June.

2.13. Diamorphine with Midazolam and Hyoscine are written up PRN on admission. The Midazolam is usually used for terminal restlessness and is widely used subcutaneously in doses from 5 – 80 mgs per 24 hours for this purpose. 20 mgs is within current guidance but at the top end for elderly patients. Elderly patients usually need a dose of between 5 – 20 mgs per 24 hours.

2.14. Diamorphine is compatible with Midazolam and can be mixed in the same syringe driver. It can be difficult to predict exactly the starting dose of Diamorphine to give in a syringe driver but many would give between 5 – 15 mgs of Diamorphine in the first 24 hours, in this case the 20 mgs is at the upper limit.

2.15. Mrs Service becomes extremely restless and agitated on the night of 4th June (probably similar to the previous night at the Queen Alexander hospital). Midazolam is now started via a syringe driver at 20 mgs. The restlessness is probably being caused by her severe breathlessness and heart disease and Diamorphine at this stage might well have been the drug of choice, but it is difficult to criticise the use of Midazolam.

2.16. She continues to deteriorate over night and the Midazolam is now replaced with Diamorphine 20 mgs a day and Midazolam 40 mgs. She then deteriorates further and dies 15 hours later.

2.17. There is no evidence in the notes that any other medical assessment was done prior to the starting of the Diamorphine and Midazolam in the syringe driver, nor is there any evidence at all that at any time after her admission to Gosport was further advice obtained from the consultant who was presumably responsible for this patient's care. It is not clear from the notes if the locum consultant (Dr Ashbal) was responsible for the patient's care once they had transferred to Gosport Hospital and it would have been good medical practice for the doctor at Gosport to have sought further advice from their consultant when a patient was transferred, apparently so seriously ill, and immediate palliative care was being

considered.

2.18. It is also possible to criticise the care at Queen Alexander. All to often when a patient is not obviously going home and a bed elsewhere has been found, the pressure is to move the patient at the first opportunity, even when it may not be in their best interest. It seems likely to me that her condition was deteriorating in the Queen Alexander Hospital and the stress of an ambulance transfer would not have helped this lady's care.

2.19. The cause of death in Mrs Service was multifactorial. In my view the dose of 20mg Diamorphine combined with the 40mg dose of Midazolam was higher than necessary in this very elderly and frail lady's terminal care and the medication may have slightly shortened life, although this opinion does not reach the standard of proof of "beyond reasonable doubt". However, I would have expected a difference of, at most, no more than a few hours to days, if a lower dose of either or both of the drugs had been used instead.

CONTENTS

1. INSTRUCTIONS

To examine and comment upon the witness statements in the case of Helena Service. In particular, if they raise issues that would impact upon any expert witness report prepared.

2. DOCUMENTATION

This report is based on the following document:

2.1 Witness statements to the hospital care and death of Helena Service provided to me by the Hampshire Constabulary (June 2006). In total 19 statements.

2.2 Report regarding Helena Service (BJC/72) Dr D Black 6th November 2004.

3. COMMENTS

3.1 Comments on Witness Statement (2.1)

3.1.1 I have read all the statements and would note that in paragraph 1.14 of my report, I state that Mrs Service was "continuously breathless". The nursing notes actually state "dyspnoeic on exertion" (298). However I interpret that as "continuously breathless" as Mrs Service was immobile (Barthel 0-4) and needed to be "nursed upright all night"

4. CONCLUSION

4.1 Having read all the documents above provided by Hampshire Constabulary, I would wish to above change to be noted. This does not change the overall conclusion of my expert report.

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Dr M C Petch

March 2006

DRAFT REPORT

Regarding

MRS HELENA SERVICE
(02.02.1898 – 05.06.1997)

PREPARED BY: Dr M C Petch

AT THE REQUEST OF: Hampshire Constabulary

1.0 Summary of Conclusions

1.1 Mrs Service was aged 99 years at the time of her death and had a long medical history with evidence of heart disease by 1989, and heart failure by 1995. The average survival of patients with this sort of heart failure is 2 years and hence Mrs Service's terminal decline in 1997 was not unexpected. Once the decision had been made that she was not for resuscitation, as it was in the Queen Alexandra Hospital in May 1997, then palliative care with increasing doses of Diamorphine and Midazolam was appropriate. These drugs were administered in accordance with cardiological practice in 1997.

2.0 Instructions

2.1 This report has been prepared on the instructions of Dave Grocott, Detective Inspector, Operation Rochester, that is an investigation by the Hampshire Police Major Crime Investigation Team in to the deaths of a number of elderly patients at Gosport War Memorial Hospital (GWMH).

2.2 The questions posed by D I Grocott are as follows:

3.0 Issues

3.1 The essential issue in this case is whether the death of Mrs Service was accelerated by the treatment that she received at GWMH, and in particular the administration of Diamorphine subcutaneously by a syringe driver.

4.0 Brief Curriculum Vitae

4.1

Code A

5.0 Documentation

5.1 This report has been prepared from copies of the medical records **(BJC/72)** including those from the RNH Haslar relating to her admissions in 1989 and 1992, and those from Queen Alexandra Hospital, St Mary's Hospital, Willow Cottage Residential Care Home, and GWMH. The last are crucial to this investigation and have been identified for me by DI Dave Grocott. The handwriting also is not always easy to read. However, page 164 of 401 dated the 3rd June 1997, entitled "transfer to Dryad Ward" refers to Dr Jane Barton's notes. Pages 37 and 38 of 401 can be more reliably identified because page 37 has at the top "Hospital – GWM, Ward – Dryad". The nursing records cannot be attributed to GWMH since the heading reads "Portsmouth Healthcare NHS Trust". I am however reliably informed that pages 22 and 23 dated the 5th June 1997 relate to GWMH. In addition to the foregoing documentation, I have also seen the statement of Dr Jane Barton dated ? 27th October 2005 which helpfully describes the standard of care available in GWMH in 1997.

6.0 Summary of Medical History

6.1 Mrs Service had a long medical history including a partial gastrectomy and cholecystectomy in 1981, and left cataract surgery in the same year. She suffered a stroke (left hemiparesis) necessitating admission to hospital between the 29th October and the 27th November 1984; in 1988 she suffered polymyalgia rheumatica and following treatment with Prednisolone developed diabetes mellitus which was considered to be iatrogenic; on the 15th August 1989 she suffered a fall with multiple rib fractures on the left side, for the first time her heart was mentioned – she had developed an abnormal rhythm (atrial fibrillation) and her heart was noted to be enlarged on the chest X-Ray; on the 13th November 1992 she was again admitted to hospital with a chest infection; she was again admitted on the 29th December 1992 with a left sided weakness and kept in hospital until the 8th January 1993.

6.2 On the 13th January 1995 Dr Althea Lord describes her domiciliary visit and her findings of shortness of breath and heart failure. Mrs Service was therefore admitted to hospital for more intensive medical treatment which appeared to be successful.

6.3 By January 1996 Mrs Service had developed gout with painful swollen wrists. By that stage she was described as being profoundly deaf; by May 1997 Mrs Service had deteriorated physically with a recurrence of her heart failure, urinary infection, chest infection and a physical state that was such that the senior registrar felt that in the event of a cardiac arrest Mrs Service should not be resuscitated. She improved to some degree but was not sufficiently independent to go back to Willow Cottage. She was therefore transferred to Dryad ward GWMH.

6.4 On admission to GWMH Mrs Service was seen by Dr Jane Barton. Her clinical note (page 164 of 401) and typed version (paragraph 20 of her statement) indicate that Mrs Service was not expected to live long. This was phrased as "needs palliative care if necessary. I am happy for nursing staff to confirm death".

6.5 The nursing records from the 3rd June 1997 describe her condition and at 02:00 state "failed to settle – very restless and agitated. Midazolam 20mg given via syringe driver over 24 hours. On the 4th June 1997 the entry reads "condition appears to have deteriorated overnight – remains restless. Seen by Dr Barton. Driver exchange with Diamorphine 20mg Midazolam 40mg at 09:20 at a rate of 50mls per hour. Rang Mr Tipping (nephew) to inform him of poorly condition", and on the 5th June 1997 "04:00 hours condition continued to deteriorate and died very peacefully at 03:45 hours. Nephew informed".

6.6 The prescription charts (pages 37 and 38 of 401) relate to the 3rd June 1997 and include Diamorphine 5 – 10mg IM under once only prescription and Diamorphine 20 – 100mg SC over 24 hours. This was administered starting on the 4th June 1997 at 09:20 hours as in the nursing records. Midazolam 20mg was also prescribed and given as was Bumetamide, Lisinopril, Allopurinol, Lanoxin, Aspirin, and Midazolam, but not the Hyoscine. This is in accordance with the Witness Statement of Dr Barton.

6.7 There is no record of a post mortem examination nor of any toxicology analysis. I have not seen a copy of the death certificate.

7.0 (1) Was Mrs Service's treatment for her congestive cardiac failure appropriate for 1997?

Yes.

(2) Given that despite her existing anti-failure therapy she remained breathless, and heart sounds revealed a gallop, what would have been considered reasonable treatment options (taking into account her age, circumstances, biochemistry etc.) in 1997.

Palliative Care

(3) Would uploads have a role for the relief of breathlessness due to chronic heart failure in 1997?

Yes.

(4) I opioids did have a role for the relief of breathlessness due to chronic heart failure in 1997, in what circumstances would they be used, in what dose and by what route?

When the decision had been taken curative treatment was no longer possible and by any parenteral route for example 2.5mg IM or IV, and 20mg SC initially. But tolerance would have developed and bigger doses would have been required.

(5) What is your opinion of Mrs Service's likely prognosis from her heart failure point of view?

Her heart failure was terminal i.e., a few days.

(6) What is your view on the prescription of Diamorphine 5 – 10mg IM prn for congestive cardiac failure?

Appropriate.

(7) What is your view on the prescription for Diamorphine 20 – 100mg SC/24h together with Midazolam 20 – 80mg SC/24h by syringe driver prn, in case she *'deteriorated and developed pulmonary oedema'*?

Appropriate.

(8) What is your view on the subsequent administration of Diamorphine 20mg SC/24h and Midazolam 40mg/24h in order to 'reduce the pulmonary oedema and the distress and agitation from the drowning sensation of the pulmonary oedema'?

Appropriate and desirable.

8.0 Opinion

8.1 Mrs Service suffered from heart failure which was well advanced in 1997 and terminal by June of that year. She was receiving appropriate treatment to correct this including the diuretic Bumetamide to alleviate the congestion, Lisinopril which is one of the angiotensin converting enzyme inhibitor drugs which has been shown both to improve survival and alleviate symptoms in heart failure, and also Digoxin (Lanoxin) which improves the strength of cardiac contraction and slows the heart rate in atrial fibrillation such that symptoms are improved.

Her other drugs including Allopurinol to counter the gouty tendency, and Aspirin to reduce blood stickiness and prevent vascular complications.

8.2 Mrs Service remained unwell despite the corrective treatment outlined above. Opiates, notably Diamorphine, are standard drugs for the alleviation of shortness of breath and distress associated with pulmonary oedema, and are particularly helpful at night. The administration of Diamorphine has been standard practice for myself and other cardiologists for many decades and remains so. Intramuscular and subcutaneous administration is usual.

8.3 Mrs Service's prognosis was hopeless. The administration of Diamorphine 5 – 10mg IM would have been entirely appropriate and the prescription for Diamorphine 20 – 100mg SC/24 hours together with Midazolam is reasonable given the circumstances of the practice described by Dr Barton in her statement. There would have been a clear, if unwritten, understanding that the nurses should start with the smaller dose, namely 20mg which, given the erratic absorption of subcutaneous drugs, would amount to less than a milligram per hour. All opiates induce tolerance and with the passage of time the dose has to be increased. Hence the nurses would have been able to implement this without further reference to Dr Barton. This practice is in keeping with the recommendations in the British National Formulary (Volume 48 September 2004 page 225) which reads as follows: "chronic pain, by mouth, or by subcutaneous or intramuscular injection, 5 – 10mg regularly every four hours"; and in the section entitled "Prescribing in Palliative Care".... "Diamorphine can be given by subcutaneous infusion in a strength of up to 250mg per ml".

9.0 Experts' Declaration

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.

2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert is required.

3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.

4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.

5. Wherever I have no personal knowledge, I have indicated the source of factual information.

6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.

7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.

8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.

9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.

10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: Code A Date: 5.4.06

8

DRAFT REPORT

regarding

HELENA SERVICE (BJC/72 and JR/16)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mrs Helena Service was a 99 year old woman who was admitted to the Queen Alexandra Hospital on the 17th May 1997, confused and disorientated most likely as a result of a chest infection ± a fast irregular pulse (atrial fibrillation) precipitating a worsening of her cardiac failure. Mrs Service was appropriately assessed, investigated and managed and her condition improved relatively quickly; she was more alert, her heart rate was controlled and her renal function improved. She remained confused at times and noisy at night. On the 26th May it is likely that Mrs Service had a further cerebrovascular accident (a stroke) affecting the left side of her body, particularly the left arm and hand and she became more dependent on the nursing staff to transfer her. As a result, she was unable to return to the rest home and she was referred to the geriatricians. Mrs Service was seen by Dr Ashbal who agreed to take her to Gosport War Memorial Hospital for assessment with regards to continuing care. Mrs Service's behaviour remained challenging at times, particularly at night. However, apart from the regular use of thioridazine as a night time sedative, Mrs Service's behaviour was managed by the nursing staff using non-drug means. On the day of her transfer to Dryad Ward, Mrs Service was seen by consultant physician Dr Miller, and was noted to be 'well'. There are no concerns regarding the care proffered to Mrs Service at the Queen Alexander Hospital.

On Dryad Ward, there was an inadequate assessment of Mrs Service's current symptoms and cardiovascular status. Mrs Service's medication was mostly continued unchanged except the thioridazine was omitted. She

was prescribed diamorphine 20–100mg SC/24h, hyoscine (hydrobriomide) 200–800microgram/24h and midazolam 20–80mg SC/24h all p.r.n. (as required). Diamorphine 5–10mg IM was prescribed as a stat dose, but not apparently given. There is inadequate justification documented in the notes for the prescription of these drugs in these doses. Midazolam 20mg SC/24h was commenced on the first night Mrs Service spent on Dryad Ward because she 'failed to settle'. Mrs Service was however, elderly, very deaf, confused/prone to confusion, had been moved to unfamiliar surroundings with unfamiliar staff and her usual night sedative had been omitted. Thus, there were many reasons why Mrs Service could have been restless on her first night on Dryad Ward. The following day, there was no documented assessment of Mrs Service's condition, but the midazolam was increased to 40mg SC/24h and diamorphine 20mg SC/24h added to the syringe driver. The increase in midazolam appeared to be in response to Mrs Service's persistent restlessness. There is no justification in the notes as to why the diamorphine was considered necessary but in her statement Dr Barton reports that in her view Mrs Service was terminally ill with heart failure'. However, blood tests were taken from Mrs Service on the same day and these would not be indicated in patients who were imminently dying and the fact that they were carried out suggests that doubt existed.

The blood test result confirmed that Mrs Service had renal impairment and a low potassium, possibly due to her medication and/or an inadequate fluid intake. These could have contributed to worsening confusion and were potentially reversible with appropriate treatment. There is no

documentation relating to these results and why it was not considered appropriate to act on them.

If it were that Mrs Service was not actively dying, as the notes on her transfer to Dryad Ward suggest, then the failure to rehydrate her, together with the use of midazolam and diamorphine could have contributed more than minimally, negligibly or trivially to her death. If it were considered that Mrs Service was actively dying, then it would have been reasonable not to have rehydrated her and the use of diamorphine and midazolam could be justified. However, in my opinion, the starting dose of diamorphine was likely to be excessive to her requirements and access to smaller doses of diamorphine (and midazolam) p.r.n. would have been a more appropriate way of initially addressing Mrs Service's symptoms, identifying her dose requirements and justifying the need for regular dosing and subsequent dose titration. Given that elderly, frail patients with significant medical morbidity can deteriorate with little or sometimes no warning, it could be argued that it is difficult to distinguish with complete confidence which of the above scenarios was most likely for Mrs Service.

2. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be suboptimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

3. ISSUES

3.1 Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day?

3.2 If the care is found to be suboptimal what treatment should normally have been proffered in this case?

3.3 If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

4. BRIEF CURRICULUM VITAE

Code A

Code A

5. *DOCUMENTATION*

This Report is based on the following documents:

[1] Full paper set of medical records of Helena Service, including the medical certificate of cause of death.

[2] Full set of medical records of Helena Service on CD-ROM. Note. The page numbering on the CD-ROM does not correspond to the page numbering on the paper set, .e.g. page 155 of 380 on CD-ROM = page 164 of 401 in paper notes.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Hampshire Constabulary Summary of Care of Helena Service.

[6] Palliative Care Handbook Guidelines on Clinical Management, Third

Edition, Salisbury Palliative Care Services (1995); also referred to as the 'Wessex Protocols.'

[7] Portsmouth Health Care NHS Trust Policies:

i) Control of Administration of Medicines by Nursing Staff Policy (January 1997).

ii) Prescription Writing Policy (July 2000).

iii) Policy for Assessment and Management of Pain (May 2001).

iv) Compendium of Drug Therapy Guidelines, Adult Patients (1998).

v) Draft Protocol for Prescription Administration of Diamorphine by Subcutaneous Infusion, Medical Director (December 1999).

vi) Medicines Audit carried out by the Trust referred to as Document 54 on page 52 in the Chi Report (reference 6).

[8] General Medical Council, Good Medical Practice (October 1995).

[9] British National Formulary (BNF). Section on Prescribing in Terminal Care (March 1997).

[10] British National Formulary (BNF). Section on Prescribing in the Elderly (March 1997).

[11] Statement of Dr Jane Barton as provided to me by Hampshire Constabulary (undated).

[12] Statement of Dr Jane Barton RE: Helena Service, 27th October 2005.

[13] Draft Report regarding Statement of Dr Jane Barton RE: Helena Service (BJC/72), Dr A Wilcock, 2nd February 2006.

[14] Draft overview of Helena Service (BJC/72), Dr A Wilcock, 12th November 2005.

[15] Report regarding Helena Service, Dr M C Petch, February 2006.

6. CHRONOLOGY/CASE ABSTRACT

Events at Queen Alexander Hospital, May 17th–June 3rd 1997

Mrs Helena Service, a 99 year old woman who lived in a rest home, was admitted to Queen Alexander Hospital on the 17th May 1997 at 14.00h. A junior doctor (House Officer) clerked Mrs Service and noted that she was very deaf, confused, disorientated and unable to carry out a mini-mental test. Because it was impossible to obtain a history from Mrs Service, this was taken from the General Practitioner's referral letter. This noted that she had recently developed a urinary tract infection, initially responding to antibiotics but was now short of breath, confused, disorientated and that the rest home were unable to cope (pages 51 and 155 of 401). A past history of gout, non-insulin dependent diabetes mellitus (NIDDM) and congestive cardiac failure (CCF) was also noted.

Review of the recent rest home (Willow Cottage) notes revealed that Mrs Service had been prescribed thioridazine at night to help her to sleep on the 21st April 1997; paracetamol on the 1st May 1997 for pain in her back due to osteoporosis; antibiotics on the 6th May 1997 for a chest infection and stronger pain killers for her back pain (no details given); her lisinopril dose was increased on 12th May 1997 because of heart failure; she was noted to be very restless on the 14th May 1997 and had developed a bed sore; on the 17th May 1997 she was described as poorly and admitted to hospital (pages 282 and 283 of 401).

Review of the notes also reveals that: in 1981 she underwent a cholecystectomy (page 374 of 401) and gasterectomy for gastric ulcers (page 233, 243, 244 and 252 of 401); in October 1984 suffered a cerebrovascular accident (a 'stroke') affecting especially her left hand and wrist. She recovered well but residual weakness remained (pages 222 and 225 of 401); her heart failure was longstanding - a chest x-ray in 1984 revealed that her heart was enlarged (pages 86, 87, 229 of 401); in 1988 had polymyalgia rheumatica, treated with steroids that precipitated her diabetes mellitus (pages 79 and 341 of 401); in August 1989 she fell and fractured her ribs, a chest X-ray again revealing signs of heart failure (page 35 of 105); in 1990 had a cataract removed (page 329 of 401); in 1992 was admitted with a chest infection, diarrhoea and vomiting and found to be in atrial fibrillation, later that year she had a further stroke with good improvement (page 70 of 401); in January 1995 heart failure was a problem, she was peripherally cyanosed and short of breath on exertion, had an elevated jugular venous pressure, a heart murmur of mitral regurgitation and oedema to her thighs. She was admitted to commence an ACE inhibitor treatment for heart failure (going home on lisinopril 5mg at night), her digoxin was also discontinued (pages 58, 59, 68, 69, 144, 146 and 325 of 401); in January 1996 she was admitted for gout affecting her wrist. History was unavailable on admission because her hearing aid wasn't working and she was profoundly deaf. Her urea was 17.6mmol/L (normal 3–7.6mmol/L), creatinine 167micromol/L (45–90micromol/L) and uric acid 0.45mmol/L (0.13–0.36mmol/L) (page 177 of 401) and she was treated with IV antibiotics and fluids. Her Barthel score was 3 on admission

and 6 on discharge, she was slightly breathless on exertion, occasionally woke at night and was prescribed temazepam 10mg p.r.n. (pages 11, 13 and 260 of 401).

Mrs Service's current medication consisted of lisinopril 2.5mg twice a day, bumetanide 1mg once a day (both for heart failure), aspirin 75mg once a day (to thin the blood), allopurinol 100mg once a day (for gout) and thioridazine 25mg at night as required 'p.r.n.' (an antipsychotic sedative) (pages 52 and 155 of 401). During the examination Mrs Service vomited. She was alert but disorientated, confused and dehydrated (+++). Other main findings were an irregular pulse (due to atrial fibrillation), crackles in her chest (suggestive of either excess fluid or infection) and mild swelling of her ankles. She was unable to cooperate with a neurological examination. The initial impression was that Mrs Service was deaf with increasing confusion possibly due to a urinary tract ± chest infection. She also had atrial fibrillation (page 156 of 401).

A number of investigations were carried out including blood tests, blood, urine and sputum cultures (to look for infection), blood gases, chest and abdominal x-rays and an electrocardiogram (ECG) (page 157 of 401). These tests confirmed that Mrs Service was dehydrated (sodium of 149mmol/L (normal range 135–146mmol/L), urea of 14.4mmol/L (normal range 3–7.6mmol/L) and creatinine 151micromol/L (normal range 45–90micromol/L) (pages 157 and 172 of 401)); had a low level of oxygen in her blood stream (PaO_2 6.7kPa, normal 11.3–12.6kPa; oxygen saturation 88.5%, normal 95–98%) (page 173 of 401); had patchy shadowing on her

chest x-ray, was constipated and confirmed to be in uncontrolled atrial fibrillation at a rate of 135 beats per minute (pages 157, 175 of 401). Her full blood count was normal (page 192 of 401).

The initial treatment plan consisted of intravenous fluid and encouraging oral fluid intake, intravenous antibiotics (cefuroxime), oxygen and digoxin to slow the rate of the atrial fibrillation (page 270 of 401). Mrs Service's oxygen saturation was to be monitored, her general observations recorded every 4h and blood sugars checked twice a day (page 157 of 401).

Her other medication was continued unchanged. (pages 270, 273 of 401). Mrs Service took thioridazine 25mg on the 24th, 25th, 26th, 27th, 28th, 30th, 31st of May and the 1st and 2nd June, generally between 22–23.00h (page 273 of 401). She was also prescribed paracetamol 1g p.r.n. but received only once dose at 08.25h on the 25th May (page 273 of 401).

That evening she was reviewed by a more experienced doctor (senior registrar) who considered that the chest x-ray and crackles were suggestive of left ventricular failure. This is a failure of the left side of the heart to pump properly, causing a build up of pressure in the veins in the lungs which in turn allows fluid to collect on the lungs (pulmonary oedema). The senior doctor did not think Mrs Service appropriate for more intensive therapies nor cardiopulmonary resuscitation and agreed with the treatment plan outlined above (page 158 of 401). The nursing care plan noted that Mrs Service was very confused and this continued into the night (page 295 of 401). The nursing notes record that she was breathless (page 297 of 401). Subsequent entries on the 21st–23rd, 25–26th, 28th May–2nd June note

that Mrs Service was breathless on exertion but do not record that she was breathless at rest (page 297 and 298 of 401).

On the 18th February 1997, Mrs Service was reviewed by the consultant, Dr Miller, and it was noted that she was more alert, her pulse rate had slowed to 80 beats per minute, blood pressure 125/80 and her chest was clear (page 158 of 401). The nursing care plan recorded that Mrs Service seemed less confused, with confusion only apparent when 'patient was unable to hear what is being said to her.' The night entry recorded 'remains confused, slept for periods' (page 295 of 401).

On the 19th May she was noted to be 'very deaf! But much better, sitting in a chair and talking++'. Blood tests revealed an improvement in her hydration state; sodium 146mmol/L, urea 7.9mmol/L and creatinine 114micromol/L (page 159 of 401). Full blood count revealed a slightly elevated white blood count $11.2x10^9$/L (neutrophils $8.2x10^9$/L) (page 189 of 401). The plan was to discontinue the intravenous fluids when oral intake adequate and change to oral antibiotics and to repeat her blood tests (pages 158 and 272 of 401). The nursing notes record that she remained 'confused at times but at times very lucid' and at night 'remains confused' (page 295 of 401).

On the 20th May 1997 she was noted to be sleeping in the chair with some shortness of breath at rest. She remained apyrexial with a blood pressure of 120/80 and pulse rate of 88. Examination revealed her to be in atrial fibrillation and slightly dry. Nursing notes recorded 'sleepy and confused after an active night; slept most of the afternoon despite

numerous attempts to remain awake by staff; drowsy early evening and slept most of the night' (page 295 of 401).

Full blood count on the 21st May 1997 revealed a persistently raised white blood cell count 13.3x10^9/L (neutrophils 10.1x10^9/L) (page 193 of 401). Nursing notes recorded 'asleep much of morning but lucid when awake; some confusion pm. Drowsy night time, remains confused, slept for short periods only' (page 295 of 401).

On the 22nd May she was noted to be apyrexial, to have a pulse rate of 80, blood pressure 120/80 and a few crackles at the bases of her lungs. The plan was to push more fluids, continue antibiotics until tomorrow and aim for home (pages 159 and 160 of 401). The nursing notes recorded 'lucid and very demanding this am. Bowels open++; night time remains confused' (page 295 of 401).

On the 23rd May 1997 she was apyrexial, comfortable at rest with a blood pressure of 120/70 and pulse of 88. Thyroid function tests were normal (page 170 of 401). The plan was to continue intravenous fluids until oral intake improved, to check her digoxin level (1.8mmol/L, normal 0.9–2.6mmol/L; page 167 of 401) and plan for home the following week (page 160 of 401). The IV cannula was pulled out, but as she was drinking well the IV fluids were not resumed (page 302 of 401). Nursing notes recorded 'no change. Night time: remains noisy at times' (page 295 of 401).

On the 24th May 1997 the nursing notes recorded 'remains confused at times' (page 295 of 401).

On the 25th May 1997, her biochemistry revealed continued improvement; sodium, potassium, urea were normal and creatinine 111micromol/L

(normal 45–90micromol/L)(page 166 of 401). Nursing notes report that she was confused at times and noisy at night (page 295 of 401).

On the 26th May 1997 she was seen by the on-call doctor at the nurses request who noticed that Mrs Service was not weight bearing and her left hand was weak. Mrs Service herself was unaware of any problem with her left hand. On examination she appeared to be using her left arm less and although more floppy was able to move it. The strength of the muscles were reduced and the reflexes were increased in the left arm and it was considered that she may have had a cerebrovascular accident (a 'stroke') or a transient ischemic attack (a 'stroke' that resolves quickly and completely) (pages 160 and 161 of 401). The nursing notes reported that she remained confused at times. There were problems with the hearing aid and the battery was changed and the ear piece cleaned that improved Mrs Service's ability to hear (page 299 of 401). That night the nursing notes recorded 'when hearing aid is in place understands the question and answers appropriately. Quiet most of the night, only asking a couple of times to be sat up' (page 296 of 401).

When reviewed on the 27th May it was noted that her left arm was weak and she was referred to Social Services (page 161 of 401). To return to the rest home, Mrs Service needed to be able to transfer with only one nurse, but she required the help of two (pages 266 and 267 of 401). Nursing notes record no problems with confusion in the day or overnight (page 296 of 401).

On the 28th May 1997 it was noted that her Barthel score was 4 and she was referred to the geriatricians for continuing care, the referral note

recording that Mrs Service had presented with left ventricular failure that had improved and that her 'Humphrey' hearing aid was needed to speak to her (page 162 of 401). The nursing notes reported that she was 'very demanding...wanting to get in/out of bed. Confusion due to hearing problems. Less confused overnight' (page 296 of 401).

On the 29th May 1997 she was seen by a locum consultant geriatrician, Dr Ashbal (page 162 of 401). The letter summarising his review of Mrs Service reads 'thank you very much for asking me to see this delightful lady, whom I saw on the ward today. She has longstanding cardiac failure and was admitted again because of breathlessness and general deterioration. She was found to be in heart failure. She is deaf and uses a deaf aid. Although clinically she is better, she is still in a degree of heart failure. She is normally in a rest home, but I doubt whether they can manage her. I will put her on the list for Gosport War Memorial Hospital for assessment, with a view to considering continuing care' (page 39 of 401). The nursing notes recorded 'remains very demanding today. At night: no change, remains quite noisy at times' (page 296 of 401).

Entries in the medical notes for the 30th May and 2nd June 1997 noted that she was well and her condition unchanged. Over this time the nursing notes record 'not confused but is quite agitated at times. At night less confused (30th May); less confused, noisy at times; slept well, less noisy (31st May); no signs of confusion but very demanding at times during the day and night (1st June); no signs of confusion. Very demanding overnight, shouted out constantly' (2nd June) (page 296 of 401).

On the 3rd June 1997 she was seen by Dr Miller, noted to be well and due to transfer to Gosport that day (page 163 of 401). The nursing transfer letter from F1 ward to Dryad Ward summarised that Mrs Service had been admitted with atrial fibrillation and confusion, a chest infection and had received IV fluids, IV antibiotics, oxygen therapy and digoxin; that she was very deaf (wears hearing aid in right ear, known as Humphrey (this was now working well, page 300 of 401)), required all care with eating and drinking and took two people to transfer (page 303 of 401). Treatment was listed as thioridazine 25mg at night, lisinopril 2.5mg twice a day, bumetamide 1mg once a day, aspirin 75mg once a day, allopurinol 100mg at night and digoxin 125microgram once a day (page 263 of 401). The medical discharge summary from F1 noted that Mrs Service had been admitted because of shortness of breath and confusion, treated with intravenous fluids, cefuroxime, oxygen and digitalisation for pulmonary oedema secondary to left ventricular failure and dehydration. It listed the medication as lisinopril, bumetamide, aspirin, allopurinol and digoxin but not the thioridazine (page 50 of 401).

Events at Gosport War Memorial Hospital, 3rd–5th June 1997

3rd June 1997

The medical notes entry reads 'Transferred to Dryad Ward, recent admission 17th May 1997, confused, off legs, URTI (upper respiratory tract infection), NIDDM, CCF (congestive cardiac failure), gout, came from a rest home. On examination slightly breathless plethoric lady, heart sounds 1 and 2 + gallop, bases clear, ankles √√ (meaning not clarified by Dr Barton,

but possibly indicates no swelling (oedema)), needs palliative care if necessary. I am happy for nursing staff to confirm death' (page 164 of 401). The nursing summary notes recorded 'admitted today from F1 ward QA. Helena is a very pleasant lady. She has a normal diet but needs assistance at meal times. She has faecal incontinence. Her buttocks are very red and sore and the skin is broken. Her skin is quite dry. She has 2 superficial grazes on her spine. Skin on lower arms is discoloured. Helena uses a Humphrey hearing aid which has a microphone. She is able to respond to questions. Helena is a non-insulin dependent diabetic, has congestive cardiac failure, suffers from confusion, has upper respiratory infection also gout. Helena has had bowels open and passed urine since admission. First swabs of MRSA screening sent (which were negative, page 165 of 401). Helena has not eaten supper this evening but has had a drink of water (page 22 of 401). Her Barthel score was 0 (page 24 of 401).

The medication chart reveals she continued her bumetamide, lisinopril, allopurinol, digoxin and aspirin as before. However, Mrs Service was not written up for thioridazine 25mg p.r.n. that she had been taking most nights (page 38 of 401). She was also prescribed diamorphine 20–100mg SC/24h, hyoscine 200–800microgram SC/24h and midazolam 20–80mg SC/24h all p.r.n. (page 37 of 401). On the once only and pre-medication drugs section diamorphine 5–10mg IM was also prescribed, but not apparently given (page 37 of 401).

The nursing summary entry for the night of 3rd June 1997 records 'Spenco mattress in situ, nursed on alternate sides overnight. Zinc and castor oil to

sore sacrum. Not passed urine. Oral fluids encouraged and taken fairly well (page 36 of 401). Tongue dry and coated – mouth care given.

4th June 1997

The nursing notes at 02.00h record 'failed to settle – very restless and agitated, midazolam 20mg given by a syringe driver (started at 02.15h) over 24 hours with some success' (pages 22, 23, 36 and 37 of 401).

Nursing summary entry reads 'condition appears to have deteriorated overnight – remains restless. Seen by Dr Barton. Driver recharged with diamorphine 20mg, midazolam 40mg at 09.20h...Rang nephew to inform him of poorly condition' (pages 23 and 37 of 401). There was no medical notes entry but a blood test was undertaken. This revealed that Mrs Service was dehydrated with sodium 156mmol/L (normal range 135–146mmol/L), urea 13.2mmol/L (3–7.6mmol/L) and creatinine 126micromol/L (45–90micromol/L). There were low values of potassium 2.7mmol/L (3.5–5mmol/L), albumin 29g/L (37–50g/L) and calcium 1.97mmol/L (2.25–2.70mmol/L) (pages 47 and 48 of 401).

5th June 1997

Nursing summary entry at 04.00h reads 'condition continued to deteriorate and died very peacefully at 03.45h. Nephew informed (pages 23 and 36 of 401).

On Mrs Service's death certificate the cause of death was given as 1a (disease or condition directly leading to death) congestive cardiac failure with an approximate interval between onset and death given as two days.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Syringe drivers, diamorphine, midazolam and hyoscine hydrobromide

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24h. Indications for its use include swallowing difficulties or a comatose patient. In the United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF 33, March 1997). Others sometimes suggest dividing by 2 or 3 depending on circumstance (Wessex protocol). Hence, 60mg of morphine taken orally a day could equate to a daily dose of 20 or 30mg of diamorphine SC. It is usual to prescribe additional doses for use 'as required' in case symptoms such as pain breakthrough. The dose is usually 1/6th of the 24h dose. Hence for someone receiving 30mg of diamorphine in a syringe driver over 24h, a

breakthrough dose would be 5mg. One would expect it to have a 2–4h duration of effect, but the dose is often prescribed to be given hourly as required. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in their terminal phase would generally aim to find a dose that improves the patients' symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg a day. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (BNF 33, March 1997) recommends 20–100mg SC over 24h. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated every 24h if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24h, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4h, and it may need to be given more frequently. As an active metabolite of

midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

Hyoscine hydrobromide is an antimuscarinic drug most commonly given to reduce excessive saliva or retained secretions ('death rattle'). It also has anti-emetic, antispasmodic (smooth muscle colic) and sedative properties. Repeated administration can lead to cummulation and this can occasionally result paradoxically in an agitated delirium, highlighted in both in the BNF and the Wessex protocol (page 41). It is usually given in a dose of 600–2400microgram SC over 24h (BNF 33, March 1997) or 400–600microgram as a stat SC dose. The Wessex protocol gives a dose range of 400–1200microgram over 24h.

The titration of the dose of analgesic or sedative medication is guided by the patients symptom control needs. The number and total dose of p.r.n. doses needed over a 24h period are calculated and this guides the increase necessary in the regular dose of the drugs in the syringe driver in a way that is proportional to the patients needs. The ideal outcome is the relief of the symptoms all of the time with no need for additional p.r.n. doses. In practice, this can be difficult to achieve and the relief of the symptoms for the majority of the time along with the use of 1–2 'as required' doses over a 24h period is generally seen as acceptable.

ii) The principle of double effect

The principle of double effect states that:

'If measures taken to relieve physical or mental suffering cause the death of a patient, it is morally and legally acceptable provided the doctor's intention is to relieve the distress and not kill the patient.'

This is a universal principle without which the practice of medicine would be impossible, given that every kind of treatment has an inherent risk. Many discussions on the principle of double effect have however, involved the use of morphine in the terminally ill. This gives a false impression that the use of morphine in this circumstance is a high risk strategy. When correctly used (i.e. in a dose *appropriate* to a patient's need) morphine does not appear to shorten life or hasten the dying process in patients with cancer. Although a greater risk is acceptable in more extreme circumstances, it is obvious that effective measures which carry less risk to life will normally be used. Thus, in an extreme situation, although it may occasionally be necessary (and acceptable) to render a patient unconscious, it remains unacceptable (and unnecessary) to cause death deliberately. As a universal principle, it is also obvious that the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

8. OPINION

Events at Queen Alexander Hospital, May 17th–June 3rd 1997

Mrs Helena Service was a 99 year old woman who lived in a rest home. It is unclear from the recent rest home notes whether she was normally confused. However, communication was hampered by her profound deafness. Prior to her admission she had received antibiotics on the 6th

May for a chest infection and her lisinopril dose increased on 12th May because of worsening heart failure. She was noted to be very restless on the 14th May and subsequently admitted on the 17th May. At this point she was confused, disorientated and unable to provide a history. Examination revealed her to be dehydrated and to have a fast irregular pulse due to uncontrolled atrial fibrillation. There were crackles in her chest and mild swelling of her ankles suggestive of cardiac failure. It is likely that the chest infection ± the atrial fibrillation had precipitated a worsening of her cardiac failure. This caused fluid to collect on her lungs (pulmonary oedema) which interfered with her ability to get enough oxygen into the blood stream (hypoxaemia). Hypoxaemia ± an infection would be sufficient to cause confusion in an elderly patient. She developed renal impairment as a result of dehydration ± heart failure. However, with intravenous fluids, antibiotics, oxygen and digoxin (to slow the rate of the atrial fibrillation), Mrs Service's condition improved relatively quickly; she was more alert, her heart rate was controlled and her renal function improved. She remained confused at times and noisy at night. On the 26th May it is likely that she had a further cerebrovascular accident (a stroke) affecting the left side of her body, particularly the left arm and hand (she had had at least two previous strokes affecting this side). This led Mrs Service to require two nurses to transfer her, when previously only one was required. As a result, she was unable to return to the rest home and she was referred to the geriatricians for consideration of continuing care. On the 26th May after her hearing aid battery was changed and the earpiece cleaned, this appeared to improve Mrs Service's ability to hear and her confusion. She was reviewed by Dr

Ashbal who noted that she was better, but still in a degree of heart failure and agreed to take her to Gosport War Memorial Hospital for assessment with a view to considering continuing care. This term has different meanings in different places and the context in which it is being used in relation to Mrs Service should be clarified. Mrs Service's behaviour remained challenging at times, particularly at night; sometimes she was 'quite agitated', 'very demanding' or 'shouting out constantly'. However, on the day of her transfer, 3rd June 1997, she was seen by consultant physician Dr Miller, and was noted to be 'well'. The nursing transfer letter and medical discharge summary gave a concise summary of her admission, noting that she required help with eating and drinking and listed all her relevant medication. Her medical discharge summary however, did not list the thioridazine 25mg p.r.n. at night that she had in effect been taking regularly.

Mrs Service appeared to have experienced an exacerbation of her long-standing cardiac failure due to a chest infection ± uncontrolled atrial fibrillation. She was appropriately assessed, investigated and managed, leading to a resolution of her confusion, dehydration and improvement in her heart failure. However, she remained agitated and demanding at times. Apart from the regular use of thioridazine at night for the 24th May–3rd June, Mrs Service's behaviour must have been managed by the nursing staff using non-drug means. I have no concerns regarding the care proffered to Mrs Service at the Queen Alexander Hospital.

Events at Gosport War Memorial Hospital, 3rd–5th June 1997.

Infrequent entries in the medical notes during Mrs Service's stay on Dryad Ward make it difficult to closely follow her progress over the last two days of her life. There is only one medical note entry prior to the confirmation of death taking up half a page. In summary and in approximate chronological order, Mrs Service was admitted to Dryad Ward. Dr Ashbal had transferred Mrs Service with the aim of assessing her for continuing care needs. There was no stated aim on the transfer note other than 'needs palliative care if necessary'. The term palliative care is used variably and the meaning here should be clarified. A brief history summarised the details on the transfer note. There was no structure to the history with regards Mrs Service's current symptoms (e.g. was pain or breathlessness a problem for her? The nursing notes recorded that she was able to respond to questions). There was a brief examination but no record of heart rate, blood pressure or jugular venous pulse, all relevant for a patient with heart failure. Heart sounds were noted and revealed a gallop rhythm that occurs in heart failure. However, her lungs were clear and ankles do not appear to have been swollen.

Mrs Service's medication was continued mostly unchanged except the thioridazine, which she had been using both at the rest home and on F1 ward, was omitted. She was prescribed diamorphine 20–100mg SC/24h, hyoscine (hydrobriomide) 200–800microgram/24h and midazolam 20–80mg SC/24h all p.r.n. (as required). On the once only and pre-medication drugs section of the drug chart, diamorphine 5–10mg IM was prescribed, but not apparently given. There is no justification documented in the notes for the

prescription of the stat dose of diamorphine p.r.n., although in her statement Dr Barton reports it was because she was concerned that '[Mrs Service] was in congestive cardiac failure'. Opioids are used for breathlessness caused by heart failure, as highlighted by Dr Petch. However, on the day of transfer to Dryad Ward Mrs Service was reported as 'well' by Dr Miller. Thus, although Mrs Service may well have been in a degree of heart failure (e.g. heart sounds revealed a gallop, but chest clear), this did not appear to be as severe as on her admission to F1 ward (e.g. crackles heard in chest, pulmonary oedema on chest x-ray) and it is of note that it was not considered necessary at that stage to prescribe or administer opioids to Mrs Service. Similarly, in my opinion, there was no clear indication for the prescription of diamorphine, hyoscine or midazolam by syringe driver on the day of her transfer.

The midazolam was prescribed in a dose range of 20–80mg SC/24h, p.r.n. and 20mg SC/24h was commenced on the first night that Mrs Service spent on Dryad Ward at 02.00h because she 'failed to settle – very restless and agitated.' Mrs Service was however, elderly, very deaf, confused/prone to confusion and had been moved to unfamiliar surroundings with unfamiliar staff. Further, she was not prescribed/given her thioridazine 25mg at night on Dryad Ward that she had been receiving as a night sedative. Thus, there were many reasons why Mrs Service could have been restless on her first night on Dryad Ward. It is of note that Mrs Service appears to have been admitted to the Queen Alexander Hospital in a more confused state than she was at the time of her transfer to Dryad Ward. Nevertheless, during her almost three weeks stay on F1, despite the fact she was

documented as being demanding and noisy at times during the night, she appears to have been managed satisfactorily by the nursing staff, without the need to use parenteral antipyschotics or sedatives, just her night time dose of oral thioridazine. Further, the notes also comment that confusion only seemed apparent when Mrs Service was unable to hear what was being said to her.

Subsequently, the midazolam was increased to 40mg SC/24h and diamorphine 20mg SC/24h added to the syringe driver. The increase in midazolam appeared to be in response to Mrs Service's persistent restlessness. There is no explanation in the notes as to why the diamorphine was considered necessary but in her statement Dr Barton reports that in her view Mrs Service was terminally ill with heart failure.....and it was appropriate to administer the diamorphine and midazolam in the hope of reducing the pulmonary oedema brought on by heart failure.' Opioids are used for breathlessness caused by heart failure, as highlighted by Dr Petch. Midazolam is used for terminal breathlessness for its anxiolytic/sedative effects. However, as noted before, on her transfer, Mrs Services cardiac failure was unlikely to have been as severe as on her admission to F1 ward, there was no assessment of Mrs Service on the 4th June 1997 that documented that she was distressed by breathlessness, had a sudden worsening of her pulmonary oedema, nor were more usual approaches to relieve acute pulmonary oedema utilised (e.g. oxygen, diuretics, nitrates, etc.). Further, blood tests were taken from Mrs Service on the 4th June 1997. Blood tests would not be indicated in

patients who were obviously dying and the fact that they were carried out suggests that doubt existed.

It is difficult to follow fully the logic of Dr Barton's statement. She states that, on her transfer, in her view, Mrs Service was 'clearly in heart failure', 'unwell and likely to die shortly' yet 'considered Mrs Service would have been more appropriate for care at the Queen Alexandra Hospital'. This suggests that Dr Barton considered that Mrs Service could have benefited from care available at Queen Alexandra Hospital that was not available on Dryad Ward. No attempts however, were made to transfer Mrs Service back to Queen Alexandra Hospital, to seek advice from Dr Ashbal or the medical team at Queen Alexandra Hospital and no changes were made to Mrs Service's heart failure medication other than the prescription of p.r.n. opioids as a one-off stat dose or by syringe driver. The results of the blood tests could not have influenced Dr Barton's initial management of Mrs Service, as these were not undertaken until the 4th June, the day after her admission.

The blood test result confirmed that Mrs Service had renal impairment and a low potassium, possibly due to her medication (the diuretics ± the lisinopril; the dose had been increased at the residential home just prior to her admission) and/or an inadequate fluid intake (her tongue was dry and coated that suggests she was dehydrated). Dehydration and low potassium could have directly or, indirectly via digoxin toxicity, contributed to worsening confusion, all of which are potentially reversible with appropriate treatment. These results were available on the 4th June 1997, but there are

no comments in the notes regarding them or why it was considered inappropriate to act upon them.

If it were that Mrs Service was not actively dying, as the notes on her transfer to Dryad Ward suggest, then the failure to rehydrate her, together with the use of midazolam and diamorphine could have contributed more than minimally, negligibly or trivially to her death. If it was considered that Mrs Service was actively dying, then it would have been reasonable not to have rehydrated her and the use of diamorphine and midazolam could be justified, albeit that the dose of diamorphine was likely to be excessive for her needs. Given that elderly, frail patients with significant medical morbidity can deteriorate with little or sometimes no warning, it could be argued that it is difficult to distinguish with complete confidence which of the above scenarios was most likely for Mrs Service.

On Mrs Service's death certificate the cause of death was given as congestive cardiac failure with an approximate interval between onset and death given as two days. This is incorrect; she had had documented cardiac failure for several years.

In conclusion, Mrs Service was elderly, severely hard of hearing, confused/prone to confusion, spending her first night in a new environment, with new staff and her usual night sedation was not given. The commencement of a syringe driver containing midazolam in a dose sufficient to sedate an elderly patient, could be interpreted as an over reaction to what is a well recognised and understandable response of a confused patient to new surroundings. Subsequently, the addition of diamorphine in a dose of 20mg SC/24h is without documented justification

in the medical and nursing notes. Mrs Service had long-standing cardiac failure and was becoming increasingly frail with a progressive decline in her Barthel score over several admissions. Nevertheless, at the time of her transfer from F1 ward she was reported as 'well', and at the time of the prescription of diamorphine, midazolam and hyoscine by syringe driver it was not apparent that she was imminently dying. This is also suggested by the fact blood tests were carried out the day after her transfer. In these circumstances, it could be argued that the lack of appropriate medical care, together with the use of midazolam and diamorphine could have contributed more than minimally, negligibly or trivially to her death. However, elderly, frail patients with significant medical morbidity can deteriorate with little or sometimes no warning and Mrs Service could have naturally entered her terminal stage. In these circumstances, the lack of medical intervention could be seen as appropriate and the use of midazolam and diamorphine reasonable. Even so, in my opinion, the starting dose of diamorphine was likely to be excessive to her requirements and access to smaller doses of diamorphine (and midazolam) p.r.n. would have been a more appropriate way of initially addressing Mrs Service's symptoms, identifying her dose requirements and justifying the need for regular dosing and subsequent dose titration.

Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

The medical provided by Dr Barton to Mrs Service following her transfer to Dryad Ward, Gosport War Memorial Hospital is suboptimal when compared

to the good standard of practice and care expected of a doctor outlined by the General Medical Council (General Medical Practice, General Medical Council, July 1995, pages 2–3) with particular reference to:

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs including, where necessary, an appropriate examination
- in providing care you must keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs, or appliances that serve patients' needs.

Specifically:

i) There was insufficient assessment and documentation of Mrs Service's symptoms and physical (particularly cardiac) state on her transfer to Dryad Ward on the 3rd June 1997.

ii) On the day of her transfer, Mrs Service was prescribed a stat dose of IM diamorphine and diamorphine and midazolam by syringe driver p.r.n. in dose ranges that would be excessive to her needs.

iii) The use of midazolam in a syringe driver, appears an excessive response to Mrs Service's 'failure to settle' on her first night in a new environment.

iv) There was insufficient assessment and documentation of Mr Service's clinical condition when she was restless on the 4th June 1997.

v) Mrs Service received a starting dose of diamorphine that was likely to be excessive for her needs.

If the care is found to be suboptimal what treatment should normally have been proffered in this case?

Issue i (lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate and contemporaneous patient records).

Mrs Service's admission to Dryad Ward was accompanied by the minimum of medical notes. A medical assessment usually consists of information obtain from the patient ± others, the existing medical records (the history), and the findings of a relevant physical examination documented in a structured fashion. Although the history can be restricted to the most salient points, it is unusual to omit relevant sections, e.g. current symptoms, drug history, etc. When a new medical team takes over the day-to-day care of a patient with serious medical problems, a physical examination is warranted to inform the ongoing management of those medical problems and to also provide a base line for future comparison. This allows monitoring of changes for the better or worse. A clear assessment and documentation of medical care is also particularly useful for on-call doctors who may have to see a patient, whom they have never met, for a problem serious enough to require immediate attention.

Dr Barton considered Mrs Service to be 'clearly in heart failure' and very unwell. Despite this, there was a lack of a documented assessment of the symptoms of heart failure, e.g. breathlessness at night or at rest, that would support the use of opioids for symptom relief; there was a lack of a documented physical examination of relevance for someone in heart failure,

e.g. pulse rate, jugular venous pulse, blood pressure, that would provide evidence that Mrs Service's condition had deteriorated compared to when on F1 ward.

Issue ii (in providing care you must prescribe only the treatment, drugs or appliances that serve patients needs).

On the day of her transfer, Mrs Service was prescribed a stat dose of IM diamorphine 5–10mg IM (but not apparently given) and diamorphine 20–100mg SC/24h, hyoscine 200–800microgram SC/24h and midazolam 20–80mg SC/24h all p.r.n. by syringe driver. The wide dose range of diamorphine 20–100mg/24h is not justified at all in the notes and likely to be excessive for a 99 year old patient with renal failure and no recent exposure to weak or strong opioids. Doses of opioids excessive to a patients needs are associated with an increase risk of drowsiness, delirium, nausea and vomiting and respiratory depression.

I note that Dr Petch considers the prescription of the diamorphine as a stat dose 'entirely appropriate' and in the syringe driver 'reasonable'. I would disagree with Dr Petch that the stat dose of diamorphine 5–10mg IM was entirely appropriate, as although, as he points out, it reflects the dose range given in the BNF, the BNF also suggests that the 10mg dose is for 'heavier, well muscled patients'. Given Mrs Service's advanced age, renal impairment and lack of exposure to other weak or strong opioid analgesics, even the 5mg dose could be excessive and, in my opinion, a stat dose of diamorphine 2.5mg IM would have been more prudent. With regards the prescription of the diamorphine in the syringe driver p.r.n., it would aid

understanding if Dr Petch could outline in more detail how a typical cardiologist utilises opioids in heart failure with regard to any existing guidelines, preferred route of administration, starting dose and schedule (*regular or p.r.n.*), rate of titration, how the magnitude of the dose change is determined, doses typically required and any special considerations necessary for a 99 year old patient. My limited understanding, from a palliative care colleague with an interest in heart failure who has published in this area and works within the cardiology clinic, is that opioids are indicated for breathlessness at night, at rest or on minimum exertion that *persists despite other heart failure treatments. They are given initially* orally, in small doses, e.g. codeine 30–60mg four times a day or morphine 1.25–5mg every four hours, and titrated accordingly. Even without taking Mrs Service's age and renal impairment into account, this experience supports a dose of 2.5mg diamorphine IM or less as an appropriate stat dose (equivalent to morphine 5–7.5mg PO) and diamorphine 10mg/24h SC as an appropriate starting dose if the oral route was unavailable (equivalent to morphine 20–30mg/24h PO).

I disagree with Dr Petch that Dr Barton's practice is in keeping with recommendations in the BNF based on the quote 'diamorphine can be given by subcutaneous infusion in a strength of up to 250mg/ml' as this arises in the mixing and compatibility section and relates specifically to the solubility of diamorphine and not as a practice recommendation.

The prescription of a syringe driver containing diamorphine, midazolam and hyoscine hydrobromide p.r.n. with such a wide dose range is not usual in my experience. This is because of the inherent risk that would arise from a

lack of clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing a drug as a range, particularly a wide range, is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. It is not usual in my experience for such decisions to be left for nurses to make alone. If there were concerns that a patient may experience, for example, episodes of pain, anxiety or agitation, it would be much more usual, and indeed seen as good practice, to prescribe appropriate doses of morphine/diamorphine or diazepam/midazolam respectively, which could be given p.r.n. PO or SC. This allows a patient to receive what they need, when they need it, and guides the doctor in deciding if a regular dose is required, the appropriate starting dose and subsequent dose titration.

Issue iii (in providing care you must prescribe only the treatment, drugs or appliances that serve patients needs).

The use of midazolam in a syringe driver appears an excessive response to Mrs Service's 'failure to settle' on her first night in a new environment. She was hard of hearing, confused/prone to confusion and agitated intermittently. In my opinion, all reasonable non-drug approaches should have been utilised and, if a drug approach was considered necessary, the administration of her usual dose of thioridazine would have been most appropriate. Subsequent nights may have improved as Mrs Service got used to her surroundings and got to know the staff and vice versa. If it were

considered that this episode was somehow different to Mrs Service's other disturbed nights, i.e. an acute delirium, then she should have been appropriately medically assessed and managed. In these circumstances, if a parenteral medication was considered necessary, then haloperidol, an antipsychotic initially in a small dose, repeated as required, is usually considered an appropriate choice. Some practitioners supplement haloperidol with midazolam, when greater levels of sedation are desirable. In my opinion, given Mrs Service's situation, this would have been most appropriately given as a small dose, e.g. midazolam 2.5–5mg p.r.n. The effect of this p.r.n. dose could have been assessed, the possible cause(s) of the agitation assessed subsequently by the medical team, the temporary or persistent state of her agitation subsequently assessed (e.g. it can be variable; typically worse at night than in the day) and hence the need to continue with only p.r.n., or to commence regular sedation established and a reasonable dose schedule justified.

The reliance on a prescription of a wide dose range of midazolam by syringe driver without clear instructions, ultimately exposed Mrs Service to the risk of receiving a continuous dose of midazolam that was not discussed with the doctor on-call beforehand; not fully justified in the medical or nursing notes (it did not appear to be for symptoms of heart failure, e.g, breathlessness, as Dr Barton envisaged) and was in stark contrast to how Mrs Service's disturbed nights on F1 ward were managed.

Issue iv (lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate and contemporaneous patient records).

There was insufficient assessment and documentation of Mr Service's clinical condition when she was restless on the 4th June 1997. There was no documented assessment of the cause(s) of Mrs Service's agitation nor cardiac state that would help justify the need for diamorphine and midazolam by syringe driver. Generally, when a patient's clinical condition changes for the worse, a thorough medical assessment should be carried out to ascertain the possible cause(s) in order to identify if they are reversible with appropriate treatment. The assessment will consist of the history, examination and appropriate investigation. Even basic observations have not been recorded including, for example, temperature, pulse rate/rhythm, blood pressure and auscultation of heart and breath sounds. This would help to identify a potentially reversible complication and Dr Barton should be asked to state on what basis she satisfied herself that Mrs Service was in a terminal decline and not unwell as a result of a potentially reversible complication. Similarly, it should be clarified why if it was considered that Mrs Service was dying, blood tests were carried out and, conversely, why the results of the blood tests were not acted upon.

Issue v (in providing care you must prescribe only the treatment, drugs or appliances that serve patients needs).

Mrs Service was commenced on diamorphine 20mg/24h SC (equivalent to morphine 40–60mg/24h PO). From the above comments, even without taking Mrs Service's age and renal impairment into account, diamorphine 10mg/24h SC would, in my opinion, have been a more prudent starting dose if the oral route was unavailable (equivalent to morphine 20–30mg/24h

PO). Doses of opioids excessive to a patients needs are associated with an increase risk of drowsiness, delirium, nausea and vomiting and respiratory depression.

If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

Dr Barton had a duty to provide a good standard of practice and care that would include good palliative and terminal care. In this regard Dr Barton fell short of a good standard of clinical care as defined by the GMC (Good Medical Practice, General Medical Council, October 1995, pages 2–3) with particular reference to a lack of clear note keeping, adequate assessment of the patient and providing treatment that likely to be excessive to the patients needs.

The stat dose of diamorphine 5–10mg IM p.r.n. for Mrs Service's heart failure, although never administered, was unjustified (no assessment of how bothered/distressed she was by breathlessness) and likely to be excessive for her needs. The use of midazolam 20mg/SC for 'failure to settle' appears an excessive response to an elderly patient's first night in new surroundings, particularly when they are confused/prone to confusion and agitation. This dose of midazolam is likely to sedate a 99 year old and hamper a subsequent assessment of the possible cause(s) in order to identify if there were temporary or not. The initial dose of diamorphine 20mg/24h SC was also likely to be excessive to her needs. A dose of diamorphine excessive to Mrs Service's needs would be associated with an

increased risk of drowsiness, confusion, agitation, nausea and vomiting and respiratory depression.

In patients with cancer, the use of diamorphine and other sedative medications (e.g. midazolam) when appropriate for the patient's needs, do not appear to hasten the dying process. This has not been examined in patients dying from other illnesses to my knowledge, but one would have no reason to suppose it would be any different. The key issue is whether the use and the dose of diamorphine and other sedatives were *appropriate* to the patient's needs. Although the principle of double effect could be invoked here (see technical issues), it remains that a doctor has a duty to employ effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose opioid that was *appropriate* and not excessive for a patients needs.

Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate and contemporaneous patient records, had been attempting to allow Mrs Service a peaceful death, albeit with what appears to be an apparent lack of sufficient knowledge, illustrated, for example, by the reliance on large dose range of diamorphine and midazolam by a syringe driver rather than a smaller, more appropriate, fixed dose along with the provision of p.r.n. doses that would allow Mrs Service's needs to guide the dose titration. Dr Barton could also be seen as a doctor who breached the duty of care she owed to Mrs Service by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded

the safety of Mrs Service by unnecessarily exposing her to doses of midazolam and diamorphine that were difficult to justify and likely to be excessive to her needs at the time they were commenced.

However, Mrs Service had significant medical problems. Although her cardiac failure appeared to be better controlled by the time of her transfer from F1 ward, she was becoming progressively frailer, increasingly dependent on others and her blood tests had deteriorated again. In this regard, it would not have been that unusual if Mrs Service had naturally entered a terminal decline. As such it is difficult to say with any certainty that the dose of midazolam or diamorphine she received would have *contributed more than minimally, negligibly or trivially to her death.*

9. LITERATURE/REFERENCES

British National Formulary 33 (March 1997):

- Prescribing in terminal care, pages 12–15
- Prescribing for the elderly, pages 16–17

Good Medical Practice, General Medical Council October 1995, pages 2–3

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition 'Wessex Protocol' Salisbury Palliative Care Services May 1995.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: _____ Date: _____

9

Version 2 of complete report 1st November 2005 – Sheila Gregory

SUMMARY OF CONCLUSIONS

Sheila Gregory a 91 year old lady with a number of serious chronic diseases suffers a fall and fractured neck of femur in August 1999. She is admitted to the Haslar Hospital and making little rehabilitation progress, with a very poor prognosis she is transferred to the Gosport War Memorial Hospital.

There is some weakness in the documentation of her condition in particular on her admission to the Gosport War Memorial Hospital and on the 18th November when her definitive final clinical deterioration is documented. If clinical examinations were undertaken they have not been recorded. General Medical Practice (GMC2001) states that "good clinical care must include adequate assessment of the patient's condition, based on the history and symptoms and if necessary an appropriate examination"..... "in providing care you must clear, accurate, legible and contemporaneous patient records which must report the relevant clinical findings, the decisions made, the information given to patient's and any drugs or other treatment prescribed". The lack of clinical examination both on admission and more important Mrs Gregory care deteriorated represents poor clinical practice to the standards set by the General Medical Council.

Despite the above I am satisfied that Mrs Gregory's death was of natural causes and that her overall clinical management in Gosport was just adequate.

1. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be sub-optimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

2. ISSUES

2.1. Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day?

2.2. If the care is found to be suboptimal what treatment should normally have been proffered in this case?

2.3. If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

3. CURRICULUM VITAE

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Code A

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Code A

4. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Sheila Gregory (BJC/21)

[2] Operation Rochester Briefing Document Criminal Investigation Summary.

[3] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[4] Commission for Health Improvement Investigation Report on Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital (July 2002).

[5] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

5 CHRONOLOGY/CASE ABSTRACT. (The numbers in brackets refer to the page of evidence, the numbers with 'H' in front are the Haslar notes).

5.1. Sheila Gregory a 91 year-old lady in 1999 was admitted as an emergency on 15th August 1998 to Haslar Hospital (H32).

5.2. She had a number of chronic conditions including a partial Thyroidectomy and Hypertension. In 1990 (H198) she was admitted with acute on chronic episode of obstructive airways disease. In 1991 (H205) an episode of abdominal pain and vomiting that was thought possible was pancreatitis. During this admission she received 6 doses on Omnopon each of 20 mgs with no ill effect (H363). (Omnopon is Papaveretum, 15.4mg is the equivalent of 10mg of Morphine). In 1995 she attends the geriatric day hospital under the care of a consultant geriatrician with a number of problems, including headaches (13), slow atrial fibrillation (33), left ventricular failure and mitral regurgitation (37) confirmed by an echo cardiogram (79). She has an episode of diplopia (39) and is noted to have marked bruising

(65).

5.3. She is thought to be depressed and is referred to a Dr Banks a psycho-geriatrician, who does not think she is significantly depressed but although she scores 10/10 on the mental test score, he does suspect possible early dementia. At that time she is on Frusemide, Thyroxine, Aspirin, regular Co-Proxamol and inhalers.

5.4. In December 1998 she is admitted severely ill to Haslar Hospital with chronic airways disease and left ventricular failure (H40). She is in severe respiratory failure with a measured partial pressure of carbon dioxide (pCO_2) of 12.6 (H49). However, she does recover and on this admission is declined Social Services intervention. In February 1999 (H31) she is reviewed in outpatients for episodic breathlessness. A chest x-ray in December 1998 (H8) confirms that she had heart failure.

5.5. On 15th August 199 she is admitted with a fractured proximal right femur (H32) and has a dynamic hip screw performed on 16th August (H32). She seems to make a relatively uneventful recovery medically, although the occupational health notes on 20th August show that she is needing two to do most things and comments that she is not overly motivated (H64). On 27th August her right leg is noted to be swollen and is started on Erythromycin (H84/85). On 1st September it is still swollen (H86).

5.6. In the meantime she has been referred to the geriatric team and is seen on 24th August (11). Dr Tandy documents that she had a fractured neck of femur, that she has had acute on chronic confusion since the operation and that she had an episode of diarrhoea. He also writes in the Haslar notes after saying that he will transfer her to Gosport, "will get home?" (H83).

5.7. She is transferred on 3rd September 1999 to Gosport and the letter from Haslar (9,10) states that she is using a Zimmer frame with help, has an indwelling catheter and is doubly incontinent. It also documents that she has had previous asthma, heart failure and is allergic to Penicillin. It states that at times she is very confused.

5.8. The notes on transfer to Dryaed Ward 966) (Dr Barton) record she had a fractured neck of femur and a past medical history of

hypothyroidism, asthma and cardiac failure. Needs help with ADL. She is incontinent and transfers for two with a Barthel of 3-4. The plan is to get to know her, gentle rehabilitation and she may need a nursing home. The record asks the nurses to make her comfortable and states "I am happy for the nursing staff to confirm death".

5.9. On 6th September (67) she is seen by a different doctor after she had been noted to have a left-sided facial droop which has resolved. An examination is recorded in the notes and it also notes that she has pain tenderness in her right wrist. ("snuffbox"). She is started on Aspirin for her atrial fibrillation and x-rays are arranged. The x-ray showed no bony injury (127). At this stage 9195) her Barthel is 2 (very heavily dependent) with a Waterlow score of 35 (191) identifying that she at very high risk of pressure sores.

5.10. She is then reviewed regularly on the ward with comment most weeks (67-69). In summary they document her very poor appetite, agitation and variable confusion with a lack of significant improvement in mobility. She remains catheterised and has faecal incontinence. Blood tests taken during this time, including a full blood count, liver function testand thyroid function test are all unremarkable (101,111,99), her weight on 22nd October is 45.3 kgs (226).

5.11. The lack of progress in rehabilitation and continued dependency, continues until the 1st November 1999 (69) when an episode of vomiting is noted. On 11th November, her Barthel is still very dependent at 6 (193).

5.12. On 15th November (69) she is noted to be less well, it is thought possible that she has a chest infection and is having nausea. An examination is undertaken and recorded in the notes but no firm diagnosis is recorded. But there appears to have been some sort of change in her status. However, on the 18th November (70) there is marked deterioration in her general condition. This is also noted in the nursing cardex (239), which states she is quite distressed and breathless. There is no medical examination recorded, however, it was decided to start oral opiates in a small dose and to"make comfortable". Dr Barton who saw her on this day records that she will speak to the granddaughter and again states that she was happy for nursing staff to certify death. She does suggest that there might have been a further stroke, but no examination is recorded.

5.13. On 19th November, nursing cardex reports her as poorly but stable. (239)
On 22nd November a further decline is noted and that she is comfortable, an examination is undertaken and recorded and notes that she is breathless, chest is clear and she has uncontrolled atrial fibrillation. The decision to continue the Diamorphine is recorded, she dies 17.20 on 22nd November, and death is verified by Staff Nurse Shaw and Staff Nurse Hamlyn (70).

5.14. There are three main drug charts in the notes for her stay in Gosport. The first is from the 3rd September to 6th October (154-166). This records regular Thyroxine, Iron Lactulose, Senna, Atrovent Becloforte, Paracetamol, Aspirin, Fluoxetine and nebulizers.

On the as required part there is Co-dydramol, Prochlorperazine, Oramorph 10mgs in 5 mls, 2.5 – 5 mls prn (never given) also Diamorphine, Hyoscine, Midazolam, all of which are never given and Thioridazine which she receives on a regular basis together with Zopiclone at night.

5.15. The next drug chart goes from 7th October – 17th November. Regular medication includes Thyroxine, Fluoxetine, Aspirin, Paracetamol, Senna, Lactulose, Thioridazine and Temazepam. She receives 3 days of antibiotics from 1st November – 3rd November.

On the as required part Oramorphine, 10mgs in 5mls 2.5 -5mls orally four hourly prn is written up and one dose is given on 11th November. Metoclopromide and Gaviscon Loperamide are also written up.

5.16. The final drug chart goes from the 18th November up unto her death. On the regular side Oramorphine 10 mgs in 5mls is written up and 2.5mls (i.e.5mgs) is given 6 hourly on 18th and 19th November and on the morning of 20th November (186). Thyroxine, Fluoxetine continue to be given regularly up until 21st November.

Diamorphine 20 – 80 mgs subcutaneously in 24 hours, together with Hyoscine, Midazolam and Cyclizine are all written up on the as required part of the drug chart on 18th November. Diamorphine 20 mgs in 24 hours with 50 mgs of Cyclizine is given in an infusion pump. The first one starting on 20th November and the second on 21st November.

6. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

6.1. This section will consider whether there were any actions so serious that they might amount to gross negligence or any unlawful acts, or deliberate unlawful killing in the care of Sheila Gregory. Also whether there were any actions or omissions by the medical team, nursing staff or attendant GP's that contributed to the demise of Sheila Gregory, in particular, whether beyond reasonable doubt, the actions or omissions more than minimally, negligibly or trivially contributed to death.

6.2. Mrs Gregory had a number of chronic diseases prior to her terminal admission following a fractured neck of femur. She had severe lung disease documented to going back to at least 1990, and in my view was extremely lucky to survive the admission in December 1998 at the age of 90 years. She also had documented heart failure, atrial fibrillation and heart cardiac valvular disease going back to at least 1995. It seems likely that she had cerebral vascular disease following the episode of diplopia in 1995 and the confusion that was subsequently documented is probably evidence of mild to moderate multiple infarct disease.

6.3. As is all too common, a very frail elderly lady has a fall and she suffered a fractured neck of femur. She is admitted to the Haslar Hospital for operative repair. There is always a very significant mortality and morbidity after fractured neck of femurs in old people, particularly in those who have had previous cardiac and other chronic diseases.

6.4. In the post operative period in Haslar, she remains doubly incontinent of both urine and faeces and has considerable confusion, especially at night. She makes very little rehabilitation progress. All of these are very poor prognostic signs at the age of 91.

6.5. She is subsequently assessed by the geriatric team and appropriately transferred to Gosport Hospital. The comment in the notes in Haslar, "will get home?" (H83) suggest that a consultant view was that even at this early stage, significant improvement was very unlikely. I would agree with that assessment.

6.6. When she is transferred to the Gosport War Memorial Hospital she is seen by Dr Barton who fails to record a clinical examination apart from some short statements about her past medical history and her functional history. However, Mrs Gregory appears to have been in a relatively stable clinical condition and no harm

seems to befall her as a result of this failure to examine her.

6.7. However, she is examined three days later by a different doctor when she had been noted to have a left sided facial droop and it seems quite likely that she had a further small stroke at this time as part of her multiple infarct disease.

6.8. Essentially she makes no improvement in rehabilitation during her two months in Gosport War Memorial. She remains extremely dependent, eating very little and reliant on very considerable nursing input. There is ongoing discussion about the possibility of a long term nursing home placement.

6.9. On 15th November she is noted to be quite unwell, the diagnosis was not entirely clear and I wonder whether something was actually starting on 1st November when there was an episode of vomiting. The patient is examined and that examination is recorded in the notes. However, by 18th November, she has very rapidly deteriorated and Dr Barton makes a record in the notes that because of her deterioration in general condition, oral opiates should be started in a small dose. Based on the nursing assessment of her distress and breathlessness, this was an appropriate response to someone who has an extremely poor prognosis, multiple chronic illnesses and is making no significant progress after 3 months in hospital. A symptomatic response to this lady's problems are a reasonable clinical decision.

6.10. She receives 5 mgs 6 hourly of Oramorphine on the 18th and 19th December, which I believe to be an appropriate dosage and therapeutic regime. No improvement is made and she starts on Diamorphine pump at 20 mgs on 20th November. It would appear that the decision to start this was a nursing one as no specific medical note is made on that day, however I believe this to have been a reasonable decision for a patient who is dying.

6.11. Diamorphine is specifically prescribed for pain and is commonly used for pain cardiac disease . However, it is also widely used for the distress and agitation that may be associated with terminal illness. Diamorphine can be mixed with Cyclizine (to prevent vomiting) in the same syringe driver. Diamorphine subcutaneously after Oramorphine is usually given a maximum ratio of 1 to 2 (for example up to 10 mgs of Diamorphine for 20 mgs of Oramorphine). On this occasion Sheila Gregory had been receiving 20 mgs of Oramorphine a day on 18th and 19th where an absolute minimum dose of Diamorphine would have been 10 mgs in the syringe driver over the first 24 hours. However the

increased to 20 mgs over 24 hours after 2 days of 20 mgs of Oramorphine would be within the range of acceptable clinical practice.

6.12. Seen on the 22nd, she is now very ill with a rapid pulse, a rapid respiratory rate with a clear sounding chest. This suggests to me that the agonal event may well have been a pulmonary embolus. However, this would not be surprising after a long period of poor mobilisation, following a fractured neck of femur.

6.13. A remaining concern regarding the clinical management is the anticipatory prescribing of strong opioid analgesia on both the first and second drug charts written between 3rd September and 17th November. Except where this would be useful as part on normal clinical management (for example after a heart attack), there appears to be no clinical justification for this prescribing pattern. However, although this may represent poor clinical practice, no harm came to Mrs Gregory as a result of it.

7. OPINION

7.1. Sheila Gregory a 91 year old lady with a number of serious chronic diseases suffers a fall and fractured neck of femur in August 1999. She is admitted to the Haslar Hospital and making little rehabilitation progress and with a very poor prognosis, she is transferred to the Gosport War Memorial Hospital.

7.2. There is some weakness in the documentation of her condition in particular on her admission to the Gosport War Memorial Hospital and on the 18th November when her definitive final clinical deterioration is documented. If clinical examinations were undertaken they have not been recorded. General Medical Practice (GMC2001) states that "good clinical care must include adequate assessment of the patient's condition, based on the history and symptoms and if necessary an appropriate examination"..... "In providing care you must clear, accurate, legible and contemporaneous patient records which must report the relevant clinical findings, the decisions made, the information given to patient's and any drugs or other treatment prescribed". The lack of clinical examination both on admission and more important Mrs Gregory care deteriorated represents poor clinical practice to the standards set by the General Medical Council.

Despite the above I am satisfied that Mrs Gregory's death was of natural causes and that her overall clinical management in Gosport

was just adequate.

8 LITERATURE/REFERENCES

1. Good Medical Practice, General Medical Council 2002
2. Withholding withdrawing life, prolonging treatments: Good Practice and decision making. General Medical Council 2002.
3. Palliative Care, Welsh J, Fallon M, Keeley PW. Brocklehurst Text Book of Geriatric Medicine, 6th Edition, 2003, Chapter 23 pages 257-270.
4. The treatment of Terminally Ill Geriatric Patients, Wilson JA, Lawson, PM, Smith RG. Palliative Medicine 1987; 1:149-153.
5. Accuracy of Prognosis, Estimates by 4 Palliative Care Teams: A Prospective Cohort Study. Higginson IJ, Costantini M. BMC Palliative Care 2002:1:129
6. The Palliative Care Handbook. Guidelines on Clinical Management, 3rd Edition. Salisbury Palliative Care Services, May 1995.

9. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
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10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

10. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: _____ Date: _____

DRAFT OVERVIEW

OF

SHEILA GREGORY (BJC/21 and JR/12)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. INSTRUCTIONS

To examine and provide a preliminary overview of the case of Sheila Gregory.

2. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Sheila Gregory (BJC/21 and JR/12).

[2] Full set of medical records of Sheila Gregory on CD-ROM (BJC/21).

[3] Hampshire Constabulary summary of care of Sheila Gregory.

3. COMMENTS

Note: These comments are based on a preliminary read through the case notes of Sheila Gregory. They are made without prejudice and a more detailed review may produce a report with differing comments and conclusions.

For brevity and in keeping with the purpose of this overview I have restricted my comments under the following sub-headings.

Was pain clearly documented as a problem and assessed?

On the 15th August 1999, Mrs Sheila Gregory fell and fractured her right hip (neck of femur) and was admitted to the Royal Hospital Haslar. The fracture was treated surgically with a dynamic hip screw on the 16th August 1999. For postoperative analgesia, Mrs Gregory required occasional doses of 'weak' opioid analgesics as required (p.r.n.); initially she took no more than two doses of tramadol 100mg (which may have worsened her confusion) and subsequently co-dydramol (2 tablets; each tablet contains paracetamol 500mg and dihydrocodeine 10mg) per day. Pain did not appear to be a problem when Mrs Gregory was reviewed by Dr Tandy on the 24th August 1999, nor in the transfer

letter written on the day of her transfer to Dryad Ward on the 3rd September 1999, at which time she was mobilising with a zimmer frame and the help of one other person. There was no mention of pain as a problem in the medical or nursing notes on her transfer to Dryad Ward. On an assessment sheet, which although undated appears as to have been filled in at the time of her transfer, the section on pain is completed to suggest that pain was present but controlled (page 243 of 346).

On the 6th September 1999, the medical notes record that Mrs Gregory had pain and tenderness in the right 'snuff box' (wrist). This could have been injured when she fell, and an X-ray was carried out to exclude a fracture. I presume it was because of this wrist pain, that paracetamol was commenced regularly (1G four times a day) and continued until 23rd October 1999, after which the administration became erratic. There was no further mention of any pain in the medical notes. In the nursing care plan, other mentions of pain were:

- 22nd October 1999 - indigestion, given Gaviscon (an antacid)
- 25th October 1999 - pain in the right leg, given paracetamol
- 16th November 1999 - 'discomfort', site not specified, given paracetamol
- 17th November 1999 - pain in neck (followed by unintelligible word ?arm; page 204/346), given paracetamol
- 19th November 1999 - breathless and pain in shoulder, given frusemide (a diuretic) but no additional analgesia. Was receiving regular morphine at this point.

Apart from the pain in the right wrist, no medical assessment is documented and the underlying cause of these other pains is unclear. Nevertheless, they were generally treated with paracetamol only.

Was the management of the pain appropriate?

On her transfer to Dryad Ward on the 3rd September 1999, Mrs Gregory was prescribed 2 co-dydramol tablets p.r.n., as at Royal Hospital Haslar. In my opinion, this was appropriate.

She was also prescribed oral morphine (Oramorph) 5–10mg every 4h p.r.n. It is unclear from the medical notes why this was considered necessary, particularly as Mrs Gregory had only been requiring occasional doses of co-dydramol. Some practitioners do use small doses of morphine rather than dihydrocodeine, and although a dose of 5–10mg is in keeping with the BNF recommendations, given Mrs Gregory's advanced age, a dose of morphine 2.5mg p.r.n. may well have sufficed. It would also have equated more closely to her dose of co-dydramol; morphine is 10 times more potent as dihydrocodeine and hence two tablets of co-dydramol (20mg dihydrocodeine) is equivalent to 2mg morphine.

On the day of her transfer, Mrs Gregory was also prescribed diamorphine 20–200mg SC/24h, hyoscine (hydrobromide) 200–800microgram SC/24h and midazolam 20–80mg SC/24h by syringe driver. There is nothing documented that supports the prescription of these drugs; at the time of her transfer there was no suggestion that Mrs Gregory had symptoms that required these drugs in these doses. Further, the medical plan for Mrs Gregory was for gentle rehabilitation. However, Mrs Gregory did not receive any diamorphine by syringe driver until 20th November 1999.

The subsequent prescription and administration of opioids does not appear to have been primarily for pain, and the exact reason for their use should be clarified. On the 17th November 1999 the nursing summary notes record that Mrs Gregory was not very well in the evening and was becoming quite distressed and breathless at times and that morphine 5mg was given to relieve

her distress with good effect. In my opinion, opioids are not indicated as a non-specific treatment of 'distress.' If Mrs Gregory was distressed because of her breathlessness, it would have been most appropriate to have first assessed and treated any underlying cause, when possible and appropriate. There are many reasons why someone may become breathless, many of which are relevant given Mrs Gregory's past medical history, e.g. chest infection, asthma/chronic obstructive airways disease, atrial fibrillation and heart failure. The latter may be particularly relevant as Mrs Gregory's only heart-failure treatment she had been receiving (captopril) was discontinued at Haslar, possibly because of low blood pressure peri-operatively.

On the 18th November 1999, she was seen by Dr Barton, and the medical notes conclude that Mrs Gregory may have had a further CVA (cerebrovascular accident; a stroke), although the medical history/physical findings that led to this conclusion are not documented. There was no documentation of breathlessness or distress, and no documentation that a physical examination had taken place. Oral morphine was commenced regularly (5mg every four hours and 10mg at night). The nursing summary note seems to indicate that the morphine was commenced because Mrs Gregory was feeling anxious. In my opinion, this is not an appropriate use of morphine.

The drug chart was rewritten on the 18th November 1999, and again included prescriptions for diamorphine (now in a range of 20–80mg SC/24h), hyoscine (hydrobromide) 200–800microgram SC/24h and midazolam 20–80mg SC/24h by syringe driver. On the afternoon of the 20th November 1999, a syringe driver was commenced containing diamorphine 20mg and cyclizine (an anti-emetic) 50mg SC over 24h. This was continued on the 21st November 1999 and Mrs Gregory died at 17.20h. Mrs Gregory had been experiencing nausea and

vomiting and this is an indication for the use of a syringe driver containing an anti-emetic. The cyclizine was prescribed as a range (50–200mg/24h) but I note Mrs Gregory received a stat dose of 50mg at 13.15h on 20th November 1999. The dose in the syringe driver (50mg/24h) was smaller than that generally given (150mg/24h). In order to comment on the appropriateness of the use of the diamorphine, clarification is required on the indication for the oral morphine.

Were excessive doses of morphine/diamorphine/midazolam administered?

In my opinion, on the day of her transfer, the prescription of diamorphine 20–200mg SC/24h and midazolam 20–80mg SC/24h by syringe driver appears unnecessary and inappropriate. However, Mrs Gregory did not receive any diamorphine by syringe driver until 20th November 1999.

On the 18th November 1999, Mrs Gregory was seen by Dr Barton and commenced on oral morphine 5mg every 4h and 10mg at night. The reason for this should be clarified. It is not unusual for a double dose to be given at 22.00h, to try and avoid the need for a 02.00h dose. This starting dose is in keeping with the BNF (i.e. 30mg/24h). However, given Mrs Gregory's advanced age, a smaller dose may well have sufficed and would have been more appropriate in my opinion (i.e. 15mg/24h). Mrs Gregory received this dose of oral morphine for 48h, between the 18–20th November 1999.

The drug chart was rewritten on the 18th November 1999 and again included prescriptions for diamorphine 20–80mg SC over 24h, hyoscine and midazolam. Mrs Gregory commenced a syringe driver containing 20mg of diamorphine on the 20th November at 17.00h. To calculate an appropriate dose of SC diamorphine, the daily oral morphine dose is divided by 2 or more generally 3. Given that Mrs Gregory had been receiving 30mg/24h of oral morphine, her SC

diamorphine dose should thus have been 10–15mg/24h rather than the 20mg/24h she received. Although these figures do not differ greatly, they may be important in an elderly patient and it should be ascertained how Dr Barton calculated or determined that the dose of diamorphine 20mg/24h was appropriate for Mrs Gregory.

Was the death of the patient anticipated?

Mrs Gregory was a frail 91 year-old with significant medical problems, namely heart failure, atrial fibrillation and a probable cerebrovascular accident (CVA) who had fell and fractured her right hip. She was confused at times. Following transfer to Dryad ward Mrs Gregory was slow to mobilise. She possibly sustained a further small stroke causing the left side of her face to droop and her to lean to the left when standing. Her mobility failed to improve significantly. On the 27th September 1999, she was noted to be 'generally less well' and on the 11th October 1999, 'very dependent and delightfully (usually) confused' and the aim then became nursing home placement. On the 15th November 1999, she was noted to be frailer, less well and to have a chest infection. She also had occasional bouts of nausea. On the 18th November 1999, a further deterioration in Mrs Gregory's general condition was noted and it was considered that she may have had a further CVA. She was commenced on oral opioids for a reason that remains to be clarified. Mrs Gregory subsequently declined further and was commenced on a syringe driver on the 20th November 1999 and died on the 22nd November 1999 at 17.20h. Earlier on that day, Mrs Gregory was reviewed by Dr Reid, who noted her to be able to give short verbal responses, to have a respiratory rate of 24 breaths/min and her chest clear at (unintelligible word; page 70/346).

Thus, Mrs Gregory's physical decline had been documented over several weeks. Part of her deterioration appeared to have been the symptom of breathlessness. It is unclear from the medical notes, what the underlying cause of this was, although it may have been multifactorial; Mrs Gregory had asthma/chronic obstructive airways disease, heart failure and a chest infection. The use of frusemide IM and subsequently orally does suggest that heart failure was considered to be a contributing factor. Contrary to this would be the finding of a clear chest on the 15th and the 22nd November 1999; in heart failure generally crackles, caused by excess fluid, are audible in the chest.

The reason for the prescription of the oral morphine and subsequently the diamorphine remains to be clarified. However, the fact that Mrs Gregory was capable of responding and had a respiratory rate of 24 breaths/min suggests that the dose of diamorphine she was receiving was not excessive to the point of rendering her unresponsive or depressing her respiration.

4. CONCLUSION

In summary, pain did not appear to be a major problem for Mrs Gregory at the time of her transfer to Dryad Ward. Any pain present appeared satisfactorily controlled with p.r.n. doses of co-dydramol 2 tablets, twice a day at most. During Mrs Gregory's time on Dryad Ward, she appears to have experienced a number of pains. Apart from the pain in the right wrist, no medical assessment is documented and their underlying cause is unclear. Nevertheless, they were generally treated with paracetamol only. Thus, in my opinion, from a pain point of view, there was no justification for the prescription of diamorphine, hyoscine and midazolam to be given in a syringe driver on the day that she was transferred to Dryad Ward and when the drug chart was rewritten on the 18th

November 1999. However, she did not receive any diamorphine until 20th November 1999. One obvious conclusion, that should be explored further, is that the use of these drugs, in these doses, was part of a 'standard' approach, that had little, if any, immediate consideration or relevance to an individual patient. The reasoning behind such an approach should be identified.

In my opinion, from a pain point of view, there was no justification for the prescription of the regular oral morphine on the 18th November 1999 and the indication for its use needs to be determined. If it was for anxiety, as the nursing notes suggest, this in my opinion is not an appropriate use of morphine. However, opioids are indicated for the relief of symptoms other than pain, e.g. cough and breathlessness, and Mrs Gregory did have breathlessness. In my experience, morphine is widely used to relieve breathlessness (generally occurring at rest) in patients with cancer. It is used less in non-cancer conditions causing breathlessness, although this practice may be increasing. Nevertheless, it is generally used for symptomatic relief of breathlessness that persists despite the optimal treatment of the underlying cause. In this regard, there is a lack of documentation in the medical notes that an assessment was made of Mrs Gregory's medical condition around the times that breathlessness seemed a particular problem, e.g. 17th and 19th November 1999. If a thorough medical assessment of Mrs Gregory's breathlessness on the 17th November 1999 had considered it to be due to heart failure, then appropriate management of her heart failure could be seen as a more appropriate response to her episodes of breathlessness and anxiety rather than the use of morphine per se. On the 19th November 1999, a stat dose of frusemide 40mg was given IM at 15.45h because of breathlessness. In my experience, it is generally the case that a patient who is considered to be a degree of heart failure sufficient to

warrant parenteral frusemide, also warrants a medical review. Given this occurred at 15.45h, I would have considered it appropriate for Dr Barton/the doctor on call to have assessed Mrs Gregory as soon as was possible the same day, and not to have left until the following morning. Even so, there was no medical notes entry for 20th November 1999, although regular oral frusemide 40mg once a day was prescribed. I am not a cardiologist however, and the opinion of one could be sought if considered necessary regarding the above.

The use of a syringe driver with an anti-emetic was reasonable, given that Mrs Gregory was experiencing nausea and vomiting, and this is an indication for its use. The appropriateness of the use of diamorphine depends on the indication for the oral morphine.

However, the above issues aside, Mrs Gregory's decline was noted over a number of weeks and this would be in keeping with a natural decline into a terminal phase. Further, whatever the reason was for the use of diamorphine, the physical findings on the day of Mrs Gregory's death would suggest that the dose she was receiving was unlikely to have been excessive to the degree that it rendered her unresponsive or was associated with respiratory depression.

SUMMARY OF CONCLUSIONS:

Mr Arthur Cunningham a 79 year-old gentleman, suffers from long-standing Parkinson's disease with multiple complications followed by a fairly rapid decline in health leading to his first admission to the Gosport War Memorial Hospital on 21st July, 1998 and a final admission 21st September, 1998.

Mr Cunningham receives terminal care including subcutaneous Diamorphine and Midazolam through a syringe driver and dies on 26th September 1998.

The expert opinion is:

> Arthur Cunningham is an example of a complex and challenging problems in geriatric medicine. He suffered from multiple chronic diseases and gradually deteriorated with increasing medical and physical dependency. It is always a challenge to clinicians to identify the point at which to stop trying to deal with each individual problem or crisis, to an acceptance the patient is dying and that symptom control is appropriate.
>
> In my view, Mr Cunningham was managed appropriately, including an appropriate decision to start a syringe driver for managing his symptoms and agitation as part of his terminal illness in September 1998.
>
> My one concern is the increased dose of Diamorphine in the syringe driver on 25th and 26th September 1998, as I was unable to find any justification for this increase in dosage in either the nursing or the medical notes. In my view this increase in medication may have slightly shortened life for at most no more than a few hours to days, however, I am not able to find evidence to satisfy myself that this is to the standard of "beyond reasonable doubt".

1. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be sub-optimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

2. ISSUES

2.1. Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day.

2.2. If the care is found to be suboptimal what treatment should normally have been proffered in this case.

2.3. If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups.

3. CURRICULUM VITAE

Code A

Code A

Code A

Code A

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Code A

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Code A

4. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Arthur Cunningham

[2] Full set of medical records of Arthur Cunningham on CD-ROM.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Commission for Health Improvement Investigation Report on Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital (July 2002).

[7] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); *Also referred to as the 'Wessex Protocols.'*

5. CHRONOLOGY/CASE ABSTRACT. (The numbers in brackets refer to the page of evidence).

5.1. During the 1980's Mr Cunningham noted a tremor in his left hand and by 1987 a clinical diagnosis of Parkinson's disease had been made and he had been started on Sinemet a drug specifically for the treatment of Parkinson's disease (445). He then remains on Sinemet in one form or another for the rest of his life. In 1992 another drug called Selegiline is added to his Sinemet (445). His only previous problem had been a lumbar spinal fusion following a war accident (375) that left him with chronic back pain and foot drop.

5.2. In 1992 he had a percutaneous nephrolithotomy for kidney stones. (9). During that admission he was written up for Omnopon 10 – 20 mgs and received a dose of 20 mgs (12). There were no ill effects.

5.3. He was assessed in December 1994 (439 and 441) for declining mobility. He was noted to have a weight of 102 kgs, a mental test score of 10 out of 10, and a Waterlow score of 13 (391) suggesting some dependency. His wife had died in 1989 (439). His Barthel was 17 (433) some help needed was with dressing. The problems were assessed to be due to be Parkinson's disease, a weak leg from his war injury and obesity.

5.4. He was followed up in 1995 with a diet and change to his Sinemet regime in the Day Hospital. He was also treated with Ranitidine and Gaviscon, presumably for acid reflux (425) and was on regular Co-proxamol for pain (425). Subsequently Enalapril was started for hypertension (399 and 417). In March 1995 his weight was 99.4 kgs (407) and he was discharged shortly after from the Day Hospital (400).

5.5. In September 1997 the GP requests a domiciliary visit (379). He notes that he has been diagnosed with diabetes and was now losing weight (379). The GP refers to diabetes being diagnosed in 1986 when this should have been 1995 (555). His Parkinson's disease has deteriorated and he is now getting dystonic movements. Dystonic movements are writhing and jumpy movement that occur as a side effect of drug therapy in people who have had Parkinson's disease for many years. These movements often occurs at times of peak drug levels and may alternate with periods of severe stiffness and immobility at times of low drug levels. It was also noted that he had lost some lower body strength (379). He was now spending most of his time in his chair (379). His drugs included the regular analgesia, Solpadol (381).

5.6. An assessment in September 1997 (375, 377) finds he has weak lower limbs and has difficulty in transfers. He can walk indoors slowly with sticks. He has a poor appetite and daily home care. He is documented to have very weak flexion and extension of the left hip, wasting of the left quadriceps and left foot drop (377). It is suggested that he comes to the Day Hospital for physiotherapy. His weight in October 1987 (629) is 84 kgs. However in November 1987 he cancels further appointments (355). In September 1997 his white cell count is 4.0 and his platelet count is 112. It is likely that his haematological abnormalities date from this time.

5.7. In March 1998 he is seen again in outpatients with new episodes of shortness of breath (139 – 141). The diagnosis is not clear but was thought possibly to be cardiac in nature. However a chest x-ray (519) was normal. There is no further investigation of this problem. One note suggests that he had just moved to a nursing home (141).

5.8. In June 1998 he is seen at the Merlin Park Residential Home by Dr Lord, following a GP request (345). He is noted to have significant weight loss, is transferring very unsteadily, is occasionally breathless and has had two falls in the home. He remains on a five times a day dose of his Sinemet and is

also on a hypertensive drug Amlodipine, Diazepam and drugs for constipation. Examination (349) finds that he has markedly dystonic movements and records that the home had noticed visual hallucinations after he moved in. Dr Lord feels that he is on too much Levodopa (the main drug in Sinemet). She feels the Sinemet is causing his dystonic movements, too low a blood pressure on standing leading to falls, and his hallucinations. The notes state that Mr Cunningham never agreed with this diagnosis. Dr Lord also feels that he is depressed (349).

5.9. On 22nd June 1998 he is brought to the Gosport War Memorial Hospital by Social Services as he was refusing to stay at Merlin Park (343). He is described as a difficult and unhappy man (59). No acute health problems are found (343). Social Services place him in the Alvestoke Nursing Home (341).

5.10. On 6th July 1998 he is seen again at the Gosport War Memorial Hospital (339) and is noted to have decreased mobility and his weight has now decreased to 68.7 kgs. He is not happy with his new nursing home placement. His functional status has declined and his Barthel is 9/20 (334). His blood count that day shows a normal haemoglobin but a white cell count of 2.7, platelets of 103 (650). The reduced white count particularly his neutrophil count and reduced platelets count is thought to be due to "likely myelodysplasia known since February 1997" (68). This was never confirmed with specialist haematologist investigation.

5.11. On 8th July he is seen by Dr Scott Brown a psychiatrist and is thought to be depressed (117). Other problems including his Parkinson's disease and his myeloproliferative disorder are noted (115).

5.12. On 20th July his care is discussed with Dr Lord in the Day Hospital (111 and 113). It is though his Parkinson's disease is stable but because of concern about his weight loss, he is referred for a speech and language assessment, which subsequently occurs on 27th July (101). This finds he has difficulty in initiating swallow but there is no aspiration. This likely to be a complication of his Parkinson's disease.

5.13. On 21st July he is admitted to Mulberry Ward with depression (323) his weight is 65.5 kgs (303) a bed sore is now noted (293) he is thought to have dementia (67) and there is a documented mental test score in June of 23 out of 29 on the Folstein Mini Mental State Examination (343). He is found to be constipated (289) is restless and demanding at night (271) (269), nursing notes comment that he can be awkward and difficult (242). Waterlow scores are recorded on a number of occasions, all between 19 and 20 suggesting very high risk of further pressure sore development (309 and 310). He is documented to have various urine tract infections including proteus (207) and enterococcus on two occasions (211) (205). On

admission his white cell count is 2.9 neutrophil count 1.4 and platelet count of 97 (201). On 12th August his white count is 3.5 his neutrophil count 1.8 and platelets 135. The blood form states "known myelodysplasia" (193). On admission his albumin is 26 (185) his urea is 6 and his creatinine 59, his prostatic-specific antigen is 6.4 (179) normal is less than 4. This raised level is not investigated any further, it might represent either benign prostate disease or early prostatic cancer.

5.14. During his admission to Mulberry ward he has a fall on the 24th July (70). He is described as quite demanding, wanting staff to come and see him every few minutes (70), he is depressed and tearful on 24th July (71), he is rude and abusive to a member of staff on 26th July (72) and apologises later in the day (73). Dr Lord sees him on 27th July (74) and finds that there were no particular new problems. He is still low in mood on 3rd August (79) calling out for assistance quite a lot (80). He needs a lot more assistance on 10th August (83). On 17th August he became noisy, shouting for help and very abusive, refusing medication (85). He is assessed for a further move to the Thalassa Nursing Home on 17th August (86). He is again confused in the middle of the night on 18th August (87). On 25th August it is noted that he has not passed much urine (90). Blood tests carried out on 26th August (175) find a Sodium 134, Potassium 5.1, Urea 28 and Creatinine 301. He has gone into acute renal failure and is examined and found to have a large palpable bladder (90). He is catheterised. On 28th August there is a significant improvement in his renal function, Sodium 140, Potassium 4.1, Urea 15.6, Creatinine 144 (173). By the time of his discharge to his current usual medication of Sinemet, pain killers and anti-hypertensive drugs; Mirtazapine (an anti-depressant), Carbamazepine 100 mgs nocte, Triclofos 20 mls nocte and Risperidone 0.5 mgs early evening, have all been started as psychotropic medication to help control his mood and agitation (161 and 163).

5.15. He is seen by Dr Lord on Mulberry Ward on 27th August the day before his discharge, the day after he has had a catheter put in. She finds him much better in mood and eating better with a weight of 69.7 kgs (327). There were 2 litres of urine passed after he was catheterised (91). He cannot wheel himself but Dr Lord is happy for him to be discharged to the Thalassa Nursing home with a follow up in the Day Hospital on 14th September. He is then discharged to the Thalassa Nursing Home on 28th August.

5.16. On 11th September (99) he is seen by the Community Psychiatric Nurse who says that he has settled well into the Thalassa Nursing Home and his mood seems good.

5.17. On 14th September he is seen in the Gosport War Memorial Day Hospital his weight is 68.6 kgs (323), brighter and says he is eating not too badly (459). His blood pressure is a little low at 108/58 and his pulse is 90 (323).

There is no comment on his pressure sore although, he is subsequently given a prescription for Metronidazole from " a swab to the sores on your bottom" (317). He is presumably still catheterised.

5.18. He appears to have a routine appointment at the Day Hospital on 17th September (908) for therapist assessment. It is noticed that the pressure sore is exudating markedly. During this session it is recorded that he would not comply with dressings and then would not wake up after bed rest. He was refusing to eat or drink and expressing a wish to die. The nursing notes state that he is seen by Dr Lord (909) who thinks he may need admission on Monday when reviewed again. I have not found any medical notes relating to this.

5.19. On 21st September (642) he is again seen in the Day Hospital by Dr Lord (909). He is recorded to be very frail with his tablets not swallowed and in his mouth. He has a very offensive large necrotic sacral ulcer. His weight is 69 kgs (642). A care plan is made by Dr Lord (643) to stop unneeded drugs, to admit to hospital for treatment of the sacral ulcer, to nurse on the side, for a high protein diet and for Oramorph prn for pain. The notes state the nursing home should keep the bed open for the next three weeks at least and the prognosis is poor (643).

5.20. He is taken to Dryad Ward (645) and seen by Dr Barton who says to make comfortable, give adequate analgesia and that "I am happy for the nursing staff to confirm death". The next medical note (which is out of sequence (644)) on 24th September, states, "remains very poorly, Son has visited again today and is aware of how unwell he is. Analgesia is controlling pain just. I am happy for the nursing staff to confirm death".

5.21. 25th September (Dr ?) Brook writes, "remains very poorly on syringe driver for TLC". There is then a nursing note on 26th September, the patient died at 23.25 on 26th September and the final medical note is on 28th September saying "death certificate discussed with Dr Lord, 1 – Bronchopneumonia, 2 – Parkinson's Disease, Sacral Ulcer".

5.22. The nursing notes are more detailed on 21st September. He is admitted (867) but at 20.30pm is noted to have remained agitated and was pulling off his dressing (880). Syringe driver is commenced "as requested" and he is peaceful. On 22nd September the Son is told that the Diamorphine pump has been "started for pain relief and to allay his anxiety". His Barthel is 0/20 (873) and Waterlow 20, suggesting high risk. The patient is recorded as "stating he had HIV disease" and trying to remove his catheter.

5.23. 23rd September (868) it is recorded that he is chesty overnight and Hyoscine is added. The Son and wife are angry that a syringe driver was commenced and the nurses "explain it was to control pain". He is agitated

at night that evening (876).

5.24. On 24th September the night staff and the day staff report pain and in the notes his Midazolam is increased to 80 mgs a day and his Diamorphine to 40 mgs. The nursing notes record that Dr Barton saw the Son, confirming the medical notes (643).

5.25. On 25th September Midazolam is continued at 80, he is on Diamorphine 60 mgs and is recorded as being peaceful (876). Finally on 26th September the notes record his Diamorphine is increased to 80 mgs and Midazolam to 100 mgs.

5.26. Drug Chart Analysis:

His original drug chart on admission to the ward on 21st September (752) prescribes Oramorphine 2.5 – 10 mgs orally 4 hourly, he receives 5 mgs at 14.50pm on 21st and 10 mgs at 20.15pm. He is also written up (753) for all his current anti-Parkinsonian and anti-psychotic medication but the notes demonstrate that on some dates the drugs are missing and on almost all occasions he is too ill to be able to take the medication on 21st – 24th September.

5.27. Diamorphine is 20 –200 mgs subcutaneously in 24 hours is written up on 21st September (756) and on the 21st at 23.10pm, 20 mgs is started. On 22nd September 20.29pm, 20 mgs is started and on 23rd September at 9.25am, 20 mgs is started. On 24th 40 mgs is started in the syringe driver at 10.55am, on 25th 60mgs is in the syringe driver (837) and on 26th 80 mgs.

5.28. Midazolam 20 – 80 mgs is written up on 21st September (756) and 20 mgs is given on 21st, 22nd and 23rd. On the 23rd though, this is increased to 60 mgs, 80 mgs on the 24th. He receives another 80 mgs on 25th and 100 mgs written up in 24 hours on 26th (837).

5.29. Hyoscine 200 – 800 micrograms sub cut in 24 hours is written up 400 micrograms are given on 22nd and 23rd September and 800 micrograms on 24th. This is then re-prescribed. Hyoscine 80 – 2 grams sub cut in 24 hours (837) and he receives 1,200 micrograms on 25th and 26th.

6. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

6.1. This section will consider if there are any actions so serious they might amount to gross negligence or any unlawful acts or deliberate unlawful killing in the care of Mr Arthur Cunningham. Also if the actions or omissions by the medical team, nursing staff or attendant GP's contributed to the demise of Mr Cunningham, in particular, whether beyond reasonable doubt, actions or admissions more than minimally,

negligently or trivially contributed to death.

6.2. Mr Cunningham's two main problems were lumbar spinal fusion as a result of a war injury, which left him his weakness in his lower legs and his progressive neurological disease, Parkinson's disease. Parkinson's disease is a degenerative disease of the central nervous system, which causes tremor, body rigidity and akinesia (stiffness in movement). It was first noted in 1980 presenting with a tremor, he was certainly on treatment by 1987. The natural history is often a good response to treatment over 5 years and then gradual increasing problems. Late Parkinson's disease becomes increasingly difficult to control with drugs; the patients get difficulty in swallowing, severe constipation, and often in later stages a dementing illness.

6.3. There are complications with the drugs as the disease progresses, as the drugs are harder to keep in an effective therapeutic range. Too much and the patients get marked writhing or shaking movements call dystonias, too little and the patient may cease up completely. The longer-term side effects of the drugs also include postural hypotension (loss of blood pressure when standing, leading to falls) and mental state deterioration, including hallucinations. To try and combat this, complex regimes are used with multiple doses at different times of days, sometimes combined with other drugs. There is no cure for the condition.

6.4. In 1992 he is troubled with kidney stones but has an uneventful operation.

6.5. In 1994 he has a decline in his conditions with reduced mobility. This is a multiple factorial problem caused by his Parkinson's disease, weak legs as a result of his war injury and his obesity of 102 kgs. He is now living alone as his wife had died in 1989. He uses an electric wheelchair effectively and his Barthel is 17 but most of the help he currently needs is with dressing.

6.6. Further problems occur include hypertension, which is treated in 1995, and diabetes mellitus (high blood sugar), which is diagnosed later in the year.

6.7. By September 1987 he is getting considerable problems in managing his mobility as well as his Parkinsonian drug regime with significant dystonic movements. He is now on multiple drugs to treat his various medical conditions. He is referred to the Day Hospital for more physiotherapy to try and support him and to change his drug regime but he cancels further appointments in November 1997 (355).

6.8. By March 1998 (141) when he is seen in the Day Hospital within the Outpatients it mentions that he was now in Solent Cliff Nursing Home, though when seen in June 1998 (345) he has moved to the Merlin Park Residential Home. Throughout this gentleman's last illness there is a pattern of him being persistently dissatisfied with the care he receives, either in hospital or in the various homes he is cared for in, leading to multiple moves. This often complicates assessment as one institution never gets entirely used to him, his management and his behaviour.

6.9. By June 1998 there is now a very marked change in his health. There has been massive weight loss from 102 kgs in 1994 (441), 84 kgs in October 1997 (629) to 68.7 kgs documented by July 1998 (339). He is walking very unsteadily, is having falls in the home, having hallucinations at night, he is depressed and has marked dystonic movements. He is not happy with the suggestion that he actually needs less medication rather than more to help manage his condition.

6.10. Whether the result of genuine unhappiness with the home or depression on top of what is now probably becoming an early dementing illness (his mental test score on 22nd June (343) was 23/29), he refuses to stay at Merlin Park. Social Services become involved and he is seen in the Day Hospital when no new acute problems on top of his known chronic problems are detected. Social Services manage to place him in the Alvestoke Nursing Home (341).

6.11. However, he is not happy at all with this placement when he is seen in the Day Hospital on 6th July 1998 (339). The plan is to investigate his weight loss and to reduce his Sinemet treatment. His Barthel is now 9/20. A further medical complication that has developed, probably since early 1997 (68), is that he has an abnormality of his full blood count with a reduced white cell count and a reduced platelet count. This suggests a problem with his bone marrow. Although the blood film say this is likely to be myelodysplagia (a pre-malignant condition of the bone marrow where there is partial bone marrow failure, but it has not progressed to Leukaemia) no definitive haematological investigations appear to have been undertaken. The main effect of this condition is he is likely to be much more susceptible to infections.

6.12. He is seen by the psychiatric team on 8th July (117) and then is admitted to hospital on 21st July to Mulberry Ward with a primary diagnosis of depression, probably on top of an underlying mild dementing illness (67). For the first time a bed-sore is noted in the nursing notes (293) although this is not commented on in the thorough medical clerking that was undertaken on admission (66).

6.13. There is no doubt that there has been a very significant decline in this gentleman's general health. He has now lost over 40 kgs of weight, including 25% of his body weight in the last year. He had rapidly declining mobility, an early bedsore, he has started to develop mental impairment and his Parkinson's disease has become increasingly difficult to manage.

6.14. Admission is characterised by descriptions of restless and demanding behaviour and occasionally aggression. I suspect he has a low-grade delirium (delirium is acute confusion on top of, in this case, an early underlying dementing illness). Probably being caused by a combination of his drugs and the urinary tract infections that are documented on serial urine samples. He is started on drugs for his (understandable) depressive illness, which in themselves may complicate his drug regime. Finally he is treated with major tranquillisers to try and control his moods and behaviours.

6.15. The outcome of this admission is that he is now on multiple medications to try and control multiple symptoms. Yet there is very little improvement or change in his behaviour, as noted in the nursing cardex.

6.16. He is planned to the Thalassa Nursing home on 28th August as his 4th residential move of the year. However, on the 25th August he is noted to be passing less urine and a blood test on 26th August shows that he has gone into quite significant acute renal failure. On examination he is found to be in retention of urine and is catheterised and two litres of urine is passed (91).

6.17. The retention of urine in itself is likely to have had multi-factorial causes, including the drugs he was on, his proven urinary tract infections and he may also have had an undiagnosed prostatic problems based on a raised PSA (179). However, he responds well to catheterisation and his renal function is dramatically improved by 28th when he is discharged, with a Urea of 15.6 and a Creatinine of 144 (173).

6.18. Following discharge things appear to go not too badly, the CPN seeing him on 11th September (99) states that his mood seems good and he is settled well. On 14th September when he is seen in the Day Hospital, his weight remains unchanged on 68.6 kgs (323) "he is brighter and says eating not too badly" (459). However, his blood pressure is rather low on 14th September at 108/58 (323) and the pressure sore must be causing concern as a swab is sent (317).

6.19. He then has a routine review, for a therapist assessment on 17th September. The nursing notes give a clue that he is quite unwell that day (908 and 909), they refer to the pressure sore now exudating

markedly, he would not comply with his dressings, he would not wake up after bed rest and was refusing to eat or drink. He was apparently expressing a wish to die. This suggests to me he was acutely delirious again and the underlying aetiology could well be sepsis from pressure sore or sepsis (which is very common) from his urinary tract after a recent catheterisation. The nursing notes say that he is seen by the consultant but I was not able to find any medical notes. The nursing notes suggest that Dr Lord considered that she needed to review him on 21st and might need admission at this stage. It is below normal acceptable good medical practice to not make a record when seeing a patient, particularly if there has been a significant change in their condition.

6.20. Mr Cunningham is reviewed again on 21st September (642) when he has rapidly deteriorated, is very ill and very frail. He has an offensive large necrotic sacral ulcer and is not able to swallow with tablets in his mouth. He is admitted to hospital appropriately. Dr Lord asked for a management plan, including nursing him on his side, a high protein diet, Oramorph PRN for pain and writes to the nursing home to keep the bed open for three weeks at least, the prognosis is poor.

6.21. This gentleman is very seriously ill, with multiple problems and has been in decline for at least three months. The consultant has to make a judgement whether these are easily reversible problems, which would need intensive therapy, including drips and surgery to the pressure sore in an acute hospital environment or whether this is likely to be the terminal event of a progressive physical decline.

6.22. In my view the combination of acute problems on top of his known progressive chronic problems, including the large necrotic pressure ulcer would mean that active treatment in an acute DGH was very likely to be futile and therefore inappropriate. It was appropriate to admit him into a caring environment for pain relief and to observe and provide symptomatic support. In my experience it is unusual for a consultant to write "poor prognosis" in the notes unless they believe the patient is terminally ill and death is likely to be imminent.

6.23. He is admitted to the ward, Dr Barton sees him and writes, "make comfortable" in the notes (645). As the patient has just been seen and examined by a consultant who has made a care plan, I think it is reasonable for no further clerking or examination to have been carried out, although many doctors would automatically do that, if briefly, so that they know the baseline of the patient. As suggested Oramorphine is written up and Mr Cunningham receives two doses on 21st.

6.24. However, a syringe driver has also been written up on admission (756) for Diamorphine and Midazolam. There is nothing in the medical notes that specifically explain why was it written up, when the drugs should be started or what dose. It would be normal medical practice to write a comment on such management plan in the notes, but it is not negligent by itself, to fail to do so.

6.25. The nursing notes state that he remains agitated, pulling off his dressings later in the day (880). A decision is made, with the drugs written up (who decides?) to start him on Diamorphine 20 mgs with 20 mgs of Midazolam in a syringe driver.

6.26. The dose of Diamorphine is within an acceptable starting range for patients in pain. Midazolam is also widely used for terminal restlessness; the dose prescribed is from 5 – 80 mgs per 24 hours. The starting dose is within the range of 5 – 20 mgs per 24 hours that is acceptable for older patients (Palliative Care. Chapter 23 in *Brocklehurst's Text Book of Geriatric Medicine* 6th Edition 2003). Diamorphine is compatible with Midazolam and can be mixed in the same syringe driver. As the patient was terminally ill and restless, despite his previous doses of Omnopon, I think this was a reasonable management decision.

6.27. By 29th he is clearly delirious and is now totally dependent with a Barthel of 0/20. There does not appear to have been very good communication with the Son as anxieties are raised about his management (868). The dose of Diamorphine and Midazolam remain unchanged on 22nd and 23rd, although he is a little agitated at night on 23rd (876) and both day and night staff report pain on 24th (869). At this stage Diamorphine is increased to 40m mgs and the Midazolam to 80 mgs. In my view, the dose of Diamorphine prescribed was appropriate, however the four-fold increase in Midazolam 20 mgs on the 23rd to 80 mgs on the 24th appears excessive.

6.28. After the pain on 24th there is no further distress noted in either the medical notes (645) or the nursing notes (869). Despite this, the Diamorphine is increased to 60 mgs a day on 25th and 80 mgs on the 26th and the Midazolam is put up to 100 mgs a day on the 26th. In my view it was reasonable to increase the palliative care regime of Diamorphine and Midazolam on both 23rd and 24th September. He was in pain and he was agitated. It might well have been better to increase the Diamorphine (as pain does seem to be a major issue here with the bed-sore) rather than the Midazolam to ensure that this dying man was symptom free and did require an increase in medication on the 24th.

6.29. The dose of Diamorphine is then increased on both the 25th and 26th to 60 then 80 mgs (837) and Midazolam is increased again on 26th September to 100 mgs. There is no justification given for this in either the nursing or the medical notes, nor at any stage is it possible to tell from the notes whether the decision to change the drug dosages was a medical or a nursing decision or which doctor or nurse made that decision.

6.30. In my view the dose of Diamorphine and Midazolam was excessive on 25th and 26th and the medication may have slightly shortened life. However, I cannot find evidence to satisfy myself to the standard of "beyond reasonable doubt". I would have expected a difference of at most, no more than a few hours to days if a lower dose of either or both of the drugs had been used instead during the last few days.

7. OPINION

7.1. Arthur Cunningham is an example of a complex and challenging problems in geriatric medicine. He suffered from multiple chronic diseases and gradually deteriorated with increasing medical and physical dependency. It is always a challenge to clinicians to identify the point to stop trying to deal with each individual problem or crisis, to an acceptance the patient is now dying and that symptom control is appropriate.

7.2. In my view, Mr Cunningham was managed appropriately, including an appropriate decision to start a syringe driver for managing his symptoms and agitation as part of his terminal illness in September 1998.

7.3. My one concern is the increased dose of Diamorphine in the syringe driver on 25th and 26th September 1998, as I was unable to find any justification for this increase in dosage in either the nursing or the medical notes. In my view this increase in medication may have slightly shortened life for at most no more than a few hours to days, however, I am not able to find evidence to satisfy myself that this is to the standard of "beyond reasonable doubt".

8 LITERATURE/REFERENCES

1. Good Medical Practice, General Medical Council 2002
2. Withholding withdrawing life, prolonging treatments: Good Practice and decision making. General Medical Council 2002.
3. Palliative Care, Welsh J, Fallon M, Keeley PW. Brocklehurst Text Book of Geriatric Medicine, 6th Edition, 2003, Chapter 23 pages 257-270.
4. The treatment of Terminally Ill Geriatric Patients, Wilson JA, Lawson, PM, Smith RG. Palliative Medicine 1987; 1:149-153.

5. Accuracy of Prognosis, Estimates by 4 Palliative Care Teams: A Prospective Cohort Study. Higginson IJ, Costantini M. BMC Palliative Care 2002:1:129
6. The Palliative Care Handbook. Guidelines on Clinical Management, 3rd Edition. Salisbury Palliative Care Services, May 1995.

9. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters, which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report, which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

10. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Version 2 of complete report 11th July 2005 – Arthur Cunningham

Signature:_____ **Code A** _____ Date: 12/7/05

12

DRAFT REPORT

regarding

ARTHUR DENNIS BRIAN CUNNINGHAM (BJC/15)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mr Cunningham was a frail 79 year old widower who lived in a nursing home. He had suffered from Parkinson's disease for many years and had an abnormal blood count possibly due to myelodysplastic syndrome. He had longstanding back pain due to an old war injury, that required maximal doses of weak (step 2) opioids. His behaviour could be difficult and this was the reason for a recent admission under the care of Dr Banks, consultant in old age psychiatry. During this admission, his abnormal behaviour and disturbed nights were considered to be due to a combination of depression and dementia. An antidepressant (mirtazapine), a mood stabiliser (carbamazepine), an antipsychotic (risperidone) and a sedative/hypnotic (triclofos) were commenced. These resulted in an improvement in Mr Cunningham's mood and sleep, which was maintained after his return to the nursing home.

Mr Cunningham was followed up at Dolphin Day Hospital on the 14th, 17th and 21st September 1998. Over this time, his sacral pressure sore worsened despite antibiotics and his general condition appeared to deteriorate; he was difficult to wake and was refusing to talk, drink or swallow medication and expressing a wish to die. On the 21st September and was admitted direct to Dryad Ward for treatment of the sore, a high protein diet and for 'oramorph (morphine solution) p.r.n. 'as required' if pain'. Dr Lord noted that Mr Cunningham's prognosis was poor but asked that the nursing home keep the bed open for the next three weeks at least.

During this admission, the medical care provided by Dr Barton fell short of a good standard of clinical care as defined by the General Medical Council that included the lack of clear note keeping, adequate assessment of the patient

and the prescription of a large dose range of diamorphine (up to 200mg) that was likely to be excessive to Mr Cunningham's needs. The lack of access to stat SC doses of diamorphine and midazolam, made some of the increases in the doses of diamorphine and midazolam he received in the syringe driver difficult to justify, especially when the increment was larger than generally seen. Further, other strategies of managing Mr Cunningham's pain on turning that may have been more successful were not pursued. In this regard, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mr Cunningham by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mr Cunningham by unnecessarily exposing him to the risk of receiving excessive doses of diamorphine. In the event, however, Mr Cunningham did not receive such high doses.

Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mr Cunningham a peaceful death, albeit with what appears to be a lack of sufficient knowledge regarding the use of diamorphine as detailed above. In my view, Mr Cunningham was dying in an expected way, the use of diamorphine, midazolam and hyoscine were justified given that both his chronic pain and behavioural disturbances required medication, and subsequently for retained secretions in his terminal phase. The starting doses used and the doses he subsequently received of diamorphine, midazolam and hyoscine were not unusual and had been arrived at in a step wise fashion. Although in my view, alternatives existed that would have better managed his pain on turning, other practitioners may well have followed a similar course to Dr Barton.

2. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to his death against the acceptable standard of the day. Where appropriate, if the care is felt to be suboptimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

3. ISSUES

3.1 Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

3.2 If the care is found to be suboptimal what treatment should normally have been proffered in this case?

3.3 If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

4. BRIEF CURRICULUM VITAE

Code A

Code A

5. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Arthur Dennis Brian Cunningham, including the entry in the Death Register.

[2] Full set of medical records of Arthur Dennis Brian Cunningham on CD-ROM.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] *Hampshire Constabulary Operation Rochester Guidance for* Medical Experts.

[5] Hampshire Constabulary Summary of Care of Arthur Cunningham.

[6] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

[7] Portsmouth Health Care NHS Trust Policies:

i) Control of Administration of Medicines by Nursing Staff Policy (January 1997).

ii) Prescription Writing Policy (July 2000).

iii) Policy for Assessment and Management of Pain (May 2001).

iv) Compendium of Drug Therapy Guidelines, Adult Patients (1998).

v) Draft Protocol for Prescription Administration of Diamorphine by Subcutaneous Infusion, Medical Director (December 1999).

vi) Medicines Audit carried out by the Trust referred to as Document 54 on page 52 in the Chi Report (reference 6).

[8] General Medical Council, Good Medical Practice (July 1998).

[9] British National Formulary (BNF). Section on Prescribing in Terminal Care (March 1998).

[10] British National Formulary (BNF). Section on Prescribing in the Elderly (March 1998).

6. CHRONOLOGY/CASE ABSTRACT

Events at Mulberry Ward, 21st July 1998 until the 28th August 1998

Mr Cunningham, a 79 year old widower who lived in Thalassa Nursing Home was admitted to Mulberry Ward, Gosport War Memorial Hospital (GWMH) under the care of Dr Banks, consultant in old age psychiatry, for

assessment of his physical and mental wellbeing (page 241 of 928). This was precipitated by the staff at the nursing home finding Mr Cunningham's behaviour difficult. It was considered that these behavioural problems related to the combination of depression and dementia (pages 67, 453 of 928). Mr Cunningham also had long-term problems relating to Parkinson's disease, constipation and was known to have an abnormal full blood count (low white cells and platelets; cells that help fight infection and the blood to clot respectively)(pages 67 and 68 of 928). The latter was discussed with Dr Cranfield, consultant haematologist, who considered it probably due to myelodysplastic syndrome (see technical issues) or possibly drug-related and it was noted that 'He [Mr Cunningham] is more susceptible to infection. Medical help should be sought early rather than later' (page 68 of 928). Repeated blood counts however, were stable and satisfactory, e.g. white cells 4.0 (neutrophils 2.8) x 10^9/L and platelets 113 x 10^9/L on the 26th August 1998 (page 191 of 928).

Mr Cunningham was also known to the geriatric services and Dr Lord, who had seen him several times over previous years. This mainly related to his Parkinson's disease (initially diagnosed in 1988) impairing his mobility, and the difficulties encountered with undesirable effects as the dose of his antiparkinsonian medication was increased; these included abnormal involuntary movements (dyskinesia), confusion (with hallucinations) and postural hypotension (low blood pressure on standing)(pages 345, 349, 351, 375, 377 of 928). Mr Cunningham had also injured his lumbar spine and both ankles in an aeroplane crash in 1945, requiring lumbar spine fusion and bone grafts. This led to numbness and weakness in the left leg and he was invalided out of the RAF. Backache, thought related to this

injury, had been reported as a considerable problem but that Solpadol (codeine 30mg and paracetamol 500mg), five to eight a day (i.e. 150–240mg codeine/day) was effective (pages 139 and 375 of 928). Other previous problems included a kidney stone (1992), a transurethral resection for an enlarged prostate (1992), diabetes mellitus (1994), initially tablet and subsequently diet controlled and high blood pressure (pages 7, 50, 65, 375, 445, 305, 379 of 928).

During his stay on Mulberry Ward, Mr Cunningham was commenced on an antidepressant, mirtazapine (page 71 of 928). It was noted that he would often call out for the first couple of hours in bed (page 72 of 928). The nurses commented that it took a long time to get him comfy at night having to make adjustments to his back rest and pillows etc. (page 72, 73 and 80 of 928) and he did complain of pain in the base of his spine (page 73 of 928). On the 4th August 1998, this led to his paracetamol being switched for co-proxamol 2 tablets four times a day, a similar strength analgesic to the Solpadol he had required before (page 80 of 928).

On the 17th August 1998 he had a very disturbed night with shouting and was subsequently commenced on an anti-epileptic drug carbamazepine 100mg at night (page 87 and 161 of 928), presumably as a mood stabiliser. The following night he was described as confused with paranoid and delusional ideas (page 87 of 928) and a sedative, triclofos 20ml (2g) at night was added. It was commented that this would be for a few nights, although this was continued long-term (page 88 and 161 of 928). Due to ongoing problems, on the 19th August 1998, an 'atypical' antipsychotic risperidone 0.5mg was added at 6pm (page 88 of 928). An antipsychotic is usually indicated in confused patients with paranoid and delusional ideas.

However, they risk worsening Parkinson's disease (see technical issues) and this may be why other approaches were tried first. An 'atypical' antipsychotic like risperidone would be less likely to worsen Mr Cunningham's Parkinson's disease compared to a 'typical' antipsychotic such as haloperidol. Mr Cunningham's mood and nights subsequently improved.

On admission to Mulberry ward, the skin over Mr Cunningham's pressure areas was intact (page 248 of 928). He was, however, at high risk of pressure sore development, scoring 19–20 on a Waterlow Score (>15 indicates high risk; >20 a very high risk of pressure sore development)(page 309 of 928). On or around the 23rd August 1998, a nursing care plan was started for a broken area on his sacrum that was treated with a thin DuoDERM dressing (page 293 of 928).

Mr Cunningham also had two urinary tract infections requiring antibiotics (pages 205 and 207 of 928) and developed renal impairment due to urinary retention, necessitating urinary catheterisation, following which his kidney function improved (urea 15.6mmol/L, creatinine 144micromol/L)(pages 173 and 175 of 928).

Mr Cunningham was reviewed by Dr Lord whilst on Mulberry Ward. Initially Dr Lord considered that his Parkinson's disease was stable and that his deteriorating mobility was more likely related to a weak pelvic girdle due to his old spinal injury (pages 74 and 105 of 928). Dr Lord suggested continuing the same dose of his antiparkinsonian medication (l-dopa) and to only add an extra controlled release formulation (Sinemet CR) at night if thought necessary. This was subsequently added by Dr Bank's team the same day (page 75 of 928). On a subsequent review on the 27th August

1998, Dr Lord considered that Mr Cunningham's Parkinson's disease had indeed deteriorated (pages 91, 92, 97 of 928) and offered to follow him up at Dolphin Day Hospital. Dr Lord also noted that Mr Cunningham was eating better and had gained weight from 65.5 to 69.7kg during his admission (pages 325, 327 and 329 of 928).

Mr Cunningham was discharged from Mulberry Ward on the 28th August 1998 on the following medication: Careldopa as Sinemet-110 (carbidopa 10mg/levodopa 100mg) one tablet four times a day; careldopa as Sinemet CR (carbidopa 50mg/levodopa 200mg) one tablet at night (*antiparkinsonian medication*); co-proxamol two tablets four times a day (*analgesic*); mirtazapine 30mg at night (*antidepressant*); risperidone 0.5mg at 6pm (*'atypical' antipsychotic*); triclofos 20ml (2g) at night (*hypnotic*); carbamazepine 100mg at night (*anti-epileptic; mood stabiliser*); amlodipine 5mg once a day (*for high blood pressure*); co-danthramer two capsules at night; magnesium hydroxide 10mg twice a day; senna two tablets at night (*laxatives*) (pages 162, 453 of 928).

Mr Cunningham's improved mood and nights appear to have been maintained on his return to Thalassa Nursing home; on the 11th September 1998, a community psychiatric nurse noted 'settled well back at the Nursing Home....no management or behavioural problems... Compliant, mood seems good' (pages 93 and 99 of 928).

Events at Dolphin Day Hospital, 14th September 1998 until 21st September 1998.

Mr Cunningham was reviewed by a doctor at Dolphin Day Hospital on the 14th September 1998. Due to increasing stiffness from his Parkinson's

disease, the careldopa (Sinemet-110) was increased to five times a day. Other plans were to liaise with the nursing home about his bowel habit, with a view to rationalising his laxative therapy, and his behaviour/sleep with a view to stopping his benzodiazepine p.r.n. ('as required'). It is unclear if Mr Cunningham was still taking a benzodiazepine p.r.n. He was not given a supply of diazepam on discharge from Mulberry Ward (pages 162, 163 of 928). The Dolphin Day Hospital nursing records note that Mr Cunningham reported that he was happy at Thalassa, that the nursing home staff said his bowels were satisfactory and that he slept well. The nursing staff at Dolphin Day Hospital were aware of his sacral sore and took a photograph (page 639 of 928); they clarified that he had a pressure relieving Spenco mattress and wheelchair cushion at the nursing home. The nursing home staff were asked to redress the sore later that week and it would be checked again at Mr Cunningham's next day hospital attendance (page 907 and 908 of 928).

Mr Cunningham next attended Dolphin Day Hospital on the 17th September 1998. It was noted that his sacral pressure sore appeared infected and he was commenced on an antibiotic, metronidazole 200mg three times a day (page 317, 459 of 928). The nursing notes entry for this visit report that the occupational therapist (OT) was to order a wheelchair and a Roho cushion. They noted that the pressure sore was exuding++ but not redressed due to reduced compliance from Mr Cunningham, although no specific details are given. It was noted that he would not wake after a rest on bed and was refusing to talk, drink or swallow medication but expressed a wish to die. It was noted he was seen by Dr Lord, and that the

plan was to possibly admit him when next reviewed (pages 908, 909 of 928).

On the 21st September 1998, Mr Cunningham was reviewed at Dolphin Day Hospital by Dr Lord who noted that he was very frail. Tablets were found in his mouth some hours after they had been given. There was an offensive smelling large necrotic sacral ulcer with a thick black scar and grazes over his buttocks (photographed, page 64 of 928). In addition there was a small black scar and redness over the left lateral malleolus (ankle). Dr Lord listed Mr Cunningham's problems as 'sacral sore (she specified 'in nursing home' possibly meaning that this is where it developed. My understanding is that it started during his admission to Mulberry ward, but considerably worsened at the nursing home), Parkinson's disease (she considered this no worse), old back injury, depression and element of dementia, diabetes mellitus – diet (controlled) and catheter for urinary retention' (page 642 of 928). Dr Lord admitted Mr Cunningham direct to Dryad Ward that day, stopped the amlodipine (his blood pressure was normal/low for someone his age), the co-danthramer laxative (this can irritate the skin around the perineum/sacrum), the metronidazole and asked for Mr Cunningham be nursed on his side and to apply Aserbine to the sacral ulcer; this is a desloughing agent, that helps to ablate local infection. She also noted that Mr Cunningham should receive a high protein diet and 'oramorph (morphine solution) p.r.n. 'as required' if pain' (page 643 of 928). Dr Lord asked that the nursing home keep the bed open for the next three weeks at least and noted that Mr Cunningham was agreeable with the admission. Dr Lord also noted that Mr Cunningham's prognosis was poor (page 457, 642, 643, 909 of 928).

Events at Dryad Ward, Gosport War Memorial Hospital, 21st September 1998 until 26th September 1998.

21st September 1998

An entry in the medical notes reads 'Transfer to Dryad Ward. Make comfortable. Give adequate analgesia. I am happy for nursing staff to confirm death' (page 645 of 928). The drug chart used in the day hospital was continued as an inpatient. This revealed that Mr Cunningham had prescriptions for regular co-proxamol, mirtazapine, risperidone, Sinemet-110, Sinemet CR, senna, carbamazepine, magnesium hydroxide and triclofos. Prescriptions for his amlodipine, co-danthramer and metronidazole had been crossed out (pages 753, 755 of 928). On the p.r.n. 'as required' section Oramorph 2.5–10mg up to every four hours and Actrapid insulin 5–10 units according to a sliding scale were prescribed (page 752 of 928). On another section, the where the word 'regular' prescription has been crossed out and replaced with p.r.n. and circled, Mr Cunningham was also prescribed diamorphine 20–200mg, hysocine (hydrobromide) 200–800microgram and midazolam 20–80mg all subcutaneously (SC) over 24h (page 756 of 928). Finally, he was prescribed metrotop, a topical antibiotic gel (page 756 of 928). Mr Cunningham received 5mg oramorph at 14.50pm and 10mg at 20.15pm (page 753 of 928). A syringe driver containing diamorphine 20mg and midazolam 20mg was commenced at 23.10pm (page 756 of 928).

At 18.00h Mr Cunningham took co-proxamol (but none thereafter), Sinemet-110 and magnesium hydroxide. Following his admission, it does

not appear as though Mr Cunningham received any mirtazapine, risperidone, Sinemet CR, carbamazepine or triclofos (753 and 755 of 928). The 'Exception to prescribed orders' section of the drug chart gives 'sedated' as the reason that Mr Cunningham did not receive his co-proxamol, Sinemet CR and senna at 22.00h (page 754 of 928).

The nursing summary notes read 'Admitted from DDH with history of Parkinson's, dementia and diabetes diet controlled diabetic. Catheterised on previous admission for retention of urine. Large necrotic sore on sacrum. Seen by Dr Barton. Dropped left foot. Back pain from old spinal injury. 14.50h Oramorph 5mg given prior to wound dressing. A later entry notes 'Remained agitated until approximately 20.30h. Syringe driver commenced as requested. Diamorphine 20mg, midazolam 20mg at 23.00h. Peaceful following (page 867 of 928).

The nursing care plan entry relating to the ulcers notes 'Dressing applied to buttock at 18.30h. Aserbine cream to black necrotic area and zinc and caster oil to surrounding skin: very agitated at 17.30pm, Oramorph 10mg/5ml at 20.20pm. Pulled off dressing to sacrum (page 880 of 928).

Nursing care plan entry relating to settling for the night notes 'Driver commenced at 23.10pm containing diamorphine 20mg and midazolam 20mg. Slept soundly following. BS (blood sugar) at 23.20pm 3.4mmol/L. 2 glasses of milk taken when awake. Much calmer this am. Sacral sore oozing but left exposed as requested' (page 876 of 928).

22nd September 1998

The drug chart reveals that Mr Cunningham took doses of Sinemet-110 at 06.00, 09.00, 12.00 and 18.00h, magnesium hydroxide at 09.00h and

senna at 22.00h (page 753 and 755 of 928). The 'Exception to prescribed orders' section of the drug chart gives 'not in stock' as the reason that Mr Cunningham did not receive his Sinemet CR and carbamazepine and 'on syringe driver' as the reason he did not receive the triclofos at 22.00h (page 754 of 928).

The nursing summary notes read 'Mr Farthing has telephoned. Explained that a syringe driver containing diamorphine and midazolam was commenced yesterday evening for pain relief and to allay his anxiety following an episode when Arthur tried to wipe sputum on a nurse saying he had HIV and was going to give to her. He also tried to remove his catheter and emptied the bag and removed his sacral dressing throwing it across the room. Finally, took off his covers and exposed himself (page 867 of 928). Syringe driver changed to 20.20h contains diamorphine 20mg and midazolam 20mg, appears less agitated this evening (page 868 of 928).

Nursing care plan relating to the ulcer notes '23.00h. Dressing came off. Reapplied as above' (page 880 of 928). Further entries on the 24th, 25th and 26th of September all report renewal of the dressing with no comments that it was of any discomfort or distress to Mr Cunningham (page 880 of 928).

Nursing care plan entry relating to settling for the night notes 'Driver running as per chart. Very settled night. Blood sugar 5mmol/L at 06.00h (page 876 of 928).

23rd September 1998

The drug chart reveals that Mr Cunningham took Sinemet-110 at 06.00h (page 753 of 928). The 'Exception to prescribed orders' section of the drug chart gives 'unable to take' as the reason that Mr Cunningham did not subsequently receive his co-proxamol, risperidone, Sinemet-110, carbamazepine and triclofos (page 754 of 928). A syringe driver containing diamorphine 20mg, hyoscine 400micrograms and midazolam 20mg SC over 24h was commenced at 09.25h. This was discarded at 20.00h to be replaced by one containing diamorphine 20mg, hyoscine 400microgram and midazolam 60mg (page 756 of 928).

The nursing summary notes read 'Seen by Dr Barton. Has become chesty overnight to have hyoscine added to driver. Stepson contacted and informed of deterioration. Mr Farthing asked if this was due to the commencement of syringe driver and informed that Mr Cunningham was on a small dosage which he needed. To phone him if any further deterioration' (page 868 of 928) An entry timed 13.00h reads 'Mr and Mrs Farthing seen by me - Sister Jean Hamblin and Staff Nurse Freda Shaw. Very angry that driver had been commenced. It was explained yet again that the contents of his syringe driver were to control his pain. It was also explained that the consultant would need to give her permission to discontinue the driver and we would need an alternative method of giving pain relief. Has also been seen by Pastor Mary for 1½h this afternoon. He is now fully aware that Brian is dying and needs to made comfortable. Driver renewed at 20.20h with diamorphine 20mg, midazolam 60mg and hyoscine 400microgram. Family have visited. (page 868 of 928).

Nursing care plan entry relating to settling for the night notes 'Became a little agitated at 23.00h, syringe driver boosted with effect. Seems in some

discomfort when moved, driver boosted prior to position change. On back at time of report. Sounds chesty this morning. Catheter draining urine very concentrated (page 876 of 928).

24th September 1998

Entry in the medical notes reads 'Remains unwell. Son has visited again today and is aware of how unwell he is. SC analgesia is controlling pain just. I am happy for nursing staff to confirm death.' This note is written out of sync, most likely in error, on the page preceding the first inpatient entry (pages 643, 645 of 928).

At 10.55h a syringe driver containing diamorphine 40mg, hyoscine 800microgram and midazolam 80mg was commenced (page 756 of 928).

The nursing summary notes read 'Report from night staff that Brian was in pain when being attended to. Also in pain with day staff especially his knees. Syringe driver renewed at 10.55 with diamorphine 40mg, midazolam 80mg and hyoscine 800micrograms. Dressing renewed this afternoon – see care plan. Son – Mr Farthing seen by Dr Barton this afternoon and is fully aware of Brian's condition. In the event of death, Brian is for cremation' (page 869 of 928). A later entry timed 21.00h notes 'Mr Cunningham's grandson telephoned, informed of grandfathers condition. Nursed on alternate sides during night, is aware of being moved. Sounds "chesty" this morning. Catheter draining (page 869 of 928).

Nursing care plan entry relating to settling for the night notes 'All care given, nursed from side to side. Peaceful nights sleep. Syringe driver running as prescribed. On back at time of report. Starting to sound chesty this morning (page 876 of 928).

25th September 1998

An entry in the medical notes reads 'Remains very poorly. On syringe driver. For TLC (tender loving care)' (page 645 of 928).

A new drug chart was written with prescriptions for diamorphine 40–200mg, hyoscine 800microgram–2g and midazolam 20–200mg all SC over 24h (page 837 of 928). Mr Cunningham received a syringe driver containing diamorphine 60mg, hyoscine 1200micrograms and midazolam 80mg (page 837 of 928).

The nursing summary notes read 'All care given this a.m. Driver recharged at 10.15h, diamorphine 60mg, midazolam 80mg and hyoscine 1200microgram.....Son present at time of report, carer also visited' (page 869 of 928).

Nursing care plan entry relating to settling for the night notes 'peaceful night, position changed still does not like being moved' (page 876 of 928).

26th September 1998

An entry was made in the medical notes by nurses Turnbull and Tubbritt to confirm Mr Cunningham's death at 23.15h (page page 645 of 928).

A syringe driver containing diamorphine 80mg, hyoscine 1200microgram and midazolam 100mg was commenced at 11.50h (page 837 of 928).

The nursing summary notes read 'Condition appears to be deteriorating slowly. All care given. Sacral sore redressed, mouth care given. Driver recharged and 11.50h, diamorphine 80mg, hyoscine 1200micrograms, midazolam 100mg. No phone calls from family this a.m. Mrs Sellwood phoned to enquire on condition (page 869 of 928). A later entry timed

'night' reads 'Brian's condition continued to deteriorate' and noted that he died at 23.15h (page 869 and 872 of 928).

Nursing care plan entry relating to settling for the night notes 'Condition continued to deteriorate. Relatives informed. Arthur died peacefully at 23.15h' (page 876 of 928).

28th September 1998

An entry in the medical notes by Dr Brook reads 'Death certificate (D/W (discussed with) Dr Lord). I. Bronchopneumonia, II. Parkinson's disease, sacral ulcer (page 645 of 928). I note that the copy of the entry in what I have assumed to be the death register, records cause of death as Ia. Bronchopneumonia only (supplied by Hampshire Constabulary).

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Myelodysplastic syndrome

This is a disorder of the stem cells in the bone marrow that reduces the effective production of various types of blood cells. It is characterised by a progressive fall in one or more of the red, white or platelet cell counts causing, for example, anaemia, reduced immunity to infections or an increased risk of bleeding; 30–40% of patients die of infection ± bleeding. In 20–40% of patients it transforms into a leukaemia.

ii) Syringe drivers, diamorphine, midazolam, haloperidol, levomepromazine (nozinan) and hyoscine hydrobromide

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24h. Indications for its

use include swallowing difficulties or a comatose patient. In the United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF number 29 (March 1995)). Others sometimes suggested dividing by 2 or 3 depending on circumstance (Wessex protocol). Hence, 60mg of morphine taken orally a day could equate to a daily dose of 20 or 30mg of diamorphine SC. It is usual to prescribe additional doses for use 'as required' in case symptoms such as pain breakthrough. The dose is usually 1/6th of the 24h dose. Hence for someone receiving 30mg of diamorphine in a syringe driver over 24h, a breakthrough dose would be 5mg. One would expect it to have a 2–4h duration of effect, but the dose is often prescribed to be given hourly if required. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated

without being drowsy. Most practitioners caring for patients with cancer in their terminal phase would generally aim to find a dose that improves the patients' symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg a day. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (March 1995) recommends 20–100mg SC over 24h. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated every 24h if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24h, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4h, and it may need to be given more frequently. As an active metabolite of midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

Haloperidol is an antipsychotic. It is frequently used in syringe drivers for its antipsychotic and anxiolytic effects in patients with terminal delirium/agitation or as an anti-emetic. Compared to other antipsychotics, like levomepromazine, it is less sedative but can cause more problems with extrapyramidal effects and should be used with caution in patients with parkinsonism or Parkinson's disease. Extrapyramidal effects include parkinsonism, acute dystonia, acute akathesia and tardive dyskinesia. Parkinsonism consists of tremor, rigidity and slowing of movements; acute dystonia is spasm of muscles including those involving the eyes, head,

neck, trunk and limbs. They are usually abrupt in onset and associated with anxiety; acute akathesia is a form of restlessness of the muscles in which the person is compelled to move or change position and is associated with variable degrees of patient distress; tardive dyskinesia typically presents as involuntary chewing movements of the face and orofacial muscles.

Levomepromazine is an antipsychotic. It is frequently used in syringe drivers for its antipsychotic and anxiolytic effects in patients with terminal delirium/agitation or as an anti-emetic. It is more sedative than haloperidol but less likely to cause extrapyramidal effects.

Hyoscine hydrobromide is an antimuscarinic drug most commonly given to reduce excessive saliva or retained secretions ('death rattle'). It also has anti-emetic, antispasmodic (smooth muscle colic) and sedative properties. Repeated administration can lead to cummulation and this can occasionally result paradoxically in an agitated delirium, highlighted in both in the BNF and the Wessex protocol (page 41). It is usually given in a dose of 600–2400microgram SC over 24h (BNF (March 1995)) or 400–600microgram as a stat SC dose. The Wessex protocol gives a dose range of 400–1200microgram over 24h.

The titration of the dose of analgesic, antipsychotic or sedative medication is guided by the patients symptom control needs. The number and total dose of 'as required' doses needed over a 24h period are calculated and this guides the increase necessary in the regular dose of the drugs in the syringe driver in a way that is proportional to the patients needs. The ideal outcome is the relief of the symptoms all of the time with no need for additional 'as required' doses. In practice, this can be difficult to achieve and the relief of the symptoms for the majority of the time along with the

use of 1–2 'as required' doses over a 24h period is generally seen as acceptable.

iii) Boosting syringe drivers

Given that it was in widespread use, I am assuming that Dryad Ward had access to the Graseby MS26 syringe driver that has a boost button, but this should be clarified. The use of the boost button is generally not recommended as, for example:

1) The dose delivered by the boost is generally insufficient

Generally, the contents of a syringe being delivered by a Graseby MS26 syringe driver would be made up to a certain length, e.g. 50mm to be infused over 24h, i.e. just over 2mm/h. One actuation of the boost button moves the plunger on the syringe driver 0.23mm. In relation to the recommended rescue dose for breakthrough pain, this is likely to be inadequate. For example, a reasonable breakthrough dose is generally 1/6th of the 24h dose and this would equate to about 8mm. Nevertheless, boosting also presents a problem on how the amount and frequency of the boosting is prescribed and how it is recorded by the nursing staff.

2) There is no lockout period

Although each booster dose is small, there is nothing to stop the boost button being repeatedly depressed and released. Hence, the potential exists for the contents of the syringe driver to be administered much more quickly than the intended 24h.

3) The overall duration of the infusion is reduced

This may cause problems in some settings, e.g. the community.

4) There are usually several drugs in the syringe driver

It may only be indicated to boost the dose of one of the drugs in the syringe driver, but all of the contents are unavoidably boosted.

Hence, rather than boosting a syringe driver, usual practice is to ensure that patients have access to stat p.r.n. medication, that they may require to control their symptoms, in appropriate doses to be given subcutaneously, e.g. an analgesic, sedative and antipsychotic.

iv) The principle of double effect

The principle of double effect states that:

'If measures taken to relieve physical or mental suffering cause the death of a patient, it is morally and legally acceptable provided the doctor's intention is to relieve the distress and not kill the patient.'

This is a universal principle without which the practice of medicine would be impossible, given that every kind of treatment has an inherent risk. Many discussions on the principle of double effect have however, involved the use of morphine in the terminally ill. This gives a false impression that the use of morphine in this circumstance is a high risk strategy. When correctly used (i.e. in a dose *appropriate* to a patient's need) morphine does not appear to shorten life or hasten the dying process in patients with cancer. Although a greater risk is acceptable in more extreme circumstances, it is obvious that effective measures which carry less risk to life will normally be used. Thus, in an extreme situation, although it may occasionally be necessary (and acceptable) to render a patient unconscious, it remains unacceptable (and unnecessary) to cause death deliberately. As a universal principle, it is also obvious that the principle of

double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

8. OPINION

Events at Mulberry Ward 21st July 1998 until 28th August 1998

Mr Cunningham was a 79 year old man who suffered from depression and dementia. He also had Parkinson's disease and probable myelodysplasia, which left him more susceptible to infection. He had chronic back pain caused by an injury to his lumbar spine. This meant that it could take a long time to get him comfortable at night, requiring several adjustments to his backrest and pillows. The pain was helped by regular co-proxamol and previously codeine, about 240mg/day, but not by paracetamol alone.

Mr Cunningham was considered to be depressed and was commenced on an antidepressant. His behaviour was erratic and he had a number of disturbed nights. He was subsequently commenced on carbamazepine and triclofos without apparent success. Carbamazepine is an anti-epileptic drug. I am not familiar with its use for a disturbed night per se in the depressed and demented elderly, but I am aware that it can be given as a mood stabilising drug, usually in the setting of a manic-depressive disorder. Triclofos is a chloral hydrate derivative. I am not familiar with the use of triclofos as a hypnotic in the confused, depressed and demented elderly. The addition of the atypical antipsychotic risperidone did however, appear to coincide with an improvement with Mr Cunningham's nights and subsequently during the admission his mood improved. He was at high risk of developing a pressure sore and the skin over his sacrum broke

down during the admission. He developed two urinary tract infections and required catheterisation for urinary retention. By the time of his discharge he was eating better and had gained weight. His mood, behaviour and nights had improved and this was maintained on his return to Thalassa Nursing Home. There are no issues relating to the standard of care or treatment proferred to Mr Cunningham during his admission to Mulberry Ward.

Events at Dolphin Day Hospital, Gosport War Memorial Hospital, 14th September 1998 until 21st September 1998

Mr Cunningham appeared happy at Thalassa and the staff reported that his behaviour was manageable and he slept well. The sacral pressure sore had progressed despite pressure relieving aids at the nursing home. The day hospital staff appropriately examined, photographed, swabbed and redressed the sacral area and arranged follow up. Over the subsequent two visits the sacral pressure sore worsened despite an antibiotic. On the 17th September 1998, Mr Cunningham's physical and mental state appeared to be deteriorating; he was difficult to wake after resting on a bed, refused to talk, drink or swallow medication and expressed a wish to die. When Dr Lord saw Mr Cunningham on the 21st September 1998, tablets were found in his mouth some hours after they had been given. Dr Lord noted that Mr Cunningham was very frail and that his prognosis was poor. Prognostication can be difficult, but increasing immobility and difficulty with swallowing/taking oral medication are recognised poor prognostic factors. However, it does not appear as though Dr Lord necessarily anticipated that Mr Cunningham was imminently dying

as she admitted him for more intensive therapy to his ulcer, as opposed to terminal care; she recommended a high protein diet, indicating that he might live long enough to benefit from this, and asked the nursing home to keep his bed open for the next three weeks at least. Dr Lord also asked that Mr Cunningham receive Oramorph p.r.n. for pain, underlining p.r.n. It should be clarified if this represents an intentional emphasis, and if so, the significance of this. There are no issues relating to the standard of care or treatment proferred to Mr Cunningham during his attendance at Dolphin Day Hospital.

Events at Dryad Ward Gosport War Memorial Hospital 21st September until 26th September 1998

Compared to the notes during Mr Cunningham's stay on Mulberry Ward and attendance at the Dolphin Day Hospital, infrequent entries in the medical notes during his stay on Dryad Ward make it difficult to closely follow Mr Cunningham's progress over the last six days of his life. There are three short entries prior to the confirmation of death, taking up half a page in length. In summary and in approximate chronological order, there is no formal clerking on Mr Cunningham's admission to Dryad ward. Instead, there is a short entry that gives the impression that Mr Cunningham was for terminal care which is at some variance to Dr Lord's assessment. The Oramorph was prescribed p.r.n. as requested by Dr Lord. In addition, diamorphine 20–200mg, hysocine (hydrobromide) 200–800microgram and midazolam 20–80mg subcutaneously (SC) over 24h were prescribed p.r.n. On the 21st September, Mr Cunningham received Oramorph 5mg at 14.50h prior to a wound dressing, which is a reasonable

approach to try and minimise discomfort and an appropriate dose given his existing analgesic use. He was then reported to be very agitated at 17.30h. Nevertheless, he took his regular co-proxamol at 18.00h and a wound dressing applied at 18.30h. At 20.20h he was given Oramorph 10mg. The reason for this is unclear and it should be clarified if the Oramorph was given for pain or anxiety. Oramorph is not indicated for anxiety per se, particularly in the confused elderly, and risks aggravating the confusion. It should be clarified why a 10mg dose was considered necessary rather than repeating the 5mg dose. Given that he was 'sedated' at 22.00h, it is possible that the 10mg dose was excessive for Mr Cunningham.

An entry in the nursing notes on the 22nd September, in response to enquiry by the family, retrospectively reports that the syringe driver was commenced on the 21st September for pain relief and anxiety following an episode the evening before (time not specified) when Mr Cunningham exhibited abnormal and possibly delusional behaviour. Given that Mr Cunningham was prone to such behaviour, it would have been particularly appropriate in my view to ensure that he continued to receive his usual carbamazepine, risperidone, mirtazapine and triclofos as recommended by the old age psychiatry team. It should be clarified why this was not done on the day of his admission. He may have been having difficulty with taking/co-operating with taking oral medication, although he managed some of his medication that day. It should also be clarified who decided to commence the syringe driver containing diamorphine 20mg and midazolam 20mg at 23.10h. Diamorphine is not indicated for anxiety per se, particularly in the confused elderly, and risks aggravating the

confusion. If it was for pain, 20mg is in keeping with the starting dose range (10–20mg/24h) that many would use for a patient with inadequately relieved pain despite the maximal use of co-proxamol/codeine. A number of practitioners probably would use midazolam in this setting, although as it impairs memory, it can sometimes aggravate rather than improve confusion and the use of an antipsychotic is preferable in my view. His Parkinson's would limit the use of the most commonly used antipsychotic, haloperidol, although a small dose of levomepromazine could have been a reasonable alternative in my view (see technical issues). A midazolam dose of 20mg is in keeping with the usual starting dose range (5–30mg/24h).

Nevertheless, most practitioners in my experience, would initially prescribe small stat PO/SC doses of an analgesic, sedative anxiolytic and antipsychotic to be used p.r.n. (e.g. diamorphine 2.5mg, midazolam 2.5mg, levomepromazine 6.25mg respectively would be reasonable given Mr Cunningham's age and frailty). Firstly, this is because the needs of patients vary greatly and makes judging their requirements difficult; sometimes multiple increasing doses are needed; sometimes, a small one-off dose is adequate as the 'crisis' is temporary. For example, whilst there are a number of possible causes for Mr Cunningham's agitation, one may have been that he was a patient with dementia reacting to the initial move to unfamiliar surroundings and unfamiliar staff. In these circumstances, non-drug approaches, maintaining his usual medication and, if necessary, intermittent sedation could be seen as more appropriate initial responses rather than commencing a syringe driver straight away. Hence, the patients' p.r.n. requirements guide the need for regular analgesia/sedation

and the appropriate dose. Secondly, the continuing use of additional p.r.n. doses informs the need to increase the regular analgesia/sedation and guides an appropriate dose increment. It should be clarified why this approach was not considered appropriate for Mr Cunningham.

Mr Cunningham's behaviour did appear to settle on the syringe driver and on the 22nd September there were no reports of pain during the night or when his dressing was reapplied to the sacral ulcer. It is unclear how sedated he was, but he was able to take his Sinemet-110 orally regularly on the 22nd September, but again, no carbamazepine, risperidone, mirtazapine or triclofos were given.

From the 23rd September Mr Cunningham's condition deteriorated; he was unable to take his oral medication and had become chesty. This was most likely the start of a bronchopneumonia. Given his overall condition, biological prospects and his expression of the wish to die, it was reasonable in my view not to pursue aggressive therapy. Hyoscine hydrobromide 400microgram was added to the syringe driver to try and reduce secretions. This was appropriate and the dose within the usual starting dose range (400–600microgram/24h). However, it should be borne in mind that hyoscine can worsen an agitated delirium (see technical issues). Mr Cunningham's son appeared angry that the syringe driver had been commenced and the reasons for this should be further explored. It was explained to him that the consultant would need to give her permission to discontinue the driver. He saw the pastor and subsequently appeared accepting of the situation. It should be clarified if Dr Barton or Dr Lord were made aware of this consultation and Dr Lord specifically asked to comment. As Mr Cunningham was no longer able to take his usual

analgesic and sedative medication, a syringe driver would be clearly indicated at this point. The syringe driver was renewed at 20.00h with an increased dose of midazolam (increased from 20mg to 60mg). It should be clarified who decided to increase the dose and why. There were no comments relating to agitation in the notes prior to its renewal and it is unclear why 60mg was chosen as opposed to an increase to 30mg or 40mg for example. Later, at 23.00h the nursing notes document that the syringe driver was boosted when Mr Cunningham became agitated and also prior to changing his position. It should be clarified what usual practice, guidelines or policy existed on Dryad Ward with regard to boosting syringe drivers. This practice is not generally recommended (see technical issues).

The medical notes entry on the 24th September reports that the analgesia was 'just' controlling Mr Cunningham's pain. It is not clear from the medical notes exactly what pain this relates to, although the night staff had reported he appeared to be in some discomfort on turning and the day staff reported that he was in pain when attended to, especially his knees. No additional details are given that would help in considering appropriate management, e.g. was it short-lived or prolonged etc. Mr Cunningham had Parkinson's disease and was immobile and highly likely to experience muscle and joint stiffness that could lead to pain on turning/moving his knees. Pain on turning, often settles quickly once in the new position. If not, it is usually managed by keeping the number of turns to a minimum, and by giving supplementary stat SC doses of diamorphine ± midazolam prior to turning. Increasing the regular opioid is not always satisfactory, as the dose of opioid required to eliminate all pain on movement can be excessive for the

patient whom for the majority of the time is resting and pain free. A dose of opioid that is excessive to a patients' need is associated with undesirable effects such as nausea, vomiting, sedation, confusion and respiratory depression. Mr Cunningham's diamorphine was increased from 20mg to 40mg. At 100%, this is a greater increment than usual (33-50% of the preceding dose) and it should be clarified why this was felt necessary. Increments of this magnitude may be appropriate, but are usually indicated/justified by the amount of additional p.r.n. doses of diamorphine a patient may be requiring. Mr Cunningham's midazolam was increased from 60mg to 80mg and the hyoscine from 400microgram to 800microgram. Similar to the reasons stated above, providing supplementary stat doses of midazolam prior to turning is often more effective than increasing the regular sedative.

On the 25th September 1998 the dose of the diamorphine in the syringe driver was increased to from 40mg to 60mg (i.e. a 50% increase) and the hyoscine from 800microgram to 1200microgram. There is no entry in the medical notes explaining this but the nursing notes suggest it was for pain on turning. Again, in my experience, when a patient is in pain on turning but at all other times pain free, settled and relaxed, it is more effective and more appropriate to provide additional analgesia and/or sedative prior to turning rather than increase the overall dose.

On the 25th the diamorphine was further increased from 60mg to 80mg (a 25% increment) and the midazolam from 80mg to 100mg. There is no reason documented for this increase and this should be clarified. Mr Cunningham died at 23.15h. Mr Cunningham's death was not unexpected, he was frail, immobile and susceptible to infection. Bronchopneumonia is

the most likely cause of death. I am uncertain why Parkinson's disease and sacral ulcer that appear to have been put on the death certificate were not on the copy of the entry of what I assume to be the death register and this should be clarified.

Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

The overall care given to Mr Cunningham whilst on Mulberry Ward or attending Dolphin Day Hospital, Gosport War Memorial Hospital was not substandard.

The medical care provided by Dr Barton to Mr Cunningham following his transfer to Dryad Ward, Gosport War Memorial Hospital is suboptimal when compared to the good standard of practice and care expected of a doctor outlined by the General Medical Council (Good Medical Practice, General Medical Council, October 1995, pages 2–3) with particular reference to:

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs including, where necessary, an appropriate examination
- in providing care you must keep clear, accurate, and contemporaneous patients records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs, or appliances that serve patients' needs
- in providing care you must be willing to consult colleagues.

Specifically:

i) The notes relating to Mr Cunningham's transfer to Dryad Ward are inadequate. On admission, even when a patient is already known to the service, they are usually clerked highlighting in particular the relevant history, examination findings, planned investigations and care plan.

ii) It is unclear why the syringe driver was prescribed p.r.n. on the 21st September 1998. No instructions were given on the drug chart on when the syringe driver should be commenced, what drugs it should contain, in what dose, how this would be decided and by whom. The dose of diamorphine was initially written as a wide dose range of 20–200mg with no justification given for this in the medical notes. Based on Mr Cunningham's existing opioid dose, whilst a starting dose of 20mg was reasonable, the higher doses are likely to be excessive for his needs. In patients with cancer, it is unusual if opioid requirements have to be increased by more than 3-fold in the terminal phase (check Lancet paper – may need to adjust), i.e. in Mr Cunningham's case, an increase from 20mg to 60mg would not be that unexpected. The need for a 10-fold increase however, i.e. 20mg to 200mg, is rarely necessary and likely to be excessive for his needs. Similarly, the indications for the prescription of the hyoscine hydrobromide and midazolam should have been documented in the medical notes.

iii) It is unclear why Mr Cunningham received the 10mg dose of morphine.

iv) It is unclear why the syringe driver was commenced on the 21st September 1998. The nursing notes retrospectively suggest that the syringe driver was commenced to allay Mr Cunningham's anxiety and pain. It is not clear who decided to start it, the drugs and the doses to use. It should be clarified why, if he was able to take oral medication, his usual medication had not

been offered to him, or if he was unable to take oral medication, why stat SC doses of a sedative or analgesic were not considered appropriate.

v) Justification for continued increase in diamorphine, midazolam and hyoscine. Mr Cunningham's diamorphine was increased four-fold and his midazolam five-fold over a six day period. This appeared from the nursing notes to be due to Mr Cunningham being 'aware of being moved/does not like being moved'. The reason for the final increase is not clear. Mr Cunningham appeared comfortable in between times 'peaceful nights sleep/'peaceful night'. In this setting increasing the regular analgesic/sedative is not always effective in my experience and other strategies could have been considered, e.g. minimising turning, stat SC doses of diamorphine and/or midazolam prior to turning. Dr Barton could have sought advice, particularly when several dose increments had not been effective in preventing Mr Cunningham's apparent distress on turning. Other practitioners may well have followed a similar course of action however.

If the care is found to be suboptimal what treatment should normally have been preferred in this case?

In relation to the above:

Issue i (lack of clear documentation that an adequate assessment has taken place)

A medical assessment usually consists of information obtained from the patient or others and existing medical records (the history), and the findings of a physical examination that is documented in a structured fashion. Although the history can be restricted to the most salient points, it is unusual to omit relevant sections, e.g. past medical history, drug history,

etc. For example, a read through Mr Cunningham's notes from his time on *Mulberry ward, would help a doctor to appreciate the importance of* ensuring the continuation of his mirtazapine, carbamazepine, triclofos and risperidone medication. Or, in circumstances where this may not be possible, providing the use of oral or, if unable to use the oral route, subcutaneous stat doses of a sedative and/or antipsychotic to be used as required.

Clerking of a patient also provides a baseline for future comparison. If new problems subsequently develop, and abnormal physical findings are found on examination, it can be helpful for the doctor when considering the differential diagnosis and management to know if the findings are really new or old. A clear assessment and documentation of subsequent medical care are particularly useful for on-call doctors who may have to see a patient, whom they have never met, for a problem serious enough to require immediate attention.

Issue ii (lack of clear, accurate, and contemporaneous patients records which report drugs prescribed; prescribing only the treatment, drugs, or appliances that serve patients' needs)

There should have been clear documentation in the medical notes as to why a syringe driver containing possibly diamorphine, midazolam and hyoscine was prescribed 'as required'. It is unusual to prescribe a syringe driver 'as required' especially containing drugs with a range of possible doses. This is because of the inherent risks that would arise from a lack of clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing a

drug as a range, particularly a wide range, is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. It is not usual in my experience for such decisions to be left for nurses to make alone.

If there were concerns that a patient may experience, for example, episodes of pain, anxiety or agitation, it would be much more usual, and indeed seen as good practice, to prescribe appropriate doses of morphine/diamorphine, diazepam/midazolam and levomepromazine respectively that could be given intermittently 'as required' orally or SC. This allows a patient to receive what they need, when they need it, and guides the doctor in deciding if a regular dose is required, the appropriate starting dose and subsequent dose titration.

The wide dose range of diamorphine 20mg–200mg, is not justified at all in the notes. Doses at the upper of this range are likely to be excessive for Mr Cunningham's needs. Doses of opioids excessive to a patient's needs are associated with an increased risk of drowsiness, delirium, nausea and vomiting and respiratory depression.

The reasons for the inclusion of midazolam and hyoscine hydrobromide in the syringe driver should also have been documented.

Issue iii (prescribing only the treatment, drugs, or appliances that serve patients' needs)

It is unclear why Mr Cunningham was given the 10mg dose of Oramorph. He had only received 5mg of Oramorph previously and this was to cover a dressing change. It would be usual to repeat the same dose of opioid (i.e.

5mg), unless it was ineffective in providing analgesia. Opioids are not indicated for the relief of anxiety and agitation per se. In a confused, elderly patient, opioids may worsen the confusion, particularly at doses associated with sedation. It is possible that the 10mg dose may have contributed to Mr Cunningham being too 'sedated' to take his 22.00h medication.

Issue vi (lack of clear, accurate, and contemporaneous patients records which report drugs prescribed; prescribing only the treatment, drugs, or appliances that serve patients' needs)

It is not clear who decided to start the syringe driver on the 21st September 1998, the drugs it contained and the doses to use. It should be clarified why, if Mr Cunningham was able to take oral medication, his usual medication had not been given, or, if unable to take oral medication, why stat SC doses of a sedative or analgesic were not considered appropriate. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. It is not usual in my experience for such decisions to be left for nurses to make alone.

Morphine is used in palliative care for generalised pain related to muscle or joint stiffness due to immobility or painful pressure sores and the starting dose of diamorphine used were within the starting dose range considered reasonable given Mr Cunningham's prior analgesic use and age.

Issue v (lack of clear, accurate, and contemporaneous patients records which report drugs prescribed; prescribing only the treatment, drugs, or appliances that serve patients' needs; willing to consult colleagues)

If symptoms are 'difficult to control', this should prompt an adequate (re)assessment to carefully (re)consider the possible contributing factors to ensure that all reasonable steps had been taken. If symptoms were not improving despite several increases in analgesic and sedative medication it would be seen as good practice for a doctor to seek additional information or advice from one of the consultants, another colleague or a member of the palliative care team. There is no documentation in the notes that suggests that Dr Barton did this.

If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

Dr Barton had a duty to provide good palliative and terminal care and an integral part of this is the relief of pain and other symptoms to ensure the comfort of the patient. In doing so, as in every form of medical care provision, she would be expected to demonstrate a good standard of practice and care. In this regard, Dr Barton fell short of a good standard of clinical care as defined by the GMC (Good Medical Practice, General Medical Council, October 1995 pages 2–3) with particular reference to a lack of clear note keeping, adequate assessment of the patient, providing treatment that could be excessive to the patients' needs and willingness to consult colleagues.

In my view, given Mr Cunningham's circumstances, the use of diamorphine, midazolam and hyoscine was reasonable. The main issues of contention are firstly, the large dose range of diamorphine prescribed for the 'as required' syringe driver (200mg), as this was likely to exceed the dose likely to be appropriate for Mr Cunningham. It is unclear how Dr Barton

determined or justified this dose. A dose of diamorphine excessive to Mr Cunningham's needs would be associated with an increased risk of drowsiness, confusion, agitation, nausea and vomiting and respiratory depression. Mr Cunningham's administered dose of diamorphine did not however, reach these high levels.

Secondly, the lack of p.r.n. stat SC doses of diamorphine and midazolam meant that the there was a lack of guidance to aid appropriate dose titration or justification for the continued increases in the doses of diamorphine and midazolam. Mostly these were increases within the 33–50% range that would be considered typical. Sometimes increases were greater than this (i.e. diamorphine 20mg to 40mg, 100%) or without documented reason/justification, e.g. the diamorphine 60mg to 80mg and the midazolam 20mg to 60mg and subsequently 80 to 100mg. It was not clear who determined these increases, Dr Barton or one of the nursing staff, and this should be clarified. However, my understanding is that Dr Barton, as the prescriber, retains overall responsibility for the administration of these drugs. Finally, other strategies exist that could have been employed to manage Mr Cunningham's pain on turning, that in my view could have been more successful than continuing to increase the regular doses, and in this regard it is possible that the doses of diamorphine and midazolam Mr Cunningham received risked being excessive for the majority of the time he was still and comfortable. Even so, at the doses Mr Cunningham did receive, they were not excessive to the point of leaving him unresponsive, as he reacted to being moved.

In patients with cancer, the use of diamorphine and other sedative medications (e.g. midazolam, haloperidol, levomepromazine) when

appropriate for the patients needs, do not appear to hasten the dying process. This has not been examined in patients dying from other illnesses to my knowledge, but one would have no reason to suppose it would be any different. The key issue is whether the use and the dose of diamorphine and other sedatives are *appropriate* to the patients needs. Although the principle of double effect could be invoked here (see technical issues), it remains that a doctor has a duty to apply effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose of strong opioid that was *appropriate* and not excessive for a patient's needs.

There appears little doubt that Mr Cunningham was 'naturally' coming to the end of his life. His death was in keeping with a progressive irreversible physical decline, documented over at least 10 days by different clinical teams, accompanied in his terminal phase by a bronchopneumonia. Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mr Cunningham a peaceful death, albeit with what appears to be an apparent lack of sufficient knowledge, illustrated, for example, by the reliance on large dose range of diamorphine by syringe driver rather than a fixed dose along with the provision of smaller 'as required' doses that would allow Mr Cunningham's needs to guide the dose titration. Dr Barton could also be seen as a doctor who breached the duty of care she owed to Mr Cunningham by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mr Cunningham by unnecessarily exposing him to potentially receiving

excessive doses of diamorphine. In the event, however, such large doses were not administered, and in my opinion, the use of diamorphine, midazolam and hyoscine in these doses could be seen as appropriate given Mr Cunningham's circumstances.

9. LITERATURE/REFERENCES

British National Formulary 35 (March 1998).

Prescribing in Terminal Care, pages 12–15.

British National Formulary 47 (March 2004).

Good Medical Practice, General Medical Council, October 1995, pages 2–3.

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition.

'Wessex Protocol' Salisbury Palliative Care Services May 1995.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.

10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: _____ Date: _____

REPORT

regarding

Geoffrey PACKMAN (Ref No. BJC/34)

PREPARED BY: Dr Jonathan Marshall

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mr Packman did not experience a significant (life threatening) gastrointestinal (GI) bleed while an in-patient at Portsmouth Hospital. He developed a mild anemia of chronic disease secondary to his underlying medical problems during that part of his admission.

Mr Packman is likely to have suffered a significant GI bleed while an in-patient at GWMH. Medical assessment at that time was limited and he was managed with escalating doses of opiate analgesia before he died on 3-9-99

2. INSTRUCTIONS

I was asked to prepare this report on the instructions of Detective Sergeant Dave GROCOTT of Hampshire Constabulary based at Fareham Police Station, Quay Street, Fareham, Hampshire PO16 0NA.

3. ISSUES

I was asked to consider the following issues.

3.1 Can you review the papers and establish beyond all reasonable doubt whether or not the gastrointestinal bleed was treatable? If it was, at what point should it have been offered?

3.2 What treatment should have been considered in Mr Packman's case?

3.3 Should non-invasive exploration have been considered by doctors whilst Mr Packman was a patient at Haslar Hospital?

3.4 Was Mr Packman morbidly obese? If so was he unfit therefore for surgery?

4. BRIEF CURRICULUM VITAE

Code A

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5. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Geoffrey Packman

6. OPINION

Question 1

Can you review the papers and establish beyond all reasonable doubt whether or not the gastrointestinal bleed was treatable? If it was, at what point should it have been offered?

Opinion: Mr Packman did not experience a *significant* (life threatening) gastrointestinal (GI) bleed while an in-patient at Portsmouth hospital between 6-8-99 and transfer to GWMH on, or around 23-8-99. There would therefore be no basis to investigate him during this part of his admission with any invasive or non-invasive procedures. His medical state was stable and there were no medical reasons to delay transfer to a 'step-down' care facility from an acute hospital.

Mr Packman was likely to have experienced a *significant* GI bleed approximately 3 days after transfer to GWMH. He was assessed as being unwell and was managed with escalating doses of opiate analgesia until he died on 3-9-99.

Basis for opinion: Mr Packman was admitted because his GP and district nurse were 'unable to cope at home' despite '3x visits/day' (by district nurse) [p40]. His main problems, recorded throughout his stay, were obesity [p40], leg oedema, cellulitis and poor mobility [p45] At the time of admission his haemoglobin was 15.7 and platelets 237 [p43]. NB: This clinical record page is un-labelled but a lab print out confirming this result is on p213. He was treated with intravenous flucloxacillin and benzyl penicillin for groin and leg cellulitis [p46]. Overall he 'doesn't look ill' and was 'mainly a nursing problem' [p47]

On 13-8-99 there is a comment about 'black stool overnight' [p52]. But, clinical examination at that time showed a soft abdomen, normal bowel sounds and normal brown stool presumably on rectal examination. Although a differential of bleeding or antibiotic related diarrhoea was proposed [p52], the presence of brown (normal) stool on examination is against significant upper or lower GI bleeding.

On 20-8-99 [p53] 'no further black motion' was recorded. No symptoms of peptic ulceration were elicited on questioning ('no nausea, no epigastric pain'). The blood pressure was stable at 140/80. Further proof to support an *absence* of significant GI bleeding is provided by the stable haemoglobin (Hb) written as 12.9. A laboratory report dated the day before (19-8-99) [p215] confirms this result.

Mr Packman's haemoglobin was 15.7 on admission (6-8-99) and as stated above was 12.9 on 19-8-99. This is a decline of 2-3 units. However, this is likely to be a trend towards the 'anemia of chronic disease' rather than a significant bleeding related fall in haemoglobin because:

- The lab report dated 19-8-99 with the Hb of 12.9 also confirms a normal platelet count of 366 [p215]. This *normal* platelet count is *against* significant bleeding as the platelet count *may* rise as a response to bleeding, especially if this has been occurring over a few days.
- A normal urea at 5.4 [p53] is also *against* a bleed as this typically *rises* in the presence of *significant upper (stomach or duodenum) GI bleeding.*
- Mr Packmans ESR was typically raised-a marker of inflammation-due to his cellulitis/leg ulceration (ESR 31 on 7-8-99 [p213] and ESR 68 on 19-8-99 [p215]). Chronic infection is associated with raised inflammatory markers (ESR) and 'anemia of chronic disease'- as in this case at this time.
- On the same dates [p213, p215] the MCV was 87.8 on both occasions. This is a *normal* 'mid range' result; A *normal* MCV helps distinguish developing borderline anemia of chronic disease (secondary to infection/cellulitis-as in this case) from iron deficiency anemia typically due to bleeding, albeit slowly, where the MCV is below normal ('microcytic anemia' MCV <80)

On 23-8-99 Mr Packman was transferred to GWMH where his problems were listed as obesity, arthritis, immobility and pressure sores. His mental state was 'very good' and he had 'no pain' [p54]. His lack of significant pain is also supported by an undated assessment on p243 ticking the 'No' box in relation to pain. While his pressure sores could be expected to give him a degree of discomfort, during the admission period at the previous hospital from7/8/99 to 23/8/99 the only analgesia he received was paracetamol 1g 6 hourly [p177 and 179]

On 25-8-99 Nursing staff report Mr Packman 'passing fresh blood PR'. A verbal message from Dr Reasley was received to stop Clexane at that time [p62]. Use of Clexane (low molecular weight heparin) was reasonable in view of Mr Packman's immobility to prevent deep vein thrombosis and pulmonary embolism. With signs of bleeding stopping heparin would be initial management. Mr Packman also complained of vomiting and was given metaclopramide 'with good effect' [p62].

Fresh blood PR is *usually* a sign of *lower* bowel GI bleeding. The commonest cause is haemorrhoids. Under normal circumstances a *non-urgent* sigmoidoscopy examination would be

desirable to confirm this and exclude bowel cancer. This could entirely reasonably be performed as an out-patient following hospital discharge. However, in brisk significant *upper* GI bleeding there is no time for the blood to be digested from stomach to rectum and produce the characteristic black and offensive smelling melena. It is therefore observed as 'passing fresh (bright red blood) PR'. This latter possibility is most likely to have occurred in Mr Packman's case because:

- He vomited [p62]-usually associated with upper GI bleeding.
- Was 'unwell' at lunchtime [p62] and Dr Barton was called. Haemorrhoidal bleeding *rarely* makes the patient unwell but significant upper GI bleeding *invariably* does.
- Experienced a further deterioration in the afternoon complaining of 'indigestion'[p62]. A symptom suggestive of upper GI pathology.
- Clearly was more unwell and so Mrs packman was called in [p62]
- A lab report dated the same day as Mr Packman became unwell (26/8/99) showed an Hb of 7.7 [p205] Yet a result from 2 days earlier (24/8/99) showed an Hb of 12.0 [p207] He had therefore lost at least 4 units of blood in that time. Both lab reports are monogrammed by NAB. There is however no documentation in terms of action taken.
- During these 2 dates the platelet count had *fallen* from 309 to 257. The *fall* in platelet count observed as evidence of bleeding superficially *contradicts* previous comments about bleeding being associated with a *rise* in platelet count. However, while in *slow* bleeding there is an opportunity for the bone marrow to try and correct the loss of platelets needed for coagulation by producing more and tending to cause a rise above normal levels, in *uncontrollable* haemorrhage there is no time for the bone marrow to respond. The net result is that platelets are consumed by the body's attempts to arrest haemorrhage faster than they can be produced by the bone marrow and the platelet count falls as a consequence. This may have occurred in Mr Packman's case.

At around this time a verbal order was received to give 10mg diamorphine from Dr Barton [p62].

On the same date (26-8-05) an assessment in the medical notes by 'NAB' states Mr Packman 'clammy and unwell'. A differential of MI (myocardial infarct) or GI bleed was put forward [p55]. It was stated that he was 'not well enough to transfer' and so diamorphine was commenced [p55]. No attempt is apparently made to ascertain why Mr Packman had become so acutely unwell. There are no clinical observations either in terms of direct questioning of the patient or of examination findings being recorded. 'Simple' treatment for an MI would be aspirin by mouth. Diamorphine would be appropriate if the patient was experiencing severe chest pain, and is standard practice, but typically as a single dose. There is no record of Mr Packman complaining of chest pain at this time and we know that in general terms he did not have severe, opiate requiring, pain (see above). No ecg was performed to look at the possibility of an MI further. Poor copy quality ecgs are in the record on p183,185,186,187 and 188; These appear normal and are undated. The top right corner marks them as 'AandE.' It is likely therefore that they were performed in AandE at admission rather than at this time.

The alternative diagnosis considered was 'GI bleed' [p55]. On the evidence available this appears more likely than MI. It was also considered more likely by the assessing doctor as the clinical details stated on the laboratory request form of 26/8/99 were 'bleeding pr.' This report was monogrammed by NAB [p205].

No documentation in terms of attempting to examine for signs of bleeding or to offer any form of resuscitation is available. '*Resuscitation*' means supporting the patient with intravenous fluids, oxygen and other measures to stabilize a clinical situation. On none of the drug charts reviewed are intravenous 'fluids' that might be used in resuscitation prescribed. 'DNR' or '*Do not resuscitate*' orders refer specifically to not commencing cardiopulmonary resuscitation if the heart stops. Mr

packman was in this 'DNR' category reasonably (high chance of technical futility) [p46] but not in a group in whom no resuscitation is attempted if they simply becomes *unwell.*

Question 2 and 3

What treatment should have been considered in Mr Packman's case? Should non-invasive exploration have been considered by doctors whilst Mr Packman was a patient at Haslar Hospital?

Opinion : Transfer for endoscopic therapy should have been considered in Mr Packman's case when the possibility of a GI bleed was first seriously considered when he deteriorated (26-8-99,[p55]). Endoscopy can only occur after resuscitative measures have been taken such as intravenous fluids, oxygen etc. Endoscopic therapy allows accurate diagnosis of the site and cause of bleeding. It also allows further procedures to try and stop the bleeding and is 'bread and butter' emergency gastroenterology available in any endoscopic unit. In the majority of patients the procedure can be performed on an 'early elective basis (ideally the morning after admission [or event])' This British Society of Gastroenterology (BSG) guideline is followed in our unit and will be followed closely by other UK centres as it is from the National Body [see references]

The critical determinant would be how fit Mr Packman was after resuscitative measures for the ambulance transfer to endoscopy.

Question 4

Was Mr Packman morbidly obese? If so was he unfit therefore for surgery?

Mr Packman was obese and it is stated throughout his record. The definition of 'morbidly obese' depends on knowing height and weight to calculate Body Mass Index (BMI). This information is not however available in this record. The balance of evidence is that he was obese and likely to meet the BMI definition of 'morbidly obese' if calculated.

Mr Packman would represent a high risk for surgery. It would be difficult to justify the potential mortality of *elective* surgery in a morbidly obese patient. However each situation is judged on its merits. A failure of endoscopic therapy to stop bleeding is an indication for emergency surgery. In these situations it has to be put to the patient and family that death during or soon after surgery is a high probability but it is essential to proceed with this high-risk option as the only possible way to save life. Rarely, limits are 'pre-set' if the patient is seriously unwell such as 'for endoscopic therapy only' or 'limit to 10 unit transfusion.' These are however technical discussions between endoscopist, surgeon and anaesthetist.

9. LITERATURE/REFERENCES

British Society of Gastroenterology (BSG) Endoscopy Committee: Management of non-variceal upper gastrointestinal haemorrhage: guidelines Published in Gut October 2002 supplement no iv vol 51

EXPERTS' DECLARATION

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11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: Code A Date: 26/4/05

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Geoffrey Packman statements 20th June 2006

CONTENTS

1. **INSTRUCTIONS**

To examine and comment upon the witness statements in the case of Geoffrey Packman. In particular, if they raise issues that would impact upon any expert witness report prepared.

2. **DOCUMENTATION**

This report is based on the following document:

2.1 Witness statements to the hospital care and death of Geoffrey Packman provided to me by the Hampshire Constabulary (June 2006). In total 27 statements.

2.2 Report regarding Geoffrey Packman (BJC/34) Dr D Black 30th October 2005.

3. **COMMENTS**

3.1 Comments on Witness Statement (2.1)

3.1.1 I have read all the statements in particular the statements of Nurse Hamblin and Hallman . Based on these and the previous statement of Dr Barton I feel that I need to produce a new version of my expert statement, taking into account some clarification over the drug chart.

4. **CONCLUSION**

4.1 Having read all the documents above provided by Hampshire Constabulary, I would wish to make changes to my expert report, and enclose a new version (20th June 2006).

Geoffrey Packman statements 20th June 2006

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4. **CONCLUSION**

4.1 Having read all the documents above provided by Hampshire Constabulary, I would wish to make changes to my expert report, and enclose a new version (20th June 2006).

Version 3 of complete report 20th June 2006 – Geoffrey Packman

SUMMARY OF CONCLUSIONS

Mr Geoffrey Packman was a 68 year old gentleman with a number of chronic problems, in particular, gross (morbid) obesity. He is known to have had leg ulcers and is admitted with a common complication of severe cellulitis. His immobility and infection leads to significant and serious pressure sores in hospital. He develops a probable gastric or duodenal ulcer (again common in patients who are seriously ill), which continues to bleed slowly, then has a massive gastro-intestinal haemorrhage in the Gosport War Memorial Hospital which is eventually the cause of death.

There are a number of weaknesses in the clinical care provided to Mr Packman:
- gastro-intestinal haemorrhage is suspected in Portsmouth, but although never disproven he is continued on his anticoagulant.
- despite the high risks being identified at admission, he does develop pressure sores rapidly during his admission in Portsmouth.
- on assessment on 25th August a further bleed does not lead to medical attention.
- on 26th August when he is identified as seriously ill, examination is either not undertaken or recorded in the notes and an investigation which is performed is never looked at or commented on. Gosport War Memorial Hospital also has communication difficulties as the laboratory simply cannot contact the hospital.
- a difficult clinical decision is made without appropriate involvement of senior medical opinion.
- prescribing management and use of drug charts by both the nursing and clinical staff, in particular for controlled drugs, is unacceptably poor.

Despite all of the above it is my opinion that Mr Packman died of natural causes and these deficiencies probably made very little difference to the eventual outcome.

1. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to his death against the acceptable standard of the day. Where appropriate, if the care is felt to be sub-optimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

2. ISSUES

2.1. Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day.

2.2. If the care is found to be suboptimal what treatment should normally have been proffered in this case.

2.3. If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups.

3. CURRICULUM VITAE

Code A

Version 3 of complete report 20th June 2006 – Geoffrey Packman

Code A

Code A

Code A

Version 3 of complete report 20th June 2006 – Geoffrey Packman

Code A

Version 3 of complete report 20th June 2006 – Geoffrey Packman

Code A

Version 3 of complete report 20th June 2006 – Geoffrey Packman

Code A

Version 3 of complete report 20th June 2006 – Geoffrey Packman

Code A

Code A

4. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Geoffrey Packman (BJC/34)

[2] Operation Rochester Briefing Document Criminal Investigation Summary.

[3] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[4] Commission for Health Improvement Investigation Report on Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital (July 2002).

[5] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

5. **CHRONOLOGY/CASE ABSTRACT.** (The numbers in brackets refer to the page of evidence).

5.1. Geoffrey Packman a sixty eight year old gentleman in 1999 was admitted as an emergency on the 6th August 1999 to Portsmouth Hospitals NHS Trust following an attendance at A&E (40,42).

5.2. Mr Packman had suffered from gross (morbid) obesity for many years; he had also had venous leg ulceration for at least five years (44), he was hypertensive and had a raised prostatic specific antigen, suggesting prostatic pathology. (8)

5.3. Following a fall at home he was completely immobile on the floor and two ambulance crews were needed to bring him to accident and emergency (42). He was currently receiving District Nursing three times a week for leg ulcer management(255). He had become increasingly immobile complicated by the fact that his wife who lived with him and provided care was being investigated for breast cancer. The admission clerking showed that he not only had leg ulcers but he had marked cellulitis, was pyrexial and in atrial fibrillation. Cellulitis was both in his groin and the left lower limb (45). He was totally dependent needing all help (143) with a Barthel of 0 (163). His white cell count was significantly raised at 25.7 (48), his liver function tests were abnormal with an AST of 196 and his renal function was impaired with a urea of 14.9 and a creatinine of 173 (47). These had all been normal earlier in the year. He was treated with intravenous antibiotics (45) in a special bed (187).

5.4. He appeared to make some progress and on 9th August his cellulitis was settling (48) . A Haemolytic Streptococcus sensitive to the penicillin he had been prescribed was identified (225). On 11th August the nursing cardex (134) stated that there appeared to have been a deterioration of his heel ulcers with a "large necrotic blister on the left heel". His haemoglobin on 12th August (211) was 13.5.

5.5. On 13th August white count was improved at 12.4 (50,52), his U's and E's were normal and the notes recorded a planned transfer to the Gosport War Memorial Hospital on 16th August.

5.6. Later on the 13th black bowel motion is noted but the doctor who examines him records a brown stool only. It is not clear whether he has had a gastro intestinal bleed (52). On 16th August no

comment is made on the possible gastrointestinal (G.I) bleed , but on 20th August his haemoglobin is noted to be 12.9 (53) no further black stools have been reported so he is planned for transfer on 23rd August. Albumin at this stage is now reduced at 29 (190).

5.7. On 17th August sacral sores are now noted in the nursing cardex (118) which by the 20th are now recorded as "deep and malodorous" (125).

5.8. He is transferred to the Gosport War Memorial Hospital on 23rd August (54). A reasonable history and examination is undertaken which notes that there was a history of possible melaena, the clinical examination recorded suggests that he is stable. Blood tests are requested for the next day. The drug chart (168) suggests that his weight is 148 kgs but it is not clear if this is an estimate or a measurement. He is very dependent with a Barthel of 6 and a Waterlow score of 18, putting him in high risk. His haemoglobin on 24th is 12 (207). The nursing cardex on the 24th notes the multiple complex pressure sores on both the buttocks and the sacrum (96-100).

5.9. On 25th August the nursing cardex reports that he is passing blood rectally and also vomiting (62,82).

5.10. On 26th August a doctor (Dr Barton) is asked to see him and records that he is clammy and unwell. (55) The notes suggest that he might have had a myocardial infarction and suggests treating him with Diamorphine and Oramorphine overnight. It records that as an alternative there might be a G.I. bleed but this is recorded as unlikely because he has not had haematemesis. It also notes that he is not well enough to transfer to an acute unit and he should be kept comfortable, including "I am happy for the nursing staff to confirm death". His Clexane (an anticoagulant given to prevent pulmonary embolus) is now stopped. The nursing cardex (62) on the same day records further deterioration throughout the day with pain in his throat and records a verbal request for Diamorphine. A full blood count is taken (this fact is not recorded in the notes) but the result is filed in the notes recording a haemoglobin markedly reduced at 7.7 (205). It also states "many attempts were made to phone Gosport War Memorial Hospital but no response from switchboard". These significant results are not commented on at any stage in the nursing or clinical notes.

5.11. On 27th August (63) the nursing notes record some improvement in the morning but discomfort in the afternoon especially with

dressings. On 28th August both the medical (55) and the nursing records (63) are noted to be very poorly with no appetite. Opiates are to continue over the weekend. 29th August he is sleeping for long periods (63) and on 30th he is still in a very poor clinical condition but eating very small amounts of diet. He is re-catheterised the same day (55).

5.12. On 31st he is recorded as passing a large amount of blood rectally (83) and on the 9th September (55 and 64) he is reviewed by a consultant Dr Reid who notes that he is continuing to pass melaena stool, there are pressure sores across the buttocks and posterior aspects of both thighs, he is now significantly confused. Dr Reid records that he should be for TLC only and that his wife is now aware of the poor prognosis. Nursing notes (64) note that the dose of drugs in the syringe driver should be increased; the previous doses were not controlling his symptoms. The nursing notes of the 2nd September (62) record the fact the Diamorphine is again increased on the 2nd to 90mgs and on 3rd September he dies at 13.50 in the afternoon (55, 64).

5.13. Drug Chart review: There are two drug charts. Chart 1 (174-178) confirms his original admission to Portsmouth Hospital Trust in particular the appropriate use of the antibiotics, Penicillin, Flucloxacillin and the prescription of the anticoagulant Clexane. This goes from 6th August – 23rd August.

5.14. The second drug chart (168-172) goes from his admission to the Gosport War Memorial Hospital on 23rd August to his death on the 3rd September. The once only part of this drug chart on 26th August states Diamorphine IM 10 mgs verbal message given 18.00 hours. Then there is two days later on 28th August, Diamorphine IM 10 mgs signed Dr Barton. This is never given, this may be a retrospective attempt to legitimise the prescription given verbally 2 days before.

5.15. On the 'as required' part of the drug chart only Gaviscon and Temazepam are written up. On the regular side of the drug chart Doxazosin, Frusemide, Clexane (until 25th August) Paracetamol, Magnesium, Metoclopramide and Loperamide are all written up. Though some of these drugs like the Magnesium appear to have been given in a "as required" fashion. Oramorphine (171) though written up regularly is never given. Diamorphine 40 – 200 mgs subcut in 24 hours is prescribed on the 26th (171) and appears to have been given as 40mgs on 30th, 31st, 1st changed to 60 mgs on 1st September and 90mgs on 2nd September. The drug chart is extremely confusing (171) as these prescriptions have not been

properly put in the day and date boxes required, and the nursing staff appear to be putting two days of prescribing into a single day box. Midazolam 20 – 80 mgs subcut in 24 hours is written up and Midazolam is probably given 20 mgs on the 30th and 31st August, 40mgs on 1st September, changed to 60mgs on 1st September and given 80mgs on 2nd September.

5.16. On the next regular page of the drug chart (172) Oramorphine 10-20mgs 4 hourly is written up and is signed up to have been given for 4 doses daily on 27th, 28th and 29th August, with two further doses in the morning of the 30th August. I cannot tell from the drug chart whether 10mgs or 20mgs is given. Oramorphine is written up 20mgs at night and given on 26th, 27th, 28th and 29th August. Hyoscine is written up but never given, although it is prescribed as a regular prescription.

6. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

6.1. This section will consider whether there were any actions so serious that they might amount to gross negligence or any unlawful acts, or deliberate unlawful killing in the care of Geoffrey Packman. Also whether there were any actions or omissions by the medical team, nursing staff or attendant GP's that contributed to the demise of Geoffrey Packman, in particular, whether beyond reasonable doubt, the actions or omissions more than minimally, negligibly or trivially contributed to death.

6.2. Mr Packman had a number of chronic diseases prior to his terminal admission. The most serious was his gross (morbid) obesity which led to severe immobility and non-healing leg ulcers.

6.3. He then develops an infection (cellulitis) of his leg ulcers which has spread to his groin causing his high white count, his pyrexia, then his total immobility requiring appropriate admission to the Portsmouth Hospitals NHS Trust. On admission he is recognised to be at high risk of pressure sore development and appears to have been put on a special bed.

6.4. He appears to make reasonable progress from the point of view of his cellulitis and is treated with appropriate antibiotics, however is noted to have developed buttock and sacral pressure sores by 17th August which are in a serious condition by 20th August.

6.5. In the meantime, a black stool is noted on 13th August and the question of whether this is melaena (blood leaking from the upper gastro-intestinal tract which turns black when passing through the

gastro-intestinal tract) and whether he has a gastric or duodenal ulcer. Normally this would be investigated with an endoscopy. However this would be quite a major procedure on such a dependent gentleman. Although in retrospect it is easy to say that this was the first bleed, it would not have been clear at the time, the lack of further melaena and the fact that haemoglobin does not significantly fall over the next week, suggests that conservative management was appropriate. However, he is not put on any prophylactic anti-ulcer medication and his anticoagulant is continued. In retrospect both of these decisions may have contributed to his subsequent problems.

6.6. He is transferred to the Gosport War Memorial Hospital on 23rd August. The prognosis for a patient with gross obesity, who is catheterised, and who has recent deep and complex pressure sores is terrible. In my experience such patients almost invariably deteriorate despite the best efforts of staff and die in hospital. He is appropriately clerked on admission and indeed appropriate investigations carried out including haemoglobin which is now 12. Although by itself this is a normal haemoglobin his level of haemoglobin has very slowly drifted down and again in retrospect suggests that he was starting to bleed slowly.

6.7. On 25th August the nursing staff note that he is passing blood rectally and he is vomiting, although the medical staff do not appear to have been asked to seem him. However on the 26th August he is seen when he is unwell, very cold and clammy. Dr Barton suggests the likeliest diagnosis is a myocardial infarction, although appropriately she does think of a gastro-intestinal bleed. No examination is recorded in the notes, nor are some simple and appropriate investigations undertaken (for example an ECG), to try and differentiate these two problems. However a blood count is sent to the laboratory and haemoglobin has now fallen to 7.7. Mr Packman has had a massive gastro-intestinal bleed, this is now a re-bleed and in itself would be a marker of significant risk of death. Proven re-bleed needing more than 4 units of blood would in a previously fit patient over 65 be an indication for an emergency operation. However as the laboratory cannot inform the hospital of this result, no-one would appear to have brought it to medical or nursing attention.

6.8. Despite this there is an important decision to be made on the 26th August. Whatever the cause, Dr Barton identifies that the patient is seriously ill and the acute problems whether a G.I. bleed or a myocardial infarction would not be appropriately managed in a community hospital. Dr Barton makes the decision that the

patient is too ill for transfer and should be managed symptomatically only at Gosport. In my view this is a complex and serious decision that should be discussed with the consultant in charge of the case as well as with the patient and their family if possible. I can find no evidence of such a discussion in the notes. It is my view however, that in view of his other problems it is within boundaries of a reasonable clinical decision to provide symptomatic care only at this stage. The chances of surviving any level of treatment, including intensive care unit and surgery were very small indeed.

6.9. Mr Packman deteriorates further in the evening and is prescribed a single dose of Diamorphine as a result of a verbal request. In paragraphs 5.13 – 5.16 I have identified significant failings in the way the drug chart has been used and written up. Controlled drugs are given on at least one occasion based on a verbal request and the prescription apparently written 2 days later. Regular drugs are written up and never given. The drug chart is used in a most irregular fashion and I do not believe that the standards of medical prescribing or nursing delivery meet the expectations of regulations on the prescription in the use of controlled drugs.

6.10. From the 26th August Mr Packman is dying and after a single dose of Diamorphine on the 26th August, receives regular Oramorphine, then Diamorphine, and Midazolam until his death. Both Oramorphine and Diamorphine while specifically prescribed for pain are commonly used to manage the stress and restlessness of terminal illness. Diamorphine is compatible with Midazolam and in itself is particularly used to terminal restlessness, and can be mixed in the same syringe driver. It is very difficult to assess the starting dose of Oramorphine and he appears to receive 60mg in total on the 26th. Calculating the dose would be complicated in this case due to his the massive obesity which might well effect the oral dose required , together with his serious pressure sores which would be extremely painful on being dressed. He appears subsequently to have been started on 40mgs of Diamorphine in 24 hours with 20mgs of Oramorphine (equivalent to another 10mgs of Diamorphine) at night, together with 20mgs of Midazolam. The dose of s/c Diamorphine is usually given in a ratio of 1:2, so 20mg might have been the equivalent of the day time dose of 40mg of Oramorphine. However I can find no evidence in the notes that there were any significant side effects from the Oramorphine or the Diamorphine, and his symptoms do seem relatively well controlled as described in the nursing notes.

6.11. He is reviewed by a consultant (Dr Reid) on 1st September where it has now become absolutely clear that it is a gastro-intestinal haemorrhage which is causing his death on top of his other problems. Dr Reid is happy with the management and later in the day the Diamorphine is increased because the previous dose is no longer controlling his symptoms. Further increase of 50% in dosage occurs on 2nd September and he dies the following day.

6.12. In my view, based on the evidence in the notes, the doses of Oramorphine and Diamorphine used although higher than might have been conventional at the start, were required to control Mr Packman's symptoms and did not contribute in any significant fashion to his death.

6.13. In my view a death certificate should read:
1a Gastro-intestinal haemorrhage
2 Pressure sores and morbid obesity

7. OPINION

7.1. Mr Geoffrey Packman was a 68 year old gentleman with a number of chronic problems, in particular, gross (morbid) obesity. He is known to have had leg ulcers and is admitted with a common complication of severe cellulitis. His immobility and infection leads to significant and serious pressure sores in hospital. He develops a probable gastric or duodenal ulcer (again common in patients who are seriously ill), which continues to bleed slowly, then has massive gastro-intestinal haemorrhage in the Gosport War Memorial Hospital which is eventually the cause of death.

7.2. There are a number of weaknesses in the clinical care provided to Mr Packman:
- gastro-intestinal haemorrhage is suspected in Portsmouth but although never disproven, he is continued on his anticoagulant.
- despite the high risks being identified at admission, he does develop pressure sores rapidly during his admission in Portsmouth.
- on assessment on 25th August a further bleed does not lead to further medical attention.
- on 26th August when he is identified as seriously ill, examination is either not undertaken or recorded in the notes and an investigation which is performed is never looked at or commented on. Gosport War Memorial Hospital also has communication difficulties as the laboratory simply cannot contact the hospital.
- a difficult clinical decision is made without appropriate involvement, of senior medical opinion.
- prescribing management and use of drug charts by both the nursing

and clinical staff, in particular for controlled drugs, is unacceptably poor.

Despite all of the above it is my opinion that Mr Packman died of natural causes and these deficiencies probably made very little difference to the eventual outcome.

8 LITERATURE/REFERENCES

1. Good Medical Practice, General Medical Council 2002
2. Withholding withdrawing life, prolonging treatments: Good Practice and decision making. General Medical Council 2002.
3. Palliative Care, Welsh J, Fallon M, Keeley PW. Brocklehurst Text Book of Geriatric Medicine, 6th Edition, 2003, Chapter 23 pages 257-270.
4. The treatment of Terminally Ill Geriatric Patients, Wilson JA, Lawson, PM, Smith RG. Palliative Medicine 1987; 1:149-153.
5. Accuracy of Prognosis, Estimates by 4 Palliative Care Teams: A Prospective Cohort Study. Higginson IJ, Costantini M. BMC Palliative Care 2002:1:129
6. The Palliative Care Handbook. Guidelines on Clinical Management, 3rd Edition. Salisbury Palliative Care Services, May 1995.

9. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters, which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report, which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.

8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

10. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature:_____ Date: _____

Version 2 of complete report 29th August 2005 – Ruby Lake

SUMMARY OF CONCLUSIONS

Ruby Lake an 84-year-old lady with a number of chronic diseases, suffers a fall and a fractured neck of femur in August 1998. She is admitted to hospital and has operative treatment but develops post-operative complications including chest infection, chest pain and confusion at night and subsequently deteriorates and dies in the Gosport War Memorial Hospital.

In my view a major problem in assessing this case is the poor documentation in Gosport Hospital in both the medical and nursing notes, making a retrospective assessment of her progress difficult. Good Medical Practice (GMC 2001) states that "*good clinical care must include adequate assessment of the patient's* condition, based on the history and symptoms and if necessary, an appropriate examination"..... "in providing care you must keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed".... "good clinical care must include – taking suitable prompt action where necessary".... "prescribe drugs and treatments, including repeat prescriptions only when you have adequate knowledge of the patient's health and medical needs". The lack of detail in particular in the medical notes, the lack of recording of why decisions were made or if the patient was properly examined represent poor clinical practice to the standard set by the General Medical Council.

In my view the combination of a lack of a documented clinical examination, the lack of prescription of appropriate oral analgesia on admission to Gosport, the decision to start a syringe driver without documentation of a clinical diagnosis or the reason for it in the medical notes, together represent a negligent standard of medical care.

Without a proven diagnosis, it is possible that the combination of Diamorphine and Midazolam together with the Hyoscine in a syringe driver contributed in part to Mrs Lake's death. However, I am unable to satisfy myself to the standard of beyond reasonable doubt that it made more than a minimal contribution.

1. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be sub-optimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

2. ISSUES

DRAFT REPORT

regarding

GEOFFREY PACKMAN (BJC/34)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mr Packman was a 67 year old man with obesity impairing his mobility, swelling of his legs and leg ulcers admitted to the Queen Alexander Hospital because of cellulitis (infection of the skin) affecting his left leg and groins. He also had pressure sores over his buttocks and thighs. He improved with treatment with antibiotics. He passed loose black stools, suggestive of melaena (blood in the stool) on a couple of occasions, but his haemoglobin was stable, excluding a significant gastrointestinal bleed. He was transferred to Dryad Ward for rehabilitation.

During his admission to Dryad Ward, the medical care provided by Dr Barton and Dr Reid was suboptimal; there was a lack of clear, accurate and contemporaneous patient records, inadequate assessment of Mr Packman's condition; a lack of consultation with colleagues and the use of diamorphine and midazolam in doses likely to be excessive to Mr Packman's needs.

Mr Packman became acutely unwell on the 26th August 1999. A blood test revealed a large drop in his haemoglobin which made a significant gastrointestinal bleed likely. This is a serious and life-threatening medical emergency which requires urgent and appropriate medical care. The commonest underlying cause, a peptic ulcer, can however, be cured. Mr Packman should have been transferred without delay to the acute hospital. However, Mr Packman was not transferred; the blood test result was not obtained or acted upon and he went on to receive doses of diamorphine and midazolam which were not obviously justified and likely to have been excessive to his needs.

In short, Dr Barton in particular, but also Dr Reid, could be seen as doctors who breached the duty of care they owed to Mr Packman by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mr Packman by failing to adequately assess his condition and taking suitable and prompt action when he became unwell with a gastrointestinal bleed. He was not appropriately assessed, resuscitated with fluids, transferred or discussed with the on-call medical team. The use of regular morphine and subsequent use of diamorphine and midazolam in doses likely to be excessive to Mr Packman's needs were inappropriate. It is the inappropriate management of Mr Packman's gastrointestinal haemorrhage together with his exposure to unjustified and inappropriate doses of diamorphine and midazolam that contributed more than minimally, negligibly or trivially to his death. As a result Dr Barton and Dr Reid leave themselves open to the accusation of gross negligence.

2. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to his death against the acceptable standard of the day. Where appropriate, if the care is felt to be suboptimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

3. ISSUES

3.1 Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

3.2 If the care is found to be suboptimal what treatment should normally have been proffered in this case?

3.3 If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

4. BRIEF CURRICULUM VITAE

Code A

Code A

5. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Geoffrey Packman, including the *medical certificate of cause of death.*

[2] Operation Rochester Briefing Document Criminal Investigation Summary.

[3] Hampshire Constabulary *Operation Rochester Guidance for* Medical Experts.

[4] Hampshire Constabulary Summary of Care of Geoffrey Packman.

[5] *Palliative Care Handbook Guidelines on Clinical Management, Third* Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

[6] Portsmouth Health Care NHS Trust Policies:

i) Control of Administration of Medicines by Nursing Staff Policy (January 1997).

ii) Prescription Writing Policy (July 2000).

iii) Policy for Assessment and Management of Pain (May 2001).

iv) Compendium of Drug Therapy Guidelines, Adult Patients (1998).

v) Draft Protocol for Prescription Administration of Diamorphine by Subcutaneous Infusion, Medical Director (December 1999).

vi) Medicines Audit carried out by the Trust referred to as Document 54 on page 52 in the Chi Report (reference 6).

[7] General Medical Council, Good Medical Practice (July 1998).

[8] British National Formulary (BNF). Section on Prescribing in Terminal Care (March 1999).

[9] British National Formulary (BNF). Section on Prescribing in the Elderly (March 1999).

[10] Statement of Dr Jane Barton as provided to me by Hampshire Constabulary (undated).

[11] Statement of Dr Jane Barton RE: Geoffrey Packman, 17th November 2005.

[12] Draft Report regarding Statement of Dr Jane Barton RE: Geoffrey Packman (BJC/34), Dr A Wilcock, 26th January 2006.

[13] Draft overview of Geoffrey Packman (BJC/34), Dr A Wilcock, 5th November 2005.

[14] Draft report regarding Geoffrey Packman, Dr Jonathan Marshall, 1st April 2005.

6. CHRONOLOGY/CASE ABSTRACT

Events at Queen Alexander Hospital, 6th–23rd August 1999

Mr Packman, a 67 year old man who lived with his wife and daughter, was admitted on the 6th August 1999 to Queen Alexander Hospital following a fall at home. Due to his obesity he was unable to get up and two ambulance crews were called to assist (page 42 of 283). He was initially seen in Accident and Emergency and then Anne Ward where he was clerked by the Senior House Officer (SHO) who noted his five year history of lower leg oedema (swelling) that had got worse over the past six months; bilateral leg ulcers for one month; increasing erythema (redness) of the groin for three weeks which had become uncomfortable; increasing weakness and difficulty mobilising for one week (page 44 of 283). Mr Packman's past medical history included hypertension (high blood pressure) since 1985 and arthritis (unspecified). He was receiving doxazosin 4mg once a day, felodipine mr 5mg once a day and bendrofluazide 5mg once a day, possibly all for his hypertension, although the latter (a diuretic, 'water tablet') is also given for oedema. Systemic enquiry revealed a poor urinary stream, constipation for one week and no problems with chest pain or shortness of breath. Mr Packman's wife was undergoing tests for possible breast cancer. He was a non-smoker. District nurses visited three times a week to apply dressings to his legs and normally he was able to mobilise around the house and occasionally outside with the use of a stick (page 44 of 283). On examination he was obese, had an elevated temperature (37.6°C), an irregular heart rate of 80 beats per minute, fine crackles in the mid zones of his chest bilaterally, a soft, non-tender abdomen and erythema of both

groins particularly on the left which leaked clear fluid. Both legs were swollen particularly the left which was also erythematous. There was bruising on his buttocks in the shape of a toilet seat. The SHO summarised Mr Packman's main problems as leg oedema, cellulitis (infection in the subcutaneous tissues of the skin) in the groin and left lower leg, immobility due to his obesity/oedema/infection and atrial fibrillation (irregular heart rhythm) (page 45 of 283). Investigations were undertaken (blood tests, blood cultures, urine analysis, chest x-ray, electrocardiograph (ECG), swabs from his groin and leg ulcers) and treatment commenced with intravenous antibiotics to treat the infection, and his dose of diuretics increased by switching the bendrofluazide to furosemide 80mg once a day (pages 45 and 174a of 283). The results of the investigations were in keeping with cellulitis: a raised white cell count of $25.7x10^9$/L, 90% neutrophils (page 213 of 283); a C-reactive protein (CRP) of 191mg/L, (normal range <5mg/L; page 202 of 283); haemolytic streptococcus, a bacteria known to cause cellulitis, grown from the sores in his groin and buttocks (pages 227 and 229 of 283) and an elevated aspartate aminotransferase at 194IU/L (normal 12–40IU/L; page 202 of 283). There was also renal impairment; urea and creatinine were elevated 14.9mmol/L (normal 3–7.6mmol/L) and 173micromol/L (normal 60–120micromol/L; page 202 of 283) respectively. Other results revealed a marginally low albumin (a protein) at 36g/L (normal range 37–50g/L), a normal haemoglobin (15.7g/dl; page 213 of 283) and negative blood and urine cultures (pages 221 and 231 of 283). An ECG was reported as showing atrial fibrillation, a common arrhythmia which causes the heart to beat irregularly, but at a satisfactory

rate of 85 beats per minute (pages 45 and 185 of 283). Mr Packman was catheterised because of urinary incontinence (page 144 of 283).

Mr Packman was reviewed later the same day by a more senior doctor (a registrar) who listed Mr Packman's problems as cellulitis of the left leg, chronic leg oedema, poor mobility, morbid obesity, hypertension and possible atrial fibrillation. He agreed with the plan to treat the cellulitis with intravenous antibiotics (flucloxacillin and penicillin G) and because of Mr Packman's immobility, obesity and cellulitis, also commenced low molecular weight heparin (enoxaparin (clexane)) to thin the blood and reduce the risk of a deep vein thrombosis in the leg. The registrar also suggested a repeat ECG rhythm strip, which subsequently confirmed atrial fibrillation (pages 48 and 185 of 283; although I am unable to comment given the quality of the copy) and, as the felopdipine and doxazosin may have been exacerbating Mr Packman's oedema, to consider other drugs to treat his hypertension. Mr Packman was deemed not appropriate for cardiopulmonary resuscitation in the event of a cardiorespiratory arrest because of his 'pre-morbid state and multiple medical problems' (page 46 of 283).

The medication chart indicates that during his stay on Anne Ward, Mr Packman received the antibiotic benzylpenicillin 1.2G intravenously four times a day from 6–11th August 1999, after which it was continued as an oral equivalent, penicillin V 500mg four times a day until 18th August 1999 (pages 174a and 177 of 283). Similarly, the antibiotic flucloxacillin 1G was given intravenously four times a day from the 6–9th August 1999, after which it was continued orally as flucloxacillin 500mg four times a day until the 18th August 1999 (pages 174a and 177 of 283). The antihypertensive

doxazosin 4mg once a day was continued unchanged (page 174a of 283) but the felodipine was reduced and subsequently discontinued on the 19th August 1999 (page 174a of 283). The diuretic furosemide 80mg once a day and the heparin enoxaparin 40mg twice a day were continued throughout his stay (pages 174a, 177 and 179 of 283). Paracetamol 1G was given at 20.10h on the 6th August and 07.15h on the 7th August as once only, nurse prescribed doses, probably to reduce his temperature as there was no mention of pain (page 130 of 283); thereafter it was prescribed regularly 1G four times a day and continued throughout his stay, although intermittently doses were declined (pages 174, 174b, 177 and 179 of 283).

Gaviscon, an antacid, generally given for the relief of dyspepsia (indigestion) was prescribed p.r.n. 'as required'; three doses were taken on the 8th and one dose each on the 9–12th and 14th August 1999 (page 174 of 283).

During his stay on Anne Ward, Mr Packman improved. His temperature and cellulitis began to settle and he was switched to oral antibiotics (pages 48 and 49 of 283). Dr Reid reviewed Mr Packman on the 9th August 1999, who recorded more oedema in the left than the right foot and more arthritis in the left than the right knee and hip, although this was mild (page 48 of 283). Mr Packman's weight was recorded as 148.6kg on 12th August 1999 (page 121 of 283). On the 13th August 1999, blood test results had improved; white blood cell count and CRP had fallen and his renal function returned to normal (pages 196, 200, 211 of 283). Following discussion with Mrs Packman, because of Mr Packman's immobility, pressure sores and social

circumstances, the plan was to transfer him to Dryad Ward for rehabilitation (pages 50, 108, 121, 122 of 283).

According to his observation chart, some time on the evening of the 11th August, Mr Packman's blood pressure was measured as he was 'feeling dizzy'; it was 'normal' for him at 170/90 but his pulse was not recorded and I can find no other mention of this episode (page 159 of 283). An entry on the comments sheet on the 11th August 1999 at 13.45h reports loose black stools (suggestive of melaena, which is blood in the stool, see technical issues; page 133 of 283). Mr Packman opened his bowels several times between the 11–13th August, with no mention of melaena (pages 134 and 135 of 283). An entry made by Dr Tandy on the 13th August 1999 noted 'black stools overnight - nil today, says bowels looser than usual. No pain. Abdomen soft. Bowel sounds normal. PR (digital examination of the rectum) normal brown stool. Chase haemoglobin to rule out bleed. ?Antibiotic related diarrhoea. Stool chart' (pages 52, 53 of 283). Mr Packman's haemoglobin was checked and was essentially stable; 13.5g/dL (12th August) 12.9g/dL (19th August), 12.9g/dL (20th August), (pages 209, 211, 215 of 283).

Blood tests carried out on the 14th August 1999, revealed normal thyroid function tests, that the aspartate aminotransferase had returned to normal (40IU/L), but that his albumin had fallen to 29g/L (normal 37–50g/L; pages 196 and 198 of 283).

On the 15th August Mr Packman was incontinent of loose faeces (page 136 of 283). An entry dated 16th August 1999 noted that Mr Packman had pressure sores over his buttocks, sacrum and thighs that required daily

dressings and that he was faecally incontinent (page 51 of 283). An entry dated 18th August 1999 reported that he was stable, and that his wounds looked better, and the antibiotics were discontinued on the 19th August (page 51 of 283). A communication sheet entry on the 19th August 1999 at 06.00h noted that Mr Packman twice passed small amounts of black tarry stools (pages 119 and 137 of 283). A later entry the same day reported bowels open small amount with no mention of melaena (page 138 of 283). An entry dated 20th August 1999 notes no further black motions, no nausea, epigastric pain or tenderness (page 53 of 283). Blood test results on the 20th August revealed a stable haemoglobin at 12.9g/dL and an improved albumin at 34g/L (pages 192 and 209 of 283).

Mr Packman's Barthel score had improved from 0 to 6 representing improvements in continence of bowels, ability to undertake his own grooming (washing face, cleaning teeth etc.) feeding himself independently and being able to transfer with major help from having been unable to transfer (page 163 of 283). Nevertheless, he remained in bed, using a monkey bar to raise himself off the bed and otherwise being moved with a hoist (page 148 of 283). The sores in his groin had improved (page 149 and 150 of 283) but the sacral pressure sore persisted, with dressings needing frequent changing due either to being sodden with exudate or soiled with faeces (page 150 of 283).

Events at Dryad Ward, 23rd August 1999 until 3rd September 1999.

23rd August 1999

An entry was made in the medical notes on 23rd August 1999, which I assume was done on Dryad ward, although this should be clarified (page 54 of 283). The clerking doctor noted that Mr Packman's ongoing problems were obesity, arthritis in his knees, immobility, pressure sores and constipation. They noted that Mr Packman was 'on a high protein diet, ?melaena 13th August 1999, haemoglobin stable' but was better in himself, with a good mental test score and no pain. There was little to find on examination bar his obesity, swollen legs and pressure sores (page 54 of 283).

The nursing summary notes recorded that Mr Packman had been 'transferred from Anne Ward following an episode of immobility and sacral sores. Catheterised. On profile bed, hoist only. Able to feed himself. Mrs Packman is awaiting a decision re mastectomy at Queen Alexander Hospital tomorrow' (page 62 of 283). Several nursing care plans were produced: 'Requires full assistance to settle at night' (page 78 of 283); 'Due to immobility...prone to constipation' (page 82 of 283); 'Urinary catheter' (page 84 of 283); 'Pressure sore areas' (page 96 of 283).

The drug chart reveals he was continued on regular doxazosin 4mg once a day, furosemide 80mg once a day, enoxaparin 40mg twice a day, paracetamol 1G four times a day; commenced on magnesium hydroxide 10ml twice a day (a laxative), subsequently taken intermittently; two doses on the 24th, one dose on the 25th, two doses on the 28th, 29th and one

dose on the 30th (page 170 of 283) and p.r.n. 'as required' gaviscon (undated but most probably on the 23rd August)(pages 168, 170 of 283).

24th August 1999

A handling profile noted in the section for pain 'needs to be controlled' (page 90 of 283). This is at odds with the medical notes entry for the 23rd August 1999 that states 'no pain' (page 54 of 283). Pain is not mentioned anywhere else. His bowels were well open (no melaena specified) and swabs taken from his pressure sores for microbiology (pages 82 and 97 of 283).

Blood test results revealed a haemoglobin of 12g/dL and a white cell count of $12.2x10^9$/L (Page 207 of 283); a marginally raised urea 8.9mmol/L (*normal 3.0–7.6mmol/L*) *and a reduced albumin 31g/L (normal 37–50g/L).* Both forms were signed with the initials 'JAB' (pages 190 and 207 of 283). Note: the biochemistry results form given as page 190, differs in my two files, one having a more complete set of results for the 24th August 1999. Temazepam 10–20mg was prescribed p.r.n. and he took 10mg at 22.10h (page 168 of 283).

25th August 1999

Mr Packman was noted to have 'bowels open medium, formed, leaking some fluid' and later 'several loose bowel actions throughout the afternoon and evening - 7–8. Some fresh blood present, ? due to medication - same stopped. For review later' (pages 82 and 83 of 283). The nursing summary notes recorded that Mr Packman had been passing fresh blood PR ? due to

the enoxaparin (clexane). A verbal order from Dr Beasley was to withhold the 18.00h dose and review with Dr Barton in the morning. Mr Packman was also vomiting and metoclopramide 10mg IM was given at 17.55h (page 171 of 283).

Mr Packman took temazepam 20mg at 22.05h and loperamide 4mg (for diarrhoea) as a one off dose at a time I can not decipher (page 168 of 283). He was also prescribed loperamide 2mg four times a day regularly on the daily review prescriptions section, and appeared to have received this at 06.00h, 12.00h and 18.00h on 25th August 1999.

26th August 1999

The nursing summary notes recorded 'fairly good morning, no further vomiting - Dr Ravi contacted re enoxaparin (clexane). Advised to discontinue and repeat haemoglobin today and tomorrow. Not for resuscitation. Unwell at lunchtime, colour poor, complaining of feeling unwell. Seen by Dr Barton this afternoon - await result of haemoglobin. Further deterioration – complaining of ? indigestion – pain in throat, not radiating – vomited again this evening. Verbal order from Dr Barton diamorphine 10mg stat - same given at 18.00h. Metoclopramide 10mg given IM. Mrs Packman informed will visit this evening (page 62 of 283).

The medical notes record 'called to see, pale, clammy, unwell. Suggest ? myocardial infarction (MI). Treat stat diamorphine and oramorph overnight. Alternative possibility gastrointestinal (GI) bleed but no haematemesis. Not well enough to transfer to acute unit. Keep comfortable. I am happy for nursing staff to confirm death (page 55 of 283). The entry in the nursing

summary notes at 19.00h recorded 'Dr Barton here. For oramorph four hourly. Wife seen by Dr Barton, explained Mr Packman's condition and medication used' (page 62 of 283).

The drug chart showed that he received diamorphine 10mg at 18.00h prescribed as a verbal order in the once only section (page 168 of 283). The prescription was repeated below this one, but it does not appear to have been given. (page 168 of 283) Oral morphine solution (Oramorph) was commenced regularly 10–20mg every four hours with 20mg at night which Mr Packman continued until 10.00h on the 30th August 1999 (page 172 of 283). Regular oral morphine solution 10mg every 4 hours was also prescribed in the daily review prescription, which appears to be an error and unnecessary duplication; none appears to have been prescribed from this section however (page 171 of 283). Diamorphine 40–200mg and midazolam 20–80mg SC/24h were also prescribed on the 26th August 1999 (page 171 of 283).

A full blood count revealed a significant fall in Mr Packman's haemoglobin to 7.7g/dL. A comment on the form reads 'many attempts were made to phone these results, no answer from Gosport War Memorial Hospital switchboard'. The results are signed with the initials JAB (page 205 of 283).

27th August 1999

The nursing summary entry noted 'some marked improvement since yesterday. Seen by Dr Barton this am - to continue with oramorph four hourly - same given tolerated well. Some discomfort this afternoon – especially when dressings being done. Wife has visited this afternoon and

is aware that condition could deteriorate again. Still remains poorly' (page 63 of 283).

Mr Packman's pressure sore dressings were renewed to all areas 'some improvement since Wednesday especially to the areas on the left buttock. Area on right buttock remains offensive and some exudates (page 97 of 283). Mr Packman night was recorded as 'oramorph given as prescribed. Comfortable night, not complaining of any chest pain' (page 79 of 283).

28th August 1999

Medical notes entry noted 'Remains poorly but comfortable so please continue opiates over weekend' (page 55 of 283). Nursing summary noted 'Remains very poorly – no appetite has refused all food. Wife visited – very distressed as she is having surgery this coming week' (page 63 of 283). The entry for the night noted 'Oramorph given as prescribed. Condition remains poorly and variable. Drinking well. Dressings remain intact' (page 63 of 283). An entry in the nursing care plan for 'requires full assistance to settle at night' noted 'Oramorph given as prescribed, condition variable, drinking well, appears hydrated. Slept long periods' (page 79 of 283).

29th August 1999

Nursing summary entry for night, noted 'Slept for long periods. Oramorph given as prescribed (page 63 of 283). The nursing care plan for 'requires full assistance to settle at night' noted 'Quite sleepy. Medication given as prescribed. Is complaining of left sided abdominal pain ?bowel or ?' (page 79 of 283).

30th August 1999

The nursing summary notes recorded 'This morning complaining of left abdominal pain', then 'Condition remains poor. Syringe driver commenced at 14.45h with diamorphine 40mg, midazolam 20mg. No further complaints of abdominal pain – very small amount of diet taken – managing mainly puddings. Recatherised this afternoon, draining (see also pages 55 and 85 of 283). When possible encourage fluids. Dressings also renewed' (page 63 of 283).

The drug chart confirms a syringe driver containing 40mg of diamorphine and 20mg of midazolam was commenced at 14.45h (page 171 of 283). However, the midazolam 20mg appears dated the 26th August 1999 (page 171 of 283).

His pressure sores were redressed. The small pressure sore on his left buttock was much cleaner; an area of slough was removed from the pressure sore on the lower right buttock exposing a large crater one inch deep which was redressed (page 98 of 283).

An entry in the nursing care plan for 'requires full assistance to settle at night' noted 'appeared to have a peaceful and comfortable night. No faecal incontinence until mane (morning) and then it was a large amount of black soft faeces' (page 79 of 283).

31st August 1999

Nursing summary noted 'Appeared to have a comfortable and peaceful night. This morning has passed a large amount of black faeces. The nursing summary for the night noted 'Comfortable night continues to pass

tarry black faeces' (page 63 of 283). This was repeated in the nursing care plan for 'Due to immobility...prone to constipation' (page 83 of 283).

Mr Packman's pressure sores on his left buttock were reported to be producing a copious amount of exudate (page 98 of 283).

An entry in the nursing care plan for 'requires full assistance to settle at night' noted 'Peaceful night. Incontinent of black tarry faeces+++ (a lot), nil taken by mouth, remains hot' (page 79 of 283).

1st September 1999

A medical notes entry made by Dr Reid notes 'Rather drowsy, but comfortable, passing melaena stools, abdomen huge, but quite soft, pressure sores over buttock and over the posterior aspect of both thighs. Remains confused. For T.L.C. (tender loving care) – stop furosemide and doxazosin. Wife aware of poor prognosis' (page 55 of 283).

The diamorphine dose in the syringe driver was increased to 60mg/24h at 19.15h (page 171 of 283). The dose of midazolam was also increased to 40mg/24h at 15.45h and 60mg/24h at 19.15h (page 171 of 283).

Nursing summary entry notes 'Dr Reid here. To continue', then 'Syringe driver renewed at 19.15h with diamorphine 60mg and midazolam 60mg as previous dose not controlling symptoms. Dressings renewed this afternoon. Mrs Packman had visited this afternoon and is aware of poor condition. Mrs Packman being admitted to E1 Ward at QA tomorrow for surgery. Please contact her son in the event of Mick's death. No night calls please' (page 64 of 283). The nursing summary nocte (night) entry reported 'Incontinent of black tarry faeces on settling. Peaceful night all care given. Syringe driver

satisfactory. Syringe driver reprimed' (page 64 of 283). The black stools were also recorded in the nursing care plan for 'Due to immobility...prone to constipation' (pages 82 and 83 of 283).

The nursing care plan relating to Mr Packman's pressure sores noted that they were contaminated with faeces and so redressed (page 98 of 283) and slough removed from the large pressure sore on his left buttock (page 100 of 283).

2nd September 1999

The nursing summary entry noted 'diamorphine increased to 90mg, midazolam 80mg (page 64 of 283). The drug chart notes this was at 18.40h (page 171 of 283). Hysocine (hydrobromide) was prescribed in a dose range of 800microgram–2g (an incorrect upper dose range) although never given (page 172 of 283).

An entry in the nursing care plan for 'Due to immobility...prone to constipation' noted 'some slight faecal soiling' (page 83 of 283) and the care plan related to his catheter noted 'some drainage but debris present' (page 85 of 283). An entry in the nursing care plan for 'requires full assistance to settle at night' noted 'Incontinent of black tarry faeces on settling. Nursed on side. Peaceful night. Strong radial pulse, open eyes when spoken to' (page 81 of 283).

3rd September 1999

A medical and nursing notes entries were made confirming death at 13.50h (pages 55 and 64 of 283). The cause of death was given as '1a Myocardial

infarction', with an approximate interval between onset and death of five days.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Syringe drivers, diamorphine, midazolam and hyoscine hydrobromide

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24h. Indications for its use include swallowing difficulties or a comatose patient. In the United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF 37, March 1999). Others sometimes suggest dividing by 2 or 3 depending on circumstance (Wessex protocol). Hence, 60mg of morphine taken orally a day could equate to a daily dose of 20 or 30mg of diamorphine SC. It is usual to prescribe additional doses for use 'as required' in case symptoms such as pain breakthrough. The dose is usually 1/6th of the 24h dose. Hence for someone receiving 30mg of diamorphine in a syringe driver over 24h, a breakthrough dose would be 5mg. One would expect it to have a 2–4h

duration of effect, but the dose is often prescribed to be given hourly as required. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in their terminal phase would generally aim to find a dose that improves the patients' symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg a day. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (BNF 37, March 1999) recommends 20–100mg SC over 24h. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated every 24h if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24h, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4h, and it may need to be given more frequently. As an active metabolite of

midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

Hyoscine hydrobromide is an antimuscarinic drug most commonly given to reduce excessive saliva or retained secretions ('death rattle'). It also has anti-emetic, antispasmodic (smooth muscle colic) and sedative properties. Repeated administration can lead to cummulation and this can occasionally result paradoxically in an agitated delirium, highlighted in both in the BNF and the Wessex protocol (page 41). It is usually given in a dose of 600–2400microgram SC over 24h (BNF 37, March 1999) or 400–600microgram as a stat SC dose. The Wessex protocol gives a dose range of 400–1200microgram over 24h.

The titration of the dose of analgesic or sedative medication is guided by the patients symptom control needs. The number and total dose of 'as required' doses needed over a 24h period are calculated and this guides the increase necessary in the regular dose of the drugs in the syringe driver in a way that is proportional to the patients needs. The ideal outcome is the relief of the symptoms all of the time with no need for additional 'as required' doses. In practice, this can be difficult to achieve and the relief of the symptoms for the majority of the time along with the use of 1–2 'as required' doses over a 24h period is generally seen as acceptable.

ii) The principle of double effect

The principle of double effect states that:

'If measures taken to relieve physical or mental suffering cause the death of a patient, it is morally and legally acceptable provided the doctor's intention is to relieve the distress and not kill the patient.'

This is a universal principle without which the practice of medicine would be impossible, given that every kind of treatment has an inherent risk. Many discussions on the principle of double effect have however, involved the use of morphine in the terminally ill. This gives a false impression that the use of morphine in this circumstance is a high risk strategy. When correctly used (i.e. in a dose *appropriate* to a patient's need) morphine does not appear to shorten life or hasten the dying process in patients with cancer. Although a greater risk is acceptable in more extreme circumstances, it is obvious that effective measures which carry less risk to life will normally be used. Thus, in an extreme situation, although it may occasionally be necessary (and acceptable) to render a patient unconscious, it remains unacceptable (and unnecessary) to cause death deliberately. As a universal principle, it is also obvious that the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

iii) Melaena.

Melaena refers to black 'tarry' faeces that are associated with gastro-intestinal haemorrhage. The black colour is caused by oxidation of the iron in haemoglobin during its passage through the ileum and colon. Bleeding originating from the lower gastrointestinal tract is generally associated with the passage of bright red blood. Only blood that originates from a high

source such as the small intestine, or bleeding from a lower source that occurs slowly enough to allow for oxidation, is associated with melaena. Thus, melaena is most often associated with haemorrhage in the stomach or duodenum and the most common cause of melaena is a peptic ulcer. If the source of bleeding is suspected to be in the upper gastrointestinal tract, an endoscopy is usually performed to diagnose the cause.

IV) Not for resuscitation

The medical notes record that Mr Packman was 'not for resuscitation' and Dr Barton refers to this in her statement. In my experience and opinion, the meaning of 'not for resuscitation' is quite specific. A medical judgement has been made that in the event of a patient's heart or breathing stopping *unexpectedly* (a cardiorespiratory arrest), there is little or no chance of cardiopulmonary resuscitation being successful (i.e. it would be medically futile) and thus should not be attempted. The decision not to resuscitate will be influenced by the presence of progressive life-threatening illness or other significant medical problems. This status does not however, mean that the patient is automatically excluded from receiving appropriate treatment for other medical problems that may arise. Thus, for example, patients with far advanced cancer, who may be admitted seriously unwell with an infection, given that cardiopulmonary resuscitation is likely to be futile, a 'not for resuscitation' decision is generally made. This does not however, prevent them from receiving appropriate treatment for their infection, even with intravenous antibiotics or fluids if necessary, when this is appropriate to their overall situation.

8. OPINION

Events at Queen Alexander Hospital, 6th–23rd August 1999

Mr Packman was a 67 year old man with obesity which limited his mobility and contributed to a several year history of swelling of his legs which in turn predisposed him to leg ulcers. Following three weeks of increasing redness of the groins he became less well with increasing weakness, leading to a fall which precipitated his admission to the Queen Alexander Hospital on the 6th August 1999. The main reason for his deterioration was cellulitis of the left leg ± groins. There were also pressure sores over his buttocks and thighs and he was noted to have atrial fibrillation (an irregular heart rhythm). He received appropriate treatment with intravenous then oral antibiotics and an increased dose in his diuretics and subsequently he and his blood test results improved. At 13.45h on the 11th August 1999 it was noted that he passed loose black stools, suggestive of melaena, blood in the stool. Sometime in the evening of 11th August 1999, Mr Packman complained of feeling dizzy and his blood pressure was checked and was normal for him at 170/90. It would be usual practice for the nursing staff to report melaena to the medical staff and it is a little surprising to find the first mention of melaena in the medical notes was two days later on the 13th August 1999 in an entry made by Dr Tandy. However, she undertook an appropriate assessment of Mr Packman including a digital rectal examination which revealed normal brown stool on the glove; his full blood count was checked and was found to be essentially stable. This would exclude a significant bleed. Although it is reported that Mr Packman had no abdominal pain, it is of note that he intermittently took Gaviscon, a treatment for indigestion,

between the 8–14th of August 1999. Mr Packman again passed small amounts of black tarry stools on the 19th August 1999; there was no nausea, epigastric pain or abdominal tenderness and his haemoglobin remained stable.

Although Mr Packman's Barthel score improved, he remained in bed requiring a hoist to be moved. His pressure sores persisted and he was transferred to Dryad Ward on the 23rd August 1999 for rehabilitation. In my opinion there are no issues relating to the standard of care or treatment proffered to Mr Packman during his admission to Anne ward and I note that Dr Marshall has no concerns regarding the management of his melaena.

Events at Dryad Ward, 23rd August 1999 until 3rd September 1999.

Infrequent entries in the medical notes during Mr Packman's stay on Dryad Ward make it difficult to closely follow his progress over the last twelve days of his life. There are five entries prior to the confirmation of death, taking up just over one and a half pages in length. In summary in approximate chronological order, Mr Packman was admitted to Dryad Ward for rehabilitation, his ongoing problems were noted to be obesity, arthritis in the knees, immobility, pressure sores and constipation. The episode of possible melaena on the 13th August 1999 was clearly noted and that his haemoglobin was stable. It was also reported that Mr Packman was better in himself with a good mental test score and no pain. The drug chart reveals he was continued on the same drugs as he received on Anne Ward bar the introduction of regular magnesium hydroxide (a laxative). On the 24th August 1999, a nursing handling profile noted in the section for pain

that it 'needed to be controlled'. This is at odds with the medical notes entry above and pain is not mentioned anywhere else. On the 25th August 1999, Mr Packman experienced seven to eight loose bowel actions throughout the afternoon and evening and fresh blood was observed. He also vomited and required an intramuscular anti-emetic. Dr Beasley, the general practitioner on-call for Dryad Ward that evening was contacted by the nursing staff whose decision was to withhold the 18.00h dose of enoxaparin and for Mr Packman to be reviewed by Dr Barton in the morning. Enoxaparin is designed to interfere with the clotting ability of the blood and thus would exacerbate any bleeding problems and it was reasonable to stop it. However, I can find no record that Mr Packman's heart rate or blood pressure were measured by the nursing staff or requested by Dr Beasley, which would help to inform the medical decision made. For example, a rapid heart rate ± a low blood pressure would potentially indicate a significant bleed and an immediate medical review in my opinion would have been indicated.

On the 26th August 1999, Mr Packman was reported to have had a fairly good morning with no further vomiting. Dr Ravi (who Dr Barton identifies as a locum consultant geriatrician) was contacted regarding the enoxaparin. He agreed with its discontinuation and asked that Mr Packman's haemoglobin be checked on the 26th and 27th August 1999. The nursing notes record that Mr Packman complained of feeling unwell at lunchtime and had a poor colour and that he was seen by Dr Barton and the plan was for to await the result of his haemoglobin. There was no entry in the medical notes regarding Dr Barton's assessment and no record that even

the basic observations of heart rate and blood pressure were taken. At approximately 18.00h on the 26th August 1999, Mr Packman complained of indigestion-like pain in his throat and vomiting. A verbal order was taken from Dr Barton for a stat dose of diamorphine 10mg and anti-emetic was also given. Dr Barton reviewed Mr Packman at 19.00h, noting that he was pale, clammy and unwell, but no basic observations (e.g. temperature, heart rate, blood pressure) or results of a medical examination (e.g. heart sounds, chest, abdomen) were recorded. Dr Barton considered that Mr Packman had had a myocardial infarction, but this was based on the history alone with no supporting evidence from an electrocardiograph (ECG). Dr Barton's plan was to treat Mr Packman with the stat dose of diamorphine and then regular oral morphine solution overnight, 10mg every four hours with 20mg at night. In my experience, it is usual to give patients who have had a myocardial infarction diamorphine as required, 'p.r.n.', but I have never seen oral morphine solution given regularly.

Dr Barton reported Mr Packman to be 'not be well enough' to transfer to the acute unit. I do not understand this comment. If Mr Packman was at home when he became this unwell, he would have been admitted to a hospital with appropriate facilities by emergency ambulance. Hence, a transfer via an emergency ambulance could have been arranged for Mr Packman. The fact that Mr Packman was not for resuscitation would not in my opinion have excluded him from receiving the most appropriate treatment and if his needs could not be met at Dryad Ward then emergency transfer to the acute hospital setting should have been undertaken. Instead Dr Barton recorded 'keep comfortable' and that she was 'happy for nursing staff to

confirm death'. In addition to the diamorphine and the oral morphine solution, Dr Barton also prescribed diamorphine 40–200mg and midazolam 20–80mg SC over 24h p.r.n.

Dr Barton also considered the alternative possibility of a gastrointestinal bleed but appeared to rule this out on the basis that there was no haematemesis. My understanding is that the absence of haematemesis does not rule out the possibility of a gastrointestinal bleed and in my opinion, a gastrointestinal bleed was much more likely given Mr Packman's pain, indigestion, melaena and falling haemoglobin. All of this information was/could have been available to Dr Barton on the evening of the 26th August 1999. In particular, the fall in haemoglobin from 12g/dl on the 24th August 1999 to 7.7g/dl on the 26th August 1999 was revealed by the blood test undertaken, analysed and reported on the 26th August 1999. A note on the report states that the lab gave up attempting to notify the ward, as it was unable to get through to Gosport War Memorial Hospital switchbaord. Nevertheless, given that Dr Barton's plan from earlier that day was to await the results of the haemoglobin and that Dr Barton considered that a gastrointestinal bleed was at least a possibility, I would have thought it reasonable for her to have made attempts to obtain the results via the on-call service.

On the 27th August 1999 there was an 'marked improvement' in Mr Packman's condition and he was seen by Dr Barton but no entry was made relating to this assessment, and as far as I can ascertain, the results of the blood test taken on the 26th August were either not obtained or acted upon, a further blood test as per Dr Ravi's plan not taken, Mr Packman's changing

condition not discussed with Dr Ravi or another consultant and he was not transferred to the acute hospital. Instead the plan was to continue with the regular morphine even though he was no longer complaining of the pain in his throat. The same can be said for the 28th August 1999.

On the 30th August 1999 (probably a Bank holiday) Mr Packman complained of left sided abdominal pain. A syringe driver was commenced at 14.45h containing diamorphine 40mg and midazolam 20mg/24h. This was a new pain, yet there is no indication that Mr Packman was either discussed with or was assessed by the on-call doctor prior to the commencement of the syringe driver. Thus it is unclear if a syringe driver containing diamorphine and midazolam was indicated or appropriate.

On the 31st August 1999 Mr Packman passed a large amount of melaena and the diagnosis of a gastrointestinal bleed should not have been in doubt. There is no evidence to suggest that his basic observations were taken or that he was assessed by a doctor. On the 1st September 1999, Mr Packman was noted by Dr Reid to be passing melaena stools, comfortable but drowsy and confused. This could have been due to Mr Packman's progressive anaemia and/or the dose of diamorphine may have been excessive for his needs. Dr Reid indicated that Mr Packman was for TLC (tender loving care). At 15.45h the dose of midazolam was increased to 40mg/24h without apparent reason. Subsequently, the diamorphine was increased to 60mg/24h and the midazolam increased to 60mg/24h at 19.15h as 'previous dose not controlling symptoms'. However, there is no explanation of what these symptoms were and if the increase was discussed with the on-call doctor.

On the 2nd September 1999, the diamorphine was increased to 90mg/24h and the midazolam to 80mg/24h without explanation. Hyoscine hydrobromide was also prescribed with an up limit of 2g. This is incorrect by a factor of 1000 as the upper limit should be 2mg. However, hyoscine hydrobromide was never given. An entry in the nursing care plan for the night time reports peaceful night, strong radial pulse, open eyes when spoken to.

Mr Packman was confirmed dead at 13.50h on the 3rd September 1999. The cause of death was given as myocardial infarction with an approximate interval between onset and death of five days. In my opinion, the circumstances of Mr Packman's deterioration and death were more in keeping with a gastrointestinal haemorrhage rather than a myocardial infarction, particularly given the fall in haemoglobin and melaena stool.

Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

The medical care provided by Dr Barton and Dr Reid to Mr Packman following his transfer to Dryad Ward, Gosport War Memorial Hospital is suboptimal when compared to the good standard of practice and care expected of a doctor outlined by the General Medical Council (General Medical Practice, General Medical Council, July 1998, pages 2-3) with particular reference to:

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs and, if necessary, an appropriate examination

- in providing care you must keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs, or appliances that serve patients' needs
- in providing care you must be willing to consult colleagues.

Specifically:

i) There was insufficient assessment and documentation of Mr Packman's clinical condition when he became less well on the afternoon of the 26th August 1999.

ii) There was insufficient assessment and documentation of Mr Packman's clinical condition when he became acutely ill on the evening of the 26th August 1999.

iii) Mr Packman was considered to have experienced either a myocardial infarction or a gastrointestinal haemorrhage, yet advice was not sought from other colleagues nor was he transferred to an appropriate place of care.

iv) Mr Packman received regular oral morphine that may have been excessive to his needs and prescribed a syringe driver, as required, with upper dose ranges of diamorphine and midazolam likely to be excessive to his needs.

v) Over the days that followed, there was a continued lack of an appropriate medical assessment of Mr Packman's condition; the results of blood tests that would have indicated a gastrointestinal bleed were either not obtained or acted upon.

vi) Mr Packman received increasing doses of diamorphine and midazolam that were likely to be excessive to his needs.

If the care is found to be suboptimal what treatment should normally have been proffered in this case?

Issue i (lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate and contemporaneous patient records).

Mr Packman was reported to be feeling unwell with a poor colour (generally indicates pallor) at lunchtime on the 26th August 1999. The nursing notes record that he was seen by Dr Barton but there is no entry in the medical notes relating to this. It is unclear what assessment was made of Mr Packman and even whether the most basic of observations were undertaken (e.g. temperature, heart rate and blood pressure). The nursing notes record only that the plan was to await the result of the haemoglobin level checked that day. When a patients' clinical condition changes for the worse, a thorough medical assessment should be carried out to ascertain the possible cause(s) and to identify if they are reversible with appropriate treatment. The assessment would consist of the history, examination and appropriate investigation.

Issue ii (lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate and contemporaneous patient records).

Dr Barton was contacted about Mr Packman when he developed his indigestion-like pain at 18.00h on the 26th August 1999 and requested that diamorphine 10mg be given by intramuscular injection. This stat dose was

appropriate given that a delay was anticipated in her getting to the hospital and the dose appropriate given Mr Packman's pain (it was considered to be a myocardial infarction), size and age. It is unclear how long it took Dr Barton to get to the hospital, but it was recorded that she was there at 19.00h.

When a patients' clinical condition changes for the worse, a thorough medical assessment should be carried out to ascertain the possible cause(s) and to identify if they are reversible with appropriate treatment. The assessment would consist of the history, examination and appropriate investigation. Dr Barton's entry in the medical notes recorded Mr Packman's appearance as pale, clammy and unwell. This suggests he was 'shocked'; a situation where a low cardiac output leads to a low blood pressure. However, basic observations such as his temperature, heart rate and blood pressure are not recorded nor is there a documented physical examination. These should have been undertaken, particularly as Dr Barton considered that Mr Packman had a serious underlying cause of being unwell, either a myocardial infarction or a gastrointestinal bleed.

There appears to have been no attempt to confirm the diagnosis of myocardial infarction; I understand there was limited access to an ECG machine out of hours at Dryad, but no attempts appear to have been made to obtain one subsequently or blood tests taken for cardiac enzymes.

Given that Dr Barton considered that a gastrointestinal bleed was a possibility, it would have been reasonable for her to have made attempts to obtain the result of the haemoglobin checked that day from the on-call pathology service. This would have revealed the fall in the haemoglobin to

7.7g/dl and made a diagnosis of gastrointestinal haemorrhage the more likely possibility.

Issue iii (providing treatment that serves the patients needs; willing to consult colleagues).

Gastrointestinal haemorrhage is a medical emergency and Mr Packman should have been thoroughly assessed and cared for in a clinical environment set up to respond to such an emergency (similarly, if he was having a myocardial infarction). I am led to believe that Dryad Ward was (understandably) limited in its ability to respond to such medical emergencies. For example, they lacked the ability to provide intravenous fluids, antibiotics or blood transfusions. Hence, I understand that the policy was to transfer patients who became acutely medically unwell to the acute hospital setting when this was appropriate. I see no reason for this not to have been appropriate for Mr Packman; he had been transferred to Dryad Ward for rehabilitation, had no known underlying life-threatening illness, death was not anticipated and a 'not for resuscitation' status should not have excluded him from receiving appropriate treatment for medical problems that arose. Whilst the cause of Mr Packman's gastrointestinal bleed is unknown, one of the commonest causes is a peptic ulcer which can be cured with appropriate treatment. Thus, Mr Packman may have had a potentially treatable and reversible medical condition, which presented with a serious complication (gastrointestinal bleeding) that should have been managed as a medical emergency. This would have included:

- obtaining intravenous access

- *taking blood for a full blood count, clotting and cross-matching for blood* transfusion
- correction of fluid losses and restoration of blood pressure
- caring for him in an clinical environment that can respond to such an emergency.

It is my understanding that Dryad Ward was not able to provide Mr Packman with such care and thus, in my opinion, he should have been transferred to the acute hospital setting. Whilst I appreciate it is not ideal to transfer medically unstable patients from one hospital to another, given the lack of even basic resuscitative measures at Gosport War Memorial Hospital, there was, in effect, little alternative and in this context, I do not understand Dr Barton's comment that Mr Packman was not well enough to transfer to an acute hospital. The lack of ability to medically stabilise a patient can not be a reason not to attempt a transfer at all, otherwise, logically, ill patients would not be able to be taken from home to hospital. Instead, patients who become unwell at home, are taken to hospital by an emergency ambulance, and in my opinion, transfer by emergency ambulance could have been arranged for Mr Packman. Even if one adopted the view of Dr Barton that he was too unwell to transfer, then there were subsequent opportunities to transfer him. For example, he was reported as showing 'some marked improvement since yesterday' on the 27th August 1999 and he lived for another eight days. Further, despite Dr Barton's assessment that Mr Packman was so unwell that he could not be transferred, there is nothing documented to suggest that she sought advice

regarding appropriate management of Mr Packman from the on-call physicians/geriatricians or the cardiologists.

Issue iv (prescribe only the treatment, drugs, or appliances that serve patients' needs).

If Mr Packman was distressed by severe pain related to a peptic ulcer (or myocardial infarction) then the prescription of morphine parenterally was reasonable. Although generally 5mg would be given, 10mg can be used in heavier patients. The repeated use of this dose, p.r.n. for the relief of severe pain, would also be reasonable. In her statement, Dr Barton concludes (point 24) that the diamorphine was additionally justified on the basis that Mr Packman had a large pressure on his sacrum and thighs which would have been causing him significant pain and discomfort. In my opinion, this is not a robust conclusion; there was no mention of Mr Packman being in pain due to his pressure sores at the Queen Alexander Hospital (where his only analgesic was paracetamol), in the medical clerking on his transfer to Dryad Ward or in the nursing care plan relating to his pressure sores. One nursing summary entry a day later on the 27th August 1999, records 'some discomfort this afternoon - especially when dressings being done.' The significance of this is unclear; a discomfort is generally used to describe a mild pain, the site of the discomfort is unspecified and there is no mention of discomfort or pain on changing his dressings that day in the nursing care plan relating to his pressure sores.

In my experience, I have never seen oral morphine solution subsequently prescribed regularly for patients considered likely to have had either a

myocardial infarction or a gastrointestinal haemorrhage and the use of regular oral morphine solution was, in my opinion, inappropriate. The oral morphine solution was prescribed as a range 10–20mg four times a day and 20mg at night; one of the problems of prescribing drugs as a range is that it can be difficult to know what dose patients actually received, when the bigger or smaller dose should be given and who should decide this. Thus, it is unclear from the prescription chart and nursing summary notes what dose of morphine Mr Packman actually received during the daytime.

Similarly, the prescription of diamorphine and midazolam in a syringe driver p.r.n., on the 26th August 1999, in my opinion, was not justified; the dose range of diamorphine 40–200mg and midazolam 20–80mg/24h would have exposed Mr Packman to doses likely to have been excessive for his needs. A dose of an opioid which is excessive to a patient's needs is associated with an increased risk of drowsiness, delirium, nausea and vomiting and respiratory depression.

It is unusual that drugs to be given by syringe driver are prescribed p.r.n. particularly in a wide dose range. This is because of the inherent risks that would arise from a lack of clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing a drug as a range, particularly a wide range, is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. Dr Barton in her statement notes that the prescription for the diamorphine and midazolam were on an anticipatory basis in case they were required in due course and that it was not her intention that they

be administered at that time (point 29). However, there are no instructions on the prescription chart that would provide a safeguard in this respect.

If there were concerns that a patient may experience, for example, episodes of pain, anxiety or agitation, it would be much more usual, and indeed seen as good practice, to prescribe appropriate doses of morphine/diamorphine, diazepam/midazolam and other drugs that could be given intermittently p.r.n. orally or SC. This allows a patient to receive what they need, when they need it and guides the doctor in deciding if a regular dose is required, or, if already taking a regular dose, how it should be titrated.

Issue v (lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate and contemporaneous patient records).

Over the days that followed, there was a continued lack of an appropriate medical assessment of Mr Packman's condition; no attempts were made to obtain an ECG or blood tests taken for cardiac enzymes; the results of blood tests that would have indicated a gastrointestinal bleed were, despite numerous opportunities were either not obtained or acted upon. Although requested by Dr Ravi, I can find no haemoglobin result for the 27th August 1999.

Issue vi (lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate and contemporaneous patient records; prescribe only the treatment, drugs, or appliances that serve patients' needs).

On Monday 30th August 1999 at 2.45pm a syringe driver was set up containing diamorphine 40mg and midazolam 20mg SC/24h. A nursing care plan queried whether Mr Packman's left sided abdominal pain was related to his bowels or some other cause. However, no medical assessment was undertaken and thus the cause of the pain and the appropriateness of the use of these two drugs in a syringe driver are unclear. There was no annotation in the nursing or medical notes to suggest that a doctor was involved in this decision, contrary to Dr Barton's stated intention (Statement of Dr Jane Barton) and illustrates the lack of a safeguard in the prescription of these drugs, in these doses, by syringe driver.

Generally, the total 24h oral dose of morphine is divided by three or occasionally by two to determine an appropriate dose, i.e. diamorphine 20–30mg/24h would generally be considered an appropriate conversion for Mr Packman and in this regard a dose of diamorphine 40mg/24h represents a 33–100% increase. In her statement, Dr Barton states that Mr Packman would have 'started to have become inured (tolerant) to the opiate medication' and an increase of this nature was in her view entirely appropriate to ensure that his pain was well controlled (point 35). In my experience and my opinion, rapid tolerance to opioids (he had been on oral morphine for four days) is not a plausible explanation in itself to justify an increase in Mr Packman's opioid dose.

Despite Mr Packman passing a large amount of black faeces on the morning of the 31st August 1999 there was no medical assessment documented.

On the 1st September 1999, Dr Reid noted that Mr Packman was drowsy, had been passing melaena stools and was confused. It is unclear if Dr Reid was aware of the haemoglobin result from the 26th August 1999 but he appeared to consider at that time Mr Packman suitable for TLC (tender loving care) only. The confusion and drowsiness may have been due to the diamorphine, midazolam or his medical condition, as he was likely to have been becoming progressively more anaemic.

Although noted to be comfortable by Dr Reid, the midazolam was increased at 15.45h to 40mg/24h (from 20mg/24h; increase of 100%) with no mention of why this increase was indicated or discussed with a doctor. Later that evening, the dose of diamorphine was increased to 60mg/24h (from 40mg/24h) and midazolam to 60mg/24h (from 40mg/24h) at 19.15h *because 'previous dose not controlling symptoms.' However, there is no* mention of what these symptoms were or that the increase was discussed with a doctor. The diamorphine increase was 50% and the midazolam dose was effectively trebled within 24h. It is difficult to assess the appropriateness of these increases. The medical and nursing notes do not suggest Mr Packman was in pain or distress. This is another reason why the use of smaller p.r.n. doses of diamorphine and midazolam is helpful; frequent use (e.g. ≥2 extra doses per 24h) suggests the need to titrate the regular medication upwards and also guides the magnitude of the required increase.

Mr Packman was noted to have had a peaceful night. However, the diamorphine was increased to 90mg/24h (from 60mg/24h; a 50% increase) and the midazolam to 80mg/24h (from 60mg/24h; a 33% increase) at

18.40h on the 2nd September 1999. There is no mention of pain or distress in the nursing or medical notes and the justification for the further increase in dose is unclear.

If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

Both Dr Barton and Dr Reid had a duty to provide a good standard of medical practice and care. In this regard, Dr Barton and Dr Reid fell short of a good standard of clinical care as defined by the GMC (Good Medical Practice, General Medical Council, July 1998 pages 2–3) with particular reference to a lack of clear note keeping, adequate assessment of the patient, providing treatment that could be excessive to the patients' needs and willingness to consult colleagues.

Mr Packman was admitted for rehabilitation and it was not anticipated that he was likely to die. Although Dr Barton considered a myocardial infarction more likely than a gastrointestinal haemorrhage, the latter would have been confirmed as the more likely if the haemoglobin result was obtained that evening or the following day. A gastrointestinal haemorrhage (or a myocardial infarction) is a serious medical emergency and requires appropriate and prompt medical attention. The cause of Mr Packman's gastrointestinal bleed is unknown. However, as the most common cause is a peptic ulcer which can be cured with appropriate treatment, it is possible that Mr Packman's deterioration was due to a potentially reversible cause that could have been managed by transfer to the acute hospital for appropriate resuscitation with intravenous fluids, blood transfusion and

further investigation. This view is in keeping with the opinion of a gastroenterologist, Dr Jonathan Marshall (report of 1st April 2005).

Dr Barton considered Mr Packman too unwell to move. In this regard it seems odd that a patient becoming acutely unwell at Gosport War Memorial Hospital would be at a disadvantage compared to if they had become acutely unwell at home. I see no reason that a patient could not be transferred by emergency ambulance if this was in their best interests. When possible they should be medically stabilised beforehand, but the lack of ability to do this should not be the reason not to attempt transfer at all. Even if one accepted the view that Mr Packman was too unwell to move, advice should have been sought on his management from the on-call physicians/geriatricians or cardiologists.

In short, Dr Barton in particular, but also Dr Reid, could be seen as doctors who breached the duty of care they owed to Mr Packman by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mr Packman by failing to adequately assess his condition and taking suitable and prompt action. Mr Packman could have had a potentially treatable and reversible medical condition, which presented with a serious complication (i.e. bleeding). He should have been urgently and appropriately assessed and transferred to an acute medical unit. He was not appropriately assessed, resuscitated with fluids, transferred or discussed with the on-call medical team. In my view, there was no obvious reason why it was not appropriate to provide Mr Packman with this usual course of action.

Morphine and diamorphine are safe drugs when used correctly. The key issue is whether the use and the dose of diamorphine and other sedatives are *appropriate* to the patients' needs. Although some might invoke the principle of double effect (see technical issues), it remains that a doctor has a duty to apply effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose of strong opioid that was *appropriate* and not excessive for a patient's needs. The stat doses of diamorphine could be seen as appropriate for the relief of severe pain. However, in my opinion, the ongoing use of regular morphine and subsequent use of diamorphine and midazolam were inappropriate; their use was not obviously justified and the doses were likely to be excessive to Mr Packman's needs. In my opinion, it is the inappropriate management of Mr Packman's gastrointestinal haemorrhage together with his exposure to unjustified and inappropriate doses of diamorphine and midazolam that contributed more than minimally, negligibly or trivially to his death. As a result Dr Barton and Dr Reid leave themselves open to the accusation of gross negligence.

9. LITERATURE/REFERENCES

British National Formulary 37 (March 1999).

Prescribing in Terminal Care, pages 11–14

Prescribing for the elderly, pages 15–16

Good Medical Practice, General Medical Council July 1998, pages 2–3

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition 'Wessex Protocol' Salisbury Palliative Care Services May 1995.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: _____ Date: _____

2000/2047/02

Field Fisher Waterhouse

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Strictly Private & Confidential

Ms Juliet St Bernard
General Medical Council
Regents Place
350 Euston Road
London
NW1 3JN

Our ref: tet/kaj/00492-15579/5921356 v1
Your ref:

Tamsin Tomlinson
Assistant Solicitor

Code A

31 August 2007

Dear Juliet

General Medical Council - Dr Barton

Further to our previous discussions please now find enclosed two folders of the expert reports in this case.

Yours sincerely

Code A

Tamsin Tomlinson
for Field Fisher Waterhouse LLP

General Medical Council	
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Original has been Photocopied to Improve Scan Quality	
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Field Fisher Waterhouse LLP Portland Tower Portland Street Manchester M1 3LF
Tel +44 (0)161 238 4900 Fax +44 (0)161 237 5357
E-mail info@ffw.com Web www.ffw.com

Field Fisher Waterhouse

GENERAL MEDICAL COUNCIL

-AND-

DR BARTON

MEDICAL REPORTS

GENERAL MEDICAL COUNCIL

DR BARTON

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4. Gladys Richards, Professor G A Ford, 12 December 2001.
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6. Helena Service, Dr D A Black, 6 November 2004.
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32. Enid Spurgin, Daniel Redfearn 22 January 2006.

33. Enid Spurgin, Dr D A Black 27 June 2005.

34. Enid Spurgin, Dr Andrew Wilcock, 5 March 2006.

16

Frimley Park Hospital NHS
NHS Trust

Portsmouth Road
Frimley
Camberley
Surrey
GU16 7UJ

Elderly Care Unit
Telephone: Code A *(direct line)*
Fax: Code A *(direct into Secretaries' office)*

Tel: 01276 604604
Fax: 01276 604148

KIM/gnt/gosport

18 October 2001

CONFIDENTIAL

Detective Superintendent J James
Hampshire Constabulary
Major Incident Complex
Kingston Crescent
North End
PORTSMOUTH
PO2 8BU

Dear DS James

CONFIDENTIAL MEDICAL REPORT REGARDING MEDICAL MANAGEMENT OF PATIENTS AT GOSPORT WAR MEMORIAL HOSPITAL

Thank you for asking me to give a report on the management of four patients who died at Gosport War Memorial Hospital. I have based my personal opinion on my qualification as a specialist in geriatric medicine, my 13 years experience as a Consultant Geriatrician with several years experience working at the local hospice.

USE OF OPIOID ANALGESICS

Opioid analgesics are used to relieve moderate to severe pain and also can be used to relieve distressing breathlessness and cough. The use of pain killing drugs in palliative care (ie the active total care of patients whose disease is not responsive to curative treatment) is described in the British National Formulary which is the standard reference work circulated to all doctors in Great Britain. The guidance in the BNF suggests that non-opioid analgesics such as Aspirin or Paracetamol should be used as first line treatment and occasionally non-steroidal anti-inflammatory drugs may help in the control of bone secondaries. If these drugs are inadequate to control the pain of moderate severity then a weak opioid such as Codeine or Dextropropoxyphene should be used either alone or in combination with the simple pain killers in adequate dosage. If these weak opioid preparations are not controlling the pain Morphine is the most useful opioid analgesic and is normally given by mouth as an oral solution every 4 hours, starting with a dose between 5 mg and 20 mg, the aim being to choose the lowest dose which prevents pain. The dose should be adjusted with careful assessment of the pain and use of other drugs should also be considered. If the pain is not well controlled the dose should be increased in a step-wise fashion to control the pain.

Sometimes modified release preparations of Morphine are given twice daily once the required dose of Morphine is established, as this may be more convenient for the patient.

If the patient becomes unable to swallow the equivalent intra-muscular dose of Morphine is half the total 24 hour dose given orally. Diamorphine is preferred for injections over Morphine as it is more soluble and can be given in smaller volume, therefore with less distress to the patient.

Subcutaneous infusions of Diamorphine by syringe driver are standard practise if the patient requires repeated intra-muscular injections, to save the patient unnecessary distress. This is standard treatment in Hospices and other medications can be added to deal with anxiety, agitation and nausea as they can safely be mixed with Diamorphine (such as Haloperidol, Cyclizine and Midazolam). The other indications for use of the parenteral route are when the patient is unable to take medicines by mouth due to upper gastro-intestinal problems and occasionally if the patient does not wish to take regular medication by mouth.

The BNF has a table showing the equivalent doses of oral Morphine and parenteral Diamorphine for intramuscular injection or subcutaneous infusion as a guide to the dosage when switching from the oral to the injection route, eg 10 mg of oral Morphine 4 hourly is equivalent to 20 mg of Diamorphine by a subcutaneous infusion every 24 hours, and 100 mg oral Morphine 4 hourly is equivalent to 240 mg of Diamorphine subcutaneously every 24 hours.

SUMMARY

It is clear from the above that a doctor trying to control pain should first start the patient on a non-opioid analgesic, move on to a weak opioid analgesic if the pain is not controlled, consider changing the patient to regular oral Morphine if the pain remains poorly controlled and only start parenteral Diamorphine if the patient is unable (or unwilling) to take Morphine by mouth and would otherwise need regular painful injections of Diamorphine to try and control the pain. There is clear guidance on the dose of Morphine to use in a syringe driver when transferring from oral Morphine to the subcutaneous route. Finally the dose of Morphine or Diamorphine should be reviewed regularly and only increased if the symptom of pain is not adequately controlled.

CASE NOTE REVIEWS

1 ARTHUR CUNNINGHAM

Mr Cunningham was known to suffer with depression, Parkinson's disease and cognitive impairment with poor short term memory. He suffered with long standing low back pain following a spinal injury sustained in the Second World War which required a spinal fusion. He suffered with hypertension and non insulin diabetes mellitus, had a previous right renal stone removed, and bladder stones, and had a previous trans-urethral prostatectomy. Myelodysplasia had been diagnosed (a bone marrow problem affecting the production of the blood constituents). Mr Cunningham had a one month admission under the care of Dr Banks for depression in July and August 1998.

Mr Cunningham was admitted by Dr Lord, Consultant Geriatrician from the Dolphin Day Hospital to Dryad Ward at Gosport War Memorial Hospital on 21 09 1998 because of a large necrotic sacral ulcer with a necrotic area over the left outer aspect of the ankle (these are signs of pressure sores). Dr Lord's intention was to give more aggressive treatment to the sacral ulcer. He was seen by Dr Barton. A dose of 2.5 mg to 10 mg of Oromorph 4 hourly was prescribed and he was given 5 mg prior to his sacral wound dressing at 1450 and a further dose of 10 mg at 2015. Diamorphine via a syringe driver was prescribed at a dose of 20 mg to 200 mg in 24 hours and this was commenced at a dose of 20 mg for 24 hours with Midazolam at 2300 on 21 09 1998. Dr Barton reviewed the patient on 23 September when he was said to be "chesty", Hyoscine was added to the syringe driver and the dose of Midazolam was increased. The patient was noted to be in some discomfort when moved on that day and the next day he was said to be "in pain" and the Diamorphine dose was increased to 40 mg for 24 hours, then 60 mg the following day and 80 mg on the 26 September, there being no further comments as to the patient's condition. The dose of Midazolam and Hyoscine was also increased. The patient died at 2315 on 26 09 1998.

Comments

All the prescriptions for opiod analgesia are written in the same hand, and I assume they are Dr Barton's prescriptions although the signature is not decipherable. Morphine was started without any attempts to control the pain with less potent drugs. There was no clear reason why the syringe driver needed to be started as the patient had only received two doses of oral Morphine, the 24 hour dose requirement of Diamorphine could not therefore be established. The dose of Diamorphine prescribed gave a tenfold range from 20 mg to 200 mg in 24 hours which is an unusually large dose range in my experience. The patient was reviewed by Dr Barton on at least one occasion and the patient was noted to be in some discomfort when moved. The dose was therefore appropriately increased to 40 mg per 24 hours but there are no further comments as to why the dose needed to be progressively increased thereafter. In my view Morphine was started prematurely, the switch to a syringe driver was made without any clear reason and the dose was increased without any clear indication.

2 ALICE WILKIE

Miss Wilkie was known to suffer with severe dementia, depression and rectal bleeding attributed to piles. She had been admitted to Philip Ward with a urinary tract infection and immobility under the care of Dr Lord and a decision was made to transfer her to Daedalus ward at Gosport War Memorial Hospital for a few weeks observation prior to a decision on placement. She was transferred on the 6 August and was seen by Dr Peters. The nurses recorded that the patient was complaining of pain but it was difficult to establish the nature or site of this pain. Diamorphine was prescribed on 20 08 1998 in a dose of 20 mg to 200 mg per 24 hours and the signature is identical to that on Mr Cunningham's case which I assume is Dr Barton's. A dose of 30 mg was given on 20 08 1998 with Midazolam and an entry in the notes, again apparently by Dr Barton, comments on a "marked deterioration over last few days". The patient was given another 30 mg of Diamorphine on 21 08 1998 and died that day at 1830. The patient was said to be comfortable and pain free by the nursing staff on the final day.

Comments

There was no clear indication for an opiod analgesic to be prescribed, and no simple analgesics were given and there was no documented attempt to establish the nature of her pain. In my view the dose of Diamorphine that was prescribed at 30 mg initially was excessive and there is no evidence that the dose was reviewed prior to her death. Again the Diamorphine prescription gave a tenfold range from 20 mg to 200 mg in 24 hours.

3 ROBERT WILSON

Mr Wilson was known to suffer with alcohol abuse with gastritis, hypothyroidism and heart failure. He was originally admitted via Accident & Emergency on the 22 September with a fractured left humerus and transferred to Dickens Ward under the care of Dr Lord. His fracture was managed conservatively. In view of the severe pain he received several doses of Morphine and was prescribed regular Paracetamol.

He was reviewed by Dr Luznat, Consultant Psychogeriatrician, who felt he had an early dementia and depression and recommended an anti-depressant. He was also noted to have poor nutrition.

Dr Lord made a decision to transfer Mr Wilson for a "short spell to a long term NHS bed" with the aim of controlling his pain and presumably to try to rehabilitate him. He was accordingly moved to Dryad ward at Gosport War Memorial Hospital on the 14 October. The transfer letter from Dickens

ward shows that he was still " in a lot of pain in arm".

The prescription appears to have been written by Dr Barton once again. Paracetamol was prescribed but never given by the nursing staff. Oramorph was prescribed 10 mg 4 hourly and 20 mg nocte commencing on 15 10 1998 and the night time dose was given with "good effect" as judged by the nursing staff. The nursing report goes on to say that Mr Wilson had become "chesty" and had "difficulty in swallowing medications". Oramorph was also prescribed 5 mg to 10 mg as required 4 hourly and four doses were given, suggesting Mr Wilson was in persisting pain. on 16 10 1998 the patient was seen by Dr Knapman. The patient was said to be unwell, breathless, unresponsive with gross swelling of the arms and legs. No ECG or oxygen saturation was recorded but the patient's dose of Frusemide (a diuretic) was increased, so I assume the patient was thought to have worsening heart failure. The nurses report a "very bubbly chest". A Diamorphine/Midazolam subcutaneous infusion was prescribed on 16 10 1998 again, in Dr Barton's handwriting, the dose range from 20 mg to 200 mg in 24 hours. 20 mg of Diamorphine was given on 16 10 1998 and the nurses commented later that the "patient appears comfortable", the dose was increased to 40 mg the next day when copious secretions were suctioned from Mr Wilson's chest. On 18 10 1998 the patient was seen by Dr Peters and the dose of Diamorphine was increased to 60 mg in 24 hours and Midazolam and Hyoscine were added. The patient died on 18 10 1998 at 2340 hours.

Comments

Mr Wilson was clearly in pain from his fractured arm at the time of transfer to Dryad ward. Simple analgesia was prescribed but never given (there was an entry earlier in the episode of care that Mr Wilson had refused Paracetamol). No other analgesia was tried prior to starting morphine. Mr Wilson had difficulty in swallowing medication. The Oramorphine was converted to subcutaneous Diamorphine in appropriate dose as judged by the BNF guidelines. The patient was reviewed by a doctor prior to the final increase in Diamorphine. Once again the Diamorphine prescription had a tenfold dose range as prescribed.

It is clear that Mr Wilson's condition suddenly deteriorated probably due to a combination of worsening heart failure and terminal bronchopneumonia and I consider that the palliative care given was appropriate. A Do Not Resuscitate decision had been made by Dr Lord on 29 09 1998.

4 EVA PAGE

Mrs Page was known to suffer with hypertension, ischaemic heart disease with heart failure and paroxysmal atrial fibrillation, depression, episodic confusion and had sustained a minor stroke in the past. She was admitted on 06 02 1998 to Victory Ward with nausea, anorexia and dehydration and had recently been treated for depression. She was transferred to Charles Ward on 19 02 1998 and had been noted to have a 5 cm mass on chest

x-ray compatible with a lung cancer. She was transferred to Dryad ward, Gosport Memorial Hospital on 27 02 1998 for palliative care. On arrival she was noted to be calling out frequently, and anxious. She was prescribed Thioridazine (a tranquilliser) but this did not relieve her distress and she was prescribed Oramorph 5 mg to 10 mg as required 4 hourly, I believe, by Dr Barton. The nurses report "no relief". She was seen by another doctor who was not named in the nursing record who prescribed regular Thioridazine and Heminevrin at night. On 01 03 1998 it is recorded that Mrs Page "spat out medication", on 02 03 1998 there was an entry, I believe by Dr Barton, stating "no improvement on major tranquillisers. I suggest adequate opioids to control fear and pain". He prescribed a Fentanyl patch 25 mg (another opioid which can be given as a skin patch) and the prescription was countersigned by Dr Lord, I believe. The nursing records state she was "very distressed", she was reviewed by Dr Barton and Diamorphine 5 mg intramuscularly was given. She was then seen by Dr Lord and a further dose of intramuscular 5 mg Diamorphine was given. On 03 03 1998 a syringe driver was started, prescribed, I believe, by Dr Barton, at a dose of 20 mg to 200 mg in 24 hours. The initial dose given was 20 mg of Diamorphine with Midazolam which was started at 1050. The nurses record "rapid deterioration ..... right side flaccid" . The patient died at 2130 that evening.

Comments

Mrs Page had a clinical diagnosis of lung cancer. There was no documentation of any symptoms relevant to this and no evidence of metastatic disease. There was no documentation of any pain experienced by the patient. When she was transferred to Dryad Ward most medication was stopped but she required sedative medication because of her distress and anxiety. No psychogeriatric advice was taken regarding her symptom control and she was started on opioid analgesia, in my view, inappropriately. Following her spitting out of medication she was given a topical form of an opioid analgesic (Fentanyl). A decision was taken to start a syringe driver because of her distress. This included Midazolam which would have helped her agitation and anxiety.

The prescription for subcutaneous Diamorphine infusion again showed a tenfold range from 20 mg to 200 mg. It was clear that her physical condition deteriorated rapidly and I suspect she may have had a stroke from the description of the nursing staff shortly prior to death.

CONCLUSIONS

I felt that the nursing records at Gosport War Memorial Hospital were comprehensive on the whole. The reason for starting opioid therapy was not apparent in several of the cases concerned. There had been no mention of any pain, shortness of breath or cough requiring relief. In several of the cases concerned oral morphine was not given for long enough to ascertain the patient's dose requirements, the reason for switching to parenteral Diamorphine via subcutaneous infusion was not documented and the prescription of a tenfold range (20 mg to 200 mg) of

Diamorphine on the "as required" section of the drug chart is, in my view, unacceptable. In my view the dose of Diamorphine should be prescribed on a regular basis and reviewed regularly by medical staff in conjunction with the nursing team. There was little indication why the dose of Diamorphine was increased in several of the cases and the dose appears to have been increased without the input of medical staff on several occasions.

Specimen signatures of Dr Lord and Dr Barton are necessary to confirm the identity of the prescribers and doctors making entries into the clinical notes.

I believe that the use of Diamorphine as described in these four cases suggest that the prescriber did not comply with standard practise. There was no involvement, as far as I could tell, from a palliative care team or specialist nurse advising on pain control. I believe these two issues require further consideration by the Hospital Trust.

I trust this report contains all the essential information you require. Please let me know if you wish me to give any further comment.

Yours sincerely

Code A

CONSULTANT PHYSICIAN AND GERIATRICIAN

MEDICO-LEGAL REPORT

Re: **Gladys Mabel RICHARDS**
Arthur "Brian" CUNNINGHAM
Alice WILKE
Robert WILSON
Eva PAGE

Prepared by:
Professor G A Ford, MA, FRCP
Consultant Physician, Freeman Hospital
Newcastle upon Tyne
Professor of Pharmacology of Old Age, University of Newcastle upon Tyne

For: **Hampshire Constabulary**

Date: **12th December 2001**

Contents

Introduction and Remit of the Report

8.1 Code A

8.2 I have been asked by Detective Superintendent John James of Hampshire Constabulary to examine the clinical notes of five patients (Gladys Mabel Richards, Arthur "Brian" Cunningham, Alice Wilkie, Robert Wilson, Eva Page) treated at the Gosport War Memorial Hospital and to apply my professional judgement to the following:

- The gamut of patient management and clinical practices exercised at the hospital
- Articulation of the leadership, roles, responsibilities and communication in respect of the clinicians involved
- The accuracy of diagnosis and prognosis including risk assessments
- An evaluation of drugs prescribed and the administration regimes
- The quality and sufficiency of the medical records
- The appropriateness and justification of the decisions that were made
- Comment on the recorded causes of death
- Articulate the duty of care issues and highlight any failures

1.3 I have prepared individual reports on each case and an additional report commenting on general aspects of care at Gosport War Hospital from a consideration of all five cases.

1.4 I have been provided with the following documents by Hampshire Constabulary, which I have reviewed in preparing this report:

- Comment on the recorded causes of death
- Letter DS J James dated 15th August 2001
- Terms of Reference document
- Hospital Medical Records of Gladys Richards, Brian Cunningham, Alice Wilkie, Robert Wilson and Eva Page
- Witness statements by Leslie France Lack, and Gillian MacKenzie
- Report of Professor Brian Livesley
- Transcripts of police interviews with Gosport War Memorial staff Dr Barton, Mr Beed, Ms Couchman, Ms Joice

- Transcript of police interviews with Royal Hospital Haslar staff Dr Reid and Flt. Lt. Edmondson
- Transcript of interviews with patient transfer staff Mr Warren and Mr Tanner
- Transcript of police interviews with or statements from following medical and nursing staff: Dr Lord, LM Baldacchino, M Berry, JM Brewer, J Cook, E Dalton, W Edgar, A Fletcher, J Florio and A Funnell.

Gladys Mabel RICHARDS

Course of Events

2.1 Gladys Richards was 91 years old when admitted as an emergency via the Accident & Emergency Department to Haslar Hospital on 29Th July 1998. She had fallen onto her right hip and developed pain. At this time she lived in a nursing home and was diagnosed as having dementia. She had experienced a number of falls in the previous 6 months and the admission notes comments "*quality of life has ↓↓ markedly last 6/12*". She was found to have a fracture of the right neck of femur. An entry in the medical notes by Surgeon Commander Malcom Pott, Consultant orthopaedic surgeon dated 30 July 1998 states '*After discussion with the patient's daughters in the event of this patient having a cardiac arrest she is NOT for cardiopulmonary resuscitation. However she is to be kept pain free, hydrated and nourished.*' Surgery (right hemiarthroplasty) was performed on 30 July 1998.

2.2 On 3rd August she was referred for a geriatric opinion and seen by Dr Reid, Consultant Physician in Geriatrics on 3rd August 1998. In his letter dated 5th August 1998 he notes she had been on treatment with haloperidol and trazadone and that her daughters thought she had been 'knocked off' by this medication for months, and had not spoken to then for 6-7 months. Her mobility had deteriorated. Her daughters commented to Dr Reid that she had spoken to them and had been brighter mentally since the trazadone had been omitted following admission. Dr Reid found Mrs Richards to be confused but pleasant and cooperative, unable to actively lift her right leg from the bed but appeared to have little discomfort on passive movement of the right hip. He commented '*I understand she has been sitting out in a chair and I think that despite her dementia, she should be afforded the opportunity to try to re-mobilise her.* He arranged for her transfer to Gosport War Memorial Hospital.

2.3 Following Dr Reid's entry in the notes on 3rd August two further entries are made in the medical notes by the on call house officer (Dr Coales?) on 8th August 1998. Dr Coales was asked to see Mrs Richards who was agitated on the ward. She had been given 2mg haloperidol and was asleep when first seen at 0045h. At 02130 hr a further entry records Mrs Richards was '*noisy and disturbing other patients n ward. Unable to reason with patient. Prescribed 25mg thioridazine'.* A transfer letter for Sergeant Curran, staff nurse to the Sister in Charge dated 10th August 1998 describes Mrs Richards status immediately prior to transfer and notes *'Is now fully weight bearing, walking with the aid of two nurses and a zimmer frame. Gladys needs total care with washing and dressing eating and drinking. Gladys is continent, when she becomes fidgety and agitated it means she wants the toilet. Occasionally incontinent at night, but usually wakes.*

2.4 On 11th August 1998 Mrs Richards was transferred to Daedalus ward. Dr Barton writes *in the medical notes "Impression frail demented lady, not obviously in pain, please make comfortable. Transfers with hoist, usually continent, needs help with ADL Barthel 2. I am happy for nursing staff to confirm death".* The summary admitting nursing notes record *"now fully weight bearing and walking with the aid of two nurses and a Zimmer frame*". On 12th August the nursing notes record "*Haloperidol given at 2330 as woke from sleep. Very agitated, shaking and crying. Didn't settle for more than a few*

minutes at a time. Did not seem to be in pain". On 13th August nursing notes record "*found on floor at 1330h. Checked for injury none apparent at time. Hoisted into safer chair. 1930 pain Rt hip internally rotated, Dr Brigg contacted advised Xray am and analgesia during the night. Inappropriate to transfer for Xray this pm.*"

2.5 On 14th August 1998 Dr Barton wrote '*sedation/pain relief has been a problem. Screaming not controlled by haloperidol 1g ? but very sensitive to Oramorph. Fell out of chair last night. R hip shorter and internally rotated, Daughter nurse and not happy. Plan Xray . Is this lady well enough for another surgical procedure?"* A further entry the same day states "*Dear Cdr Spalding, further to our telephone conversation thank you for seeing this unfortunate lady who slipped from her chair and appears to have dislocated her R hip. Hemiarthroplasty was done on 30-8-98. I am sending Xrays. She has had 2.5ml of 10mg/5ml oramoroph at midday. Many thanks*".

2.6 Following readmission to Haslar hospital Mrs Richards underwent manipulation of R hip under iv.sedation (2 mg midazolam) at 1400h. At 2215h the same day she was not responding to verbal stimulation but observations of blood pressure, pulse, respiration and temperature were all in the normal range. A further entry on 17th August by Dr Hamlin (House Officer) states "*fit for discharge today (Gosport War Mem) To remain in straight knee splint for 4/52. For pillow between legs (abduction) at night.*" A transfer letter to the nurse in charge at Daedalus ward states "*Thank you for taking Mrs Richards back under your care... was decided to pass an indwelling catheter which still remains in situ. She has been given a canvas knee immobilising splint to discourage any further dislocation and this must stay in situ for 4 weeks. When in bed it is advisable to encourage abduction by using pillows or abduction wedge. She can however mobilise fully weight bearing*".

2.7 Nursing notes record on 17th August " 1148h *returned from R.N.Haslar patient very distressed appears to be in pain. No canvas under patient – transferred on sheet by crew."* Later that day at 1305h "*in pain and distress, agreed with daughter to give her mother Oramorph 2.5mg in 5ml*". A further hip Xray was performed which demonstrated no fracture. Dr Barton writes on 17th August 1998 *"readmission to Daedalus ward. Closed reduction under iv sedation. Remained unresponsive for some hours. Now appears peaceful. Can continue haloperidol, only for Oramorph if in severe pain. See daughter again"* and on 18th August "*still in great pain, nursing a problem, I suggest sc diamorphine/ haloperidol/midazolam. I will see daughters today. Please make comfortable*". Nursing notes record "*reviewed by Dr Barton for pain control via syringe driver*". At 2000h "*patient remained peaceful and sleeping. Reacted to pain when being moved – this was pain in both legs*". On 19th August the nursing notes record "*Mrs Richards comfortable*" and in a separate entry "*apparently pain free*". There are no nursing entries I can find on 20th August. I can find no entries in the nursing notes describing fluid or food intake following admission on 17th August.

2.8 The next entry in the medical notes is on 21st August by Dr Barton "*much more peaceful. Needs hyoscine for rattly chest*". The nursing notes record "*patient's overall condition deteriorating. Medication keeping her comfortable*". A staff

nurse records Mrs Richards's death in the notes at 2120h later that day. The cause of death was recorded as bronchopneumonia.

2.9 Medication charts record the following administration of opiate, analgesic and sedative drugs during Mrs Richards's first admission to Haslar Hospital.

29 July 2000h Trazadone 100mg (then discontinued)
29 July to 11th August. Haloperidol 1mg twice daily
30 July 0230h Morphine iv 2.5mg
31 July 0150h morphine iv 2.5mg
1905h morphine iv 2.5 mg
1 Aug 1920h morphine iv 2.5mg
2 Aug 0720h morphine iv 2.5mg
Cocodamol two tablets as required taken on 16 occasions at varying times between 1-9th August

2.10 Medication charts record the following administration of opiate, analgesic and sedative drugs during Mrs Richards second admission to Haslar Hospital

14 Aug 1410h midazolam 2mg iv
15 Aug 0325h cocodamol two tablets orally
16 Aug 0410h haloperidol 2mg orally
0800h haloperidol 1mg orally
1800h haloperidol 1mg orally
2310h haloperidol 2mg orally
17 Aug 0800h haloperidol 1mg orally

2.11 Medication charts record the following administration of opiate and sedative drugs on Daedalus ward:

11 Aug	1115h	5mg/5ml Oramorph
	1145h	10 mg Oramorph
	1800h	1 mg haloperidol
12 Aug	0615h	10 mg Oramorph
		haloperidol
13 Aug	2050h	10mg Oramorph
14 Aug	1150h	10mg Oramorph
17 Aug	1300h	5mg Oramorph
	?	5 mg Oramorph
	1645h	5mg Oramorph
	2030h	10mg Oramorph
18 Aug	0230h	10mg Oramorph
	?	10mg Oramorph
	1145h	diamorphine 40mg/24hr, haloperidol 5mg/24hr midazolam 20mg/24hrby
19 Aug	1120h	diamorphine 40mg/24hr, haloperidol 5mg/24hr midazolam 20mg/24hr, hyoscine 400microg/24hr
20 Aug	1045h	diamorphine 40mg/24hr, haloperidol 5mg/24hr midazolam 20mg/24hr, hyoscine 400microg/24hr
21 Aug	1155h	diamorphine 40mg/24h, haloperidol 5mg/24hr midazolam 20mg/24hr, hyoscine 400microg/24hr

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

2.12 Primary responsibility for the medical care of Mrs Richards during her two admissions to Gosport Hospital lay with Dr Lord, as the consultant responsible for his care. My understanding is that day-to-day medical care was delegated to the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital (statement of Dr Lord in interview with DC Colvin and DC McNally). Primary responsibility for the medical care of Mrs Richards during her two admissions to Queen Alexandra Hospital lay with Surgeon Commander Scott, Consultant Orthopaedic Surgeon. Junior medical staff were responsible for day-to-day medical care of Mrs Richards whilst at Queen Alexandra Hospital. Ward nursing staff were responsible for assessing and monitoring Mrs Richards and informing medical staff of any significant deterioration.

2.13 Dr Reid, Consultant Geriatrician was responsible for assessing Mrs Richards and making recommendations concerning her future care following her orthopaedic surgery, and arranged transfer to Gosport Hospital for rehabilitation.

Accuracy of diagnosis and prognosis including risk assessments

2.14 The initial assessment by the orthopaedic team was in my opinion competent and the admitting medical team obtained a good history of her decline in the previous six months. Surgeon Commander Pott discussed management options with the family and a decision was made to proceed with surgery but for Mrs Richards to not undergo cardiopulmonary resuscitation if she sustained a cardiac arrest, with a clear decision to keep Mrs Richards pain free, hydrated and nourished. There are good reasons to offer surgery for a fractured neck of femur to very frail patients with dementia even when a high risk of peri-operative death or complications is present. This is because without surgery patients continue to be in pain, remain immobile and nearly invariably develop serious complications such as pneumonia and pressure sores, which are usually fatal. From the information I have seen I would, as a consultant physician/geriatrician recommended the initial management undertaken. I consider it good management that the trazadone as discontinued when the history from the daughters suggested this might have been responsible for decline in the recent past.

2.15 After Mrs Richards was stable a few days following surgery it was appropriate to refer her for a geriatric opinion, and Dr Reid rapidly provided this. Dr Reid's assessment was in my opinion thorough and competent. He identified the potential for her to benefit from rehabilitation. I would consider his decision to refer her for rehabilitation despite her dementia to be appropriate. An elderly care rehabilitation, rather than an acute orthopaedic ward is in general a preferable environment to undertake such rehabilitation. It is implicit in his decision to transfer her to Gosport War Memorial Hospital that she would receive rehabilitation there and not care on a continuing care ward without input from a rehabilitation team. Dr Lord in an interview with DC McNally and DC Colvin describes Daedalus ward as "*Back in '98 .. Daedalus was a continuing care ward with 24 beds of which 8 beds were for slow stream stroke*

rehabilitation". Although Mrs Richards had a fractured neck of femur and not stroke as her primary problem requiring rehabilitation I would assume, in the light of Dr Reid's letter that she was transferred to one of the 8 slow stream rehabilitation beds on Daedalus ward.

2.16 The transfer letter from Sergeant Curran provides a clear description of Mrs Richards's status at the time of transfer. The observation that she was walking with the aid of two nurses and a zimmer frame, and the usual cause of agitation was when she needed to use the toilet are relevant to subsequent events following transfer to Gosport Hospital. The use of a Barthel Index score as a measure of disability is good practice and demonstrates that Mrs Richards was severely dependent at the time of her transfer to Gosport Hospital.

2.17 The initial entry by Dr Barton following Mrs Richards' transfer to Daedalus ward does not mention that she has been transferred for rehabilitation, and focuses on keeping her 'comfortable' despite recording that she is "*not obviously in pain*". The statement '*I am happy for nursing staff to confirm death*" also suggests that Dr Barton's assessment was that Mrs Richards might die in the near future. Dr Barton in her statement to DS Sackman and DC Colvin, confirms this when she states "*I appreciated that there was a possibility that she might die sooner rather than later*". Dr Barton refers to her admission as a "*holding manoeuvre*" and her statement suggests a much more negative view of the potential for rehabilitation. She does not describe any rehabilitation team or focus on the ward and suggests her transfer was necessary because she was not appropriate for an acute bed, rather than her being appropriate for rehabilitation- "*.her condition was not appropriate for an acute bed. ....seen whether she would recover and mobilise after surgery. If as was more likely she would deteriorate due to her age, her dementia, her frail condition and the shock of the fall followed by the major surgery, then she was to be nursed in a clam environment away from the stresses of an acute ward*". In my opinion this initial note entry and the statement by Dr Baron indicate a much less proactive view of rehabilitation, less appreciation than Dr Reid of the potential for Mrs Richards to recover to her previous level of functioning, and probably a failure to appreciate the potential benefits of appropriate multidisciplinary rehabilitation to Mrs Richards. This leads me to believe that Dr Barton's approach to Mrs Richards was in the context of considering her as a continuing care patient who was likely to die on the ward. It was not wrong or incorrect of Dr Barton to believe Mrs Richards might die on the ward, but I would consider her apparent failure to recognise Mrs Barton's rehabilitation needs may have led to subsequent sub-optimal care.

2.18 There are a number of explanations and contributory factors that may have led to Dr Barton possibly not recognising Mrs Richard's rehabilitation needs in addition to her nursing and analgesic needs. First she may have not clearly understood Dr Reid's assessment that she needed rehabilitation. In her statement Dr Barton states " *Dr Reid was of the view that, despite her dementia, she should be given the opportunity to try to remobilise*" which suggests Dr Barton may not have considered the necessity for Mrs Richards to receive Physiotherapy as a necessary part of her opportunity to remobilise. Second the ward had both continuing care and rehabilitation beds and these patients may require very different care. It is not uncommon for "slow stream" rehabilitation beds to be in the same ward as continuing care beds, but it does

require much broader range of care to meet the medical and social needs of these patients. I would anticipate that some patients would move from the slow stream rehabilitation to continuing care category. Dr Lord describes the existence of fortnightly multidisciplinary ward case conference suggesting there was a structured team approach that would have made Dr Barton and nursing staff aware of rehabilitation needs of patients. In Mrs Richards's case no such case conference took place because she became too unwell in a short period. Third Dr Barton may not have received sufficient training or gained adequate experience of rehabilitation or geriatrics despite working under the supervision of Dr Lord. Dr Lord states that Dr Barton was "*an experienced GP*" who had rights of admission to a GP ward and that Dr Lord had admitted patients "*under her care say for palliative care*". Experience in palliative care may possibly have influenced her understanding and expectations of rehabilitating older patients.

2.19 The assessment of Mrs Richard's agitation the following day on 12th August was in my opinion sub-optimal. The nursing records state that she did not appear to be in pain. There is no entry from Dr Barton this day but in her statement she states which I have some difficulty in interpreting: "*When I assessed Mrs Richards on her arrival she was clearly confused and unable to give any history. She was pleasant and co-operative on arrival and did not appear to be in pain. Later her pain relief and sedation became a problem. She was screaming. This can be a symptom of dementia but could also be caused by pain. In my opinion it was caused by pain as it was not controlled by Haloperidol alone. Screaming caused by dementia is frequently controlled by this sedative. Given my assessment that she was in pain I wrote a prescription for a number of drugs on 11th August, including Oramorph and Diamorphine. This allowed nursing staff to respond to their clinical assessment of her needs rather than wait until my next visit the following day. This is an integral part of team management. It was not in fact necessary to give diamorphine over the first few days following her admission but a limited number of small doses of Oramorph were given totalling 20mg over the first 24 hours and 10mg daily thereafter. This would be an appropriate level of pain relief after such a major orthopaedic procedure*".

2.20 I am unable establish from the notes and Dr Barton's statement whether she saw Mrs Richards in pain after she wrote in the notes and then wrote up the opiate drugs later on the 11th August, or if she wrote up these drugs after seeing her when she was not in pain, because she considered she might develop pain and agitation. In either case there is no evidence that the previous information provided by Sergeant Curran that Mrs Richards usually required the toilet when she was agitated was considered by Dr Barton. Screaming is a well-described behavioural disturbance in dementia (Dr Barton was clearly aware of this), which can be due to pain but is often not. In some cases it is not possible to identify a clear precipitating cause although a move to a new ward could precipitate such a behavioural disturbance. I would consider the assumption by Dr Barton that Mrs Richards screaming was due to pain was not supported by her own recorded observations. There is no evidence from the notes that Dr Barton examined Mrs Richards in the first two days to find any evidence on clinical examination that pain from her hip was the cause of her screaming. If the screaming had been worse on weight bearing or movement of the hip this would have provided supportive evidence that her screaming was

due to hip pain. Staff Nurse Jennifer Brewer in her interview with DC Colvin and DC McNally states that the nursing staff had considered the need for toileting and other potential causes of Mrs Richards screaming.

2.21 Mrs Richards pain following surgery had been controlled at Haslar hospital by intermittent doses of intravenous morphine and then intermittent doses of cocodamol (paracetamol and codeine phosphate). Dr Barton did not prescribe cocodamol or another mild or moderate analgesic to Mrs Richards to take on a prn basis when she was transferred. This makes me consider it probable that Dr Barton prescribed prn Oramorph, diamorphine, hyoscine and midazolam when she first saw Mrs Richards and she was not in pain. If this is the case it is highly unusual practice in a patient who has been transferred for rehabilitation, was not taking any regular or intermittent analgesics for 36 hours prior to transfer, and had last taken two tablets of cocodamol. In a rehabilitation or continuing care ward without resident medical staff I would consider it reasonable and usual practice to prescribe a mild or moderate analgesic to take on an as required basis in case further pain developed. In Mrs Richards's case a reasonable choice would have been cocodamol since she had been taking this a few days earlier without problems. I do not consider it was appropriate to administer intermittent doses of oramorph to Mrs Richards before first prescribing paracetamol, non-steroidal anti-inflammatory drugs or mild opiate. It is not appropriate to prescribe powerful opiate drugs as a first line treatment for pain not clearly due to a fracture or dislocation to a patient such as Mrs Richards 12 days following surgery. Dr Barton's statement that diamorphine and oramorph were appropriate analgesics at this stage following surgery when she had been pain free is incorrect and in my opinion would not be a view held by the vast majority of practising general practitioners and geriatricians.

2.22 The management of Mrs Richards when sustained a dislocation of her hip on 13th August was in my opinion sub-optimal. The hip dislocation most likely occurred following the fall from her chair at 1330h. The nursing notes suggest signs of a dislocation were noted at 1930h. If there was a delay in recognising the dislocation I would not consider this indicates poor care, as hip fractures and dislocations can be difficult to detect in patients who have dementia and communication difficulties. Mrs Richards suspected dislocation or fracture was discussed with the on-call doctor, Dr Briggs, who I would assume is a medical house officer. Given the concern about a fracture or dislocation I would judge it would have been preferable for her to b transferred to the orthopaedic ward that evening and be assessed by the orthopaedic team. I certainly consider the case should have been discussed with either the on call consultant geriatrician or the orthopaedic team. The benefits of transfer that evening in a patient where it was highly probable a fracture or dislocation were present would have been Mrs Richards could have received manipulation earlier the following morning and possibly that same evening, and that traction could have been applied even if reduction was not attempted.

2.23 Mrs Richards was found to have a dislocation of her right hip and this was manipulated under intravenous sedation the same day. Although she was initially unresponsive, most probably due to prolonged effects of the intravenous midazolam, 3 days later on 17th August she was mobilising and fully weight bearing and not requiring any analgesia. Although there are few medical note entries, the management at Haslar hospital during this period

appears to be appropriate and competent. Shortly after transfer back to Daedalus ward Mrs Richards again became very distressed. The nursing notes indicate there was an incorrect transfer by the ambulance staff of Mrs Richards onto her bed. Repeat dislocation of the right hip was reasonably suspected but not found on a repeat Xray. My impression is that this transfer may have precipitated hip or other musculoskeletal pain in Mrs Richards but that other causes of screaming were possible.

2.24 Intermittent doses of oral morphine were first administered to Mrs Richards, again without first determining whether less powerful analgesics would have been helpful. On 18th August Dr Barton suggested commencing subcutaneous diamorphine, haloperidol and midazolam. The diamorphine and midazolam had been prescribed 7 days earlier. An infusion of the three drugs was commenced later that morning and hyoscine was added on 19th August. Both Dr Barton's notes and the nursing notes indicate Mrs Richards was in pain, although it is not clear what they considered was the cause of the pain at this stage, having excluded a fracture or dislocation of the right hip. Dr Barton states in her prepared statement "... *it was my assessment that she had developed a haematoma or large collection of bruising around the area where the prosthesis had been lying while dislocated*".

2.25 Although there are no clear descriptions of Mrs Richard's conscious level in the last few days, her level of alertness appears to have deteriorated once the subcutaneous infusion of diamorphine, haloperidol and midazolam was commenced. It also seems that she was not offered fluids or food and intravenous or subcutaneous fluids were not considered as an alternative. My interpretation is that this was most probably because medical and nursing staff were of the opinion that Mrs Richards were dying and that provision of fluids or nutrition would not change this outcome. In her prepared statement Dr Barton states "*As their mother was not eating or drinking or able to swallow, subcutaneous infusion of pain killers was the best way to control her pain.*" and "*I was aware that Mrs Richards was not taking food or water by mouth*". She then goes on to say "*I believe I would have explained to the daughters that subcutaneous fluids were not appropriate*".

Evaluation of drugs prescribed and the administration regimens

2.26 The decision to prescribe oral opiates and subcutaneous diamorphine to Mrs Richards initial admission to Daedalus ward was in my opinion inappropriate and placed Mrs Richards at significant risk of developing adverse effects of excessive sedation and respiratory depression. The prescription of oral paracetamol, mild opiates such as codeine or non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen would have been appropriate oral and preferable with a better risk/benefit ratio. The prescription of subcutaneous diamorphine, haloperidol and midazolam infusions to be taken if required was inappropriate even if she was experiencing pain. Subcutaneous opiate infusions should be used only in patients whose pain is not controlled by oral analgesia and who cannot swallow oral opiates. The prescription by Dr Barton on 11th August of three sedative drugs by subcutaneous infusion was in my opinion reckless and inappropriate and placed Mrs Richards at serious risk of developing coma and respiratory depression had these been administered by the nursing staff. It is exceptionally unusual to prescribe subcutaneous infusion of these three drugs with powerful effects on conscious level and respiration to

frail elderly patients with non-malignant conditions in a continuing care or slow stream rehabilitation ward and I have not personally used, seen or heard of this practice in other care of the elderly rehabilitation or continuing care wards. The prescription of three sedative drugs is potentially hazardous in any patient but particularly so in a frail older patient with dementia and would be expected to carry a high risk of producing respiratory depression or coma.

2.27 I consider the statement by Dr Barton "*my use of midazolam in the dose of 20mg over 24 hours was as a muscle relaxant, to assist movement of Mrs Richards for nursing procedures in the hope that she could be as comfortable as possible. I felt it appropriate to prescribe an equivalence of haloperidol to that which she had been having orally since her first admission.*" Indicates poor knowledge of the indications for and appropriate use of midazolam administered by subcutaneous infusion to older people. Midazolam is primarily used for sedation and is not licensed for use as a muscle relaxant. Doses of benzodiazepine that produce significant muscle relaxation in general produce unacceptable depression of conscious level, and it is not usual practice amongst continuing care and rehabilitation wards to administer subcutaneous midazolam to assist moving patients.

Quality and sufficiency of the medical records

2.28 The medical and nursing records relating to Mrs Richards admissions to Daedalus ward are in my opinion not of an adequate standard. The medical notes fail to adequately account for the reasons why oramorph and then infusions of diamorphine and haloperidol were used. The nursing records do not adequately document hydration and nutritional needs of Mrs Richards during her admissions to Daedalus ward.

Appropriateness and justification of the decisions that were made

2.29 There are a number of decisions made in the care of Mrs Richards that I consider to be inappropriate. The initial management of her dislocated hip prosthesis was sub-optimal. The decision to prescribe oral morphine without first observing the response to milder opiate or other analgesic drugs was inappropriate. The decision to prescribe diamorphine, haloperidol and midazolam by subcutaneous infusion was, in my opinion, highly inappropriate.

Recorded cause of death

2.30 The recorded cause of death was bronchopneumonia. I understand that the cause of death was discussed with the coroner. A post mortem was not obtained and the recorded cause was certainly a possible cause of Mrs Richards's death. I am surprised the death certificate makes no mention of Mrs Richards's fractured neck of femur or her dementia. It is possible that Mrs Richards died from drug induced respiratory depression without bronchopneumonia present or from the combined effects of bronchopneumonia and drug-induced respiratory depression. Mrs Richards was at high risk of developing pneumonia because of the immobility that resulted following her transfer back to Daedalus ward even if she had not received sedative and opiate drugs. Bronchopneumonia can also occur as a secondary complication of opiate and sedative induced respiratory depression. In the absence of post-mortem, radiological data (chest Xray) or recordings of Mr Cunningham's respiratory rate I would consider the recorded cause of death of bronchopneumonia was possible. However given the rapid decline in

conscious level that preceded the development of respiratory symptoms (rattly chest) I would consider it more likely that Mrs Richards became unconscious because of the sedative and opiate drugs she received by subcutaneous infusion, that these drugs caused respiratory depression and that Mrs Richards died from drug induced respiratory depression and/or without bronchopneumonia resulting from immobility or drug induced respiratory depression. There are no accurate records of Mrs Richards respiratory rate but with the doses used and her previous marked sedative response to intravenous midazolam it is highly probable that respiratory depression was present.

Duty of care issues

2.31 Medical and nursing staff on Daedalus ward had a duty of care to deliver medical and nursing care to attempt to monitor Mrs Richards and to document the effects of drugs prescribed. In my opinion this duty of care was not adequately met. The prescription of diamorphine, midazolam and haloperidol was extremely hazardous and Mrs Richards was inadequately monitored. The duty of care of the medical and nursing staff to meet Mrs Richard's hydration and nutritional needs was also in my opinion probably not met.

Summary

2.32 Gladys Richards was a frail older lady with dementia who sustained a fractured neck of femur, successfully surgically treated with a hemiarthroplasty, and then complicated by dislocation. During her two admissions to Daedalus ward there was inappropriate prescribing of opiates and sedative drugs by Dr Baron. These drugs in combination are highly likely to have produced respiratory depression and/or the development of bronchopneumonia that led to her death. In my opinion it is likely the administration of the drugs hastened her death. There is some evidence that Mrs Richards was in pain during the three days prior to her heath and the administration of opiates can be justified on these grounds. However Mrs Richards was at high risk of developing pneumonia and it possible she would have died from pneumonia even if she had not been administered the subcutaneous sedative and opiate drugs.

Arthur "Brian" CUNNINGHAM

Course of Events

3.1 Mr Cunningham was 79 years old when admitted to Dryad ward, Gosport Hospital under the care of Dr Lord. Dr Lord had assessed him on a number of occasions in the previous 4 years. A letter dated 2nd December 1994 from Dr Bell, Clinical Assistant, indicates Parkinson's disease had been diagnosed in the mid 1980s and that he was having difficulties walking at this time. In 1998 it was noted he had experienced visual hallucinations and had moved into Merlin Park Rest Home. His weight was 69Kg in August 1998. In July 1998 he was admitted under the care of Dr Banks, Consultant in Old Age Psychiatry to Mulberry Ward A and discharged after 6 weeks to Thalassa Nursing Home. He was assessed to have Parkinson's disease and dementia, depression and myelodysplasia. Dr Lord in a letter dated 1 September 1998 summarises her assessment of Mr Cunningham when she saw him on Mulberry Ward A on 27 August 1998 before he was discharged to Thalassa Nursing Home. At this time he required 1-2 people to transfer and was unable to wheel himself around in his wheelchair. She commented that more levodopa might be required but was concerned it would upset his mental state. She arranged to review him at the Dolphin Day Hospital.

3.2 On 21st September 1998 he was seen at the Dolphin Day Hospital by Dr Lord who recorded *'very frail, tablets found in mouth, offensive large necrotic sacral sore with thick black scar. PD - no worse. Diagnoses listed as sacral sore (in N/H), PD, old back injury, depression and element of dementia, diabetes mellitus –diet, catheterised for retention. Plan – stop codanthramer and metronidazole. looks fine. TCI Dyad today –aserbine for sacral ulcer – nurse on side – high protein diet – oramorph prn if pain. N/Home to keep bed open for next 3/52 at least. Pt informed of admission agrees. Inform N/Home Dr Banks and social worker. Analgesics prn.'* He was admitted to Dyad ward. An entry by Dr Baron on 21 September states *'make comfortable, give adequate analgesia. Am happy for nursing staff to confirm death.'* On 24th September Dr Lord has written *'remains unwell. Son has ??? again today and is aware of how unwell he is. sc analgesia is controlling pain just. I am happy for nursing staff to confirm death.'* The next entry by Dr Brook is on 25th September *'remains very poorly. On syringe driver. For TLC'.*

3.3 Medication charts record the following administration of opiate and sedative drugs:

21 Sep 1415h Oramorph 5mg
1800h Coproxamol two tablets
(subsequent regular doses not administered)
2015h Oramorph10mg
21 Sep 2310h Diamorphine 20mg/24hr, midazolam 20mg/24hr infusion sc
22 Sep 2020h Diamorphine 20mg/24hr, midazolam 20mg/24hr infusion sc
23 Sep 0925h Diamorphine 20mg/24hr, hyoscine 200microg/24hr
midazolam 20 mg/24hr infusion sc
2000h Diamorphine 20mg/24hr, hyoscine 200microg/24hr
midazolam 60mg/24hr infusion sc
24 Sep 1055h Diamorphine 20mg/24hr, hyoscine 800microg/24hr
midazolam 80mg/24hr infusion sc
25 Sep 1015h Diamorphine 60mg/24hr, hyoscine 1200mg/24hr

midazolam 80mg/24hr infusion
26 Sep 1150h Diamorphine 80mg/24hr, hyoscine 1200mg/24hr
midazolam 100mg/24hr infusion
Sinemet 110 5 times/day was discontinued on 23rd September

3.4 The nursing notes relating to the admission to Dyad ward record on 21st Sept *'remained agitated until approx 2030h. Syringe driver commenced as requested (unclear who made this request) diamorphine 20mg, midazolam 20mg at 2300. Peaceful following".* On 22nd Sep *'explained that a syringe driver contains diamorphine and midazolam was commenced yesterday evening for pain relief and to allay his anxiety following an episode where Arthur tried to wipe sputum on a nurse saying he had HIV and going to give it to her. He also tried to remove his catheter and empty the bag and removed his sacral dressing throwing it across the room. Finally he took off his covers and exposed himself.'*

3.5 On 23rd Sep *'Has become chesty overnight to have hyoscine added to driver. Stepson contacted and informed of deterioration. Mr Farthing asked is this was due to the commencement of the syringe driver and informed that Mr Cunningham was on a small dosage which he needed.'* A later entry *'now fully aware that Brian is dying and needs to be made comfortable. Became a little agitated at 2300h, syringe driver adjusted with effect. Seems in some discomfort when moved, driver boosted prior to position change'.* On 24th Sept *'report from night staff that Brian was in pain when attended to, also in pain with day staff – especially his knees. Syringe driver renewed at 1055".* On 25th Sept *'All care given this am. Driver recharged at 1015 –diamorphine 60mg, midazolam 80mg and hyoscine 1200mcg at a rate of 50mmols/hr. Peaceful night - unchanged, still doesn't like being moved.'* On 26th September *'condition appears to be deteriorating slowly'.*

3.6 On 26th September staff nurse Tubbritt records death at 2315h. Cause of death was recorded on the death certificate as bronchopneumonia with contributory causes of Parkinson's disease and Sacral Ulcer.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

3.7 Primary responsibility for the medical care of Mr Cunningham during his last admission lay with Dr Lord, as the consultant responsible for his care. She saw Mr Cunningham 5 days before his death in the Dolphin Day Hospital, and 2 days before his death on Dyad ward. My understanding is that day-to-day medical care was the responsibility of the clinical assistant Dr Barton and *during out of hours period the on call doctor based at the Queen Alexander* Hospital. Ward nursing staff were responsible for assessing and monitoring Mr Cunningham and informing medical staff of any significant deterioration.

Accuracy of diagnosis and prognosis including risk assessments

3.8 Initial assessment by Dr Lord was comprehensive and appropriate with a clear management plan described. The nursing staff record Mr Cunningham was agitated following admission on 21st September. Dr Lord had prescribed prn (intermittent as required) oramorph for pain. Nursing staff made the decision to administer oramorph but there is no clear recording in the nursing notes that he

was in pain or the site of pain. The nursing entry on 22nd Sept indicates a syringe driver was commenced for 'pain relief and to allay anxiety. Again the site of pain is not states. My interpretation of the records is that the nursing staff considered his agitation was due to pain from his sacral ulcer. The medical and nursing teams view on the cause of Mr Cunningham's deterioration on 23rd September when he became 'chesty' are not explicitly stated, but would seem to have been thought to be due to bronchopneumonia since this was the cause of death later entered on the death certificate. The medical and nursing staff may not have considered the possibility that Mr Cunningham's respiratory symptoms and deterioration may have been due to opiate and benzodiazepine induced respiratory depression. The nursing staff filed to appreciate that the agitation Mr Cunningham experienced on 23rd Sept at 2300h may have been due to the midazolam and diamorphine. It was appropriate for nursing staff to discuss Mr Cunningham's condition with medical staff at this stage.

3.9 When Dr Lord reviewed Mr Cunningham on 24th September the notes imply that he was much worse that when she had seen him 3 days earlier. There is clear recording by Dr Lord that Mr Cunningham was in pain. The following day the diamorphine dose was increased three fold from 20mg/24hr to 60mg/24hr and the dose was further increased on 26th September to 80mg/24hr although the nursing and medical notes do not record the reason for this. The notes suggest that the nursing and medical staff may have failed to consider causes of agitation other than pain in Mr Cunningham or to recognise the adverse consequences of opiates and sedative drugs on respiratory function in frail older individuals.

Evaluation of drugs prescribed and the administration regimens

3.10 The prescription of oramorph to be taken 4 hourly as required by Mr Cunningham was reasonable if his pain was uncontrolled from cocodamol. I consider the decision by Dr Barton to prescribe and administer diamorphine and midazolam by subcutaneous infusion the same evening he was admitted was highly inappropriate, particularly when there was a clear instruction by Dr Lord that he should be prescribed intermittent (underlined instruction) doses of oramorph earlier in the day. I consider the undated prescription by Dr Baron of subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr to be poor practice and potentially very hazardous. In my opinion it is poor management to initially commence both diamorphine and midazolam in a frail elderly underweight patient such as Mr Cunningham. The combination could result in profound respiratory depression and it would have been more appropriate to review the response to diamorphine alone before commencing midazolam, had it been appropriate to commence subcutaneous analgesia, which as I have stated before was not the case.

3.11 In my opinion it is doubtful the nursing and medical staff understood that when a syringe infusion pump rate is increased it takes an often appreciable effect of time before the maximum effect of the increased dose rate becomes evident. Typically the time period would be 5 drug half-lives. In the case of diamorphine this would be between 15 and 25 hours in an older frail individual.

Quality and sufficiency of the medical records

3.12 In my opinion the medical and nursing records are inadequate following Mr Cunningham's admission to Dryad ward. The initial assessment by Dr Lord on 21st September is in my opinion competent and appropriate. The medical notes following this are inadequate and do not explain why he was commenced on subcutaneous infusions of diamorphine and midazolam. The nursing notes are variable and at times inadequate.

Appropriateness and justification of the decisions that were made

3.13 An inappropriately high dose of diamorphine and midazolam was first prescribed. There was a failure to recognise or respond to drug induced problems. Inappropriate dose escalation of diamorphine and midazolam and poor assessment by Dr Lord. The assessment by Dr Lord on 21st September 1998 was thorough and competent and a clear plan of management was outlined. There is a clear note by Dr Lord that oramorph was to be given intermittently (PRN) for pain and not regularly. It is not clear from the medical and nursing notes why Mr Cunningham was not administered the regular cocodamol he was prescribed following the initial dose he received at 1800h following admission. It is good practice to provide regular oral analgesia, with paracetamol and a mild opiate, particularly when a patient has been already taking this medication and to use prn morphine for breakthrough pain. I consider the prescription by Dr Barton on admission of prn subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr to be unjustified, poor practice and potentially very hazardous. It is particularly notable that only hours earlier Dr Lord had written that oramorph was to be given intermittently and this had been underlined in the medical notes. There is no clear justification in the notes for the commencement of subcutaneous diamorphine and midazolam on the evening following admission. If increased opiate analgesia was required increasing the oramorph dose and frequency could have provided this. I would judge it poor management to initially commence both diamorphine and midazolam. The combination could result in profound respiratory depression and it would have been more appropriate to review the response to diamorphine alone before commencing midazolam.

3.14 I am concerned by the initial note entry by Dr Barton on 21st September 1998 that she was happy for nursing staff to confirm death. There was no indication by Dr Lord that Mr Barton was expected to die, and Dr Barton does not list the reason she would have cause to consider Mr Cunningham would die within the next 24 hours before he was reviewed the following day by medical staff. In my opinion it is of concern that the nursing notes suggest the diamorphine and midazolam infusions were commenced because of Mr Cunningham's behaviour recorded in the nursing entry on 22nd September.

3.15 Hyoscine was commenced on 23rd September after Mr Cunningham had become 'chesty' overnight. I consider it very poor practice that there is no record of Mr Cunningham being examined by a doctor following admission on 21st September, and a decision to treat this symptomatically with hyoscine appears to have been made by the medical staff. At this stage Mr Cunningham's respiratory signs are likely to have been due to bronchopneumonia or respiratory depression resulting in depressed clearance of bronchial secretions. A medical assessment was very necessary at this

stage to diagnose the cause of symptoms and to consider treatment with antibiotics or reduction in the dose of diamorphine and midazolam.

3.16 Again I consider it very poor practice that the midazolam was increased from 20mg/24hr to 60mg/24 hr at 2000h on 23rd September. There is no entry in the medical notes to explain this dose increase. The decision to triple the midazolam dose appears to have been made by a member of nursing staff as the nursing notes record *"agitated at 2300h, syringe driver boosted with effect"*.

3.17 A medical assessment should have been obtained before the decision to increase the midazolam dose was made. At the very least Mr Cunningham's problems should have been discussed with on call medical staff. Mr Cunningham's agitation may have been due to pain, where increasing analgesia would have been appropriate, or hypoxia (lack of oxygen). If Mr Cunningham's agitation was due to hypoxia a number of interventions may have been indicated. Reducing the diamorphine and midazolam dose would have been appropriate if hypoxia was due to respiratory depression. Commencement of oxygen therapy and possibly antibiotics would have been appropriate if hypoxia was due to pneumonia. Reducing the dose diamorphine or midazolam would have been indicated if hypoxia was due to drug-induced respiratory depression. The decision to increase the midazolam dose was not appropriately made by the ward nursing staff without discussion with medical staff.

3.18 When Mr Cunningham was reviewed by Dr Lord on 24th September he was very unwell but there is not a clear description of his respiratory status or whether he had signs of pneumonia. At this stage Dr Lord notes Mr Cunningham is in pain, but does not state the site of his pain. It is not clear to me whether the subsequent alteration in infusion rate of diamorphine, hyoscine and midazolam was discussed with and sanctioned by Dr Lord or Dr Barton. I consider the increase in midazolam from 60mg/24 hr to 80mg/24 hr was inappropriate as a response to the observation that Mr Cunningham was in pain. It would have been more appropriate to increase the diamorphine dose or even consider treatment with a non-steroidal anti-inflammatory drug. The increase in midazolam dose to 80mg/24 hr would simply make Mr Cunningham less conscious than he already appears to have been (there is not a clear description of his conscious level at this stage).

3.19 The increase in hyoscine dose to 800microg/24 hr is also difficult to justify when there is no record that the management of bronchial secretions was a problem. The subsequent threefold increase in diamorphine dose later that day to 60mg/24 hr is in my view very poor practice. Such an increase was highly likely to result in respiratory depression and marked depression of conscious level, both of which could lead to premature death. The description of Mr Cunningham, was that analgesia was 'just' controlling pain and a more cautious increase in diamorphine dose, certainly no more than two fold, was indicated with careful review of respiratory status and conscious level after steady state levels of diamorphine would have been obtained about 20 hours later. A more appropriate response to deal with any acute breakthrough pain is to administer a single prn (intermittent) dose of opiate by the oral or intramuscular route, depending on whether Mr Cunningham was unable to swallow at this time.

3.20 The increase in both diamorphine dose and midazolam dose on 26th September is difficult to justify when there is no record in the medical or nursing notes that Mr Cunningham's pain was uncontrolled. Although it is possible to accept the increase in diamorphine dose may have been appropriate if Mr Cunningham was observed to be in pain, I find the further increase in midazolam dose to 100mg/24hr of great concern. I would anticipate that this dose of midazolam administered with 80mg/24hr of diamorphine would be virtually certain to produce respiratory depression and severe depression of conscious level. This would be expected to result in death in a frail individual such as Mr Cunningham. I would expect to see very clear reasons for the use of such doses recorded in the medical notes.

3.21 I can find no record of Mr Cunningham receiving food or fluids following his admission on 21st September despite a note from Dr Lord that Mr Cunningham was to receive a 'high protein diet'. There is no indication in the medical or nursing notes as to whether this had been discussed, but given that Mr Cunningham was admitted with the intention of returning to his Nursing Home (it was to be held open for 3 weeks) I would expect the notes to record a clear discussion and decision making process involving senior medical staff accounting for the decision to not administer subcutaneous fluids and/or nasogastric nutrition once Mr Cunningham was commenced on drugs which may have made him unable to swallow fluids or food.

Recorded causes of death

3.22 The recorded cause of death was bronchopneumonia with contributory causes of Parkinson's disease and sacral ulcer. A post mortem was not obtained and the recorded causes were in my opinion reasonable. It is possible that Mr Cunningham died from drug induced respiratory depression without bronchopneumonia present or from the combined effects of bronchopneumonia and drug-induced respiratory depression. Mr Cunningham was at high risk of developing pneumonia even if he had not received sedative or opiate drugs, bronchopneumonia can occur as a secondary complication of opiate and sedative induced respiratory depression. In the absence of post-mortem, radiological data (chest Xray) or recordings of Mr Cunningham's respiratory rate I would consider the recorded cause of death of bronchopneumonia as reasonable. Even if the staff had considered Mr Cunningham had drug-induced respiratory depression as a contributory factor, it would not be usual medical practice to enter this as a contributory cause of death where the administration of such drugs was considered appropriate for symptom relief.

Duty of care issues

3.23 Medical and nursing staff on Dryad ward had a duty of care to deliver medical and nursing care to attempt to heal Mr Cunningham's sacral ulcer and to document the effects of drugs prescribed. In my opinion this duty of are was not adequately met and the denial of fluid and diet and prescription of high doses of diamorphine and midazolam was poor practice and may have contributed to Mr Cunningham's death.

Summary

3.24 In summary although Mr Cunningham was admitted for medical and nursing care to attempt to heal and control pain from his sacral ulcer, Dr Barton and the ward staff appear to have considered Mr Cunningham was dying and had been admitted for terminal care. The medical and nursing records are inadequate in documenting his clinical state at this time. The initial prescription of subcutaneous diamorphine, midazolam and hyoscine by Dr Barton was in my view reckless. The dose increases undertaken by nursing staff were inappropriate if not undertaken after medical assessment and review of Mr Cunningham. I consider it highly likely that Mr Cunningham experienced respiratory depression and profound depression of conscious level due to the infusion of diamorphine and midazolam. I consider the doses of these drugs prescribed and administered were inappropriate and that these drugs most likely contributed to his death through pneumonia and/or respiratory depression.

ALICE WILKIE

Course of Events

4.1 Alice Wilkie was 81 years old when admitted under the care of Dr Lord, by her general practitioner on 31st July 1998 from Addenbrooke Rest Home to Phillip Ward, Department of Medicine for Elderly People, at the Queen Alexandra Hospital, Portsmouth. The general practitioner referral letter states "*This demented lady has been in this psychogeriatric care home for a year. She had a UTI early this week and has not responded to trimethoprim. Having fallen last night, she is not refusing fluids and is becoming a little dry*". The medical admitting notes record she was taking prozac (fluoxetine) syrup 20 mg once daily, codanthramer 5-10ml nocte, lactulose 10ml once daily zopiclone 1.875 or 3.75mg nocte and promazine syrup 25mg as required. On examination she had a fever and bilateral conjunctivitis but no other significant findings. The admitting doctor diagnosed a urinary tract infection and commenced intravenous antibiotics to be administered after a blood culture and catheter specimen of urine had been obtained. The following day DNR (do not resuscitate) is recorded in the notes. On 3rd August 1998 the medical notes record the fever had settled, that she was taking some fluids orally, was taking the antibiotic Augmentin elixir orally and receiving subcutaneous fluids. The notes then record (date not clear) that her Mental Test Score was 0/10 and Barthel 1/20 (indicating severe dependency). Mrs Wilkie was to be transferred to Daedalus NHS continuing care ward on 6th August 1998 with a note that her bed was to be kept at Addenbrooke Rest Home.

4.2 Following transfer on 6th August an entry in the medical notes states "*Transferred from Phillips Ward. For 4-6/52 only. On Augmentin for UTI*". Dr Lord writes on 10th August 1998 '*Barthel 2/20. Eating and drinking better. Confused and slow. Give up place at Addenbrooke's. R/V* (review) *in 1/12* (one month) *–if no specialist medical or nursing problems D* (discharge) *to a N/Home. Stop fluoxetine'*. The next entry is by Dr Barton on 21st August "*Marked deterioration over last few days. sc analgesia commenced yesterday. Family aware and happy*". The final entry is on the same day at 1830h where death is confirmed. The most recent record of the patient's weight I can find is 56Kg in April 1994.

4.3 The nursing notes, which have daily entries during her one week stay on Phillip ward note she was catheterised, was confused at times and was sleeping well prior to transfer. The nursing notes on Daedalus ward record "6/8/98 *Transferred from Philip ward QAH for 4-6 weeks assessment and observation and then decide on placement. Medical history of advanced dementia, urinary tract infection and dehydration"* and that she was seen by Dr Peters. The nursing assessment sheet notes *"does have pain at times unable to ascertain where"*. The nutrition care plan states on 6th August 1998 "*Due to dementia patient has a poor dietary intake*". And dietary intake is recorded between 12th August and 18th August but not before or following these dates. Nursing entries in the contact record state on 17th August 1998 "*Condition has generally deteriorated over the weekend Daughter seen- aware that mums condition is worsening, agrees active treatment not appropriate and to use of syringe driver if Mrs Wilkie is in pain*". There is no entry in the notes on 20th August or preceding few days indicating Mrs Wilkie was in pain.

4.4 A nursing entry on 21st August 1998 at 1255h states "*Condition deteriorating during morning. Daughter and granddaughters visited and stayed. Patient comfortable and pain free*". There are a number of routine entries in the period 6th August 1998 to death on 21st August 1998 in nutrition, pressure area care, constipation, catheter care, and personal hygiene. The nursing care plan records no significant deterioration until 21st August where it is noted death was pronounced at 2120h by staff nurse Sylvia Roberts. Cause of death was recorded as bronchopneumonia.

4.5 The drug charts records that Dr Barton prescribed as a regular daily review (not intermittent as required) prescription diamorphine 20-200mg/24hr, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr all to be administered subcutaneously. The prescription is not dated. Drugs were first administered on 20th August, diamorphine at 30mg/24hr and midazolam 20mg/24hr from 1350h and then again on 21st August. Mrs Wilkie had not been prescribed or administered any analgesic drugs during her admission to Daedalus ward prior to administration of the diamorphine and midazolam infusions. During the period 16th-18th August she was prescribed and received zopiclone (a sedative hypnotic) 3.75mg nocte and co-danthramer 5-10ml (a laxative) orally.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

4.6 Primary responsibility for the medical care of Mrs Wilkie during her admission to Daedalus ward lay with Dr Lord, as the consultant responsible for her care. She saw Mrs Wilkie on 10th August 1998, 11 days prior to her death. My understanding is that day-to-day medical care was the responsibility of the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital. Ward nursing staff were responsible for assessing and monitoring Mrs Wilkie and informing medical staff of any significant deterioration.

Accuracy of diagnosis and prognosis including risk assessments

4.7 The initial diagnosis of a urinary tract infection and dehydration was reasonable and appears correct. Mrs Wilkie had a diagnosis of dementia, which there was clear evidence for. The entry by Dr Lord on 10th August 1998 provides a reasonable assessment of her functional level at this time, and a plan to review appropriate placement in one month's time. No diagnosis was made to explain the deterioration Mrs Wilkie is reported to have experienced around 15th August. There is no medical assessment in the notes following 10th August except documentation on 21st August 1998 of a marked deterioration. There is no clear evidence that Mrs Wilkie was in pain although she was commenced on opiate analgesics.

Evaluation of drugs prescribed and the administration regimens

4.8 No information is recorded in the medical or nursing notes to explain why Mrs Wilkie was commenced on diamorphine and hyoscine infusions. In my opinion there was no indication for the use of diamorphine and hyoscine in Mrs Wilkie. Other oral analgesics, such as paracetamol and mild opiate drugs could and should first have been tried, if Mrs Wilkie was in pain, although there is no evidence that she was. If these were inadequate oral morphine would have

been the next appropriate choice. From the information I have seen in the notes it appears the diamorphine and midazolam may have been commenced for non-specific reasons, perhaps as a non-defined palliative reasons as it was judged she was likely to die in the near future.

4.9 I consider the undated prescription by Dr Barton of subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr to be poor practice and potentially very hazardous. I consider it poor and hazardous management to initially commence both diamorphine and midazolam in a frail elderly underweight patient with dementia such as Mrs Wilkie. The combination could result in profound respiratory depression and it would have been more appropriate to review the response to diamorphine alone before commencing midazolam, had it been appropriate to commence subcutaneous analgesia, which as I have stated before was not the case.

Quality and sufficiency of the medical records

4.10 The medical and nursing records during her stay on Daedalus ward are inadequate not sufficiently detailed, and do not provide a clear picture of Mrs Wilkie's condition. In my opinion the standard of the notes falls below the expected level of documentation on a continuing care or rehabilitation ward. The assessment by Dr Lord on 10th August 1998 is the only satisfactory *medical note entry during her 15 day stay on Daedalus ward.*

Appropriateness and justification of the decisions that were made

4.11 As discussed above I do not consider the decision to commence diamorphine and hyoscine was appropriate on the basis of the information recorded in the clinical notes.

Recorded causes of death

4.12 There was no specific evidence that bronchopneumonia was present, although this is a common pre-terminal event in frail older people, and is often entered as the final cause of death in frail older patients. I am surprised the death certificate did not apparently refer to Mrs Wilkie's dementia as a contributory cause. It is possible Mrs Wilkie's death was due at least in part to respiratory depression from the diamorphine she received, or that the diamorphine led to the development of bronchopneumonia. However since there are no clear observations of Mrs Wilkie's respiratory observations it is difficult to know whether respiratory depression was present Mrs Wilkie deteriorated prior to administration of diamorphine and midazolam infusion, and in view of this, my opinion would be that although the opiate and sedative drugs administered may have hastened death, and these drugs were not indicated, Mrs Wilkie may well have died at the time she did even if she had not received the diamorphine and midazolam infusions.

Duty of care issues

4.13 Medical and nursing staff on Daedalus ward had a duty of care to deliver medical and nursing care, to monitor, and to document the effects of drugs prescribed to Mrs Wilkie. In my opinion this duty of care was not adequately met, the prescription of diamorphine and midazolam was poor practice and this may have contributed to Mrs Wilkie's death.

Summary

4.14 In my opinion the prescription of subcutaneous diamorphine and midazolam was inappropriate, and probably resulted in depressed conscious level and respiratory depression, which may have hastened her death. However Mrs Wilkie was a frail very dependent lady with dementia who was at high risk of developing pneumonia. It is possible she would have died from pneumonia even if she had not been administered the subcutaneous sedative and opiate drugs.

Robert WILSON

5.1 Mr Wilson was 75 years old man when he was admitted to Queen Alexandra Hospital on 22nd September 1998 after he sustained a proximal fracture of the left humerus. He was treated with morphine, initially administered intravenously and then subcutaneously. He developed vomiting. On 24th September he was given 5mg diamorphine and lost sensation in the left hand. On 29th September an entry in the medical notes states "*ref to social worker, review resus status. Not for resuscitation in view of quality of life and poor prognosis*".

5.2 On 7th October the notes record he was "*not keen on residential home and wished to return to his own home*". Dr Lusznat, Consultant in Old Age Psychiatry on 8th October 1998, saw him. Dr Lusznat's letter on 8th October notes that Mr Wilson had been sleepy and withdrawn and low in mood but was now eating and drinking well and appeared brighter in mood. His Barthel score was 5/20. Dr Lusznat noted he had a heavy alcohol intake during the last 5 years. At the time he was seen by Dr Lusznat her was prescribed thiamine 100 mg daily, multivitamins two tablets daily, senna two tablets daily, magnesium hydroxide 10 mls twice daily and paracetamol 1g four time daily. On examination he had mildly impaired cognitive function (Mini Mental State Examination 24/30). Dr Lusznat considered Mr Wilson might have developed an early dementia, which could have been alcohol related, Alzheimer's disease or vascular dementia. An antidepressant trazadone 50mg nocte was commenced. Dr Lusznat states at the end of her letter "*On the practical side he may well require nursing home care though at the moment he is strongly opposed to that idea I shall be happy to arrange follow up by our team once we know when and where he is going to be discharged*". On 13th October the medical notes record a ward round took place, that he required both nursing and medical care, was at risk of falling and that a short spell in long-term NHS care would be appropriate. Reviewing the drug charts Mr Wilson was taking regular soluble paracetamol (1g four times daily) and codeine phosphate 30mg as required for pain. Between 8th and 13th October Mr Wilson was administered four doses of 30mg codeine. Mr Wilson's weight in March 1997 was 93Kg

5.3 On the 14th October Mr Wilson was transferred to Dryad Ward. An entry in the medical notes by Dr Barton reads "*Transfer to Dryad ward continuing care. HPC fracture humerus. needs help with ADL (*activities of Daily Living*), hoisting, continent, Barthel 7. Lives with wife. Plan further mobilisation*". On 16th November the notes record; '*Decline overnight with S.O.B. o/e ? weak pulse. Unresponsive to spoken work. Oedema ++ in arms and legs. Diagnosis ?silent MI, ? decreased __ function. ↑frusemide to 2 x 40mg om* '. On 17th October the notes record '*comfortable but rapid deterioration*'. On 18th October staff nurse Collins records death at 2340h. Cause of death is recorded as congestive cardiac failure.

5.4 Nursing notes state in the summary section on 14th October "*History of left humerus fracture, arm in collar and cuff. Long history of heavy drinking. LVF chronic oedematous legs. S/B Dr Barton. Oramorph 10mg/5ml given. Continent of urine – uses bottles*". On 15th October "*Commenced oramorph 10mg/5ml 4 hrly for pain in L arm. Wife seen by sis. Hamblin who explained Robert's condition is poor*". An earlier note states "*settled and slept well*". On 16th October "*seen by Dr Knapman an as deteriorated over night. Increase*

*frusemide to 80mgdaily. For A.N.C (*active nursing care*)*". Later that day a further entry states "*Patient very bubbly chest this pm. Syringe driver commenced 20mg diamorphine, 400mcgs hyoscine. Explained to family reason for driver*". A separate note on 16th October in the nursing care plan states "*More secretions – pharyngeal – during the night, but Robert hasn't been distressed. Appears comfortable*". On 17th October 0515h "*Hyoscine increased to 600mcgs as oro-pharyngeal secretions increasing. Diamorphine 20mg.*" Later that day a further entry states "*Slow deterioration in already poor condition. Requiring suction very regularly – copious amounts suctioned. Syringe driver reviewed at 15.50 s/c diamorphine 40mg, midazolam 20mcgs, hyoscine 800 mcgs*". A later note states "*night: noisy secretions but not distressing Robert. Suction given as required during night. Appears comfortable*". On 18th October "*further deterioration in already poor condition. Syringe driver reviewed at 14:40 s/c diamorphine 60mg, midazolam 40mg, hyoscine 1200mcg. Continues to require regular suction*".

5.5 The medication charts record administration of the following drugs:

14 Sep 1445h oramorph 10mg
2345h oramorph 10mg
16 Sep 1610h diamorphine 20mg/24 hr, hyoscine 400 microg/24hr subcutaneous infusion
17 Sep 0515h diamorphine 20mg/24hr, hyoscine 600 microg/24hr
1550h diamorphine 40mg/24hr, hyoscine 800 microg/24hr midazolam 20mg/24hr
18 Sep 1450h diamorphine 60mg/24hr, hyoscine 1200 microg/24hr midazolam 40mg/24hr

Frusemide was administered at a dose of 80mg daily at 0900h on 15th and 16th October. An additional 80 mg oral dose was administered at an unstated time on 16th October.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

5.6 Responsibility for the care of Mr Wilson during his admission to Dryad ward lay with Dr Lord as the consultant responsible for his care. My understanding is that day to day medical care was delegated to the clinical assistant Dr Barton and during the out of hours responsibility was with the on call doctor based at Queen Alexandra Hospital. Ward nursing staff were responsible for assessing and monitoring Mr Wilson and informing medical staff of any significant deterioration.

5.7 Dr Lusznat was responsible for assessing Mr Wilson and making further recommendations concerning his future care when he was seen at Queen Alexandra Hospital.

Accuracy of diagnosis and prognosis including risk assessments

5.8 Dr Barton assessed Mr Wilson on 14th October the day he was transferred to Dyad ward. There was a plan to attempt to improve his mobilisation through rehabilitation. There is no record of any significant symptomatic medical problems, in particular any record that Mr Wilson was in pain in the medical

notes. The nursing notes suggest Mr Wilson was prescribed oramorph for pain in his arm following his admission to Dryad Ward. He was prescribed paracetamol to take as required but did not receive any paracetamol whilst on Dryad Ward.

5.9 Mr Wilson deteriorated on 15th September when he became short of breath. The working diagnosis was of heart failure due to a myocardial infarct. I do not consider the assessment by the on call doctor of Mr Wilson was adequate or competent. There is no record of his blood pressure, clinical examination findings in the chest (which might have indicated whether he had signs of pulmonary oedema or pneumonia). In my opinion an ECG should have been obtained that night, and a Chest Xray obtained the following morning to provide supporting evidence for the diagnosis. Mr Wilson was admitted for rehabilitation not terminal care and it was necessary and appropriate to perform reasonable clinical assessments and investigations to make a correct diagnosis.

5.10 Following treatment Mr Wilson was noted to have had a rapid deterioration. The medical and nursing teams appear to have failed to consider that Mr Wilson's deterioration may have been due to the diamorphine infusion. In my opinion when Mr Wilson was unconscious the diamorphine infusion should have been reduced or discontinued. The nursing and medical staff failed to record Mr Wilson's respiratory rate, which was likely to have been reduced, because of respiratory depressant effects of the diamorphine. The diamorphine and hyoscine infusion should have been discontinued to determine whether this was contributing to his deteriorating state. There is no record of the reason for the prescribing of the midazolam infusion commenced the day before his death. At this time the nursing notes record he was comfortable. Mr Wilson did not improve. The medical and nursing teams did not appear to consider that the diamorphine, hyoscine and midazolam infusion could be a major contributory factor in Mr Wilson's subsequent decline. The infusion should have been discontinued and the need for this treatment, in my opinion unnecessary at the time of commencement, reviewed.

Evaluation of drugs prescribed and the administration regimens

5.11 The initial prescription and administration of oramorph to Mr Wilson following his transfer to Dryad ward was in my opinion inappropriate. His pain had been controlled with regular paracetamol and as required codeine phosphate (a mild opiate) prior to his transfer, and in the first instance these should have been discontinued.

5.12 I am unable to establish when Dr Barton wrote the prescription for subcutaneous diamorphine 20-200mg/24hr, hyoscine 200-800microg/24hr, and midazolam 20-80mg/24hr as these are undated. The administration of diamorphine and hyoscine by subcutaneous infusion as a treatment for the diagnosis of a silent myocardial infarction was in my opinion inappropriate. The prescription of a single dose of intravenous opiate is standard treatment for a patient with chest pain following myocardial infarction is appropriate standard practice but was not indicated in Mr Wilson's case as he did not have pain. The prescription of an initial single dose of diamorphine is appropriate as a treatment for pulmonary oedema if a patient fails to respond to intravenous diuretics such as frusemide. Mr Wilson was not administered intravenous

frusemide or another loop diuretic. Instead only a single additional oral dose of frusemide was administered. In my opinion this was an inadequate response to Mr Wilson's deterioration. The prescription of continuous subcutaneous infusion of diamorphine and hyoscine is not appropriate treatment for a patient who is pain free with a diagnosis of a myocardial infarction and heart failure. When opiates are used to treat heart failure, close monitoring of blood pressure and respiratory rate, preferably with monitoring of oxygen saturation is required. This was not undertaken.

5.13 The increase in diamorphine dose to 40mg/24hr and then 60mg/24 hr in the following 48 hours is not appropriate when the nursing and medical notes record no evidence that Mr Wilson was in pain or distressed at this time. This was poor practice and potentially very hazardous. Similarly the addition of midazolam and subsequent increase in dose to 40mg/24hr was in my opinion highly inappropriate and would be expected to carry a high risk of producing profound depression of conscious level and respiratory drive.

Quality and sufficiency of the medical records

5.14 The initial entry in the medical records by Dr Barton on 14th October is reasonable and sufficient. The subsequent entries relating to Mr Wilson's deterioration are in my opinion inadequate, and greater detail and the results of examination findings should have been recorded. No justification for the increases in diamorphine, midazolam and hyoscine dose are written in the medical notes. The nursing notes are generally of adequate quality but I can find no record of fluid and food intake by Mr Wilson.

Appropriateness and justification of the decisions that were made

5.15 I consider the prescription of oramorph was inappropriate. The subsequent prescription and administration of diamorphine, hyoscine and midazolam was highly inappropriate, not justified by information presented in the notes and could be expected to result in profound depression of conscious level and respiratory depression in a frail elderly man such as Mr Wilson.

Recorded causes of death

5.16 The recorded cause of death was congestive cardiac failure. The limited clinical information recorded in the absence of a chest Xray result or post-mortem findings, suggest this may have been the cause of Mr Wilson's death. However in my opinion it is highly likely that the diamorphine, hyoscine and midazolam infusion led to respiratory depression and/or bronchopneumonia and it is possible that Mr Wilson died from drug induced respiratory depression.

Duty of care issues

5.17 Medical and nursing staff on Dryad ward had a duty of care to deliver appropriate medical and nursing care to Mr Wilson, and to monitor the effects of drugs prescribed. In my opinion this duty of care was not adequate. The administration of high doses of diamorphine and midazolam was poor practice and may have contributed to Mr Wilson's death.

Summary

5.18 Mr Wilson was a frail elderly man with early dementia who was physically dependent. Following his admission to Dryad ward he was, in my opinion, inappropriately treated with high doses of opiate and sedative drugs. These drugs are likely to have produced respiratory depression and/or the development of bronchopneumonia and may have contributed to his death.

Eva PAGE

6.1 Eva Page was 87 years old when admitted as an emergency on 6th February 1998 to the Department of Medicine for Elderly People at Queen Alexandra Hospital. The medical notes record that she had experienced a general deterioration over the last 5 days was complaining of nausea and reduced appetite and was dehydrated. She had felt 'depressed' during the last few weeks. On admission she was taking ramipril 5mg once daily (a treatment for heart failure and hypertension), frusemide 40mg once daily (treatment for fluid retention), digoxin 125microg once daily (to control irregular heart rate), sotalol 40 mg twice daily (to control irregular heart rate), aspirin 75 mg once daily (to prevent stroke and myocardial infarction) and sertraline 50mg once daily (an antidepressant commenced by her general practitioner on 26th January 1998). A discharge summary and medical notes relating to an admission in May 1997 states that she was admitted with acute confusion, had reduced movement on the right side and was discharged back to her residential home on aspirin. No admitting diagnosis is recorded in the clerking notes written by Dr Harris on 6th February 1998 but they record that *"patient refuses iv fluids and is willing to accept increased oral fluids"*.

6.2 On 7th February 1998 the medical notes record an opacity seen on the chest Xray and sate *"mood low. Feels frightened – doesn't know why. Nausea and ??. Little else. Nil clinically."* An increased white cell count is noted (13.0) and antibiotics commenced. A subsequent chest Xray report (undated) states there is a 5cm mass superimposed on the left hilum highly suspicious of malignancy. The medical notes on 11 February 1998 record this at the Xray meeting. On 12th February 1998 the notes record (? Dr Shain) *'In view of advanced age aim in the management should be palliative care. Charles Ward is suitable. Not for CPR'.* On 13th February the notes record *'remains v low Appears to have 'given up' d/w son re probably diagnosis d/w RH (residential home) re ability to cope'.* The notes record *'son agrees not suitable for invasive Tx* (treatment). *Matron from RH visiting today will check on ability to cope.'*

6.3 On 19th February the notes record she fell on the ward and experienced minor cuts. On 16th February *'gradual deterioration, no pain, confused. For Charles Ward she could be discharged to community from Charles Ward'.* On 19th February the notes summarise her problems *'probable Carcinoma of the bronchus, previous left ventricular failure, atrial fibrillation, digoxin toxicity and a transient ischaemic attack, that she was sleepy but responsive, states that she is frightened but doesn't know why. Says she has forgotten things, not possible to elicit what she can't remember, low MTS (mental test score). Plan encourage oral fluids, s/c fluid over night if tolerated. Continue antidepressants'*. On 18th February the medical notes state *"No change. Awaiting Charles Ward bed"*.

6.4 The nursing notes record she was confused but mobilised independently. On 19th February she was transferred to Charles Ward instead of the preferred option of a bed at Gosport Hospital, which the notes record was full ('no beds'). The Queen Alexandra Hospital medical notes record a summary of her problems on 19th February prior to transfer as follows " *Diagnosis CA bronchus probable [no histology] Diag based on CXR. PMH 95 LVF + AF 95 Digoxin toxicity 97 TIA. Admitted 6.2.98 general deterioration CXR ? Ca Bronchus.*

Well defined O lesion. Exam: sleepy but responsive answers appropriately. States that she is frightened but doesn't know why. Says she has forgotten things. Not possible to elicit what she can't remember. Low MTS" and *"Feels in general tired and very thirsty. Plan encourage oral fluids, s/c fluid overnight is tolerated continue antidepressants".*

6.5 The medical notes on 23rd February record diagnoses of depression, dementia, ? Ca bronchus, ischaemic heart disease and congestive heart failure. On 25th February Dr Lord records in the medical notes "*confused and some agitation towards afternoon – evening try tds* (three times daily) *thioridazine, son in Gosport, transfer to Gosport 27/2, heminevrin prn nocte'.* A further entry states *'All other drugs stopped by Dr Lord'.*

6.6 Mrs Page was transferred to Dryad ward at Gosport War Memorial Hospital on 27th February 1998. Dr Barton writes in the medical notes "*Transfer to Dryad ward continuing care, Diagnosis of Ca Bronchus on CXR on admission. Generally unwell off legs, not eating, bronchoscopy not done, catheterised, needs help with eating and drinking, needs hoisting, Barthel 0. Family seen and well aware of prognosis. Opiates commenced. I'm happy for nursing staff to confirm death".* The nursing notes state she was admitted for *'palliative care'*, that she had a urinary catheter (inserted on 22nd February 1998) was incontinent of faeces, and was dependent for washing and dressing but could hold a beaker and pick up small amounts of food. Barthel Index was 2/20. The nursing action plan states *'encourage adequate fluid intake'.* On 28th February an entry in the medical notes by Dr Laing (duty GP) record *'asked to see: confused. Feels 'lost' agitated esp. night/evening, not in pain, to give thioridazine 25mg tds regular, heminevrin noct.* The nursing notes record she was very distressed and that she was administered thioridazine and Oramorph 2.5ml.

6.7 On 2nd March Dr Barton records *'no improvement on major tranquillisers. I suggest adequate opioids to control fear and pain; Son to be seen by Dr Lord today'.* A subsequent entry by Dr Lord on the same day states *' spitting out thioridazine, quieter on prn sc diamorphine. Fentanyl patch started today. Agitated and calling out even when staff present (diagnoses) 1) Ca Bronchus 2) ? Cerebral metastases. -ct* (continue) *fentanyl patches.'* A further entry by Dr Lord that day records *'son seen. Concerned about deterioration today. Explained about agitation and that drowsiness was probably due in part to diamorphine. He accepts that his mother is dying and agrees we continue present plan of Mx* (management)".

6.8 On 2nd March the nursing notes record "*commenced on Fentanyl 25mcg this am. Very distressed this morning seen by Dr Barton to have and diamorphine 5mg i/m (intramuscular) same given 0810h by a syringe driver.* A further entry the same day states *"S/B Dr Lord. Diamorphine 5mg i/m given for syringe driver with diamorphine loaded".* On 3rd March a rapid deterioration in Mrs Page's condition is recorded *'Neck and left side of body rigid – right side rigid,* At 1050h diamorphine and midazolam were commenced by syringe driver. Death is recorded later that day at 2130h, 4 days following admission to Dyad ward.

6.9 The prescription charts (which are incompletely copied in notes made available to me) indicate she received the following drugs during this admission Two doses of intramuscular diamorphine 5 mg were administered at 0800 and 1500h (date not visible)

28 Feb 1998	1300h thioridazine 25mg
	1620h oramorph 5mg
	2200h heminevrin 250mg in 5ml
1 Mar 1998	0700h thioridazine 25 mg
	1300h thioridazine 25 mg
	2200h heminevrin 250mg
2 Mar 1998	0700h thioridazine 25mg
	0800h fentanyl 25microg
3 Mar 1998	1050h diamorphine 20mg/24hr, midazolam 20 mg/24hr by subcutaneous infusion

On 27th February Dr Barton prescribed thioridazine 25mg (prn tds) and Oramorph (10mg/5ml) 4hrly prn. On 2nd March Dr Barton prescribed fentanyl 25microg patch (x3 days) to take as required (prn). On 3rd March Dr Barton prescribed diamorphine 20-200mg/24hr, hyoscine 200-800ucg/24hr and midazolam 20-80mg/24hr by subcutaneous infusion.
The notes do not indicate that the fentanyl patch was removed and I would assume this was continued when the diamorphine and midazolam infusion was commenced.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

6.10 Primary responsibility for the medical care of Mrs Page during her admission to Dryad Ward lay with Dr Lord, as the consultant responsible for his care. She saw Mrs Page 2 days before her transfer to Dryad ward and two days following her admission, the day before she died. My understanding is that day-to-day medical care was the responsibility of the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital. Ward nursing staff were responsible for assessing and monitoring Mrs Page and informing medical staff of any significant deterioration.

Accuracy of diagnosis and prognosis including risk assessments

6.11 The assessment and management of Mrs Page at Alexandra Hospital was in my opinion competent and considered. From the information in the clinical notes I would agree with the diagnosis of probable carcinoma of bronchus. The decision to prescribe an antidepressant was in my opinion appropriate. Prior to transfer to Dryad ward she was not in pain but was transferred for palliative care. Although Mrs Page was clearly very dependent and unwell, it is not clear why Dr Barton prescribed opiates to Mrs Page on admission to Dryad ward when there is no evidence she was in pain. I suspect the reason was to provide relief for Mrs Page's anxiety and agitation. This is a reasonable indication for opiates in the palliative care of a patient with known inoperable carcinoma. Mrs Page was noted to be severely dependent, Barthel Index 0, and in conjunction with a probable carcinoma of the bronchus the assessment that she required palliative care and was likely to die in the near future was appropriate.

Evaluation of drugs prescribed and the administration regimens

6.12 The prescription of the major tranquilliser thioridazine for anxiety was reasonable and appropriate. The prescribing of the sedative/hypnotic drug heminevrin was similarly reasonable although potential problems of sedation from the combination need to be considered. Mrs Page was not in pain but I consider the prescription of oramorph on 28th February to attempt to improve her distress was reasonable. By 2nd March Mrs Page remained very distressed despite prescription of Oramorph, thioridazine and heminevrin. Since the notes reported she was more settled following intramuscular diamorphine and she had been spitting out her oral medication, I would consider it appropriate to prescribe a transdermal fentanyl patch to provide continuing opioid drugs to Mrs Page. The lowest dose patch was administered but it would have been important to be aware of the potential for depression of respiration and/or conscious level that could occur.

6.13 I do not understand why subcutaneous diamorphine and midazolam infusions were commenced on 3rd March when Mrs Page had deteriorated whilst on the fentanyl patch. There is no indication in the notes that Mrs Page was in pain or distressed. The notes describe her as having undergone a rapid deterioration, which could have been due to a number of different causes, including a stroke or an adverse effect of the fentanyl patch. In my opinion the prescription by Dr Barton of subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr was poor practice and potentially very hazardous. I would judge it poor management to initially commence both diamorphine and midazolam in a frail elderly underweight patient such as Mrs Page who was already receiving transdermal fentanyl. I would expect very clear reasons to support the use of the drugs to be recorded in the medical notes. The combination could result in profound respiratory depression and there are no symptoms recorded which suggest the administration of either drug was appropriate.

Quality and sufficiency of the medical records

6.14 The medical and nursing records relating to Mrs Page's admission to Dryad ward are in my view of adequate quality, although as stated above the reasons for the use of midazolam and diamorphine are not recorded in either the medical or nursing notes.

Appropriateness and justification of the decisions that were made

6.15 In my opinion the majority of management and prescribing decisions made by medical and nursing staff were appropriate. The exception is the prescription of diamorphine and midazolam on the day of Mrs Page's death. From the information I have seen in the notes it appears that Dr Barton may have commenced the diamorphine and midazolam infusion for non-specific reasons or for non-defined palliative reasons when it was judged she was likely to die in the near future.

Recorded causes of death

6.16 In the absence of a post-mortem the recorded cause of death is reasonable. Mrs Page had a probable carcinoma of the bronchus and experienced a slow deterioration in her general health and functional abilities. It is possible that Mrs Page died from drug induced respiratory depression. However Mrs Page was at high risk of dying from the effects of her probable carcinoma of the bronchus even if she had not received sedative and opiate drugs. Bronchopneumonia

can also occur as a complication of opiate and sedative induced respiratory depression but also in patients deteriorating from malignancy. In the absence of post-mortem, radiological data (chest Xray) or recordings of Mrs Page's respiratory rate I would consider the recorded cause of death was possible. The deterioration on between the 2nd March and 3rd March could have been secondary to the fentanyl patch she received but again could have occurred in the absence of receiving this drug. There are no accurate records of Mrs Page's respiratory rate but significant potentially fatal respiratory depression was likely to have resulted could have resulted from the combination of diamorphine, midazolam and fentanyl.

Duty of care issues

6.17 Medical and nursing staff on Dryad ward had a duty of care to deliver medical and nursing care, to monitor Mrs Page and to document the effects of drugs prescribed. In my opinion this duty of care was adequately met except during the last day of her life when the prescription of diamorphine and midazolam was poor practice and may have contributed to Mrs Wilkie's death.

Summary

6.18 Mrs Page was a frail elderly lady with probable carcinoma of the bronchus who had been deteriorating during the two weeks prior to admission to Dryad ward. In general I consider the medical and nursing care she received was appropriate and of adequate quality. However I cannot identify a reason for the prescription of subcutaneous diamorphine, midazolam and hyoscine by Dr Barton on the 3rd March. In my view this was an inappropriate, potentially hazardous prescription. I would consider it highly likely that Mrs Page experienced respiratory depression and profound depression of conscious level from the combination of these two drugs and fentanyl but I cannot exclude other causes for her deterioration and death at this time such as stroke or pneumonia.

Opinion on clinical management at Gosport War Memorial Hospital based on review of five cases presented by Hampshire Police

7.1 My opinion on the five cases I have been asked to review at Gosport War Memorial Hospital must be considered in context. My understanding is that the five cases have been selected by Hampshire Police because of concerns expressed relating to the management of these patients. Therefore my comments should not be interpreted as an opinion on the quality of care in general at Gosport War Memorial Hospital or of the general quality of care by the clinicians involved. My comments also relate to a period 2-4 years ago and the current clinical practice at the hospital may be very different today. An opinion on the quality of care in general at the hospital or of the clinicians would require a systematic review of cases, selected at random or with pre-defined patient characteristics. Examination of selected cases is not an appropriate mechanism to comment on the general quality of care of an institution or individual practitioners.

7.2 However having reviewed the five cases I would consider they raise a number of concerns that merit further examination by independent enquiry. Such enquiries could be made through further police interviews or perhaps more appropriately through mechanisms within the National Health Service, such as the Commission for Health Improvement, and professional medical and nursing bodies such as the General Medical Council or United Kingdom Central Council for Nursery, Midwifery and Health Visiting.

7.3 My principle concerns relate to the following three areas of practice: prescription and administration of subcutaneous infusions of opiate and sedative drugs in patients with non-malignant disease, lack of training and appropriate medical supervision of decisions made by nursing staff, and the level of nursing and non-consultant medical skills on the wards in relation to the management of older people with rehabilitation needs.

7.4 In all five cases subcutaneous infusions of diamorphine and in combination with sedative drugs were administered to older people who were mostly admitted for rehabilitation. One patient with carcinoma of the bronchus was admitted for palliative care. Although intravenous infusion of these drugs are used frequently in intensive care settings, very close monitoring of patients is undertaken to ensure respiratory depression does not occur. Subcutaneous infusion of these drugs is also used in palliative care, but the British National Formulary indicates this route should be used only when the patient is unable to take medicines by mouth, has malignant bowel obstruction or where the patient does not wish to take regular medication (Appendix 2). In only one case were these criteria clearly fulfilled i.e. in Mrs Page who was refusing to take oral medication. Opiate and sedative drugs used were frequently used at excessive doses and in combination with often no indication for dose escalation that took place. There was a failure by medical and nursing staff to recognise or respond to severe adverse effects of depressed respiratory function and conscious level that seemed to have occurred in all five patients. Nursing and medical staff appeared to have little knowledge of the adverse effects of these drugs in older people.

7.5 Review of the cases suggested that the decision to commence and increase the dose of diamorphine and sedative drugs might have been made by nursing staff without appropriate consultation with medical staff. There is a possibility that prescriptions of subcutaneous infusions of diamorphine, midazolam and hyoscine may have been routinely written up for many older frail patients admitted to Daedalus and Dryad wards, which nurses then had the discretion to commence. This practice if present was highly inappropriate, hazardous to patients and suggests failure of the senior hospital medical and managerial staff to monitor and supervise care on the ward. Routine use of opiate and sedative drug infusions without clear indications for their use would raise concerns that a culture of "involuntary euthanasia" existed on the ward. Closer enquiry into the ward practice, philosophy and individual staff's understanding of these practices would be necessary to establish whether this was the case. Any problems may have been due to inadequate training in management of older patients. It would be important to examine levels of staffing in relation to patient need during this period, as the failure to keep adequate nursing records could have resulted from under-staffing of the ward. Similarly there may have been inadequate senior medical staff input into the wards, and it would be important to examine this in detail, both in terms of weekly patient contact and in time available to lead practice development on the wards. My review of Dr Lord's medical notes and her statement leads me to conclude she is a competent, thoughtful geriatrician who had a considerable clinical workload during the period the above cases took place.

7.6 I consider the five cases raise serious concerns about the general management of older people admitted for rehabilitation on Daedalus and Dryad wards and that the level of skills of nursing and non-consultant medical staff, particularly Dr Barton, were not adequate at the time these patients were admitted.

7.7 Having reviewed the five cases presented to me by Hampshire Police, I consider they raise serious concerns about nursing and medical practice on Daedalus and Dryad wards at Gosport War Memorial Hospital. In my opinion a review of practice at the institution is necessary, if this has not already taken place. I would recommend that if criminal proceedings do not take place, that these cases are brought to the attention of the General Medical Council and United Kingdom Central Council for Nursery, Midwifery and Health Visiting, in relation to the professional competence of the medical and nursing staff, and the Commission for Health Improvement, in relation to the quality of service provided to older people in the Trust.

APPENDIX 1

Pharmacology of Opiate and Sedative Drugs

Morphine

8.1 Morphine is a potent opiate analgesic considered by many to the 'drug of choice' for the control of acute pain (Therapeutic Drugs Dollery). Recommended starting dosage regimens for a fit adult of 70Kg are for intravenous bolus dosing 2.5mg every 5 min until analgesia achieved with monitoring of the duration of pain and dosing interval, or a loading dose of 5-15mg over 30min than 2,5mg – 5mg every hour. A standard reference text recommends 'morphine doses should be reduced in elderly patients and titrated to provide optimal pain relief with minimal side effects'. Morphine can be used for sedation where sedation and pain relief are indicated, Dollery comments *'it should be noted that morphine is not indicated as a sedative drug for long-term use. Rather the use of morphine is indicated where the requirement for pain relief and sedation coexist such as in patients admitted to intensive care units and other high dependency areas, the morphine dose should be titrated to provide pain relief and an appropriate level of sedation. Frequently other pharmacological agents (e.g.: benzodiazepines) are added to this regimen to increase the level of sedation".*

8.2 Diamorphine

8.3

8.4 **Fentanyl**

8.5 Fentanyl is a transdermal opioid analgesic available as a transdermal patch. The '25' patch releases 25microg/hr.

8.6 The British National Formulary (*copy of prescribing in palliative care attached* Appendix 2) comments on the use of syringe drivers in prescribing in palliative care that drugs can usually be administered by mouth to control symptoms, and that indications for the parenteral route are: patient unable to take medicines by mouth, where there is malignant bowel obstruction, and where the patient does not wish to take regular medication by mouth, It comments that staff using syringe drivers should be adequately trained and that incorrect use of syringe drivers is a common cause of drug errors.

Heminevrin

Midazolam

8.1 Midazolam is a benzodiazepine sedative drug. It is used as a hypnotic, preoperative medication, sedation for procedures such as dentistry and GO endoscopy, long-term sedation and induction of general anaesthesia. Iot is not licensed for subcutaneous use, but is described in the British National Formulary prescribing in palliative care section as 'suitable for a very restless patient: it is given in a subcutaneous infusion dose of 20-100mg/24 hrs.

8.2 DA standard text describes the use of sedation with midazolam in the intensive care unit setting, and states, "*sedation is most commonly met by a combination of a benzodiazepine and an opioid, and midazolam has generally replaced diazepam in this respect*". It goes on to state, "in critically ill patients, prolonged sedation may follow the use of midazolam infusions as a result of delayed administration". Potentially life threatening adverse effects are described, "Midazolam can cause dose-related CNS depression, respiratory and

cardiovascular depression. There is a wide variation in susceptibility to its effects, the elderly being particularly sensitive. Respiratory depression, respiratory arrest, hypotension and even death have been reported following its use usually during conscious sedation. The elderly are listed as a high-risk group; the elderly are particularly sensitive to midazolam. The dose should be *reduced and the drug given slowly intravenously in a diluted form until the* desired response is achieved. In drug interactions the following is stated. "*midazolam will also potentiate the central depressant effects of opioids, barbituates, and other sedatives and anaesthetics, and profound and prolonged respiratory depression might result.*

8.3

Hyoscine

8.4 The British National Formulary describes hyoscine hydrobromide as an antagonist (blocking drug) of acetylcholine. It reduces salivary and respiratory secretions and provides a degree of amnesia, sedation and antiemesis (antinausea). IN some patients, especially the elderly, hyoscine may cause the *central anticholinergic syndrome (excitement, ataxia, hallucinations,* behavioural abnormalities, and drowsiness). The palliative care section describes it as being given in a subcutaneous infusion dose of 0.6-2.4mg/24 hours.

8.5

Use of syringe drivers

8.1 The BNF states 'oral medication is usually satisfactory unless there is severe nausea and vomiting, dysphagia, weakness, or coma in which case parenteral medication may be necessary. In the pain section it comments the non-opioid analgesics aspirin or paracetamol given regularly will often make the use of opioids unnecessary. An opioid such as codeine or dextropropoxyphene alone or in combination with a non-opioid analgesic at adequate dosage may be helpful in the control of moderate pain id non-opioids are not sufficient. If these preparations are not controlling the pain, morphine is the most useful opioid analgesic. Alternatives to morphine are hydromoprhine, oxycodone and transdermal fentanyl. In prescribing morphine it states 'morphine is given as an oral solution or as standard tablets every 4 hour, the initial dose depending largely on the patient's previous treatment. A dose of 5-10mg is enough to replace a weaker analgesic. If the first dose of morphine is no more effective than the previous analgesic it should be increased by 50% the aim being to choose the lowest dose which prevents pain. The dose should be adjusted with careful assessment of the pain and the use of adjuvant analgesics (such as NSAIDs) should also be considered. Although morphine in a dose of 5-10mg is usually adequate there should be no hesitation in increasing it stepwise according to response to 100mg or occasionally up to 500mg or higher if necessary. The BNF comments on the parenteral route '*diamorphine is preferred for injection. The equivalent intramuscular or subcutaneous dose of diamorphine is approximately a third of the oral dose of morphine.*'

8.2 In the chapter on pain relief in 'Drugs and the Older Person' Crome writes on the treatment of acute pain ' *treat the underlying cause and give adequate pain relief. The nature of the painful condition, the response of the patient and the presence of comorbidity will dictate whether to start with a mild analgesic or to go immediately to a more potent drug. In order to avoid the situation that patients remain in pain, "starting low" must be followed by regular re-evaluation with, if necessary, frequent increases in drug dose. The usual method of*

prescribing morphine for chronic pain is to start with standard oral morphine in a dose of 5-10mg every four hours. The dose should be halved in frail older people.

Prescribing for the Elderly

The British National Formulary states in Prescribing for the Elderly section "*The ageing nervous system shows increased susceptibility to many commonly used drugs, such as opioid analgesics, benzodiazepines, antipsychotics and antiparkinsonian drugs, all of which must be used with caution*".

APPENDIX 2

BNF Prescribing in palliative care

Frimley Park Hospital NHS
NHS Trust

Portsmouth Road
Frimley
Camberley
Surrey
GU16 7UJ

Tel: 01276 604604
Fax: 01276 604148

Elderly Care Unit
Telephone: Code A *(direct line)*
Fax: Code A *(direct into Secretaries' office)*

KIM/gnt/gosport

18 October 2001

CONFIDENTIAL

Detective Superintendent J James
Hampshire Constabulary
Major Incident Complex
Kingston Crescent
North End
PORTSMOUTH
PO2 8BU

Dear DS James

CONFIDENTIAL MEDICAL REPORT REGARDING MEDICAL MANAGEMENT OF PATIENTS AT GOSPORT WAR MEMORIAL HOSPITAL

Thank you for asking me to give a report on the management of four patients who died at Gosport War Memorial Hospital. I have based my personal opinion on my qualification as a specialist in geriatric medicine, my 13 years experience as a Consultant Geriatrician with several years experience working at the local hospice.

USE OF OPIOID ANALGESICS

Opioid analgesics are used to relieve moderate to severe pain and also can be used to relieve distressing breathlessness and cough. The use of pain killing drugs in palliative care (ie the active total care of patients whose disease is not responsive to curative treatment) is described in the British National Formulary which is the standard reference work circulated to all doctors in Great Britain. The guidance in the BNF suggests that non-opioid analgesics such as Aspirin or Paracetamol should be used as first line treatment and occasionally non-steroidal anti-inflammatory drugs may help in the control of bone secondaries. If these drugs are inadequate to control the pain of moderate severity then a weak opioid such as Codeine or Dextropropoxyphene should be used either alone or in combination with the simple pain killers in adequate dosage. If these weak opioid preparations are not controlling the pain Morphine is the most useful opioid analgesic and is normally given by mouth as an oral solution every 4 hours, starting with a dose between 5 mg and 20 mg, the aim being to choose the lowest dose which prevents pain. The dose should be adjusted with careful assessment of the pain and use of other drugs should also be considered. If the pain is not well controlled the dose should be increased in a step-wise fashion to control the pain.

Sometimes modified release preparations of Morphine are given twice daily once the required dose of Morphine is established, as this may be more convenient for the patient.

If the patient becomes unable to swallow the equivalent intra-muscular dose of *Morphine is half the total 24 hour dose given orally. Diamorphine is preferred for* injections over Morphine as it is more soluble and can be given in smaller volume, therefore with less distress to the patient.

Subcutaneous infusions of Diamorphine by syringe driver are standard practise if the patient requires repeated intra-muscular injections, to save the patient unnecessary distress. This is standard treatment in Hospices and other medications can be added to deal with anxiety, agitation and nausea as they can safely be mixed with Diamorphine (such as Haloperidol, Cyclizine and Midazolam). The other indications for use of the parenteral route are when the patient is unable to take medicines by mouth due to upper gastro-intestinal problems and occasionally if the patient does not wish to take regular medication by mouth.

The BNF has a table showing the equivalent doses of oral Morphine and parenteral Diamorphine for intramuscular injection or subcutaneous infusion as a guide to the dosage when switching from the oral to the injection route, eg 10 mg of oral Morphine 4 hourly is equivalent to 20 mg of Diamorphine by a subcutaneous infusion every 24 hours, and 100 mg oral Morphine 4 hourly is equivalent to 240 mg of Diamorphine subcutaneously every 24 hours.

SUMMARY

It is clear from the above that a doctor trying to control pain should first start the patient on a non-opioid analgesic, move on to a weak opioid analgesic if the pain is not controlled, consider changing the patient to regular oral Morphine if the pain remains poorly controlled and only start parenteral Diamorphine if the patient is unable (or unwilling) to take Morphine by mouth and would otherwise need regular painful injections of Diamorphine to try and control the pain. There is clear guidance on the dose of Morphine to use in a syringe driver when transferring from oral Morphine to the subcutaneous route. Finally the dose of Morphine or Diamorphine should be reviewed regularly and only increased if the symptom of pain is not adequately controlled.

CASE NOTE REVIEWS

1 ARTHUR CUNNINGHAM

Mr Cunningham was known to suffer with depression, Parkinson's disease and cognitive impairment with poor short term memory. He suffered with long standing low back pain following a spinal injury sustained in the Second World War which required a spinal fusion. He suffered with hypertension and non insulin diabetes mellitus, had a previous right renal stone removed. and bladder stones, and had a previous trans-urethral prostatectomy. Myelodysplasia had been diagnosed (a bone marrow problem affecting the production of the blood constituents).. Mr Cunningham had a one month admission under the care of Dr Banks for depression in July and August 1998.

Mr Cunningham was admitted by Dr Lord, Consultant Geriatrician from the Dolphin Day Hospital to Dryad Ward at Gosport War Memorial Hospital on 21 09 1998 because of a large necrotic sacral ulcer with a necrotic area over the left outer aspect of the ankle (these are signs of pressure sores). Dr Lord's intention was to give more aggressive treatment to the sacral ulcer. He was seen by Dr Barton. A dose of 2.5 mg to 10 mg of Oromorph 4 hourly was prescribed and he was given 5 mg prior to his sacral wound dressing at 1450 and a further dose of 10 mg at 2015. Diamorphine via a syringe driver was prescribed at a dose of 20 mg to 200 mg in 24 hours and this was commenced at a dose of 20 mg for 24 hours with Midazolam at 2300 on 21 09 1998. Dr Barton reviewed the patient on 23 September when he was said to be "chesty", Hyoscine was added to the syringe driver and the dose of Midazolam was increased. The patient was noted to be in some discomfort when moved on that day and the next day he was said to be "in pain" and the Diamorphine dose was increased to 40 mg for 24 hours. then 60 mg the following day and 80 mg on the 26 September, there being no further comments as to the patient's condition. The dose of Midazolam and Hyoscine was also increased. The patient died at 2315 on 26 09 1998.

Comments

All the prescriptions for opiod analgesia are written in the same hand, and I assume they are Dr Barton's prescriptions although the signature is not decipherable. Morphine was started without any attempts to control the pain with less potent drugs. There was no clear reason why the syringe driver needed to be started as the patient had only received two doses of oral Morphine, the 24 hour dose requirement of Diamorphine could not therefore be established. The dose of Diamorphine prescribed gave a ten fold range from 20 mg to 200 mg in 24 hours which is an unusually large dose range in my experience. The patient was reviewed by Dr Barton on at least one occasion and the patient was noted to be in some discomfort when moved. The dose was therefore appropriately increased to 40 mg per 24 hours but there are no further comments as to why the dose needed to be progressively increased thereafter. In my view Morphine was started prematurely, the switch to a syringe driver was made without any clear reason and the dose was increased without any clear indication.

2 ALICE WILKIE

Miss Wilkie was known to suffer with severe dementia, depression and rectal bleeding attributed to piles. She had been admitted to Philip Ward with a urinary tract infection and immobility under the care of Dr Lord and a decision was made to transfer her to Daedalus ward at Gosport War Memorial Hospital for a few weeks observation prior to a decision on placement. She was transferred on the 6 August and was seen by Dr Peters. The nurses recorded that the patient was complaining of pain but it was difficult to establish the nature or site of this pain. Diamorphine was prescribed on 20 08 1998 in a dose of 20 mg to 200 mg per 24 hours and the signature is identical to that on Mr Cunningham's case which I assume is Dr Barton's. A dose of 30 mg was given on 20 08 1998 with Midazolam and an entry in the notes, again apparently by Dr Barton, comments on a "marked deterioration over last few days". The patient was given another 30 mg of Diamorphine on 21 08 1998 and died that day at 1830. The patient was said to be comfortable and pain free by the nursing staff on the final day.

Comments

There was no clear indication for an opiod analgesic to be prescribed, and no simple analgesics were given and there was no documented attempt to establish the nature of her pain. In my view the dose of Diamorphine that was prescribed at 30 mg initially was excessive and there is no evidence that the dose was reviewed prior to her death. Again the Diamorphine prescription gave a tenfold range from 20 mg to 200 mg in 24 hours.

3 ROBERT WILSON

Mr Wilson was known to suffer with alcohol abuse with gastritis, hypothyroidism and heart failure. He was originally admitted via Accident & Emergency on the 22 September with a fractured left humerus and transferred to Dickens Ward under the care of Dr Lord. His fracture was managed conservatively. In view of the severe pain he received several doses of Morphine and was prescribed regular Paracetamol.

He was reviewed by Dr Luznat, Consultant Psychogeriatrician, who felt he had an early dementia and depression and recommended an anti-depressant. He was also noted to have poor nutrition.

Dr Lord made a decision to transfer Mr Wilson for a "short spell to a long term NHS bed" with the aim of controlling his pain and presumably to try to rehabilitate him. He was accordingly moved to Dryad ward at Gosport War Memorial Hospital on the 14 October. The transfer letter from Dickens

ward shows that he was still " in a lot of pain in arm".

The prescription appears to have been written by Dr Barton once again. Paracetamol was prescribed but never given by the nursing staff. Oramorph was prescribed 10 mg 4 hourly and 20 mg nocte commencing on 15 10 1998 and the night time dose was given with "good effect" as judged by the nursing staff. The nursing report goes on to say that Mr Wilson had become "chesty" and had "difficulty in swallowing medications". Oramorph was also prescribed 5 mg to 10 mg as required 4 hourly and four doses were given, suggesting Mr Wilson was in persisting pain. on 16 10 1998 the patient was seen by Dr Knapman. The patient was said to be unwell, breathless, unresponsive with gross swelling of the arms and legs. No ECG or oxygen saturation was recorded but the patient's dose of Frusemide (a diuretic) was increased, so I assume the patient was thought to have worsening heart failure. The nurses report a "very bubbly chest". A Diamorphine/Midazolam subcutaneous infusion was prescribed on 16 10 1998 again, in Dr Barton's handwriting, the dose range from 20 mg to 200 mg in 24 hours. 20 mg of Diamorphine was given on 16 10 1998 and the nurses commented later that the "patient appears comfortable", the dose was increased to 40 mg the next day when copious secretions were suctioned from Mr Wilson's chest. On 18 10 1998 the patient was seen by Dr Peters and the dose of Diamorphine was increased to 60 mg in 24 hours and Midazolam and Hyoscine were added. The patient died on 18 10 1998 at 2340 hours.

Comments

Mr Wilson was clearly in pain from his fractured arm at the time of transfer to Dryad ward. Simple analgesia was prescribed but never given (there was an entry earlier in the episode of care that Mr Wilson had refused Paracetamol). No other analgesia was tried prior to starting morphine. Mr Wilson had difficulty in swallowing medication. The Oramorphine was converted to subcutaneous Diamorphine in appropriate dose as judged by the BNF guidelines. The patient was reviewed by a doctor prior to the final increase in Diamorphine. Once again the Diamorphine prescription had a tenfold dose range as prescribed.

It is clear that Mr Wilson's condition suddenly deteriorated probably due to a combination of worsening heart failure and terminal bronchopneumonia and I consider that the palliative care given was appropriate. A Do Not Resuscitate decision had been made by Dr Lord on 29 09 1998.

4 EVA PAGE

Mrs Page was known to suffer with hypertension, ischaemic heart disease with heart failure and paroxysmal atrial fibrillation, depression, episodic confusion and had sustained a minor stroke in the past. She was admitted on 06 02 1998 to Victory Ward with nausea, anorexia and dehydration and had recently been treated for depression. She was transferred to Charles Ward on 19 02 1998 and had been noted to have a 5 cm mass on chest

x-ray compatible with a lung cancer. She was transferred to Dryad ward, Gosport Memorial Hospital on 27 02 1998 for palliative care. On arrival she was noted to be calling out frequently, and anxious. She was prescribed Thioridazine (a tranquilliser) but this did not relieve her distress and she was prescribed Oramorph 5 mg to 10 mg as required 4 hourly, I believe, by Dr Barton. The nurses report "no relief". She was seen by another doctor who was not named in the nursing record who prescribed regular Thioridazine and Heminevrin at night. On 01 03 1998 it is recorded that Mrs Page "spat out medication", on 02 03 1998 there was an entry, I believe by Dr Barton, stating "no improvement on major tranquillisers. I suggest adequate opioids to control fear and pain". He prescribed a Fentanyl patch 25 mg (another opioid which can be given as a skin patch) and the prescription was countersigned by Dr Lord, I believe. The nursing records state she was "very distressed", she was reviewed by Dr Barton and Diamorphine 5 mg intramuscularly was given. She was then seen by Dr Lord and a further dose of intramuscular 5 mg Diamorphine was given. On 03 03 1998 a syringe driver was started, prescribed, I believe, by Dr Barton, at a dose of 20 mg to 200 mg in 24 hours. The initial dose given was 20 mg of Diamorphine with Midazolam which was started at 1050. The nurses record "rapid deterioration ..... right side flaccid" . The patient died at 2130 that evening.

Comments

Mrs Page had a clinical diagnosis of lung cancer. There was no documentation of any symptoms relevant to this and no evidence of metastatic disease. There was no documentation of any pain experienced by the patient. When she was transferred to Dryad Ward most medication was stopped but she required sedative medication because of her distress and anxiety. No psychogeriatric advice was taken regarding her symptom control and she was started on opioid analgesia, in my view, inappropriately. Following her spitting out of medication she was given a topical form of an opioid analgesic (Fentanyl). A decision was taken to start a syringe driver because of her distress. This included Midazolam which would have helped her agitation and anxiety.

The prescription for subcutaneous Diamorphine infusion again showed a tenfold range from 20 mg to 200 mg. It was clear that her physical condition deteriorated rapidly and I suspect she may have had a stroke from the description of the nursing staff shortly prior to death.

CONCLUSIONS

I felt that the nursing records at Gosport War Memorial Hospital were comprehensive on the whole. The reason for starting opioid therapy was not apparent in several of the cases concerned. There had been no mention of any pain, shortness of breath or cough requiring relief. In several of the cases concerned oral morphine was not given for long enough to ascertain the patient's dose requirements, the reason for switching to parenteral Diamorphine via subcutaneous infusion was not documented and the prescription of a tenfold range (20 mg to 200 mg) of

Diamorphine on the "as required" section of the drug chart is, in my view, unacceptable. In my view the dose of Diamorphine should be prescribed on a regular basis and reviewed regularly by medical staff in conjunction with the nursing team. There was little indication why the dose of Diamorphine was increased in several of the cases and the dose appears to have been increased without the input of medical staff on several occasions.

Specimen signatures of Dr Lord and Dr Barton are necessary to confirm the identity of the prescribers and doctors making entries into the clinical notes.

I believe that the use of Diamorphine as described in these four cases suggest that the prescriber did not comply with standard practise. There was no involvement, as far as I could tell, from a palliative care team or specialist nurse advising on pain control. I believe these two issues require further consideration by the Hospital Trust.

I trust this report contains all the essential information you require. Please let me know if you wish me to give any further comment.

Yours sincerely

Code A

DR K I MUNDY FRCP
CONSULTANT PHYSICIAN AND GERIATRICIAN

MEDICO-LEGAL REPORT

Re: **Gladys Mabel RICHARDS**
Arthur "Brian" CUNNINGHAM
Alice WILKE
Robert WILSON
Eva PAGE

Prepared by:
Professor G A Ford, MA, FRCP
Consultant Physician, Freeman Hospital
Newcastle upon Tyne
Professor of Pharmacology of Old Age, University of Newcastle upon Tyne

For: **Hampshire Constabulary**

Date: **12th December 2001**

Contents

Introduction and Remit of the Report

8.1 Code A

8.2 I have been asked by Detective Superintendent John James of Hampshire Constabulary to examine the clinical notes of five patients (Gladys Mabel Richards, Arthur "Brian" Cunningham, Alice Wilkie, Robert Wilson, Eva Page) treated at the Gosport War Memorial Hospital and to apply my professional judgement to the following:

- The gamut of patient management and clinical practices exercised at the hospital
- Articulation of the leadership, roles, responsibilities and communication in respect of the clinicians involved
- The accuracy of diagnosis and prognosis including risk assessments
- An evaluation of drugs prescribed and the administration regimes
- The quality and sufficiency of the medical records
- The appropriateness and justification of the decisions that were made
- Comment on the recorded causes of death
- Articulate the duty of care issues and highlight any failures

1.3 I have prepared individual reports on each case and an additional report commenting on general aspects of care at Gosport War Hospital from a consideration of all five cases.

1.4 I have been provided with the following documents by Hampshire Constabulary, which I have reviewed in preparing this report:

- Comment on the recorded causes of death
- Letter DS J James dated 15th August 2001
- Terms of Reference document
- Hospital Medical Records of Gladys Richards, Brian Cunningham, Alice Wilkie, Robert Wilson and Eva Page
- Witness statements by Leslie France Lack, and Gillian MacKenzie
- Report of Professor Brian Livesley
- Transcripts of police interviews with Gosport War Memorial staff Dr Barton, Mr Beed, Ms Couchman, Ms Joice

- Transcript of police interviews with Royal Hospital Haslar staff Dr Reid and Flt. Lt. Edmondson
- Transcript of interviews with patient transfer staff Mr Warren and Mr Tanner
- Transcript of police interviews with or statements from following medical and nursing staff: Dr Lord, LM Baldacchino, M Berry, JM Brewer, J Cook, E Dalton, W Edgar, A Fletcher, J Florio and A Funnell.

Gladys Mabel RICHARDS

Course of Events

2.1 Gladys Richards was 91 years old when admitted as an emergency via the Accident & Emergency Department to Haslar Hospital on 29Th July 1998. She had fallen onto her right hip and developed pain. At this time she lived in a nursing home and was diagnosed as having dementia. She had experienced a number of falls in the previous 6 months and the admission notes comments "*quality of life has ↓↓ markedly last 6/12*". She was found to have a fracture of the right neck of femur. An entry in the medical notes by Surgeon Commander Malcom Pott, Consultant orthopaedic surgeon dated 30 July 1998 states '*After discussion with the patient's daughters in the event of this patient having a cardiac arrest she is NOT for cardiopulmonary resuscitation. However she is to be kept pain free, hydrated and nourished.*' Surgery (right hemiarthroplasty) was performed on 30 July 1998.

2.2 On 3rd August she was referred for a geriatric opinion and seen by Dr Reid, Consultant Physician in Geriatrics on 3rd August 1998. In his letter dated 5th August 1998 he notes she had been on treatment with haloperidol and trazadone and that her daughters thought she had been 'knocked off' by this medication for months, and had not spoken to then for 6-7 months. Her mobility had deteriorated. Her daughters commented to Dr Reid that she had spoken to them and had been brighter mentally since the trazadone had been omitted following admission. Dr Reid found Mrs Richards to be confused but pleasant and cooperative, unable to actively lift her right leg from the bed but appeared to have little discomfort on passive movement of the right hip. He commented '*I understand she has been sitting out in a chair and I think that despite her dementia, she should be afforded the opportunity to try to re-mobilise her.* He arranged for her transfer to Gosport War Memorial Hospital.

2.3 Following Dr Reid's entry in the notes on 3rd August two further entries are made in the medical notes by the on call house officer (Dr Coales?) on 8th August 1998. Dr Coales was asked to see Mrs Richards who was agitated on the ward. She had been given 2mg haloperidol and was asleep when first seen at 0045h. At 02130 hr a further entry records Mrs Richards was '*noisy and disturbing other patients n ward. Unable to reason with patient. Prescribed 25mg thioridazine'.* A transfer letter for Sergeant Curran, staff nurse to the Sister in Charge dated 10th August 1998 describes Mrs Richards status immediately prior to transfer and notes *'Is now fully weight bearing, walking with the aid of two nurses and a zimmer frame. Gladys needs total care with washing and dressing eating and drinking. Gladys is continent, when she becomes fidgety and agitated it means she wants the toilet. Occasionally incontinent at night, but usually wakes.*

2.4 On 11th August 1998 Mrs Richards was transferred to Daedalus ward. Dr Barton writes *in the medical notes "Impression frail demented lady, not obviously in pain, please make comfortable. Transfers with hoist, usually continent, needs help with ADL Barthel 2. I am happy for nursing staff to confirm death".* The summary admitting nursing notes record *"now fully weight bearing and walking with the aid of two nurses and a Zimmer frame"*. On 12th August the nursing notes record "*Haloperidol given at 2330 as woke from sleep. Very agitated, shaking and crying. Didn't settle for more than a few*

*minutes at a time. Did not seem to be in pain".*On 13th August nursing notes record "*found on floor at 1330h. Checked for injury none apparent at time. Hoisted into safer chair. 1930 pain Rt hip internally rotated, Dr Brigg contacted advised Xray am and analgesia during the night. Inappropriate to transfer for Xray this pm."*

2.5 On 14th August 1998 Dr Barton wrote '*sedation/pain relief has been a problem. Screaming not controlled by haloperidol 1g ? but very sensitive to Oramorph. Fell out of chair last night. R hip shorter and internally rotated, Daughter nurse and not happy. Plan Xray . Is this lady well enough for another surgical procedure?"* A further entry the same day states "*Dear Cdr Spalding, further to our telephone conversation thank you for seeing this unfortunate lady who slipped from her chair and appears to have dislocated her R hip. Hemiarthroplasty was done on 30-8-98. I am sending Xrays. She has had 2.5ml of 10mg/5ml oramoroph at midday. Many thanks".*

2.6 Following readmission to Haslar hospital Mrs Richards underwent manipulation of R hip under iv sedation (2 mg midazolam) at 1400h. At 2215h the same day she was not responding to verbal stimulation but observations of blood pressure, pulse, respiration and temperature were all in the normal range. A further entry on 17th August by Dr Hamlin (House Officer) states "*fit for discharge today (Gosport War Mem) To remain in straight knee splint for 4/52. For pillow between legs (abduction) at night.*" A transfer letter to the nurse in charge at Daedalus ward states "*Thank you for taking Mrs Richards back under your care... was decided to pass an indwelling catheter which still remains in situ. She has been given a canvas knee immobilising splint to discourage any further dislocation and this must stay in situ for 4 weeks. When in bed it is advisable to encourage abduction by using pillows or abduction wedge. She can however mobilise fully weight bearing".*

2.7 Nursing notes record on 17th August " 1148h *returned from R.N.Haslar patient very distressed appears to be in pain. No canvas under patient – transferred on sheet by crew."* Later that day at 1305h "*in pain and distress, agreed with daughter to give her mother Oramorph 2.5mg in 5ml*". A further hip Xray was performed which demonstrated no fracture. Dr Barton writes on 17th August 1998 *"readmission to Daedalus ward. Closed reduction under iv sedation. Remained unresponsive for some hours. Now appears peaceful. Can continue haloperidol, only for Oramorph if in severe pain. See daughter again"* and on 18th August "*still in great pain, nursing a problem, I suggest sc diamorphine/ haloperidol/midazolam. I will see daughters today. Please make comfortable".* Nursing notes record "*reviewed by Dr Barton for pain control via syringe driver".* At 2000h "*patient remained peaceful and sleeping. Reacted to pain when being moved – this was pain in both legs".* On 19th August the nursing notes record "*Mrs Richards comfortable*" and in a separate entry "*apparently pain free*". There are no nursing entries I can find on 20th August. I can find no entries in the nursing notes describing fluid or food intake following admission on 17th August.

2.8 The next entry in the medical notes is on 21st August by Dr Barton "*much more peaceful. Needs hyoscine for rattly chest*". The nursing notes record "*patient's overall condition deteriorating. Medication keeping her comfortable*". A staff

nurse records Mrs Richards's death in the notes at 2120h later that day. The cause of death was recorded as bronchopneumonia.

2.9 Medication charts record the following administration of opiate, analgesic and sedative drugs during Mrs Richards's first admission to Haslar Hospital.

29 July 2000h Trazadone 100mg (then discontinued)
29 July to 11th August. Haloperidol 1mg twice daily
30 July 0230h Morphine iv 2.5mg
31 July 0150h morphine iv 2.5mg
1905h morphine iv 2.5 mg
1 Aug 1920h morphine iv 2.5mg
2 Aug 0720h morphine iv 2.5mg
Cocodamol two tablets as required taken on 16 occasions at varying times between 1-9th August

2.10 Medication charts record the following administration of opiate, analgesic and sedative drugs during Mrs Richards second admission to Haslar Hospital

14 Aug 1410h midazolam 2mg iv
15 Aug 0325h cocodamol two tablets orally
16 Aug 0410h haloperidol 2mg orally
0800h haloperidol 1mg orally
1800h haloperidol 1mg orally
2310h haloperidol 2mg orally
!7 Aug 0800h haloperidol 1mg orally

2.11 Medication charts record the following administration of opiate and sedative drugs on Daedalus ward:

11 Aug	1115h	5mg/5ml Oramorph
	1145h	10 mg Oramorph
	1800h	1 mg haloperidol
12 Aug	0615h	10 mg Oramorph
		haloperidol
13 Aug	2050h	10mg Oramorph
14 Aug	1150h	10mg Oramorph
17 Aug	1300h	5mg Oramorph
	?	5 mg Oramorph
	1645h	5mg Oramorph
	2030h	10mg Oramorph
18 Aug	0230h	10mg Oramorph
	?	10mg Oramorph
	1145h	diamorphine 40mg/24hr, haloperidol 5mg/24hr midazolam 20mg/24hrby
19 Aug	1120h	diamorphine 40mg/24hr, haloperidol 5mg/24hr midazolam 20mg/24hr, hyoscine 400microg/24hr
20 Aug	1045h	diamorphine 40mg/24hr, haloperidol 5mg/24hr midazolam 20mg/24hr, hyoscine 400microg/24hr
21 Aug	1155h	diamorphine 40mg/24h, haloperidol 5mg/24hr midazolam 20mg/24hr, hyoscine 400microg/24hr

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

2.12 Primary responsibility for the medical care of Mrs Richards during her two admissions to Gosport Hospital lay with Dr Lord, as the consultant responsible for his care. My understanding is that day-to-day medical care was delegated to the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital (statement of Dr Lord in interview with DC Colvin and DC McNally). Primary responsibility for the medical care of Mrs Richards during her two admissions to Queen Alexandra Hospital lay with Surgeon Commander Scott, Consultant Orthopaedic Surgeon. Junior medical staff were responsible for day-to-day medical care of Mrs Richards whilst at Queen Alexandra Hospital. Ward nursing staff were responsible for assessing and monitoring Mrs Richards and informing medical staff of any significant deterioration.

2.13 Dr Reid, Consultant Geriatrician was responsible for assessing Mrs Richards and making recommendations concerning her future care following her orthopaedic surgery, and arranged transfer to Gosport Hospital for rehabilitation.

Accuracy of diagnosis and prognosis including risk assessments

2.14 The initial assessment by the orthopaedic team was in my opinion competent and the admitting medical team obtained a good history of her decline in the previous six months. Surgeon Commander Pott discussed management options with the family and a decision was made to proceed with surgery but for Mrs Richards to not undergo cardiopulmonary resuscitation if she sustained a cardiac arrest, with a clear decision to keep Mrs Richards pain free, hydrated and nourished. There are good reasons to offer surgery for a fractured neck of femur to very frail patients with dementia even when a high risk of peri-operative death or complications is present. This is because without surgery patients continue to be in pain, remain immobile and nearly invariably develop serious complications such as pneumonia and pressure sores, which are usually fatal. From the information I have seen I would, as a consultant physician/geriatrician recommended the initial management undertaken. I consider it good management that the trazadone as discontinued when the history from the daughters suggested this might have been responsible for decline in the recent past.

2.15 After Mrs Richards was stable a few days following surgery it was appropriate to refer her for a geriatric opinion, and Dr Reid rapidly provided this. Dr Reid's assessment was in my opinion thorough and competent. He identified the potential for her to benefit from rehabilitation. I would consider his decision to refer her for rehabilitation despite her dementia to be appropriate. An elderly care rehabilitation, rather than an acute orthopaedic ward is in general a preferable environment to undertake such rehabilitation. It is implicit in his decision to transfer her to Gosport War Memorial Hospital that she would receive rehabilitation there and not care on a continuing care ward without input from a rehabilitation team. Dr Lord in an interview with DC McNally and DC Colvin describes Daedalus ward as "*Back in '98 .. Daedalus was a continuing care ward with 24 beds of which 8 beds were for slow stream stroke*

rehabilitation". Although Mrs Richards had a fractured neck of femur and not stroke as her primary problem requiring rehabilitation I would assume, in the light of Dr Reid's letter that she was transferred to one of the 8 slow stream rehabilitation beds on Daedalus ward.

2.16 The transfer letter from Sergeant Curran provides a clear description of Mrs Richards's status at the time of transfer. The observation that she was walking with the aid of two nurses and a zimmer frame, and the usual cause of agitation was when she needed to use the toilet are relevant to subsequent events following transfer to Gosport Hospital. The use of a Barthel Index score as a measure of disability is good practice and demonstrates that Mrs Richards was severely dependent at the time of her transfer to Gosport Hospital.

2.17 The initial entry by Dr Barton following Mrs Richards' transfer to Daedalus ward does not mention that she has been transferred for rehabilitation, and focuses on keeping her 'comfortable' despite recording that she is "*not obviously in pain*". The statement '*I am happy for nursing staff to confirm death*" also suggests that Dr Barton's assessment was that Mrs Richards might die in the near future. Dr Barton in her statement to DS Sackman and DC Colvin, confirms this when she states "*I appreciated that there was a possibility that she might die sooner rather than later*". Dr Barton refers to her admission as a "*holding manoeuvre*" and her statement suggests a much more negative view of the potential for rehabilitation. She does not describe any rehabilitation team or focus on the ward and suggests her transfer was necessary because she was not appropriate for an acute bed, rather than her being appropriate for rehabilitation- "*.her condition was not appropriate for an acute bed. ....seen whether she would recover and mobilise after surgery. If as was more likely she would deteriorate due to her age, her dementia, her frail condition and the shock of the fall followed by the major surgery, then she was to be nursed in a clam environment away from the stresses of an acute ward*". In my opinion this initial note entry and the statement by Dr Baron indicate a much less proactive view of rehabilitation, less appreciation than Dr Reid of the potential for Mrs Richards to recover to her previous level of functioning, and probably a failure to appreciate the potential benefits of appropriate multidisciplinary rehabilitation to Mrs Richards. This leads me to believe that Dr Barton's approach to Mrs Richards was in the context of considering her as a continuing care patient who was likely to die on the ward. It was not wrong or incorrect of Dr Barton to believe Mrs Richards might die on the ward, but I would consider her apparent failure to recognise Mrs Barton's rehabilitation needs may have led to subsequent sub-optimal care.

2.18 There are a number of explanations and contributory factors that may have led to Dr Barton possibly not recognising Mrs Richard's rehabilitation needs in addition to her nursing and analgesic needs. First she may have not clearly understood Dr Reid's assessment that she needed rehabilitation. In her statement Dr Barton states " *Dr Reid was of the view that, despite her dementia, she should be given the opportunity to try to remobilise*" which suggests Dr Barton may not have considered the necessity for Mrs Richards to receive Physiotherapy as a necessary part of her opportunity to remobilise. Second the ward had both continuing care and rehabilitation beds and these patients may require very different care. It is not uncommon for "slow stream" rehabilitation beds to be in the same ward as continuing care beds, but it does

require much broader range of care to meet the medical and social needs of these patients. I would anticipate that some patients would move from the slow stream rehabilitation to continuing care category. Dr Lord describes the existence of fortnightly multidisciplinary ward case conference suggesting there was a structured team approach that would have made Dr Barton and nursing staff aware of rehabilitation needs of patients. In Mrs Richards's case no such case conference took place because she became too unwell in a short period. Third Dr Barton may not have received sufficient training or gained adequate experience of rehabilitation or geriatrics despite working under the supervision of Dr Lord. Dr Lord states that Dr Barton was "*an experienced GP*" who had rights of admission to a GP ward and that Dr Lord had admitted patients "*under her care say for palliative care*". Experience in palliative care may possibly have influenced her understanding and expectations of rehabilitating older patients.

2.19 The assessment of Mrs Richard's agitation the following day on 12th August was in my opinion sub-optimal. The nursing records state that she did not appear to be in pain. There is no entry from Dr Barton this day but in her statement she states which I have some difficulty in interpreting: "*When I assessed Mrs Richards on her arrival she was clearly confused and unable to give any history. She was pleasant and co-operative on arrival and did not appear to be in pain. Later her pain relief and sedation became a problem. She was screaming. This can be a symptom of dementia but could also be caused by pain. In my opinion it was caused by pain as it was not controlled by Haloperidol alone. Screaming caused by dementia is frequently controlled by this sedative. Given my assessment that she was in pain I wrote a prescription for a number of drugs on 11th August, including Oramorph and Diamorphine. This allowed nursing staff to respond to their clinical assessment of her needs rather than wait until my next visit the following day. This is an integral part of team management. It was not in fact necessary to give diamorphine over the first few days following her admission but a limited number of small doses of Oramorph were given totalling 20mg over the first 24 hours and 10mg daily thereafter. This would be an appropriate level of pain relief after such a major orthopaedic procedure*".

2.20 I am unable establish from the notes and Dr Barton's statement whether she saw Mrs Richards in pain after she wrote in the notes and then wrote up the opiate drugs later on the 11th August, or if she wrote up these drugs after seeing her when she was not in pain, because she considered she might develop pain and agitation. In either case there is no evidence that the previous information provided by Sergeant Curran that Mrs Richards usually required the toilet when she was agitated was considered by Dr Barton. Screaming is a well-described behavioural disturbance in dementia (Dr Barton was clearly aware of this), which can be due to pain but is often not. In some cases it is not possible to identify a clear precipitating cause although a move to a new ward could precipitate such a behavioural disturbance. I would consider the assumption by Dr Barton that Mrs Richards screaming was due to pain was not supported by her own recorded observations. There is no evidence from the notes that Dr Barton examined Mrs Richards in the first two days to find any evidence on clinical examination that pain from her hip was the cause of her screaming. If the screaming had been worse on weight bearing or movement of the hip this would have provided supportive evidence that her screaming was

due to hip pain. Staff Nurse Jennifer Brewer in her interview with DC Colvin and DC McNally states that the nursing staff had considered the need for toileting and other potential causes of Mrs Richards screaming.

2.21 Mrs Richards pain following surgery had been controlled at Haslar hospital by intermittent doses of intravenous morphine and then intermittent doses of cocodamol (paracetamol and codeine phosphate). Dr Barton did not prescribe cocodamol or another mild or moderate analgesic to Mrs Richards to take on a prn basis when she was transferred. This makes me consider it probable that Dr Barton prescribed prn Oramorph, diamorphine, hyoscine and midazolam when she first saw Mrs Richards and she was not in pain. If this is the case it is highly unusual practice in a patient who has been transferred for rehabilitation, was not taking any regular or intermittent analgesics for 36 hours prior to transfer, and had last taken two tablets of cocodamol. In a rehabilitation or continuing care ward without resident medical staff I would consider it reasonable and usual practice to prescribe a mild or moderate analgesic to take on an as required basis in case further pain developed. In Mrs Richards's case a reasonable choice would have been cocodamol since she had been taking this a few days earlier without problems. I do not consider it was appropriate to administer intermittent doses of oramorph to Mrs Richards before first prescribing paracetamol, non-steroidal anti-inflammatory drugs or mild opiate. It is not appropriate to prescribe powerful opiate drugs as a first line treatment for pain not clearly due to a fracture or dislocation to a patient such as Mrs Richards 12 days following surgery. Dr Barton's statement that diamorphine and oramorph were appropriate analgesics at this stage following surgery when she had been pain free is incorrect and in my opinion would not be a view held by the vast majority of practising general practitioners and geriatricians.

2.22 The management of Mrs Richards when sustained a dislocation of her hip on 13th August was in my opinion sub-optimal. The hip dislocation most likely occurred following the fall from her chair at 1330h. The nursing notes suggest signs of a dislocation were noted at 1930h. If there was a delay in recognising the dislocation I would not consider this indicates poor care, as hip fractures and dislocations can be difficult to detect in patients who have dementia and communication difficulties. Mrs Richards suspected dislocation or fracture was discussed with the on-call doctor, Dr Briggs, who I would assume is a medical house officer. Given the concern about a fracture or dislocation I would judge it would have been preferable for her to b transferred to the orthopaedic ward that evening and be assessed by the orthopaedic team. I certainly consider the case should have been discussed with either the on call consultant geriatrician or the orthopaedic team. The benefits of transfer that evening in a patient where it was highly probable a fracture or dislocation were present would have been Mrs Richards could have received manipulation earlier the following morning and possibly that same evening, and that traction could have been applied even if reduction was not attempted.

2.23 Mrs Richards was found to have a dislocation of her right hip and this was manipulated under intravenous sedation the same day. Although she was initially unresponsive, most probably due to prolonged effects of the intravenous midazolam, 3 days later on 17th August she was mobilising and fully weight bearing and not requiring any analgesia. Although there are few medical note entries, the management at Haslar hospital during this period

appears to be appropriate and competent. Shortly after transfer back to Daedalus ward Mrs Richards again became very distressed. The nursing notes indicate there was an incorrect transfer by the ambulance staff of Mrs Richards onto her bed. Repeat dislocation of the right hip was reasonably suspected but not found on a repeat Xray. My impression is that this transfer may have precipitated hip or other musculoskeletal pain in Mrs Richards but that other causes of screaming were possible.

2.24 Intermittent doses of oral morphine were first administered to Mrs Richards, again without first determining whether less powerful analgesics would have been helpful. On 18th August Dr Barton suggested commencing subcutaneous diamorphine, haloperidol and midazolam. The diamorphine and midazolam had been prescribed 7 days earlier. An infusion of the three drugs was commenced later that morning and hyoscine was added on 19th August. Both Dr Barton's notes and the nursing notes indicate Mrs Richards was in pain, although it is not clear what they considered was the cause of the pain at this stage, having excluded a fracture or dislocation of the right hip. Dr Barton states in her prepared statement "... *it was my assessment that she had developed a haematoma or large collection of bruising around the area where the prosthesis had been lying while dislocated*".

2.25 Although there are no clear descriptions of Mrs Richard's conscious level in the last few days, her level of alertness appears to have deteriorated once the subcutaneous infusion of diamorphine, haloperidol and midazolam was commenced. It also seems that she was not offered fluids or food and intravenous or subcutaneous fluids were not considered as an alternative. My interpretation is that this was most probably because medical and nursing staff were of the opinion that Mrs Richards were dying and that provision of fluids or nutrition would not change this outcome. In her prepared statement Dr Barton states "*As their mother was not eating or drinking or able to swallow, subcutaneous infusion of pain killers was the best way to control her pain.*" and "*I was aware that Mrs Richards was not taking food or water by mouth*". She then goes on to say "*I believe I would have explained to the daughters that subcutaneous fluids were not appropriate*".

Evaluation of drugs prescribed and the administration regimens

2.26 The decision to prescribe oral opiates and subcutaneous diamorphine to Mrs Richards initial admission to Daedalus ward was in my opinion inappropriate and placed Mrs Richards at significant risk of developing adverse effects of excessive sedation and respiratory depression. The prescription of oral paracetamol, mild opiates such as codeine or non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen would have been appropriate oral and preferable with a better risk/benefit ratio. The prescription of subcutaneous diamorphine, haloperidol and midazolam infusions to be taken if required was inappropriate even if she was experiencing pain. Subcutaneous opiate infusions should be used only in patients whose pain is not controlled by oral analgesia and who cannot swallow oral opiates. The prescription by Dr Barton on 11th August of three sedative drugs by subcutaneous infusion was in my opinion reckless and inappropriate and placed Mrs Richards at serious risk of developing coma and respiratory depression had these been administered by the nursing staff. It is exceptionally unusual to prescribe subcutaneous infusion of these three drugs with powerful effects on conscious level and respiration to

frail elderly patients with non-malignant conditions in a continuing care or slow stream rehabilitation ward and I have not personally used, seen or heard of this practice in other care of the elderly rehabilitation or continuing care wards. The prescription of three sedative drugs is potentially hazardous in any patient but particularly so in a frail older patient with dementia and would be expected to carry a high risk of producing respiratory depression or coma.

2.27 I consider the statement by Dr Barton "*my use of midazolam in the dose of 20mg over 24 hours was as a muscle relaxant, to assist movement of Mrs Richards for nursing procedures in the hope that she could be as comfortable as possible. I felt it appropriate to prescribe an equivalence of haloperidol to that which she had been having orally since her first admission.*" Indicates poor knowledge of the indications for and appropriate use of midazolam administered by subcutaneous infusion to older people. Midazolam is primarily used for sedation and is not licensed for use as a muscle relaxant. Doses of benzodiazepine that produce significant muscle relaxation in general produce unacceptable depression of conscious level, and it is not usual practice amongst continuing care and rehabilitation wards to administer subcutaneous midazolam to assist moving patients.

Quality and sufficiency of the medical records

2.28 The medical and nursing records relating to Mrs Richards admissions to Daedalus ward are in my opinion not of an adequate standard. The medical notes fail to adequately account for the reasons why oramorph and then infusions of diamorphine and haloperidol were used. The nursing records do not adequately document hydration and nutritional needs of Mrs Richards during her admissions to Daedalus ward.

Appropriateness and justification of the decisions that were made

2.29 There are a number of decisions made in the care of Mrs Richards that I consider to be inappropriate. The initial management of her dislocated hip prosthesis was sub-optimal. The decision to prescribe oral morphine without first observing the response to milder opiate or other analgesic drugs was inappropriate. The decision to prescribe diamorphine, haloperidol and midazolam by subcutaneous infusion was, in my opinion, highly inappropriate.

Recorded cause of death

2.30 The recorded cause of death was bronchopneumonia. I understand that the cause of death was discussed with the coroner. A post mortem was not obtained and the recorded cause was certainly a possible cause of Mrs Richards's death. I am surprised the death certificate makes no mention of Mrs Richards's fractured neck of femur or her dementia. It is possible that Mrs Richards died from drug induced respiratory depression without bronchopneumonia present or from the combined effects of bronchopneumonia and drug-induced respiratory depression. Mrs Richards was at high risk of developing pneumonia because of the immobility that resulted following her transfer back to Daedalus ward even if she had not received sedative and opiate drugs. Bronchopneumonia can also occur as a secondary complication of opiate and sedative induced respiratory depression. In the absence of post-mortem, radiological data (chest Xray) or recordings of Mr Cunningham's respiratory rate I would consider the recorded cause of death of bronchopneumonia was possible. However given the rapid decline in

conscious level that preceded the development of respiratory symptoms (rattly chest) I would consider it more likely that Mrs Richards became unconscious because of the sedative and opiate drugs she received by subcutaneous infusion, that these drugs caused respiratory depression and that Mrs Richards died from drug induced respiratory depression and/or without bronchopneumonia resulting from immobility or drug induced respiratory depression. There are no accurate records of Mrs Richards respiratory rate but with the doses used and her previous marked sedative response to intravenous midazolam it is highly probable that respiratory depression was present.

Duty of care issues

2.31 Medical and nursing staff on Daedalus ward had a duty of care to deliver medical and nursing care to attempt to monitor Mrs Richards and to document the effects of drugs prescribed. In my opinion this duty of care was not adequately met. The prescription of diamorphine, midazolam and haloperidol was extremely hazardous and Mrs Richards was inadequately monitored. The duty of care of the medical and nursing staff to meet Mrs Richard's hydration and nutritional needs was also in my opinion probably not met.

Summary

2.32 Gladys Richards was a frail older lady with dementia who sustained a fractured neck of femur, successfully surgically treated with a hemiarthroplasty, and then complicated by dislocation. During her two admissions to Daedalus ward there was inappropriate prescribing of opiates and sedative drugs by Dr Baron. These drugs in combination are highly likely to have produced respiratory depression and/or the development of bronchopneumonia that led to her death. In my opinion it is likely the administration of the drugs hastened her death. There is some evidence that Mrs Richards was in pain during the three days prior to her heath and the administration of opiates can be justified on these grounds. However Mrs Richards was at high risk of developing pneumonia and it possible she would have died from pneumonia even if she had not been administered the subcutaneous sedative and opiate drugs.

Arthur "Brian" CUNNINGHAM

Course of Events

3.1 Mr Cunningham was 79 years old when admitted to Dryad ward, Gosport Hospital under the care of Dr Lord. Dr Lord had assessed him on a number of occasions in the previous 4 years. A letter dated 2nd December 1994 from Dr Bell, Clinical Assistant, indicates Parkinson's disease had been diagnosed in the mid 1980s and that he was having difficulties walking at this time. In 1998 it was noted he had experienced visual hallucinations and had moved into Merlin Park Rest Home. His weight was 69Kg in August 1998. In July 1998 he was admitted under the care of Dr Banks, Consultant in Old Age Psychiatry to Mulberry Ward A and discharged after 6 weeks to Thalassa Nursing Home. He was assessed to have Parkinson's disease and dementia, depression and myelodysplasia. Dr Lord in a letter dated 1 September 1998 summarises her assessment of Mr Cunningham when she saw him on Mulberry Ward A on 27 August 1998 before he was discharged to Thalassa Nursing Home. At this time he required 1-2 people to transfer and was unable to wheel himself around in his wheelchair. She commented that more levodopa might be required but was concerned it would upset his mental state. She arranged to review him at the Dolphin Day Hospital.

3.2 On 21st September 1998 he was seen at the Dolphin Day Hospital by Dr Lord who recorded *'very frail, tablets found in mouth, offensive large necrotic sacral sore with thick black scar. PD - no worse. Diagnoses listed as sacral sore (in N/H), PD, old back injury, depression and element of dementia, diabetes mellitus –diet, catheterised for retention. Plan – stop codanthramer and metronidazole. looks fine. TCI Dyad today –aserbine for sacral ulcer – nurse on side – high protein diet – oramorph prn if pain. N/Home to keep bed open for next 3/52 at least. Pt informed of admission agrees. Inform N/Home Dr Banks and social worker. Analgesics prn.'* He was admitted to Dyad ward. An entry by Dr Baron on 21 September states *'make comfortable, give adequate analgesia. Am happy for nursing staff to confirm death.'* On 24th September Dr Lord has written *'remains unwell. Son has ??? again today and is aware of how unwell he is. sc analgesia is controlling pain just. I am happy for nursing staff to confirm death.'* The next entry by Dr Brook is on 25th September *'remains very poorly. On syringe driver. For TLC'.*

3.3 Medication charts record the following administration of opiate and sedative drugs:

21 Sep 1415h Oramorph 5mg
1800h Coproxamol two tablets
(subsequent regular doses not administered)
2015h Oramorph10mg
21 Sep 2310h Diamorphine 20mg/24hr, midazolam 20mg/24hr infusion sc
22 Sep 2020h Diamorphine 20mg/24hr, midazolam 20mg/24hr infusion sc
23 Sep 0925h Diamorphine 20mg/24hr, hyoscine 200microg/24hr
midazolam 20 mg/24hr infusion sc
2000h Diamorphine 20mg/24hr, hyoscine 200microg/24hr
midazolam 60mg/24hr infusion sc
24 Sep 1055h Diamorphine 20mg/24hr, hyoscine 800microg/24hr
midazolam 80mg/24hr infusion sc
25 Sep 1015h Diamorphine 60mg/24hr, hyoscine 1200mg/24hr

midazolam 80mg/24hr infusion
26 Sep 1150h Diamorphine 80mg/24hr, hyoscine 1200mg/24hr
midazolam 100mg/24hr infusion
Sinemet 110 5 times/day was discontinued on 23rd September

3.4 The nursing notes relating to the admission to Dyad ward record on 21st Sept *'remained agitated until approx 2030h. Syringe driver commenced as requested* (unclear who made this request) *diamorphine 20mg, midazolam 20mg at 2300. Peaceful following".* On 22nd Sep *'explained that a syringe driver contains diamorphine and midazolam was commenced yesterday evening for pain relief and to allay his anxiety following an episode where Arthur tried to wipe sputum on a nurse saying he had HIV and going to give it to her. He also tried to remove his catheter and empty the bag and removed his sacral dressing throwing it across the room. Finally he took off his covers and exposed himself.'*

3.5 On 23rd Sep *'Has become chesty overnight to have hyoscine added to driver. Stepson contacted and informed of deterioration. Mr Farthing asked is this was due to the commencement of the syringe driver and informed that Mr Cunningham was on a small dosage which he needed.'* A later entry *'now fully aware that Brian is dying and needs to be made comfortable. Became a little agitated at 2300h, syringe driver adjusted with effect. Seems in some discomfort when moved, driver boosted prior to position change'.* On 24th Sept *'report from night staff that Brian was in pain when attended to, also in pain with day staff – especially his knees. Syringe driver renewed at 1055".* On 25th Sept *'All care given this am. Driver recharged at 1015 –diamorphine 60mg, midazolam 80mg and hyoscine 1200mcg at a rate of 50mmols/hr. Peaceful night - unchanged, still doesn't like being moved.'* On 26th September *'condition appears to be deteriorating slowly'.*

3.6 On 26th September staff nurse Tubbritt records death at 2315h. Cause of death was recorded on the death certificate as bronchopneumonia with contributory causes of Parkinson's disease and Sacral Ulcer.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

3.7 Primary responsibility for the medical care of Mr Cunningham during his last admission lay with Dr Lord, as the consultant responsible for his care. She saw Mr Cunningham 5 days before his death in the Dolphin Day Hospital, and 2 days before his death on Dyad ward. My understanding is that day-to-day medical care was the responsibility of the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital. Ward nursing staff were responsible for assessing and monitoring Mr Cunningham and informing medical staff of any significant deterioration.

Accuracy of diagnosis and prognosis including risk assessments

3.8 Initial assessment by Dr Lord was comprehensive and appropriate with a clear management plan described. The nursing staff record Mr Cunningham was agitated following admission on 21st September. Dr Lord had prescribed prn (intermittent as required) oramorph for pain. Nursing staff made the decision to administer oramorph but there is no clear recording in the nursing notes that he

was in pain or the site of pain. The nursing entry on 22nd Sept indicates a syringe driver was commenced for 'pain relief and to allay anxiety. Again the site of pain is not states. My interpretation of the records is that the nursing staff considered his agitation was due to pain from his sacral ulcer. The medical and nursing teams view on the cause of Mr Cunningham's deterioration on 23rd September when he became 'chesty' are not explicitly stated, but would seem to have been thought to be due to bronchopneumonia since this was the cause of death later entered on the death certificate. The medical and nursing staff may not have considered the possibility that Mr Cunningham's respiratory symptoms and deterioration may have been due to opiate and benzodiazepine induced respiratory depression. The nursing staff filed to appreciate that the agitation Mr Cunningham experienced on 23rd Sept at 2300h may have been due to the midazolam and diamorphine. It was appropriate for nursing staff to discuss Mr Cunningham's condition with medical staff at this stage.

3.9 When Dr Lord reviewed Mr Cunningham on 24th September the notes imply that he was much worse that when she had seen him 3 days earlier. There is clear recording by Dr Lord that Mr Cunningham was in pain. The following day the diamorphine dose was increased three fold from 20mg/24hr to 60mg/24hr and the dose was further increased on 26th September to 80mg/24hr although the nursing and medical notes do not record the reason for this. The notes suggest that the nursing and medical staff may have failed to consider causes of agitation other than pain in Mr Cunningham or to recognise the adverse consequences of opiates and sedative drugs on respiratory function in frail older individuals.

Evaluation of drugs prescribed and the administration regimens

3.10 The prescription of oramorph to be taken 4 hourly as required by Mr Cunningham was reasonable if his pain was uncontrolled from cocodamol. I consider the decision by Dr Barton to prescribe and administer diamorphine and midazolam by subcutaneous infusion the same evening he was admitted was highly inappropriate, particularly when there was a clear instruction by Dr Lord that he should be prescribed intermittent (underlined instruction) doses of oramorph earlier in the day. I consider the undated prescription by Dr Baron of subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr to be poor practice and potentially very hazardous. In my opinion it is poor management to initially commence both diamorphine and midazolam in a frail elderly underweight patient such as Mr Cunningham. The combination could result in profound respiratory depression and it would have been more appropriate to review the response to diamorphine alone before commencing midazolam, had it been appropriate to commence subcutaneous analgesia, which as I have stated before was not the case.

3.11 In my opinion it is doubtful the nursing and medical staff understood that when a syringe infusion pump rate is increased it takes an often appreciable effect of time before the maximum effect of the increased dose rate becomes evident. Typically the time period would be 5 drug half-lives. In the case of diamorphine this would be between 15 and 25 hours in an older frail individual.

Quality and sufficiency of the medical records

3.12 In my opinion the medical and nursing records are inadequate following Mr Cunningham's admission to Dryad ward. The initial assessment by Dr Lord on 21st September is in my opinion competent and appropriate. The medical notes following this are inadequate and do not explain why he was commenced on subcutaneous infusions of diamorphine and midazolam. The nursing notes are variable and at times inadequate.

Appropriateness and justification of the decisions that were made

3.13 An inappropriately high dose of diamorphine and midazolam was first prescribed. There was a failure to recognise or respond to drug induced problems. Inappropriate dose escalation of diamorphine and midazolam and poor assessment by Dr Lord. The assessment by Dr Lord on 21st September 1998 was thorough and competent and a clear plan of management was outlined. There is a clear note by Dr Lord that oramorph was to be given intermittently (PRN) for pain and not regularly. It is not clear from the medical and nursing notes why Mr Cunningham was not administered the regular cocodamol he was prescribed following the initial dose he received at 1800h following admission. It is good practice to provide regular oral analgesia, with paracetamol and a mild opiate, particularly when a patient has been already taking this medication and to use prn morphine for breakthrough pain. I consider the prescription by Dr Barton on admission of prn subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr to be unjustified, poor practice and potentially very hazardous. It is particularly notable that only hours earlier Dr Lord had written that oramorph was to be given intermittently and this had been underlined in the medical notes. There is no clear justification in the notes for the commencement of subcutaneous diamorphine and midazolam on the evening following admission. If increased opiate analgesia was required increasing the oramorph dose and frequency could have provided this. I would judge it poor management to initially commence both diamorphine and midazolam. The combination could result in profound respiratory depression and it would have been more appropriate to review the response to diamorphine alone before commencing midazolam.

3.14 I am concerned by the initial note entry by Dr Barton on 21st September 1998 that she was happy for nursing staff to confirm death. There was no indication by Dr Lord that Mr Barton was expected to die, and Dr Barton does not list the reason she would have cause to consider Mr Cunningham would die within the next 24 hours before he was reviewed the following day by medical staff. In my opinion it is of concern that the nursing notes suggest the diamorphine and midazolam infusions were commenced because of Mr Cunningham's behaviour recorded in the nursing entry on 22nd September.

3.15 Hyoscine was commenced on 23rd September after Mr Cunningham had become 'chesty' overnight. I consider it very poor practice that there is no record of Mr Cunningham being examined by a doctor following admission on 21st September, and a decision to treat this symptomatically with hyoscine appears to have been made by the medical staff. At this stage Mr Cunningham's respiratory signs are likely to have been due to bronchopneumonia or respiratory depression resulting in depressed clearance of bronchial secretions. A medical assessment was very necessary at this

stage to diagnose the cause of symptoms and to consider treatment with antibiotics or reduction in the dose of diamorphine and midazolam.

3.16 Again I consider it very poor practice that the midazolam was increased from 20mg/24hr to 60mg/24 hr at 2000h on 23rd September. There is no entry in the medical notes to explain this dose increase. The decision to triple the midazolam dose appears to have been made by a member of nursing staff as the nursing notes record "*agitated at 2300h, syringe driver boosted with effect*".

3.17 A medical assessment should have been obtained before the decision to increase the midazolam dose was made. At the very least Mr Cunningham's problems should have been discussed with on call medical staff. Mr Cunningham's agitation may have been due to pain, where increasing analgesia would have been appropriate, or hypoxia (lack of oxygen). If Mr Cunningham's agitation was due to hypoxia a number of interventions may have been indicated. Reducing the diamorphine and midazolam dose would have been appropriate if hypoxia was due to respiratory depression. Commencement of oxygen therapy and possibly antibiotics would have been appropriate if hypoxia was due to pneumonia. Reducing the dose diamorphine or midazolam would have been indicated if hypoxia was due to drug-induced respiratory depression. The decision to increase the midazolam dose was not appropriately made by the ward nursing staff without discussion with medical staff.

3.18 When Mr Cunningham was reviewed by Dr Lord on 24th September he was very unwell but there is not a clear description of his respiratory status or whether he had signs of pneumonia. At this stage Dr Lord notes Mr Cunningham is in pain, but does not state the site of his pain. It is not clear to me whether the subsequent alteration in infusion rate of diamorphine, hyoscine and midazolam was discussed with and sanctioned by Dr Lord or Dr Barton. I consider the increase in midazolam from 60mg/24 hr to 80mg/24 hr was inappropriate as a response to the observation that Mr Cunningham was in pain. It would have been more appropriate to increase the diamorphine dose or even consider treatment with a non-steroidal anti-inflammatory drug. The increase in midazolam dose to 80mg/24 hr would simply make Mr Cunningham less conscious than he already appears to have been (there is not a clear description of his conscious level at this stage).

3.19 The increase in hyoscine dose to 800microg/24 hr is also difficult to justify when there is no record that the management of bronchial secretions was a problem. The subsequent threefold increase in diamorphine dose later that day to 60mg/24 hr is in my view very poor practice. Such an increase was highly likely to result in respiratory depression and marked depression of conscious level, both of which could lead to premature death. The description of Mr Cunningham, was that analgesia was 'just' controlling pain and a more cautious increase in diamorphine dose, certainly no more than two fold, was indicated with careful review of respiratory status and conscious level after steady state levels of diamorphine would have been obtained about 20 hours later. A more appropriate response to deal with any acute breakthrough pain is to administer a single prn (intermittent) dose of opiate by the oral or intramuscular route, depending on whether Mr Cunningham was unable to swallow at this time.

3.20 The increase in both diamorphine dose and midazolam dose on 26th September is difficult to justify when there is no record in the medical or nursing notes that Mr Cunningham's pain was uncontrolled. Although it is possible to accept the increase in diamorphine dose may have been appropriate if Mr Cunningham was observed to be in pain, I find the further increase in midazolam dose to 100mg/24hr of great concern. I would anticipate that this dose of midazolam administered with 80mg/24hr of diamorphine would be virtually certain to produce respiratory depression and severe depression of conscious level. This would be expected to result in death in a frail individual such as Mr Cunningham. I would expect to see very clear reasons for the use of such doses recorded in the medical notes.

3.21 I can find no record of Mr Cunningham receiving food or fluids following his admission on 21st September despite a note from Dr Lord that Mr Cunningham was to receive a 'high protein diet'. There is no indication in the medical or nursing notes as to whether this had been discussed, but given that Mr Cunningham was admitted with the intention of returning to his Nursing Home (it was to be held open for 3 weeks) I would expect the notes to record a clear discussion and decision making process involving senior medical staff accounting for the decision to not administer subcutaneous fluids and/or nasogastric nutrition once Mr Cunningham was commenced on drugs which may have made him unable to swallow fluids or food.

Recorded causes of death

3.22 The recorded cause of death was bronchopneumonia with contributory causes of Parkinson's disease and sacral ulcer. A post mortem was not obtained and the recorded causes were in my opinion reasonable. It is possible that Mr Cunningham died from drug induced respiratory depression without bronchopneumonia present or from the combined effects of bronchopneumonia and drug-induced respiratory depression. Mr Cunningham was at high risk of developing pneumonia even if he had not received sedative or opiate drugs, bronchopneumonia can occur as a secondary complication of opiate and sedative induced respiratory depression. In the absence of post-mortem, radiological data (chest Xray) or recordings of Mr Cunningham's respiratory rate I would consider the recorded cause of death of bronchopneumonia as reasonable. Even if the staff had considered Mr Cunningham had drug-induced respiratory depression as a contributory factor, it would not be usual medical practice to enter this as a contributory cause of death where the administration of such drugs was considered appropriate for symptom relief.

Duty of care issues

3.23 Medical and nursing staff on Dryad ward had a duty of care to deliver medical and nursing care to attempt to heal Mr Cunningham's sacral ulcer and to document the effects of drugs prescribed. In my opinion this duty of are was not adequately met and the denial of fluid and diet and prescription of high doses of diamorphine and midazolam was poor practice and may have contributed to Mr Cunningham's death.

Summary

3.24 In summary although Mr Cunningham was admitted for medical and nursing care to attempt to heal and control pain from his sacral ulcer, Dr Barton and the ward staff appear to have considered Mr Cunningham was dying and had been admitted for terminal care. The medical and nursing records are inadequate in documenting his clinical state at this time. The initial prescription of subcutaneous diamorphine, midazolam and hyoscine by Dr Barton was in my view reckless. The dose increases undertaken by nursing staff were inappropriate if not undertaken after medical assessment and review of Mr Cunningham. I consider it highly likely that Mr Cunningham experienced respiratory depression and profound depression of conscious level due to the infusion of diamorphine and midazolam. I consider the doses of these drugs prescribed and administered were inappropriate and that these drugs most likely contributed to his death through pneumonia and/or respiratory depression.

ALICE WILKIE

Course of Events

4.1 Alice Wilkie was 81 years old when admitted under the care of Dr Lord, by her general practitioner on 31st July 1998 from Addenbrooke Rest Home to Phillip Ward, Department of Medicine for Elderly People, at the Queen Alexandra Hospital, Portsmouth. The general practitioner referral letter states "*This demented lady has been in this psychogeriatric care home for a year. She had a UTI early this week and has not responded to trimethoprim. Having fallen last night, she is not refusing fluids and is becoming a little dry*". The medical admitting notes record she was taking prozac (fluoxetine) syrup 20 mg once daily, codanthramer 5-10ml nocte, lactulose 10ml once daily zopiclone 1.875 or 3.75mg nocte and promazine syrup 25mg as required. On examination she had a fever and bilateral conjunctivitis but no other significant findings. The admitting doctor diagnosed a urinary tract infection and commenced intravenous antibiotics to be administered after a blood culture and catheter specimen of urine had been obtained. The following day DNR (do not resuscitate) is recorded in the notes. On 3rd August 1998 the medical notes record the fever had settled, that she was taking some fluids orally, was taking the antibiotic Augmentin elixir orally and receiving subcutaneous fluids. The notes then record (date not clear) that her Mental Test Score was 0/10 and Barthel 1/20 (indicating severe dependency). Mrs Wilkie was to be transferred to Daedalus NHS continuing care ward on 6th August 1998 with a note that her bed was to be kept at Addenbrooke Rest Home.

4.2 Following transfer on 6th August an entry in the medical notes states "*Transferred from Phillips Ward. For 4-6/52 only. On Augmentin for UTI*". Dr Lord writes on 10th August 1998 '*Barthel 2/20. Eating and drinking better. Confused and slow. Give up place at Addenbrooke's. R/V* (review) *in 1/12* (one month) *–if no specialist medical or nursing problems D* (discharge) *to a N/Home. Stop fluoxetine*'. The next entry is by Dr Barton on 21st August "*Marked deterioration over last few days. sc analgesia commenced yesterday. Family aware and happy*". The final entry is on the same day at 1830h where death is confirmed. The most recent record of the patient's weight I can find is 56Kg in April 1994.

4.3 The nursing notes, which have daily entries during her one week stay on Phillip ward note she was catheterised, was confused at times and was sleeping well prior to transfer. The nursing notes on Daedalus ward record "6/8/98 *Transferred from Philip ward QAH for 4-6 weeks assessment and observation and then decide on placement. Medical history of advanced dementia, urinary tract infection and dehydration*" and that she was seen by Dr Peters. The nursing assessment sheet notes *"does have pain at times unable to ascertain where"*. The nutrition care plan states on 6th August 1998 "*Due to dementia patient has a poor dietary intake*". And dietary intake is recorded between 12th August and 18th August but not before or following these dates. Nursing entries in the contact record state on 17th August 1998 "*Condition has generally deteriorated over the weekend Daughter seen- aware that mums condition is worsening, agrees active treatment not appropriate and to use of syringe driver if Mrs Wilkie is in pain*". There is no entry in the notes on 20th August or preceding few days indicating Mrs Wilkie was in pain.

4.4 A nursing entry on 21st August 1998 at 1255h states "*Condition deteriorating during morning. Daughter and granddaughters visited and stayed. Patient comfortable and pain free*". There are a number of routine entries in the period 6th August 1998 to death on 21st August 1998 in nutrition, pressure area care, constipation, catheter care, and personal hygiene. The nursing care plan records no significant deterioration until 21st August where it is noted death was pronounced at 2120h by staff nurse Sylvia Roberts. Cause of death was recorded as bronchopneumonia.

4.5 The drug charts records that Dr Barton prescribed as a regular daily review (not intermittent as required) prescription diamorphine 20-200mg/24hr, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr all to be administered subcutaneously. The prescription is not dated. Drugs were first administered on 20th August, diamorphine at 30mg/24hr and midazolam 20mg/24hr from 1350h and then again on 21st August. Mrs Wilkie had not been prescribed or administered any analgesic drugs during her admission to Daedalus ward prior to administration of the diamorphine and midazolam infusions. During the period 16th-18th August she was prescribed and received zopiclone (a sedative hypnotic) 3.75mg nocte and co-danthramer 5-10ml (a laxative) orally.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

4.6 Primary responsibility for the medical care of Mrs Wilkie during her admission to Daedalus ward lay with Dr Lord, as the consultant responsible for her care. She saw Mrs Wilkie on 10th August 1998, 11 days prior to her death. My understanding is that day-to-day medical care was the responsibility of the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital. Ward nursing staff were responsible for assessing and monitoring Mrs Wilkie and informing medical staff of any significant deterioration.

Accuracy of diagnosis and prognosis including risk assessments

4.7 The initial diagnosis of a urinary tract infection and dehydration was reasonable and appears correct. Mrs Wilkie had a diagnosis of dementia, which there was clear evidence for. The entry by Dr Lord on 10th August 1998 provides a reasonable assessment of her functional level at this time, and a plan to review appropriate placement in one month's time. No diagnosis was made to explain the deterioration Mrs Wilkie is reported to have experienced around 15th August. There is no medical assessment in the notes following 10th August except documentation on 21st August 1998 of a marked deterioration. There is no clear evidence that Mrs Wilkie was in pain although she was commenced on opiate analgesics.

Evaluation of drugs prescribed and the administration regimens

4.8 No information is recorded in the medical or nursing notes to explain why Mrs Wilkie was commenced on diamorphine and hyoscine infusions. In my opinion there was no indication for the use of diamorphine and hyoscine in Mrs Wilkie. Other oral analgesics, such as paracetamol and mild opiate drugs could and should first have been tried, if Mrs Wilkie was in pain, although there is no evidence that she was. If these were inadequate oral morphine would have

been the next appropriate choice. From the information I have seen in the notes it appears the diamorphine and midazolam may have been commenced for non-specific reasons, perhaps as a non-defined palliative reasons as it was judged she was likely to die in the near future.

4.9 I consider the undated prescription by Dr Barton of subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr to be poor practice and potentially very hazardous. I consider it poor and hazardous management to initially commence both diamorphine and midazolam in a frail elderly underweight patient with dementia such as Mrs Wilkie. The combination could result in profound respiratory depression and it would have been more appropriate to review the response to diamorphine alone before commencing midazolam, had it been appropriate to commence subcutaneous analgesia, which as I have stated before was not the case.

Quality and sufficiency of the medical records

4.10 The medical and nursing records during her stay on Daedalus ward are inadequate not sufficiently detailed, and do not provide a clear picture of Mrs Wilkie's condition. In my opinion the standard of the notes falls below the expected level of documentation on a continuing care or rehabilitation ward. The assessment by Dr Lord on 10th August 1998 is the only satisfactory medical note entry during her 15 day stay on Daedalus ward.

Appropriateness and justification of the decisions that were made

4.11 As discussed above I do not consider the decision to commence diamorphine and hyoscine was appropriate on the basis of the information recorded in the clinical notes.

Recorded causes of death

4.12 There was no specific evidence that bronchopneumonia was present, although this is a common pre-terminal event in frail older people, and is often entered as the final cause of death in frail older patients. I am surprised the death certificate did not apparently refer to Mrs Wilkie's dementia as a contributory cause. It is possible Mrs Wilkie's death was due at least in part to respiratory depression from the diamorphine she received, or that the diamorphine led to the development of bronchopneumonia. However since there are no clear observations of Mrs Wilkie's respiratory observations it is difficult to know whether respiratory depression was present Mrs Wilkie deteriorated prior to administration of diamorphine and midazolam infusion, and in view of this, my opinion would be that although the opiate and sedative drugs administered may have hastened death, and these drugs were not indicated, Mrs Wilkie may well have died at the time she did even if she had not received the diamorphine and midazolam infusions.

Duty of care issues

4.13 Medical and nursing staff on Daedalus ward had a duty of care to deliver medical and nursing care, to monitor, and to document the effects of drugs prescribed to Mrs Wilkie. In my opinion this duty of care was not adequately met, the prescription of diamorphine and midazolam was poor practice and this may have contributed to Mrs Wilkie's death.

Summary

4.14 In my opinion the prescription of subcutaneous diamorphine and midazolam was inappropriate, and probably resulted in depressed conscious level and respiratory depression, which may have hastened her death. However Mrs Wilkie was a frail very dependent lady with dementia who was at high risk of developing pneumonia. It is possible she would have died from pneumonia even if she had not been administered the subcutaneous sedative and opiate drugs.

Robert WILSON

5.1 Mr Wilson was 75 years old man when he was admitted to Queen Alexandra Hospital on 22nd September 1998 after he sustained a proximal fracture of the left humerus. He was treated with morphine, initially administered intravenously and then subcutaneously. He developed vomiting. On 24th September he was given 5mg diamorphine and lost sensation in the left hand. On 29th September an entry in the medical notes states *"ref to social worker, review resus status. Not for resuscitation in view of quality of life and poor prognosis".*

5.2 On 7th October the notes record he was *"not keen on residential home and wished to return to his own home".* Dr Lusznat, Consultant in Old Age Psychiatry on 8th October 1998, saw him. Dr Lusznat's letter on 8th October notes that Mr Wilson had been sleepy and withdrawn and low in mood but was now eating and drinking well and appeared brighter in mood. His Barthel score was 5/20. Dr Lusznat noted he had a heavy alcohol intake during the last 5 years. At the time he was seen by Dr Lusznat her was prescribed thiamine 100 mg daily, multivitamins two tablets daily, senna two tablets daily, magnesium hydroxide 10 mls twice daily and paracetamol 1g four time daily. On examination he had mildly impaired cognitive function (Mini Mental State Examination 24/30). Dr Lusznat considered Mr Wilson might have developed an early dementia, which could have been alcohol related, Alzheimer's disease or vascular dementia. An antidepressant trazadone 50mg nocte was commenced. Dr Lusznat states at the end of her letter *"On the practical side he may well require nursing home care though at the moment he is strongly opposed to that idea I shall be happy to arrange follow up by our team once we know when and where he is going to be discharged".* On 13th October the medical notes record a ward round took place, that he required both nursing and medical care, was at risk of falling and that a short spell in long-term NHS care would be appropriate. Reviewing the drug charts Mr Wilson was taking regular soluble paracetamol (1g four times daily) and codeine phosphate 30mg as required for pain. Between 8th and 13th October Mr Wilson was administered four doses of 30mg codeine. Mr Wilson's weight in March 1997 was 93Kg

5.3 On the 14th October Mr Wilson was transferred to Dryad Ward. An entry in the medical notes by Dr Barton reads *"Transfer to Dryad ward continuing care. HPC fracture humerus. needs help with ADL (*activities of Daily Living*), hoisting, continent, Barthel 7. Lives with wife. Plan further mobilisation".* On 16th November the notes record; *'Decline overnight with S.O.B. o/e ? weak pulse. Unresponsive to spoken work. Oedema ++ in arms and legs. Diagnosis ?silent MI, ? decreased __ function. ↑frusemide to 2 x 40mg om '.* On 17th October the notes record *'comfortable but rapid deterioration'.* On 18th October staff nurse Collins records death at 2340h. Cause of death is recorded as congestive cardiac failure.

5.4 Nursing notes state in the summary section on 14th October *"History of left humerus fracture, arm in collar and cuff. Long history of heavy drinking. LVF chronic oedematous legs. S/B Dr Barton. Oramorph 10mg/5ml given. Continent of urine – uses bottles".* On 15th October *"Commenced oramorph 10mg/5ml 4 hrly for pain in L arm. Wife seen by sis. Hamblin who explained Robert's condition is poor".* An earlier note states *"settled and slept well".* On 16th October *"seen by Dr Knapman an as deteriorated over night. Increase*

frusemide to 80mgdaily. For A.N.C (active nursing care)". Later that day a further entry states "*Patient very bubbly chest this pm. Syringe driver commenced 20mg diamorphine, 400mcgs hyoscine. Explained to family reason for driver*". A separate note on 16th October in the nursing care plan states "*More secretions – pharyngeal – during the night, but Robert hasn't been distressed. Appears comfortable*". On 17th October 0515h "*Hyoscine increased to 600mcgs as oro-pharyngeal secretions increasing. Diamorphine 20mg.*" Later that day a further entry states "*Slow deterioration in already poor condition. Requiring suction very regularly – copious amounts suctioned. Syringe driver reviewed at 15.50 s/c diamorphine 40mg, midazolam 20mcgs, hyoscine 800 mcgs*". A later note states "*night: noisy secretions but not distressing Robert. Suction given as required during night. Appears comfortable*". On 18th October "*further deterioration in already poor condition. Syringe driver reviewed at 14:40 s/c diamorphine 60mg, midazolam 40mg, hyoscine 1200mcg. Continues to require regular suction*".

5.5 The medication charts record administration of the following drugs:

14 Sep 1445h oramorph 10mg
2345h oramorph 10mg
16 Sep 1610h diamorphine 20mg/24 hr, hyoscine 400 microg/24hr subcutaneous infusion
17 Sep 0515h diamorphine 20mg/24hr, hyoscine 600 microg/24hr
1550h diamorphine 40mg/24hr, hyoscine 800 microg/24hr
midazolam 20mg/24hr
18 Sep 1450h diamorphine 60mg/24hr, hyoscine 1200 microg/24hr
midazolam 40mg/24hr

Frusemide was administered at a dose of 80mg daily at 0900h on 15th and 16th October. An additional 80 mg oral dose was administered at an unstated time on 16th October.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

5.6 Responsibility for the care of Mr Wilson during his admission to Dryad ward lay with Dr Lord as the consultant responsible for his care. My understanding is that day to day medical care was delegated to the clinical assistant Dr Barton and during the out of hours responsibility was with the on call doctor based at Queen Alexandra Hospital. Ward nursing staff were responsible for assessing and monitoring Mr Wilson and informing medical staff of any significant deterioration.

5.7 Dr Lusznat was responsible for assessing Mr Wilson and making further recommendations concerning his future care when he was seen at Queen Alexandra Hospital.

Accuracy of diagnosis and prognosis including risk assessments

5.8 Dr Barton assessed Mr Wilson on 14th October the day he was transferred to Dyad ward. There was a plan to attempt to improve his mobilisation through rehabilitation. There is no record of any significant symptomatic medical problems, in particular any record that Mr Wilson was in pain in the medical

notes. The nursing notes suggest Mr Wilson was prescribed oramorph for pain in his arm following his admission to Dryad Ward. He was prescribed paracetamol to take as required but did not receive any paracetamol whilst on Dryad Ward.

5.9 Mr Wilson deteriorated on 15th September when he became short of breath. The working diagnosis was of heart failure due to a myocardial infarct. I do not consider the assessment by the on call doctor of Mr Wilson was adequate or competent. There is no record of his blood pressure, clinical examination findings in the chest (which might have indicated whether he had signs of pulmonary oedema or pneumonia). In my opinion an ECG should have been obtained that night, and a Chest Xray obtained the following morning to provide supporting evidence for the diagnosis. Mr Wilson was admitted for rehabilitation not terminal care and it was necessary and appropriate to perform reasonable clinical assessments and investigations to make a correct diagnosis.

5.10 Following treatment Mr Wilson was noted to have had a rapid deterioration. The medical and nursing teams appear to have failed to consider that Mr Wilson's deterioration may have been due to the diamorphine infusion. In my opinion when Mr Wilson was unconscious the diamorphine infusion should have been reduced or discontinued. The nursing and medical staff failed to record Mr Wilson's respiratory rate, which was likely to have been reduced, because of respiratory depressant effects of the diamorphine. The diamorphine and hyoscine infusion should have been discontinued to determine whether this was contributing to his deteriorating state. There is no record of the reason for the prescribing of the midazolam infusion commenced the day before his death. At this time the nursing notes record he was comfortable. Mr Wilson did not improve. The medical and nursing teams did not appear to consider that the diamorphine, hyoscine and midazolam infusion could be a major contributory factor in Mr Wilson's subsequent decline. The infusion should have been discontinued and the need for this treatment, in my opinion unnecessary at the time of commencement, reviewed.

Evaluation of drugs prescribed and the administration regimens

5.11 The initial prescription and administration of oramorph to Mr Wilson following his transfer to Dryad ward was in my opinion inappropriate. His pain had been controlled with regular paracetamol and as required codeine phosphate (a mild opiate) prior to his transfer, and in the first instance these should have been discontinued.

5.12 I am unable to establish when Dr Barton wrote the prescription for subcutaneous diamorphine 20-200mg/24hr, hyoscine 200-800microg/24hr, and midazolam 20-80mg/24hr as these are undated. The administration of diamorphine and hyoscine by subcutaneous infusion as a treatment for the diagnosis of a silent myocardial infarction was in my opinion inappropriate. The prescription of a single dose of intravenous opiate is standard treatment for a patient with chest pain following myocardial infarction is appropriate standard practice but was not indicated in Mr Wilson's case as he did not have pain. The prescription of an initial single dose of diamorphine is appropriate as a treatment for pulmonary oedema if a patient fails to respond to intravenous diuretics such as frusemide. Mr Wilson was not administered intravenous

frusemide or another loop diuretic. Instead only a single additional oral dose of frusemide was administered. In my opinion this was an inadequate response to Mr Wilson's deterioration. The prescription of continuous subcutaneous infusion of diamorphine and hyoscine is not appropriate treatment for a patient who is pain free with a diagnosis of a myocardial infarction and heart failure. When opiates are used to treat heart failure, close monitoring of blood pressure and respiratory rate, preferably with monitoring of oxygen saturation is required. This was not undertaken.

5.13 The increase in diamorphine dose to 40mg/24hr and then 60mg/24 hr in the following 48 hours is not appropriate when the nursing and medical notes record no evidence that Mr Wilson was in pain or distressed at this time. This was poor practice and potentially very hazardous. Similarly the addition of midazolam and subsequent increase in dose to 40mg/24hr was in my opinion highly inappropriate and would be expected to carry a high risk of producing profound depression of conscious level and respiratory drive.

Quality and sufficiency of the medical records

5.14 The initial entry in the medical records by Dr Barton on 14th October is reasonable and sufficient. The subsequent entries relating to Mr Wilson's deterioration are in my opinion inadequate, and greater detail and the results of examination findings should have been recorded. No justification for the increases in diamorphine, midazolam and hyoscine dose are written in the medical notes. The nursing notes are generally of adequate quality but I can find no record of fluid and food intake by Mr Wilson.

Appropriateness and justification of the decisions that were made

5.15 I consider the prescription of oramorph was inappropriate. The subsequent prescription and administration of diamorphine, hyoscine and midazolam was highly inappropriate, not justified by information presented in the notes and could be expected to result in profound depression of conscious level and respiratory depression in a frail elderly man such as Mr Wilson.

Recorded causes of death

5.16 The recorded cause of death was congestive cardiac failure. The limited clinical information recorded in the absence of a chest Xray result or post-mortem findings, suggest this may have been the cause of Mr Wilson's death. However in my opinion it is highly likely that the diamorphine, hyoscine and midazolam infusion led to respiratory depression and/or bronchopneumonia and it is possible that Mr Wilson died from drug induced respiratory depression.

Duty of care issues

5.17 Medical and nursing staff on Dryad ward had a duty of care to deliver appropriate medical and nursing care to Mr Wilson, and to monitor the effects of drugs prescribed. In my opinion this duty of care was not adequate. The administration of high doses of diamorphine and midazolam was poor practice and may have contributed to Mr Wilson's death.

Summary

5.18 Mr Wilson was a frail elderly man with early dementia who was physically dependent. Following his admission to Dryad ward he was, in my opinion, inappropriately treated with high doses of opiate and sedative drugs. These drugs are likely to have produced respiratory depression and/or the development of bronchopneumonia and may have contributed to his death.

Eva PAGE

6.1 Eva Page was 87 years old when admitted as an emergency on 6th February 1998 to the Department of Medicine for Elderly People at Queen Alexandra Hospital. The medical notes record that she had experienced a general deterioration over the last 5 days was complaining of nausea and reduced appetite and was dehydrated. She had felt 'depressed' during the last few weeks. *On admission she was taking ramipril 5mg once daily (a treatment for* heart failure and hypertension), frusemide 40mg once daily (treatment for fluid retention), digoxin 125microg once daily (to control irregular heart rate), sotalol 40 mg twice daily (to control irregular heart rate), aspirin 75 mg once daily (to prevent stroke and myocardial infarction) and sertraline 50mg once daily (an antidepressant commenced by her general practitioner on 26th January 1998). A discharge summary and medical notes relating to an admission in May 1997 states that she was admitted with acute confusion, had reduced movement on the right side and was discharged back to her residential home on aspirin. No admitting diagnosis is recorded in the clerking notes written by Dr Harris on 6th February 1998 but they record that *"patient refuses iv fluids and is willing to accept increased oral fluids*".

6.2 On 7th February 1998 the medical notes record an opacity seen on the chest Xray and sate "*mood low. Feels frightened – doesn't know why. Nausea and ??. Little else. Nil clinically.*" An increased white cell count is noted (13.0) and antibiotics commenced. A subsequent chest Xray report (undated) states there is a 5cm mass superimposed on the left hilum highly suspicious of malignancy. The medical notes on 11 February 1998 record this at the Xray meeting. On 12th February 1998 the notes record (? Dr Shain) '*In view of advanced age aim in the management should be palliative care. Charles Ward is suitable. Not for CPR*'. On 13th February the notes record '*remains v low Appears to have 'given up' d/w son re probably diagnosis d/w RH (residential home) re ability to cope*'. The notes record *'son agrees not suitable for invasive Tx* (treatment). *Matron from RH visiting today will check on ability to cope.*'

6.3 On 19th February the notes record she fell on the ward and experienced minor cuts. On 16th February '*gradual deterioration, no pain, confused. For Charles Ward she could be discharged to community from Charles Ward*'. On 19th February the notes summarise her problems '*probable Carcinoma of the bronchus, previous left ventricular failure, atrial fibrillation, digoxin toxicity and a transient ischaemic attack, that she was sleepy but responsive, states that she is frightened but doesn't know why. . Says she has forgotten things, not possible to elicit what she can't remember, low MTS (mental test score). Plan encourage oral fluids, s/c fluid over night if tolerated. Continue antidepressants*'. On 18th February the medical notes state "*No change. Awaiting Charles Ward bed*".

6.4 The nursing notes record she was confused but mobilised independently. On 19th February she was transferred to Charles Ward instead of the preferred option of a bed at Gosport Hospital, which the notes record was full ('no beds'). The Queen Alexandra Hospital medical notes record a summary of her problems on 19th February prior to transfer as follows " *Diagnosis CA bronchus probable [no histology] Diag based on CXR. PMH 95 LVF + AF 95 Digoxin toxicity 97 TIA. Admitted 6.2.98 general deterioration CXR ? Ca Bronchus.*

Well defined O lesion. Exam: sleepy but responsive answers appropriately. States that she is frightened but doesn't know why. Says she has forgotten things. Not possible to elicit what she can't remember. Low MTS" and *"Feels in general tired and very thirsty. Plan encourage oral fluids, s/c fluid overnight is tolerated continue antidepressants".*

6.5 The medical notes on 23rd February record diagnoses of depression, dementia, ? Ca bronchus, ischaemic heart disease and congestive heart failure. On 25th February Dr Lord records in the medical notes "*confused and some agitation towards afternoon – evening try tds* (three times daily) *thioridazine, son in Gosport, transfer to Gosport 27/2, heminevrin prn nocte'.* A further entry states *'All other drugs stopped by Dr Lord'.*

6.6 Mrs Page was transferred to Dryad ward at Gosport War Memorial Hospital on 27th February 1998. Dr Barton writes in the medical notes "*Transfer to Dryad ward continuing care, Diagnosis of Ca Bronchus on CXR on admission. Generally unwell off legs, not eating, bronchoscopy not done, catheterised, needs help with eating and drinking, needs hoisting, Barthel 0. Family seen and well aware of prognosis. Opiates commenced. I'm happy for nursing staff to confirm death".* The nursing notes state she was admitted for *'palliative care'*, that she had a urinary catheter (inserted on 22nd February 1998) was incontinent of faeces, and was dependent for washing and dressing but could hold a beaker and pick up small amounts of food. Barthel Index was 2/20. The nursing action plan states '*encourage adequate fluid intake'.* On 28th February an entry in the medical notes by Dr Laing (duty GP) record '*asked to see: confused. Feels 'lost' agitated esp. night/evening, not in pain, to give thioridazine 25mg tds regular, heminevrin noct.* The nursing notes record she was very distressed and that she was administered thioridazine and Oramorph 2.5ml.

6.7 On 2nd March Dr Barton records *'no improvement on major tranquillisers. I suggest adequate opioids to control fear and pain; Son to be seen by Dr Lord today'.* A subsequent entry by Dr Lord on the same day states *' spitting out thioridazine, quieter on prn sc diamorphine. Fentanyl patch started today. Agitated and calling out even when staff present (diagnoses) 1) Ca Bronchus 2) ? Cerebral metastases. -ct* (continue) *fentanyl patches.'* A further entry by Dr Lord that day records '*son seen. Concerned about deterioration today. Explained about agitation and that drowsiness was probably due in part to diamorphine. He accepts that his mother is dying and agrees we continue present plan of Mx* (management)".

6.8 On 2nd March the nursing notes record "*commenced on Fentanyl 25mcg this am. Very distressed this morning seen by Dr Barton to have and diamorphine 5mg i/m (intramuscular) same given 0810h by a syringe driver.* A further entry the same day states *"S/B Dr Lord. Diamorphine 5mg i/m given for syringe driver with diamorphine loaded".* On 3rd March a rapid deterioration in Mrs Page's condition is recorded '*Neck and left side of body rigid – right side rigid,* At 1050h diamorphine and midazolam were commenced by syringe driver. Death is recorded later that day at 2130h, 4 days following admission to Dyad ward.

6.9 The prescription charts (which are incompletely copied in notes made available to me) indicate she received the following drugs during this admission Two doses of intramuscular diamorphine 5 mg were administered at 0800 and 1500h (date not visible)

28 Feb 1998	1300h thioridazine 25mg
	1620h oramorph 5mg
	2200h heminevrin 250mg in 5ml
1 Mar 1998	0700h thioridazine 25 mg
	1300h thioridazine 25 mg
	2200h heminevrin 250mg
2 Mar 1998	0700h thioridazine 25mg
	0800h fentanyl 25microg
3 Mar 1998	1050h diamorphine 20mg/24hr, midazolam 20 mg/24hr by subcutaneous infusion

On 27th February Dr Barton prescribed thioridazine 25mg (prn tds) and Oramorph (10mg/5ml) 4hrly prn. On 2nd March Dr Barton prescribed fentanyl 25microg patch (x3 days) to take as required (prn). On 3rd March Dr Barton prescribed diamorphine 20-200mg/24hr, hyoscine 200-800ucg/24hr and midazolam 20-80mg/24hr by subcutaneous infusion.
The notes do not indicate that the fentanyl patch was removed and I would assume this was continued when the diamorphine and midazolam infusion was commenced.

Opinion on patient management

Leadership, roles, responsibilities and communication in respect of the clinicians involved

6.10 Primary responsibility for the medical care of Mrs Page during her admission to Dryad Ward lay with Dr Lord, as the consultant responsible for his care. She saw Mrs Page 2 days before her transfer to Dryad ward and two days following her admission, the day before she died. My understanding is that day-to-day medical care was the responsibility of the clinical assistant Dr Barton and during out of hours period the on call doctor based at the Queen Alexander Hospital. Ward nursing staff were responsible for assessing and monitoring Mrs Page and informing medical staff of any significant deterioration.

Accuracy of diagnosis and prognosis including risk assessments

6.11 The assessment and management of Mrs Page at Alexandra Hospital was in my opinion competent and considered. From the information in the clinical notes I would agree with the diagnosis of probable carcinoma of bronchus. The decision to prescribe an antidepressant was in my opinion appropriate. Prior to transfer to Dryad ward she was not in pain but was transferred for palliative care. Although Mrs Page was clearly very dependent and unwell, it is not clear why Dr Barton prescribed opiates to Mrs Page on admission to Dryad ward when there is no evidence she was in pain. I suspect the reason was to provide relief for Mrs Page's anxiety and agitation. This is a reasonable indication for opiates in the palliative care of a patient with known inoperable carcinoma. Mrs Page was noted to be severely dependent, Barthel Index 0, and in conjunction with a probable carcinoma of the bronchus the assessment that she required palliative care and was likely to die in the near future was appropriate.

Evaluation of drugs prescribed and the administration regimens

6.12 The prescription of the major tranquilliser thioridazine for anxiety was reasonable and appropriate. The prescribing of the sedative/hypnotic drug heminevrin was similarly reasonable although potential problems of sedation from the combination need to be considered. Mrs Page was not in pain but I consider the prescription of oramorph on 28th February to attempt to improve her distress was reasonable. By 2nd March Mrs Page remained very distressed despite prescription of Oramorph, thioridazine and heminevrin. Since the notes reported she was more settled following intramuscular diamorphine and she had been spitting out her oral medication, I would consider it appropriate to prescribe a transdermal fentanyl patch to provide continuing opioid drugs to Mrs Page. The lowest dose patch was administered but it would have been important to be aware of the potential for depression of respiration and/or conscious level that could occur.

6.13 I do not understand why subcutaneous diamorphine and midazolam infusions were commenced on 3rd March when Mrs Page had deteriorated whilst on the fentanyl patch. There is no indication in the notes that Mrs Page was in pain or distressed. The notes describe her as having undergone a rapid deterioration, which could have been due to a number of different causes, including a stroke or an adverse effect of the fentanyl patch. In my opinion the prescription by Dr Barton of subcutaneous diamorphine 20-200mg/24hr prn, hyoscine 200-800microg/24hr and midazolam 20-80mg/24hr was poor practice and potentially very hazardous. I would judge it poor management to initially commence both diamorphine and midazolam in a frail elderly underweight patient such as Mrs Page who was already receiving transdermal fentanyl. I would expect very clear reasons to support the use of the drugs to be recorded in the medical notes. The combination could result in profound respiratory depression and there are no symptoms recorded which suggest the administration of either drug was appropriate.

Quality and sufficiency of the medical records

6.14 The medical and nursing records relating to Mrs Page's admission to Dryad ward are in my view of adequate quality, although as stated above the reasons for the use of midazolam and diamorphine are not recorded in either the medical or nursing notes.

Appropriateness and justification of the decisions that were made

6.15 In my opinion the majority of management and prescribing decisions made by medical and nursing staff were appropriate. The exception is the prescription of diamorphine and midazolam on the day of Mrs Page's death. From the information I have seen in the notes it appears that Dr Barton may have commenced the diamorphine and midazolam infusion for non-specific reasons or for non-defined palliative reasons when it was judged she was likely to die in the near future.

Recorded causes of death

6.16 In the absence of a post-mortem the recorded cause of death is reasonable. Mrs Page had a probable carcinoma of the bronchus and experienced a slow deterioration in her general health and functional abilities. It is possible that Mrs Page died from drug induced respiratory depression. However Mrs Page was at high risk of dying from the effects of her probable carcinoma of the bronchus even if she had not received sedative and opiate drugs. Bronchopneumonia

can also occur as a complication of opiate and sedative induced respiratory depression but also in patients deteriorating from malignancy. In the absence of post-mortem, radiological data (chest Xray) or recordings of Mrs Page's respiratory rate I would consider the recorded cause of death was possible. The deterioration on between the 2nd March and 3rd March could have been secondary to the fentanyl patch she received but again could have occurred in the absence of receiving this drug. There are no accurate records of Mrs Page's respiratory rate but significant potentially fatal respiratory depression was likely to have resulted could have resulted from the combination of diamorphine, midazolam and fentanyl.

Duty of care issues

6.17 Medical and nursing staff on Dryad ward had a duty of care to deliver medical and nursing care, to monitor Mrs Page and to document the effects of drugs prescribed. In my opinion this duty of care was adequately met except during the last day of her life when the prescription of diamorphine and midazolam was poor practice and may have contributed to Mrs Wilkie's death.

Summary

6.18 Mrs Page was a frail elderly lady with probable carcinoma of the bronchus who had been deteriorating during the two weeks prior to admission to Dryad ward. In general I consider the medical and nursing care she received was appropriate and of adequate quality. However I cannot identify a reason for the prescription of subcutaneous diamorphine, midazolam and hyoscine by Dr Barton on the 3rd March. In my view this was an inappropriate, potentially hazardous prescription. I would consider it highly likely that Mrs Page experienced respiratory depression and profound depression of conscious level from the combination of these two drugs and fentanyl but I cannot exclude other causes for her deterioration and death at this time such as stroke or pneumonia.

Opinion on clinical management at Gosport War Memorial Hospital based on review of five cases presented by Hampshire Police

7.1 My opinion on the five cases I have been asked to review at Gosport War Memorial Hospital must be considered in context. My understanding is that the five cases have been selected by Hampshire Police because of concerns expressed relating to the management of these patients. Therefore my comments should not be interpreted as an opinion on the quality of care in general at Gosport War Memorial Hospital or of the general quality of care by the clinicians involved. My comments also relate to a period 2-4 years ago and the current clinical practice at the hospital may be very different today. An opinion on the quality of care in general at the hospital or of the clinicians would require a systematic review of cases, selected at random or with pre-defined patient characteristics. Examination of selected cases is not an appropriate mechanism to comment on the general quality of care of an institution or individual practitioners.

7.2 However having reviewed the five cases I would consider they raise a number of concerns that merit further examination by independent enquiry. Such enquiries could be made through further police interviews or perhaps more appropriately through mechanisms within the National Health Service, such as the Commission for Health Improvement, and professional medical and nursing bodies such as the General Medical Council or United Kingdom Central Council for Nursery, Midwifery and Health Visiting.

7.3 My principle concerns relate to the following three areas of practice: prescription and administration of subcutaneous infusions of opiate and sedative drugs in patients with non-malignant disease, lack of training and appropriate medical supervision of decisions made by nursing staff, and the level of nursing and non-consultant medical skills on the wards in relation to the management of older people with rehabilitation needs.

7.4 In all five cases subcutaneous infusions of diamorphine and in combination with sedative drugs were administered to older people who were mostly admitted for rehabilitation. One patient with carcinoma of the bronchus was admitted for palliative care. Although intravenous infusion of these drugs are used frequently in intensive care settings, very close monitoring of patients is undertaken to ensure respiratory depression does not occur. Subcutaneous infusion of these drugs is also used in palliative care, but the British National Formulary indicates this route should be used only when the patient is unable to take medicines by mouth, has malignant bowel obstruction or where the patient does not wish to take regular medication (Appendix 2). In only one case were these criteria clearly fulfilled i.e. in Mrs Page who was refusing to take oral medication. Opiate and sedative drugs used were frequently used at excessive doses and in combination with often no indication for dose escalation that took place. There was a failure by medical and nursing staff to recognise or respond to severe adverse effects of depressed respiratory function and conscious level that seemed to have occurred in all five patients. Nursing and medical staff appeared to have little knowledge of the adverse effects of these drugs in older people.

7.5 Review of the cases suggested that the decision to commence and increase the dose of diamorphine and sedative drugs might have been made by nursing staff without appropriate consultation with medical staff. There is a possibility that prescriptions of subcutaneous infusions of diamorphine, midazolam and hyoscine may have been routinely written up for many older frail patients admitted to Daedalus and Dryad wards, which nurses then had the discretion to commence. This practice if present was highly inappropriate, hazardous to patients and suggests failure of the senior hospital medical and managerial staff to monitor and supervise care on the ward. Routine use of opiate and sedative drug infusions without clear indications for their use would raise concerns that a culture of "involuntary euthanasia" existed on the ward. Closer enquiry into the ward practice, philosophy and individual staff's understanding of these practices would be necessary to establish whether this was the case. Any problems may have been due to inadequate training in management of older patients. It would be important to examine levels of staffing in relation to patient need during this period, as the failure to keep adequate nursing records could have resulted from under-staffing of the ward. Similarly there may have been inadequate senior medical staff input into the wards, and it would be important to examine this in detail, both in terms of weekly patient contact and in time available to lead practice development on the wards. My review of Dr Lord's medical notes and her statement leads me to conclude she is a competent, thoughtful geriatrician who had a considerable clinical workload during the period the above cases took place.

7.6 I consider the five cases raise serious concerns about the general management of older people admitted for rehabilitation on Daedalus and Dryad wards and that the level of skills of nursing and non-consultant medical staff, particularly Dr Barton, were not adequate at the time these patients were admitted.

7.7 Having reviewed the five cases presented to me by Hampshire Police, I consider they raise serious concerns about nursing and medical practice on Daedalus and Dryad wards at Gosport War Memorial Hospital. In my opinion a review of practice at the institution is necessary, if this has not already taken place. I would recommend that if criminal proceedings do not take place, that these cases are brought to the attention of the General Medical Council and United Kingdom Central Council for Nursery, Midwifery and Health Visiting, in relation to the professional competence of the medical and nursing staff, and the Commission for Health Improvement, in relation to the quality of service provided to older people in the Trust.

APPENDIX 1

Pharmacology of Opiate and Sedative Drugs

Morphine

8.1 Morphine is a potent opiate analgesic considered by many to the 'drug of choice' for the control of acute pain (Therapeutic Drugs Dollery). Recommended starting dosage regimens for a fit adult of 70Kg are for intravenous bolus dosing 2.5mg every 5 min until analgesia achieved with monitoring of the duration of pain and dosing interval, or a loading dose of 5-15mg over 30min than 2,5mg – 5mg every hour. A standard reference text recommends 'morphine doses should be reduced in elderly patients and titrated to provide optimal pain relief with minimal side effects'. Morphine can be used for sedation where sedation and pain relief are indicated, Dollery comments *'it should be noted that morphine is not indicated as a sedative drug for long-term use. Rather the use of morphine is indicated where the requirement for pain relief and sedation coexist such as in patients admitted to intensive care units and other high dependency areas, the morphine dose should be titrated to provide pain relief and an appropriate level of sedation. Frequently other pharmacological agents (e.g.: benzodiazepines) are added to this regimen to increase the level of sedation".*

8.2 Diamorphine

8.3

8.4 **Fentanyl**

8.5 Fentanyl is a transdermal opioid analgesic available as a transdermal patch. The '25' patch releases 25microg/hr.

8.6 The British National Formulary (copy of prescribing in palliative care attached Appendix 2) comments on the use of syringe drivers in prescribing in palliative care that drugs can usually be administered by mouth to control symptoms, and that indications for the parenteral route are: patient unable to take medicines by mouth, where there is malignant bowel obstruction, and where the patient does not wish to take regular medication by mouth, It comments that staff using syringe drivers should be adequately trained and that incorrect use of syringe drivers is a common cause of drug errors.

Heminevrin

Midazolam

8.1 Midazolam is a benzodiazepine sedative drug. It is used as a hypnotic, preoperative medication, sedation for procedures such as dentistry and GO endoscopy, long-term sedation and induction of general anaesthesia. Iot is not licensed for subcutaneous use, but is described in the British National Formulary prescribing in palliative care section as 'suitable for a very restless patient: it is given in a subcutaneous infusion dose of 20-100mg/24 hrs.

8.2 DA standard text describes the use of sedation with midazolam in the intensive care unit setting, and states, "*sedation is most commonly met by a combination of a benzodiazepine and an opioid, and midazolam has generally replaced diazepam in this respect*". It goes on to state, "in critically ill patients, prolonged sedation may follow the use of midazolam infusions as a result of delayed administration". Potentially life threatening adverse effects are described, "Midazolam can cause dose-related CNS depression, respiratory and

cardiovascular depression. There is a wide variation in susceptibility to its effects, the elderly being particularly sensitive. Respiratory depression, respiratory arrest, hypotension and even death have been reported following its use usually during conscious sedation. The elderly are listed as a high-risk group; the elderly are particularly sensitive to midazolam. The dose should be reduced and the drug given slowly intravenously in a diluted form until the desired response is achieved. In drug interactions the following is stated. "*midazolam will also potentiate the central depressant effects of opioids, barbituates, and other sedatives and anaesthetics, and profound and prolonged respiratory depression might result.*

8.3

Hyoscine

8.4 The British National Formulary describes hyoscine hydrobromide as an antagonist (blocking drug) of acetylcholine. It reduces salivary and respiratory secretions and provides a degree of amnesia, sedation and antiemesis (antinausea). IN some patients, especially the elderly, hyoscine may cause the central anticholinergic syndrome (excitement, ataxia, hallucinations, behavioural abnormalities, and drowsiness). The palliative care section describes it as being given in a subcutaneous infusion dose of 0.6-2.4mg/24 hours.

8.5

Use of syringe drivers

8.1 The BNF states 'oral medication is usually satisfactory unless there is severe nausea and vomiting, dysphagia, weakness, or coma in which case parenteral medication may be necessary. In the pain section it comments the non-opioid analgesics aspirin or paracetamol given regularly will often make the use of opioids unnecessary. An opioid such as codeine or dextropropoxyphene alone or in combination with a non-opioid analgesic at adequate dosage may be helpful in the control of moderate pain id non-opioids are not sufficient. If these preparations are not controlling the pain, morphine is the most useful opioid analgesic. Alternatives to morphine are hydromoprhine, oxycodone and transdermal fentanyl. In prescribing morphine it states 'morphine is given as an oral solution or as standard tablets every 4 hour, the initial dose depending largely on the patient's previous treatment. A dose of 5-10mg is enough to replace a weaker analgesic. If the first dose of morphine is no more effective than the previous analgesic it should be increased by 50% the aim being to choose the lowest dose which prevents pain. The dose should be adjusted with careful assessment of the pain and the use of adjuvant analgesics (such as NSAIDs) should also be considered. Although morphine in a dose of 5-10mg is usually adequate there should be no hesitation in increasing it stepwise according to response to 100mg or occasionally up to 500mg or higher if necessary. The BNF comments on the parenteral route '*diamorphine is preferred for injection. The equivalent intramuscular or subcutaneous dose of diamorphine is approximately a third of the oral dose of morphine.*'

8.2 In the chapter on pain relief in 'Drugs and the Older Person' Crome writes on the treatment of acute pain ' *treat the underlying cause and give adequate pain relief. The nature of the painful condition, the response of the patient and the presence of comorbidity will dictate whether to start with a mild analgesic or to go immediately to a more potent drug. In order to avoid the situation that patients remain in pain, "starting low" must be followed by regular re-evaluation with, if necessary, frequent increases in drug dose. The usual method of*

prescribing morphine for chronic pain is to start with standard oral morphine in a dose of 5-10mg every four hours. The dose should be halved in frail older people.

Prescribing for the Elderly

The British National Formulary states in Prescribing for the Elderly section "*The ageing nervous system shows increased susceptibility to many commonly used drugs, such as opioid analgesics, benzodiazepines, antipsychotics and antiparkinsonian drugs, all of which must be used with caution*".

APPENDIX 2

BNF Prescribing in palliative care

DRAFT REPORT

regarding

RUBY LAKE (BJC/67)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mrs Ruby Lake was a frail 84 year old who was admitted to hospital having fallen and fractured her left hip on 5th August 1998. This was surgically repaired and she had a difficult post-operative course due to events associated with her pre-existing heart and kidney problems, leading to heart failure, atrial fibrillation and renal impairment, along with a chest infection and episodic confusion/agitation at night. A combination of fluids, diuretics and antibiotics were required to support her through this period. At the time of Dr Lord's review, she summarised Mrs Lake as frail and quite unwell and was uncertain as to whether there would be significant improvement. Subsequent to Dr Lord's review, Mrs Lake experienced chest pains that appeared either related to her ischaemic heart disease or were musculoskeletal in origin, for which GTN (an anti-anginal treatment) or codeine/paracetamol were effective respectively. Apart from these episodes of pain, Mrs Lake appeared to be progressing rather than deteriorating whilst awaiting transfer to Gosport War Memorial Hospital and had begun to mobilise. On the day prior to transfer, for a period of time, she was noted to appear confused and had a temperature. However, on the day of the transfer she was reported to be well, comfortable and happy with a normal temperature.

Infrequent entries in the medical notes during her stay on Dryad Ward make it difficult to closely follow Mrs Lake's progress over the last three days of her life. She apparently settled in well, but the next day complained of chest pain. A syringe driver containing diamorphine and midazolam was commenced later that day. Mrs Lake became drowsy, her chest bubbly and the doses of drugs in the syringe driver were modified

over the next two days to diamorphine 60mg, midazolam 60mg and hyoscine hydrobromide 800microgram/24h. Mrs Lake was confirmed dead at 18.25h on the 21st August, the cause of death stated as bronchopneumonmia.

Dr Barton does not appear to have provided Mrs Lake a good standard of clinical care as defined by the GMC; Mrs Lake was not adequately medically assessed by Dr Barton at the time of her transfer or after her complaints of chest pain; there was no justification given for the prescription of morphine or the drugs administered in the syringe driver.

A lack of documentation makes it difficult to understand why Mrs Lake may have deteriorated in the rapid way that she did. A rapid deterioration often suggests an acute underlying medical cause. In this regard, a thorough medical assessment when she complained of chest pain (or indeed at the time of her transfer) may have identified possible contributing factors, such as a chest infection, that could have been appropriately treated. It is therefore possible that her physical state had deteriorated in a temporary or reversible way and that with appropriate medical care she would have recovered.

If it were that Mrs Lake had naturally entered the terminal phase of her life, at best, Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mrs Lake a peaceful death, albeit with what appears to be an inappropriate use of medication due to a lack of sufficient knowledge. However, given the lack of medical and nursing records to the contrary, reasonable doubt exists that Mrs Lake had definitely entered her terminal stage. Given this doubt, at worst, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Lake by failing to provide treatment with a reasonable amount of

skill and care. This was to a degree that disregarded the safety of Mrs Lake by failing to adequately assess her physical state at the time of her transfer and when she complained of chest pain, failing to take suitable and prompt action when necessary and if her physical state had deteriorated in a temporary or reversible way exposing her to the inappropriate use of diamorphine and midazolam in doses that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

2. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be suboptimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

3. ISSUES

3.1 Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day?

3.2 If the care is found to be suboptimal what treatment should normally have been proffered in this case?

3.3 If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

4. BRIEF CURRICULUM VITAE

Code A

5. DOCUMENTATION

This Report is based on the following documents:

[1] Set of medical records on paper and CD-ROM of Ruby Lake (BJC-67).

[2] Set of medical records on paper of Ruby Lake (JR-19A).

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Commission for Health Improvement Investigation Report on Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital (July 2002).

[6] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

[7] Portsmouth Health Care NHS Trust Policies:

i) Control of Administration of Medicines by Nursing Staff Policy (January 1997).

ii) Prescription Writing Policy (July 2000).

iii) Policy for Assessment and Management of Pain (May 2001).

iv) Compendium of Drug Therapy Guidelines, Adult Patients (1998).

v) Medicines Audit carried out by the Trust referred to as Document 54 on page 52 in the Chi Report (reference 6).

[8] General Medical Council, Good Medical Practice (October 1995).

[9] British National Formulary (BNF). Section on Prescribing in Palliative Care (March 1998).

[10] British National Formulary (BNF). Section on Prescribing for the

Elderly (March 1998).

6. CHRONOLOGY/CASE ABSTRACT

Events at the Royal Naval Hospital, Haslar

Mrs Ruby Lake, an 84 year old widow who lived alone, was admitted on the 5th August 1998 to the Royal Naval Hospital, Haslar, Gosport under the care of Surgeon Captain Farquharson-Roberts, following a fall at home in which she sustained a fractured neck of her left femur (top part of her left leg)(page 53 of 181). Her past medical history revealed a number of heart problems; left ventricular failure (heart failure), a probable myocardial infarction ('heart attack'), hypertension (raised blood pressure), cardiomegaly (enlarged heart), aortic valve sclerosis (thickening of one of the heart valves) and atrial fibrillation (irregular heart beat) (page 52 of 181; pages 37, 42 and 59 of 443). In addition, renal failure (in association with the use of a non-steroidal anti-inflammatory drug), generalised osteoarthritis, gout, leg ulcers, liposclerosis, sicca (Sjogren's) syndrome (dry eyes and mouth) and possibly rheumatoid arthritis (all summarised on page 73 of 443). Subsequently, a consultant rheumatologist considered that she possibly had CREST syndrome (page 352 of 443). This is the association of calcinosis (calcification of the skin), Raynaud's phenomenon (poor circulation to the fingers) oesophageal involvement (difficulty swallowing), sclerodactyly (thin fingers) and telangiectasia (dilated blood vessels in the skin). It is a variant of systemic sclerosis (scleroderma), a systemic connective tissue disorder characterised mainly by inflammation of subcutaneous connective tissue, followed by a progressive fibrosis leading to atrophy of skin, subcutaneous fat and associated tissue and an

arteritis (inflammation of the small blood vessels) of the skin. It may also affect skeletal muscles and other organs, e.g. the heart (cardiomyopathy causing heart failure), lungs (fibrosis causing shortness of breath), kidneys, (causing renal failure) and gastro-intestinal tract (hypomotility leading to bacterial overgrowth, which in turn leads to malabsorption). In addition to the problems with the skin, symptoms can thus include oesophageal reflux or heartburn, difficulty swallowing, bloating after meals, weight loss, diarrhoea, constipation, shortness of breath, joint pain and dry and sore eyes. The disease is generally progressive, with some experiencing remission with a slow progression. Those with only skin involvement have a better prognosis. Death may occur from gastro-intestinal, cardiac, kidney or pulmonary involvement.

Mrs Lake's medication consisted of allopurinol 100mg twice a day (to prevent gout), bumetamide 1mg once a day (a water tablet), digoxin 62.5microgram once a day (for atrial fibrillation).

Mrs Lake reported that she was usually mobile, independent and self caring, could walk 100 yards before stopping due to her arthritis rather than angina (page 52 of 181).

Abnormal findings on initial examination were a 'regularly irregular' pulse rate of 72 beats per minute and a possible mass in the right iliac fossa (page 53 of 181). Blood tests revealed a raised white cell count (12.87 x 10^9/L; normal 4–11) due to a neutrophillia (page 6 of 181) and an elevated urea (16.8 mmol/L; normal 2.5–6.1)(page 9 of 181). According to a chest x-ray report, the lung fields were clear but the heart was enlarged (page 27 of 181). However, it should be clarified if this report relates to the chest x-ray taken on the 5th August 1998, as the date of the report is given as the

7th September 1998. Her ECG (electrocardiograph) on the 5th August 1998 revealed a normal heart rhythm but abnormal T wave inversion in leads I and avl and poor R wave progression in the anterior chest leads (page 86 of 181). I am not a cardiologist, who would be best placed to interpret ECGs, but my understanding is that the changes in this and Mrs Lakes other ECGs, could be consistent with the use of digoxin, cardiac ischaemia (reduced blood flow to the heart muscle) or left ventricular hypertrophy (enlargement of one of the chambers in the left side of the heart).

Mrs Lake underwent a left hemi-arthroplasty on the 5th August 1998 (page 57 of 181). The operation went without incident but Mrs Lake had a difficult post-operative course.

On the 6th August Mrs Lake had problems with vomiting and shortness of breath. Her pulse was regular but her jugular venous pressure was elevated 3cm (assessed by how high above the sternal angle (part of the breast bone) the blood level is in the large veins of the neck when sitting and resting back 45°) and bilateral fine crackles were heard in the bases of her lungs (page 60 and 61). In view of these findings it was considered that she had excess fluid in the circulation causing heart failure. Infection was another possibility and her white cell count was elevated at 18.8×10^9/L (mainly due to neutrophils, the type increased by infection). Mrs Lake's intravenous infusion of fluid was stopped for several hours and subsequently restarted at a slower rate. A urinary catheter was inserted to monitor her urine output and she was commenced on antibiotics, Augmentin 375mg three times a day by mouth (page 61 of 181).

Over the following days, it appeared difficult to give her sufficient fluids to maintain a reasonable urine output and avoid renal impairment (urea and creatinine increased to 17.3mmol/L and 144micromols/L respectively) without easily risking fluid overload and heart failure. Hence her intravenous fluids were adjusted several times and additional diuretics (to remove excess water) were given intermittently (pages 63 and 64 of 181).

On the 9th August, Mrs Lake's problems were listed as poor mobility, shortness of breath on exertion, nausea and diarrhoea (page 64 and 65 of 181). Blood tests revealed ongoing renal impairment (urea of 25.6mmol/L and creatinine 141micromol/L).

On the 10th of August Mrs Lake was reported to be unwell, drowsy and experiencing vomiting and diarrhoea. Her pulse had increased to a rate of 120 per minute and was now irregularly irregular. Her blood pressure was 120/60mmHg (probably low for her; she had previous readings of 160/90) (page 62 of 181)). Two ECGs were carried out in succession that revealed changes from her original ECG (page 86 of 181). The automatic report of the first stated 'sinus arrhythmia, rate varies from 79 to 158, ventricular premature complex, diffuse ST-T abnormalities' (page 84 of 181). The second ECG showed atrial fibrillation (irregular heart beat, page 82 of 181). She was reviewed by a more senior doctor, a senior house officer, who found inspiratory crepitations (crackles) at her left lung base (page 67 of 181). It was considered that she was dehydrated, with a chest infection and had possibly had a myocardial infarction (page 68 of 181). Blood tests revealed a re-increase in her white cell count to 15.27 x 10^9/L and an increase in her urea to 25mmol/L. A chest x-ray revealed an infection at the base of her left lung and no heart failure (page 69 of 181). Intravenous

fluids were given and her antibiotic, Augmentin, was switched to intravenous administration 600mg three times a day, instead of orally. Later that day, Mrs Lake was reported to have improved (page 69 of 181). An entry in the nursing records noted 'antibiotics changed to IV (intravenous) as unable to swallow large tablets' (page 165 of 181).

On the 11th August 1998, her improvement continued. Her temperature was normal, she had a clear chest and a good urine output. She was switched to oral antibiotics (page 70 of 181). Later that night she again appeared to have heart failure and required further intravenous furosemide (page 71 of 181).

On the 12th August, the antibiotics and intravenous fluids were discontinued. Mrs Lake was not in heart failure, the diarrhoea had settled and she had sat out. She was noted to be developing a bed sore on her sacrum (base of the spine). The plan was to allow her to mobilise with a physiotherapist and encourage oral fluids (page 71 of 181). She was referred to Dr Lord 'from the point of view of her future management' with a referral letter summarising that Mrs Lake's post-operative recovery was slow, with episodes of confusion, pulmonary oedema (due to left ventricular failure), vomiting and diarrhoea (page 72 and 73 of 181). Dr Lord reviewed Mrs Lake later that day and listed her problems as: left cemented hemi-arthroplasty of hip; LBBB plus LVF – improving (left bundle branch block (an ECG abnormality) and left ventricular failure; sick sinus syndrome/AF (atrial fibrillation); dehydration – but improving (possibly referring to a urea 17.7mmol/L on the 12th August (page 107 of 181); bilateral buttock ulcers; bilateral leg ulcers; hypokalaemia (low potassium) 3.0mmol/L (lower limit of normal 3.6mmol/L; page 107 of 181);

normochromic anaemia (possibly referring to a haemoglobin of 105g/L (lower limit of normal 105g/L) on the 11th August; page 92 of 181); vomiting and diarrhoea query cause. Dr Lord suggested potassium supplements (Slow K, 2 twice a day) for the low potassium; to hydrate orally and stool cultures to look for infection. Dr Lord noted that 'it is difficult to know how much she will improve but I'll take her to an NHS continuing care bed at GWMH next week' (page 73 and 74 of 181). Dr Lord's summary of this assessment was dictated on the 14th August and typed on the 17th August (page 23 of 181) in which she summarised Mrs Lake as 'frail and quite unwell at present' and notes that she is uncertain as to whether there will be significant improvement (page 23 of 181).

Stool cultures taken on the 8th August were normal with no blood, mucous or fat globules (page 113 of 181) and urine and blood cultures taken on the 10th August revealed no bacterial growth (pages 35 and 111 of 181). The cardiac enzymes measured on the 10th and 12th August did not suggest that she had had a heart attack (pages 107 and 109 of 181).

On the 13th August an entry in the nursing notes (unspecified time in the am) records that Mrs Lake complained of central chest pain, oxygen was given, together with 2 sprays of GTN (glyceryl trinitrate; an anti-anginal treatment given by spray under the tongue) with effect. An ECG was reviewed by a doctor and no further action taken (page 168 of 181). There is no mention of this episode in the medical notes.

Several entries in the nursing notes report that Mrs Lake was at times agitated in the night, e.g. 8th, 10th, 12th, 13th August 1998 (pages 164, 166, 167,168 of 181).

On the 14th of August Mrs Lake is reported as well and to have stood with the physiotherapist (page 74 of 181). Her potassium level was improving (potassium 3.4mmol/L; page 101 of 181).

On the 15th August the nursing records at 07.00h note that 'Ruby had some pain due to arthritis in her left shoulder overnight. She had paracetamol as charted with good effect' (page 169 of 181). Later that day the nursing notes record 'c/o (complaining of) pain in left shoulder/chest on inspiration, O_2 (oxygen) remains in situ. Dr's (doctors) to review, ? muscular' (page 169 of 181). In the entry in the medical notes follows, the house officer notes that it was 'left sided chest pain in ribs through to her back – since being manhandled. Worse on coughing, tender over ribs. ECG – nil changes (page 78 of 181), no effect with GTN (Glyceryl Trinitrate)' (page 75 of 181). Her oxygen saturation level was normal on the oxygen (98%). Her pulse was noted to be 100 beats per minute irregularly irregular (as in atrial fibrillation). The impression was that this was 'musculoskeletal chest pain but consider PE (pulmonary embolism, a blood clot that has travelled to the lungs) or angina' (page 75 of 181). Blood tests revealed a normal potassium of 4.5mmol/L, a stable urea of 20.4mmol/L and normal cardiac enzymes. Mrs Lake was prescribed codeine phosphate 30mg and she received a dose at 22.35h (page 175 of 181) with 'good effect' (page 170 of 181). The nursing notes of the 16th August timed at 07.00h summarise this medical review. Later the same day at 17.00h, they record that Mrs Lake had had a comfortable afternoon, that her oxygen saturations were 96% without oxygen and that she had gone out with her family around the grounds (page 172 of 181). Mrs Lake received another dose of codeine 30mg at 22.00h on the 16th August

(page 175 of 181). The only other analgesic that she received was paracetamol 1gram at 20.00h on the 17th August (for a raised temperature) and at 08.08h on the 18th August (not specified if for pain or a raised temperature) (page 175 of 181).

On the 17th August the medical notes record that Mrs Lake was well, did not have a raised temperature or chest pain, was mobilising slowly and awaiting transfer to Gosport War Memorial Hospital (76 of 181). The nursing notes for the 17th August report that Mrs Lake had a good nights sleep after settling late and frequently calling out (page 170 of 181). A later entry (20.15h) reports that Mrs Lake 'seemed confused this afternoon...Pyrexial at 38.8ºC at 19.45h, paracetamol given' (page 171 of 181).

On the 18th August an entry in the nursing notes made at 02.00h reports 'increased shortness of breath, recommenced on oxygen therapy, encouraged to expectorate. Apyrexial.....' (page 171 of 181). There is no mention that a doctor was informed at that time of her increased confusion and pyrexia.

On the 18th August the medical notes entry timed at 09.00h report that Mrs Lake was well, comfortable and happy but that the evening before she had a temperature of 38.5ºC. It was now 37.3ºC. She was mobilising well and was due transfer to Gosport War Memorial Hospital that day. Her oxygen was discontinued and the transfer went ahead (page 76 of 181). The transfer letter written for the staff at Gosport War Memorial Hospital summarised in some detail Mrs Lake's progress and current status, e.g. noting that 'she has had a slow recovery, exacerbated by bouts of angina and breathlessness. This appeared secondary to fluid overload.....this has

now resolved, it appears.....and she [Mrs Lake] is usually lucid and only very occasionally seems confused at night' (page 22 of 443). There is no mention that her temperature had recently been elevated or that she had been using oxygen up to the day of transfer.

Events at Dryad Ward Gosport War Memorial Hospital

Mrs Lake was transferred to Dryad Ward, Gosport War Memorial Hospital on the 18th August 1998, under the care of Dr Lord. There are two entries in the medical notes that cover a period of three days taking up one page in length (page 77 of 443). One is the note made on transfer, the other is the confirmation of death. This makes events difficult to follow in any depth. What follows is a record of events summarised from the medical notes, summary notes and nursing care plan.

The 18th August 1998 entry in the medical notes made by Dr Barton, reads (abbreviations removed), 'Transfer to Dryad Ward continuing care. History of presenting complaint: fractured left neck of femur 5th August 1998. Past medical history: angina and congestive cardiac failure. Catheterised, transfers with two, needs some help with activities of daily living. Bartel score of 6. Get to know. Gentle rehabilitation. I am happy for nursing staff to confirm death (page 77 of 443). The next entry on the 21st August 1998 notes that Mrs Lake had died at 18.25h (page 77 of 443).

The medication chart reveals that she was prescribed digoxin 62.5micrograms once a day, Slow K 2 twice a day, bumetamide 1mg once a day, allopurinol 100mg twice a day (although it appears it was only given once a day) as she had been at Haslar hospital (page 369 of 443). New additions were temazepam 10–20mg at night, although none was taken

and morphine (Oramorph, 10mg/5ml) 5–10mg as required (page 369 of 443). Doses of morphine were administered on the 18th August (5mg at 14.15h) and 19th August (10mg at 00.15h and 11.50h)(page 369 of 443).

It is unclear why she received the dose on the 18th August. The nursing summary notes on the 18th August report Mrs Lake to be 'a pleasant lady, happy to be here..... settled quite well. Fairly cheerful this pm' (page 394 of 443). The nursing care plan dated the 18th August 1998 noted 'settled and slept well from 22.00h until midnight. Woke very distressed and anxious. Says she needs someone with her. Oramorph 5mg given 00.15h with little effect. Very anxious during the night. Confused at times' (page 388 of 443). I assume this entry, although dated the 18th August, relates to the night of the 18th August/early hours of the 19th August, but this should be clarified.

On the 19th August 1998 various untimed entries in the nursing plan reported: 'helped a little in washing and dressing, unsteady in walking' (page 374 of 443); 'catheter draining well/clear urine' (page 382 of 443); 'assisted wash given. Patient very breathless' (page 384 of 443). The nursing summary notes records at 11.50h 'complaining of chest pain. Not radiating down arm - no worse on exertion, pulse 96, grey around mouth. Oramorph 10mg/5ml given. Doctor notified. Pain only relieved for a short period - very anxious. Diamorphine 20mg, midazolam 20mg commenced in syringe driver' (page 394 of 443). There is no entry in the medical notes relating to the chest pain or commencement of the syringe driver. The diamorphine, hyoscine hydrobromide and midazolam were prescribed by Dr Barton (page 368 of 443). The nursing care plan entry for the 19th August then reads 'comfortable night. Settled well. Drowsy but rousable

this am. Sips of oral fluids tolerated. Syringe driver satisfactory (page 388 of 443).

On the 20th August, entries in the nursing care plan report 'condition continues to deteriorate. Remains very "bubbly", suction attempted without success, distressed when turned. Syringe driver recharged at 07.35h. Oral care given, catheter draining. Looks flushed (page 388 of 443). The nursing summary notes recorded at 12.15h 'condition appears to have deteriorated overnight, driver recharged 10.10h diamorphine 20mg, midazolam 20mg, hyoscine 400microgram. Family informed of condition. Daughter present at time of report' (page 394 of 443). At an unspecified time at 'night' the entry reads 'general condition continues to deteriorate very "bubbly", suction attempted without success. Position changed frequently Ruby ? rousable and distressed when moved. Syringe driver recharged diamorphine 60mg, midazolam 60mg and hyoscine 800microgram 07.35h. Daughter has enquired 08.00h Ruby's condition' (pages 394 and 395 of 443).

The medication chart contains prescriptions for diamorphine 20–200mg/24h, hyoscine (hydrobromide) 200–800micrograms/24h and midazolam 20–80mg/24h by SC infusion (page 368 of 443). It is unclear when this prescription was written as it is undated. A syringe driver containing diamorphine 20mg and midazolam 20mg was commenced at 16.00h on the 19th August 1998 (page 368 of 443). This appears to be have been changed at 09.15h on the 20th August 1998 to also contain 400micrograms of hyoscine hydrobromide. Red writing through this prescription appears to read 'destroyed'. This is unclear however, even on the CD-ROM. This may have been because a new syringe driver was

commenced at 16.50h on the 20th August to contain diamorphine 40mg, midazolam 40mg and hyoscine hydrobromide 800micrograms (page 368 of 443). This in turn also appears to have red writing through saying 'destroyed'. A syringe driver was commenced on the 21st August at 07.35h containing diamorphine 60mg, midazolam 60mg and hyoscine hydrobromide 800microgram.

Mrs Lake was confirmed dead on the 21st August at 18.25h. The cause of death stated on the copy of the death certificate supplied, dated the 25th August 1998 was 1A Bronchopneumonia.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Syringe drivers, diamorphine, midazolam and hyoscine hydrobromide

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24h. Indications for its use include swallowing difficulties or a comatose patient. In the United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF number 35 (March 1998)). Others sometimes suggested dividing by 2 or 3 depending on

circumstance (Wessex protocol). Hence, 60mg of morphine taken orally a day could equate to a daily dose of 20 or 30mg of diamorphine SC. It is usual to prescribe additional doses for use 'as required' in case symptoms such as pain breakthrough. The dose is usually 1/6th of the 24h dose. Hence for someone receiving 30mg of diamorphine in a syringe driver over 24h, a breakthrough dose would be 5mg. One would expect it to have a 2–4h duration of effect, but the dose is often prescribed to be given hourly if required. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in their terminal phase would generally aim to find a dose that improves the patient's symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg/24h. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The Wessex protocol suggests a range with the lowest dose of 5mg/24h. The regular dose would then be titrated every 24h if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a

syringe driver over 24h, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4h, and it may need to be given more frequently. As an active metabolite of midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

Hyoscine hydrobromide is an antimuscarinic drug most commonly given to reduce excessive saliva or retained secretions ('death rattle'). It also has anti-emetic, antispasmodic (smooth muscle colic) and sedative properties. Repeated administration can lead to cumulation and this can occasionally result paradoxically in an agitated delirium, highlighted in both in the BNF and the Wessex protocol (page 41). It is usually given in a dose of 600–2400microgram/24h SC (BNF (March 1998)) or 400–600microgram as a stat SC dose. The Wessex protocol gives a dose range of 400–1200microgram/24h.

The titration of the dose of analgesic, sedative or antisecretory medication is guided by the patients symptom control needs. The number and total dose of 'as required' doses required over a 24h period are calculated and this guides the increase necessary in the regular dose of the drugs in the syringe driver in a way that is proportional to the patients needs. The ideal outcome is the relief of the symptoms all of the time with no need for additional 'as required' doses. In practice, this can be difficult to achieve and the relief of the symptoms for the majority of the time along with the use of 1–2 'as required' doses over a 24h period is generally seen as acceptable.

8. OPINION

Events at Haslar Hospital 5th August 1998 to 18th August 1998

Mrs Ruby Lake was a frail 84 year old who was admitted to hospital having fallen and fractured her hip. This was surgically repaired but she had a difficult post-operative course due to events associated with her pre-existing heart and kidney problems, leading to heart failure, atrial fibrillation and renal impairment, along with a chest infection and episodic confusion/agitation at night. A combination of fluids, diuretics and antibiotics were required to support her through this period. At the time of Dr Lord's review on the 12th August 1998, she summarised Mrs Lake as frail and quite unwell and was uncertain as to whether there would be significant improvement.

Subsequent to Dr Lord's review, Mrs Lake experienced a number of pains: 1) a central chest pain requiring the use of oxygen together with GTN (glyceryl trinitrate; an anti-anginal treatment given by spray under the tongue) with effect (page 168 of 181); 2) a pain in her left shoulder put down to arthritis (page 169 of 181) and 3) a pain in her left shoulder/chest worse on inspiration (page 169 of 181) considered most likely to be musculoskeletal in origin, due to the presence of tenderness over her ribs, lack of effect of GTN (anti-anginal treatment) and a normal ECG (page 75 of 181). For this pain, Mrs Lake received codeine 30mg with good effect (page 170 of 181) and she took two doses in total. The only other analgesic that she received was paracetamol on two occasions although for at least one of these it was for a raised temperature.

Apart from these episodes of pain, Mrs Lake appeared to be progressing rather than deteriorating whilst awaiting transfer to Gosport War Memorial

Hospital and had began to mobilise. However, on the afternoon of the day prior to transfer she was noted to appear confused and had a temperature of 38.8ºC for which paracetamol was given (page 171 of 181). Nevertheless, on the day of the transfer she was reported to be well, comfortable and happy with a normal temperature.

Events at Gosport War Memorial Hospital, Dryad Ward 18th January 1998 to 21st August 1998

Compared to the notes during Mrs Lake's stay at Haslar Hospital, infrequent entries in the medical notes during her stay on Dryad Ward make it difficult to closely follow Mrs Lake's progress over the last three days of her life. There are two entries taking up less than one page in length. In summary, and in approximate chronological order, Mrs Lake was prescribed morphine (as Oramorph) on the day of her transfer. There was no record or assessment of any pain in the medical or nursing notes relating to this. A dose of 5mg was administered on the 18th August at 14.50h and doses of 10mg on the 19th of August at 00.15 and 11.50h (page 369 of 443). One of these doses (00.15h) appears to have been in response to Mrs Lake waking up distressed and anxious saying that she needed someone with her. This is not a usual indication for the use of oramorph and indeed the nursing care plan entry goes on to say it had little effect (page 388 of 443). A further dose (11.50h) was given for what appears to have been chest pain. It is not clear what the underlying nature of this chest pain is from the nursing summary notes. It reports that the pain was only relieved for a short period of time by the morphine and that Mrs Lake was very anxious. The nursing summary notes indicate that the

doctor was notified (page 394 of 443). There is no entry in the medical notes to indicate that Mrs Lake was subsequently medically assessed. However, a syringe driver containing diamorphine 20mg and midazolam 20mg/24h was commenced at 16.00h the same day. These drugs were prescribed by Dr Barton (page 368 of 443). However, it is unclear whether they were prescribed the day of Mrs Lake's transfer on the 18th August 1998 or after Mrs Lake's complaints of chest pain on the 19th August 1998 and this should be clarified.

Subsequently Mrs Lake became drowsy, her chest bubbly and she was reported to be distressed when being turned by the nurses. The doses of drugs in the syringe driver were modified over the next two days to contain diamorphine 60mg, midazolam 60mg and hyoscine hydrobromide 800microgram/24h. There is no indication in the medical notes as to who decided that the diamorphine and midazolam were to be increased, why the hyoscine hydrobromide was added and increased and why smaller doses of these medications to be given 'as required' doses were not considered appropriate. Mrs Lake was confirmed dead at 18.25h on the 21st August, the cause of death stated as bronchopneumonmia.

Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day?

Care afforded to Mrs Lake whilst at Haslar Hospital

A review of Mrs Lake's temperature chart indicates that her temperature had been 38ºC or above several times over the two days prior to her transfer (page 137 of 181). As infection is a common cause of this, and

given in particular Mrs Lake's difficult post-operative period, it would in my opinion have been appropriate to consider the common sites of a possible infection and to undertake an examination with this in mind, e.g. of her chest, wound and urine as a minimum. If this did happen, it is not documented in the notes. Further, it would have been helpful to have mentioned her fluctuating temperature in the nursing transfer letter. Her increased temperature was however documented in the medical notes and it should be clarified if these were sent with Mrs Lake to Gosport War Memorial Hospital.

Care afforded to Mrs Lake whilst at Gosport War Memorial Hospital

The medical care provided by Dr Barton to Mrs Lake following her transfer to Dryad Ward, Gosport War Memorial Hospital is suboptimal when compared to the good standard of practice and care expected of a doctor outlined by the General Medical Council, Good Medical Practice, October 1995, (pages 2–3) with particular reference to:

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs including, where necessary, an appropriate examination; providing or arranging investigations or treatment where necessary; taking suitable and prompt action when necessary
- in providing care you must keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs or appliances that serve the patients' needs.

Specifically:

i) The notes relating to Mrs Lake's transfer to Dryad Ward are inadequate. On transfer from one service to another, a patient is usually re-clerked highlighting in particular the relevant history, examination findings and planned investigations to be carried out.

ii) There is no documentation relating to why the morphine was prescribed.

iii) There is no documented medical assessment of Mrs Lake after she complained of chest pain on Dryad Ward.

iv) There is no justification documented for the use of the diamorphine and midazolam by syringe driver on the 19th August 1998.

v) There is no justification documented in the medical notes relating to the increases in the dose of diamorphine to 40mg and subsequently 60mg/24h; midazolam to 40mg/24h and subsequently 60mg/24h and hyoscine hydrobromide to 800microgram/24h.

If the care is found to be suboptimal what treatment should normally have been proffered in this case?

Issue i and ii (failure to take an adequate history and examination on transfer; failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed; in providing care you must prescribe only the treatment, drugs or appliances that serve the patients' needs)

Upon Mrs Lake's transfer to Dryad Ward there should have been an adequate assessment of her condition based on the history and findings from a clinical examination. This would be important given her difficult post-operative course

and would also act as an important baseline against which to compare any future changes. For example, a thorough assessment may have detected signs of a chest infection that could have led to antibiotics being given. It may also have been appropriate to have undertaken some investigations. Mrs Lake's potassium level had returned to normal, but she was continued on the potassium supplements. Regular blood test monitoring is advisable in this situation to ensure potassium levels do not become abnormally and dangerously high.

The plan for Mrs Lake was for 'gentle rehabilitation' and so it should be clarified if Dr Barton wrote in the medical notes that she was happy for the nursing staff to confirm death as a 'routine' comment, added to all patients' notes, rather than because of any specific concerns relating to Mrs Lake. If it was because of specific concerns, I would have expected this to have prompted a particularly thorough physical assessment.

There is no record made of the reason for prescribing the morphine as required on the day of Mrs Lake's transfer. Morphine is indicated for the relief of pain, breathlessness or cough. In patients with cancer this is generally when underlying causes have been treated, when appropriate and possible, and simpler measures have been tried and failed. If the morphine was prescribed for pain this was not documented in the medical or nursing notes, nor was any pain assessed. As the Wessex Guidelines (page 2) point out, an accurate pain assessment is essential both for diagnostic and therapeutic purposes. An assessment should have included as a minimum the noting of the site, severity, aggravating/relieving factors that together with a physical examination would help identify the most likely cause of the pain. It is particularly unclear why morphine was considered necessary given Mrs Lake had been previously obtaining relief from paracetamol or codeine. In someone of this age and frailty, in my opinion, 2.5–5mg would have been a more reasonable starting dose.

Issue iii (failure to adequately assess the patient's condition)

Given Mrs Lake's known history of ischaemic heart disease, any complaints of chest pain, in my opinion, should be assumed to be related to the heart until proven otherwise. Any complaint of chest pain must therefore be taken seriously and warrant a medical review that would include a pain history and examination of the chest, heart and lungs as a minimum. If indicated, further tests, e.g. temperature, ECG, chest x-ray would then be carried out.

The notes during Mrs Lake's stay at Haslar Hospital suggest possibly two different types of chest pain. The first was central and responded to anti-anginal therapy (GTN) (page 168 of 181) and would be consistent with a cardiac cause of her pain. This may have been the episodes of angina the nursing transfer note was referring to (page 22 of 443). The pain could also be consistent with oesophageal spasm (the tube that connects the mouth to the stomach). The other pain was originally considered due to arthritis in her left shoulder. However, later the same day it appeared to be a combination of pain in her left shoulder and chest made worse on breathing in. Examination revealed tenderness over the ribs, no changes on her ECG and there was no relief from GTN. It was therefore considered that this pain was most likely musculoskeletal (page 75 of 181). She received codeine for this with good effect. This type of pain could also be consistent with pleurisy, which can be caused by a chest infection. The lack of a documented medical assessment of Mrs Lake's condition on Dryad Ward, makes it impossible to provide a firm opinion, but given her intermittent temperatures and subsequent difficulties with respiratory tract secretions, it is a possibility that she was experiencing chest pain related to a chest infection. In keeping with this, the cause of her death two days later was given as bronchopneumonia.

Issues iv and v (failure to adequately assess the patient's condition; failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients

and any drugs or other treatment prescribed; in providing care you must prescribe only the treatment, drugs or appliances that serve the patients' needs)

There should be clear documentation that justifies the use of the syringe driver and the drugs it contained.

It is not usually necessary to utilise the subcutaneous (SC) route unless a patient is unwilling or unable to take medications orally (e.g. difficulty swallowing, nausea and vomiting). From the drug chart Mrs Lake did not appear to have these problems that day (page 369 of 443). It is unclear when the syringe driver was actually prescribed by Dr Barton and this should be clarified. The dose of diamorphine was written as a dose range of 20–200mg/24h. Without details of the indication for the use of diamorphine, it is difficult to comment on the appropriateness of the starting dose of diamorphine of 20mg/24h. However, given that the most morphine Mrs Lake had received in one day was 20mg, in my opinion, if a syringe driver was deemed necessary, a starting dose of diamorphine 10mg/24h would have been more appropriate. The dose of midazolam was written as a dose range of 20–80mg/24h. Without details of the indication for the use of midazolam, it is difficult to comment on the appropriateness of the starting dose of midazolam of 20mg/24h, but it is consistent with that recommended by the BNF (March 1998). The dose of hyoscine hydrobromide was written as a dose range of 200–800microgram/24h. Although its use is not justified in the medical notes, from the nursing notes it appears to have been included in the syringe driver because of respiratory secretions.

The medication chart lacks clear prescribing instructions on what combination of drugs can be given, and in what dose in the syringe driver. Each of the drugs are written as a large dose range and, in my opinion, that for the diamorphine (i.e. 20–200mg/24h) is likely to far exceed Mrs Lake's needs. There are no instructions on the medication chart to indicate by how much the dose of the drugs can be altered within this range, how often and by whom,

e.g. the hyoscine hydrobromide was written as a dose range of 200–800microgram/24h but was commenced at a dose of 400micrograms/24h; doses in the syringe driver were increased before the previous syringe driver had run the full course, and it should be clarified who decided this. For these reasons, prescribing any drug as a range is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient, should decide on and prescribe any change in medication. Such decisions are not usually left to a nurse to make alone.

There is no justification documented in the medical notes for the use of diamorphine or midazolam in the syringe driver. The nursing notes appear to suggest it was in response to Mrs Lake's complaints of chest pain and this should be clarified. Mrs Lake's previous complaints of chest pain were possibly related either to her ischaemic heart disease or to musculoskeletal pain from her chest wall and neither of these in my opinion would justify the use of a syringe driver with diamorphine and midazolam. If the pain was thought due to ischaemic heart disease then anti-anginal therapy should have been administered; if considered musculoskeletal, the notes from Haslar suggest that paracetamol and/or codeine were effective for this.

There are however, numerous causes of chest pain, underscoring the importance of undertaking a thorough medical assessment of Mrs Lake's condition. Nevertheless, for none of the common causes of chest pain that I can think of that Mrs Lake was at risk of, would it be usual practice to commence a syringe driver containing diamorphine and midazolam. For example, if she was experiencing pleurisy due to a chest infection, antibiotics would usually be given. Whilst waiting for the antibiotics to work, pain relief may be necessary, but this would usually consist of paracetamol or codeine and only if these had been ineffective, morphine. If a patient was particularly distressed by severe pain despite the above, then small doses of diamorphine and midazolam might be justified. However, in these circumstances, in my opinion, rather than commence a syringe driver, it would be most appropriate

to offer small doses on an as required basis, e.g. diamorphine 2.5mg and midazolam 2.5mg SC, for someone of Mrs Lake's age and frailty.

There should have been an ongoing assessment documented in the medical notes to explain why Mrs Lake required increases in the dose of diamorphine from 20, to 40 and subsequently 60mg/24h over a three day period. Without knowing the specific indication for the use of diamorphine and its subsequent increase, it is impossible to know if it was likely to be appropriate or excessive to her needs. Increasing doses of opioids that are excessive to a patient's needs would be associated with increasing drowsiness, delirium (confusion), nausea and vomiting and respiratory depression.

The dose of midazolam increased from 20 to 40 to 60mg/24h over a three day period and all are likely to lead to drowsiness in a frail, elderly patient. Although the nursing care plan notes that Mrs Lake was distressed on turning, no additional detail is given that would help in considering appropriate management, e.g. was the distress due to pain, generalised stiffness, pressure area sores, was it short-lived or prolonged etc.

Medications to control symptoms are usually commenced at a starting dose appropriate to the patient, e.g. considering their age, frailty etc. and their particular symptom control needs, and titrated upwards only to control these symptoms without necessarily rendering the patient unresponsive. If there were concerns that the patient might experience, for example, episodes of pain or anxiety, it would be much more usual, and indeed seen as good practice, to prescribe appropriate doses of morphine/diamorphine, or diazepam/midazolam respectively that could be given intermittently as required orally or SC. This allows the patient to receive what they need, when they need it and guides the doctor in deciding if a regular dose is required, the appropriate starting dose and subsequent dose titration (see technical issues).

If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

Dr Barton does not appear to have provided Mrs Lake a good standard of clinical care as defined by the GMC (General Medical Council, Good Medical Practice, October 1995, pages 2–3).

Mrs Lake was old and frail with significant medical problems. Nevertheless, she had been supported through a difficult post-operative period and despite her reports of chest pain and the intermittently raised temperatures, in general she had progressing rather than deteriorating at the time of her transfer to Dryad ward. Mrs Lake was not adequately medically assessed by Dr Barton at the time of her transfer in my opinion. There was no justification given for the prescription of morphine. Mrs Lake seemed to settle into Dryad Ward well, but complained of chest pain the following day. It is documented in the nursing notes that a doctor was informed but there is no documented evidence that Dr Barton assessed Mrs Lake. A syringe driver was commenced containing diamorphine and midazolam with no documented justification for its use. It should be clarified if Dr Barton did see Mrs Lake and when and why she prescribed the drugs for use in the syringe driver.

A lack of documentation makes it difficult to understand why Mrs Lake may have deteriorated in the rapid way that she did. A rapid deterioration often suggests an acute underlying medical cause. In this regard, a thorough medical assessment when she complained of chest pain (or indeed at the time of her transfer) may have identified possible contributing factors, such as a chest infection, that could have been appropriately treated. It is therefore possible that her physical state had deteriorated in a temporary or reversible way and that with appropriate medical care she would have recovered. It is possible that Mrs Lake had naturally entered the terminal phase of her life. However, this is generally heralded by a more gradual decline over several days or weeks and this did not appear to be the case with Mrs Lake, for example, the plan for Mrs Lake made only the day before her deterioration

was for 'gentle rehabilitation.' Finally, sometimes even in the presence of an acute medical deterioration, a decision is taken not to medically intervene other than to make the patient comfortable. This is usually considered if the patient's quality of life and biological prospects are so poor that medical interventions could be seen as prolonging the dying process. Even so, in these circumstances, in my opinion, the reasoning behind this decision should be clearly documented and the relatives involved in the decision making whenever possible. On reading the notes, Mrs Lake's quality of life and biological prospects did not appear to obviously justify such an approach.

In patients with cancer, the use of diamorphine and midazolam when appropriate for the patients needs does not appear to hasten the dying process. This has not been examined in patients dying from other illnesses to my knowledge, but one would have no reason to suppose it would be any different. The key issue is whether the use and the dose of diamorphine and midazolam are *appropriate* to the patients needs. In situations where they are inappropriate or excessive to the patients needs, it would be difficult to exclude with any certainty that they did not contribute more than minimally, negligibly or trivially to the death of the patient.

If it were that Mrs Lake had naturally entered the terminal phase of her life, at best, Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mrs Lake a peaceful death, albeit with what appears to be an inappropriate use of medication due to a lack of sufficient knowledge. For example, insufficient use of small doses of medication on an as required basis, to guide appropriate dose titration; inappropriately large dose ranges of drugs prescribed for use in syringe drivers without sufficient safeguards.

However, in my opinion, given the lack of medical and nursing records to the contrary, reasonable doubt exists that Mrs Lake had definitely entered her terminal stage. Given this doubt, at worst, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Lake by failing to provide

treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Lake by failing to adequately assess her physical state at the time of her transfer and when she complained of chest pain, failing to take suitable and prompt action when necessary and if her physical state had deteriorated in a temporary or reversible way exposing her to the inappropriate use of diamorphine and midazolam in doses that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

9. LITERATURE/REFERENCES

British National Formulary (March 1998), Prescribing in Palliative Care Section.

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition

General Medical Council, Good Medical Practice, October 1995, pages 2–3.

'Wessex Protocol' Salisbury Palliative Care Services May 1995 pages 3–4, 30–31.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.

8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: _____ Date: _____

2.1. Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day.

2.2. *If the care is found to be suboptimal what treatment should* normally have been proffered in this case.

2.3. If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups.

3. CURRICULUM VITAE

Code A

Code A

Code A

Code A

Code A

Code A

Version 2 of complete report 29th August 2005 – Ruby Lake

Code A

Code A

Version 2 of complete report 29th August 2005 – Ruby Lake

Code A

4. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Ruby Lake (BJC/67)

[2] Operation Rochester Briefing Document Criminal Investigation Summary.

[3] *Hampshire Constabulary Operation Rochester Guidance for Medical* Experts.

[4] Commission for Health Improvement Investigation Report on *Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital* (July 2002).

[5] Palliative Care Handbook Guidelines on Clinical *Management, Third Edition, Salisbury Palliative Care Services (1995);* Also referred to as the 'Wessex Protocols.'

5 CHRONOLOGY/CASE ABSTRACT. (The numbers in brackets refer to the page of evidence, the numbers with 'H' in front are the Haslar notes).

5.1. Ruby Lake an 84-year-old lady in 1998, was admitted as an emergency on 5th August 1998 to the Haslar Hospital (H52).

5.2. In 1982 she had been diagnosed with osteoarthritis (211). In 1989 she was noted to have varicose leg ulcers (73) and in 1990 was documented as having gross lipodermatus sclerosis (239). In 1993 she had problems with left ventricular failure, atrial fibrillation, aortic sclerosis and during that admission had a bout of acute renal failure with her urea rising to 25.7 (60). Her Barthel was 18 in 1993 (179).

5.3. In 1995 she was admitted with an acute arthritis and was noted to have a positive rheumatoid factor (30) and a positive ANF. She had mild chronic renal failure, which was noted to be worse when using non-steroidal anti-inflammatory drugs (31) her creatinine rose to 178 when Brufen was introduced (69). Her mental test score was 10/10 (70) but she did have some mobility problems and was seen by an Occupational Therapist and a Physiotherapist (93) (164).

5.4. In 1997 she was under the care of the Dermatologist with considerable problems from her leg ulcers and she was now having pain at night and was using regular Co proxamol (239). In 1998 she was seen by a Rheumatologist who thought she had CREST syndrome including leg ulcers, calcinosis, telangiectasia, and osteoarthritis, (353).

5.5. On 29th June 1998 she was admitted to the Gosport War Memorial Hospital under the care of her GP Dr North (300). The medical clerking is virtually non-existent (75), simply saying that she was admitted for her leg ulcer treatment and her pulse, blood pressure and temperature being recorded. It was noted that she was having continual pain and Tramadol 50 mgs at night was added to her regular 3 times a day Co proxamol. (197) She was seen by a Consultant Dermatologist during this admission (76).

5.6. The nursing cardex showed that she was continent with no confusion (298) however; she was sleeping downstairs (299). Her Barthel was 12 (314) and her Waterlow pressure score was 16 (high risk). She appears to have been discharged home.

5.7. She was admitted to the Haslar Hospital on 5th August having fallen and sustained a fractured neck of femur. This is operated upon successfully. By the 8th she is noted to be short of breath and probably in left ventricular failure with fluid overload (H63). Her renal function has deteriorated from a urea of 16 and a creatinine of 119 on admission (H9) to a urea of 25 and a creatinine of 127 (H68) by the

10th. Certainly on the 10th she appear unwell (H17) and it was not clear if this was a possible myocardial infarction or a chest infection (H17). However a chest x-ray is thought to show a chest infection and she is treated with regular Augmentin, an antibiotic (H69). On 11th her white count is significantly raised at 18.8 (H96). She has a mild anaemia post operatively of 10.5 (H92) her haemoglobin was normal on admission at 13.1 (H16).

5.8. On 13th August she is found to be brighter and sitting out and walking short distances with frame (H18) and this functional improvement continues, documented in the notes up to 17th August (H18). However, she is noted to have had an episode of chest pain on 15th August (H75). There is no doubt that her ECG changes between her admission ECG (H86) and the ECG(s) on 13th August and 15th August (H80 and H78). This is not commented on in the notes.

5.9. The nursing cardex shows that she is unsettled most nights, for example, 10/8 (H166), 13/8 (H168), 16/8 (H170) and on the night before discharge from Haslar on 17th August she "settled late after frequent calling out". The nursing notes also show that she had a continuing niggling pyrexial and was still significantly pyrexial the day before discharge (H137). It also documents that on the day of discharge, she has increased shortness of breath and oxygen is restarted (H171).

5.10. Her drug chart shows that she receives low molecular weight Heparin as a prophylaxis against deep venous thrombosis (Calciparine) from admission until discharge. Diamorphine 2.5 mgs IV is giving as a single dose on 5th August (H128). Co-proxamol is given from 5th – 8th August (H128) and then replaced by Paracetamol written up on the 'as required' part of the drug chart, which she receives almost every day, up to and including the day she is discharged 18th August (H175). The discharge letter mentions her regular drugs of Allopurinol, Bumetanide, Digoxin and Slow K, but does not mention the analgesia (H44).

5.11. She is seen by Dr Lord on 14th August (25-26). She notes that Mrs Lake's appetite is poor, is in atrial fibrillation and may have Sick Sinus Syndrome (an irregularity of cardiac rhythm). She has been dehydrated, hypokalaemic, and has a normochromic anaemia. She notes her leg ulcers and her pressure sores. She agrees to transfer her to the Gosport War Memorial Hospital and is uncertain as to

whether there will be significant improvement.

5.12. She is admitted to Dryad Ward on 18th August (77) and the medical notes states that she had a fractured neck of femur and a past medical history of angina and congestive cardiac failure. The rest of the medical notes, note that she is continent, transfers with two, needs help with ADL's, a Barthel of 6. The management plan is "get to know, gentle rehabilitation". The next line states "I am happy for the nursing staff to confirm death". The next and final line in the medical notes (77) is a nursing note from 21st August that Mrs Lake had died peacefully at 18.25 hrs.

5.13. The nursing care plan, on admission, noted her pressure sores (375), her leg ulcer care (377) and notes that she communicates well (387) but does have some pain (387).

5.14. On 18th August the nursing continuation notes state that she awoke distressed and anxious and was given Oramorphine (388), it states that she was very anxious and confused at times. On 19th August it said that she was comfortable at night, settled well, drowsy but rousable. Syringe driver satisfactory. On 20th August it stated continued to deteriorate. The nursing summary (394) states on 18th August, pleasant lady, happy to be here. On 19th August at 11.50 am she complains of chest pain and looks "grey around mouth". Oramorphine is given. She is noted to be very anxious and the doctor is notified. The pain is apparently only relieved for short period and she is commenced on a syringe drive.

On 20th August she continued to deteriorate overnight, the family have been informed and "very bubbly". On 21st August she deteriorates slowly.

5.15. Drug Chart Review: Admission on 18th August, Digoxin, Slow K, Bumetanide and Allopurinol are written up as per the discharge note from Haslar (369). On the 'as required' part of the drug chart (369) Oramorphine 10 mgs in 5 mls, 2.5 – 5 mgs is written up together with Temazepam. No Temazepam is given but 3 doses of Oramorph are given, one on the 18th August and two doses on 19th August.

5.16. On 19th August (368) Diamorphine 20 – 200 mgs sub cut in 24 hours is written up 20 mgs is started on 19th August, 20 mgs is started on 20th August, then discarded, and 40 mgs started, on 21st August 60

mgs is started. Hyoscine 200-800 micrograms subcut in 24 hours is also prescribed on 19th August. 400 micrograms is started on 20th August and replaced later in the day by 800 micrograms, which is continued on 21st August. Midazolam 20 – 80 mgs subcut in 24 hours is written up and 20 mgs prescribed on 20th August, replaced later in the day by 40 mgs and finally by 60 mgs on 21st August.

6. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

6.1. This section will consider whether there were any actions so serious that they might amount to gross negligence or any unlawful acts, or deliberate unlawful killing in the care of Ruby Lake. Also whether there were any actions or omissions by the medical team, nursing staff or attendant GP's that contributed to the demise of Ruby Lake, in particular, whether beyond reasonable doubt, the actions or omissions more than minimally, negligibly or trivially contributed to death.

6.2. Mrs Lake had a number of chronic diseases prior to her terminal admission following a fractured neck of femur. She had cardiac disease with known atrial fibrillation, aortic sclerosis and heart failure, documented in 1993. She also had not just osteoarthritis but an auto-immune arthritis that was thought variously to be either rheumatoid arthritis or variant auto-immune arthritis (the CREST syndrome). She also had problems as a result of her long-standing varicose swelling of her lower limbs, with many years of unresolved and very painful leg ulcers. Finally she had impaired renal function, developed mild acute renal failure when she was given on occasion, non-steroidal anti-inflammatory drugs.

6.3. She is admitted by her GP into a GP bed consultant ward in June 1998. Beyond measuring her blood pressure, there is no medical clerking and the medical notes are rudimentary at best. Significant information is available from the nursing cardex, which confirms that she is continent and there is no confusion. However, she does have some dependency with a Barthel of 12. Her pain relief is increased by adding Tramadol (an oral opiate like drug) to her Co proxamol and she is able to be discharged home, having been seen by the Dermatologist.

6.4. As is all too common, she subsequently has a fall and suffers a fractured neck of femur. She is admitted to the Haslar Hospital for operative repair. There is always a very significant mortality and morbidity after fractured neck of femurs in old people, particularly in those who have previous cardiac and other chronic diseases.

6.5. She is clearly unwell on 10th August, this is thought to have probably have been a chest infection and she is treated appropriately with antibiotics. However, her pyrexia never actually settles prior to discharge. She also suffers from at least one other episode of chest pain, again no diagnosis is come to in the medical notes, although her ECGs do appear to have changed during her admission, suggesting that this was either coronary event, including a possible heart attack or even a possible pulmonary embolus, despite her prophylactic anti-DVT therapy.

6.6. She is documented to be confused on many evenings, including the evening before transfer from Haslar to Gosport War Memorial Hospital. There may be multiple reasons for this, simply having an operation after a fractured neck of femur can cause acute confusion which is more obvious in the evenings. Chest infections and cardiac events can also cause acute confusion. She was on regular oral Co proxamol and Tramadol prior to her admission. The Tramadol was not continued and the Co proxamol was replaced after a few days with Paracetamol which she does receive on a regular basis for pain, although it is not clear whether this is pain from her leg ulcers or her chest. It is therefore possible that she is also getting drug withdrawal symptoms and this is a further contributing factor to cause her restlessness and confusion at night.

6.7. She is seen by Dr Lord who does a thorough assessment and arranges for an appropriate transfer to Gosport War Memorial Hospital. It is clear though from the notes that on the day of transfer she is still not right. She had been pyrexial the day before, she had been confused the night before transfer and she is more breathless needing oxygen on the day of transfer. It might have been wiser not to transfer her in this unstable clinical state.

6.8. When she is transferred to the Gosport War Memorial Hospital she is seen by Dr Barton who fails to record a clinical examination, apart from a statement regarding her functional status, that she is catheterised, needs two to transfer and needs help with ADL and documents a Barthel of 6. An opportunity to assess her apparent unstable clinical state appears to have been missed. The nursing cardex states the Bartel is 9 (373) and that in the nursing cardex, she can wash with the aid of one and is independent in feeding.

6.9. The continuation notes of Dr Barton (77) then mention rehabilitation with a statement about being happy for the nursing staff to confirm death. There are no further medical notes at all

and in view of the subsequent changing clinical condition documented in the nursing cardex on 19th August and that the nurses contacted the doctor (388) this is a poor standard of care. It also makes it very difficult to assess whether appropriate medical management was given to Mrs. Lake.

6.10. On admission the regular drugs being prescribed at Haslar were continued but the Paracetamol and Tramadol she had received in the Gosport War Memorial Hospital only a month before were not prescribed, nor was any other milder analgesia such as Paracetamol. The only analgesia written up was Oramorphine on the 'as required' part of the drug prescription. While it is probably appropriate for somebody who might have been having episodes of angina and left ventricular failure while in Gosport to have a Morphine drug available for nurses to give, it is very poor prescribing to write up no other form of analgesia, particularly if a doctor is not on site. The nursing staff could have no alternative but to go straight to a strong opioid analgesia. On her first night she is documented as anxious and confused. This is then treated by giving a dose of Oramorphine despite there being no record in the medical or nursing cardex that it was pain causing this confusion. It should be noted this was probably no different from her evenings in Haslar which did not need any specific medication management. In my view this is poor nursing and medical care in the management of confusion in the evening.

6.11. On 19th August an event happened at 11.50 in the morning with the nursing notes recording that she had marked chest pain and was grey around her mouth. This could have been a heart attack, it could have been a pulmonary embolus, it could have been another episode of angina, it could simply have been some non-specific chest pain. No investigations are put in train to make a diagnosis, she does not appear to have been medically assessed, or if she was it was not recorded in the notes and would be poor medical practice. However, if the patient was seriously distressed, it would have been appropriate to have given the Oramorphine 10 mgs that was written up on the 'as required' side of the drug chart. The first aim would be to relieve distress while a diagnosis was made.

6.12. Later on 19th August s syringe driver is started containing Diamorphine 20 mgs and 20 mgs of Midazolam. The only justification for this is recorded in the nursing notes (394) where it says pain is relieved for a short period. I am unable to find any records of observations, for example, pulse or blood pressure

while the patient continues to have pain.

6.13. The syringe driver is continued the next day and Hyoscine is added and the dose of Diamorphine, Midazolam and Hyoscine all increase during the afternoon of the 20th and again when the syringe driver is replaced on 21st. Mrs Lake dies peacefully on 21st August.

6.14. Diamorphine is specifically prescribed for pain, is commonly used for pain in cardiac disease as well as in terminal care. Diamorphine is compatible with Midazolam and can be mixed in the same syringe driver. Diamorphine subcutaneously after oral morphine is usually given at a maximum ratio of 1 to 2 (up to 10 mgs of Diamorphine for 20 mgs or Oramorphine). She had received 20 mgs of Oramorphine on 19th and appears to have been in continuing pain so I thinks it is probably reasonable to have started with 20 mgs of Diamorphine in the syringe driver over the first 24 hours.

6.15. Midazolam is widely used subcutaneously as doses from 5 – 80 mgs per 24 hours and is particularly used for terminal restlessness. The dose of Midazolam used was 20 mgs for the first 24 hours, which is within current guidance, although many believe that elderly patients need a lower dose of 5 – 20 mgs per 24 hours (palliative care). (Chapter 23 in the Brocklehurst's Text Book of Geriatric Medicines 6th Edition 2003). The original dose of Diamorphine appeared to be for continued chest pain. It is unusual to use continuous Diamorphine for chest pain without making a specific diagnosis. It is possible the patient had had a myocardial infarction and was now in cardiogenic shock. In that case it would be very reasonable to use a syringe driver and indeed to add Midazolam and Hyoscine over the subsequent 48 hours. This can only be supposition without adequate documentation.

6.16. In my view it is impossible from the notes to determine the cause of death and a Coroner's Post Mortem should have been held.

7. OPINION

7.1. Ruby Lake an 84-year-old lady with a number of chronic diseases, suffers a fall and a fractured neck of femur in August 1998. She is admitted to hospital and has operative treatment but develops post-operative complications including chest infection, chest pain and confusion at night and subsequently deteriorates and dies in the

Gosport War Memorial Hospital.

7.2. In my view a major problem in assessing this case is the poor documentation in Gosport Hospital in both the medical and nursing notes, making a retrospective assessment of her progress difficult. Good Medical Practice (GMC 2001) states that "good clinical care must include adequate assessment of the patient's condition, based on the history and symptoms and if necessary, an appropriate examination"..... "in providing care you must keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed".... "good clinical care must include – taking suitable prompt action where necessary".... "prescribe drugs and treatments, including repeat prescriptions only when you have adequate knowledge of the patient's health and medical needs". The lack of detail in particular in the medical notes, the lack of recording of why decisions were made or if the patient was properly examined represent poor clinical practice to the standard set by the General Medical Council.

In my view the combination of a lack of a documented clinical examination, the lack of prescription of appropriate oral analgesia on admission to Gosport, the decision to start a syringe driver without documentation of a clinical diagnosis or the reason for it in the medical notes, together represent a negligent standard of medical care.

Without a proven diagnosis, it is possible that the combination of Diamorphine and Midazolam together with the Hyoscine in a syringe driver contributed in part to Mrs Lake's death. However, I am unable to satisfy myself to the standard of beyond reasonable doubt that it made more than a minimal contribution.

8 LITERATURE/REFERENCES

1. Good Medical Practice, General Medical Council 2002
2. Withholding withdrawing life, prolonging treatments: Good Practice and decision making. General Medical Council 2002.
3. Palliative Care, Welsh J, Fallon M, Keeley PW. Brocklehurst Text Book of Geriatric Medicine, 6th Edition, 2003, Chapter 23 pages 257-270.
4. The treatment of Terminally Ill Geriatric Patients, Wilson JA, Lawson, PM, Smith RG. Palliative Medicine 1987; 1:149-153.

5. Accuracy of Prognosis, Estimates by 4 Palliative Care Teams: A Prospective Cohort Study. Higginson IJ, Costantini M. BMC Palliative Care 2002:1:129
6. The Palliative Care Handbook. Guidelines on Clinical Management, 3rd Edition. Salisbury Palliative Care Services, May 1995.

9. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters, which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report, which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

10. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Version 2 of complete report 29th August 2005 – Ruby Lake

Signature:_____ Date: _____

DRAFT REPORT

regarding

STATEMENT OF DR JANE BARTON

RE: RUBY LAKE (BJC/67)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. INSTRUCTIONS

To examine and comment upon the statement of Dr Jane Barton RE: Ruby Lake. In particular, if it raises issues that would impact upon any expert witness report prepared.

2. DOCUMENTATION

This Report is based on the following documents:

[1] Statement of Dr Jane Barton RE: Ruby Lake as provided to me by Hampshire police (signed and dated 14-07-05).

[2] Statement of Dr Jane Barton as provided to me by Hampshire police (undated).

[3] Report regarding Ruby Lake (BJC/67) Dr A Wilcock, 23rd August 2005.

3. COMMENTS

Having compared and contrasted the above documentation, I make the following comments that in my view may be relevant. They are in the order in which they arise in the Statement of Dr Jane Barton RE: Ruby Lake.

Points 16 and 17

Following her assessment of Mrs Lake, Dr Lord concluded that 'it is difficult to know how much she will improve but I'll take her to an NHS continuing care bed at GWMH next week'. Dr Barton takes this statement to mean that Dr Lord considered 'Mrs Lake may very well not recover.....and might die.' As this statement could also be interpreted that Mrs Lake may not recover her physical state as it was prior to her fracture, clarification of its meaning should be sought from Dr Lord.

Point 20

Dr Barton states that she is 'unable now at this remove of time to recall anything about her [Mrs Lake].' Given the lack of adequate documentation in the medical notes, subsequently a number of the points she makes are based on what she believed she would have done, e.g. points 24, 28, 29, 31, 33, 35 and 38.

Point 20

Dr Barton should be asked to clarify why, given her stated awareness that 'Mrs Lake was in a frail condition and quite unwell' [point 22], she did not undertake and record a physical examination in her transfer note of the 18th August 1998?

Point 21

Dr Barton states she noted a Bartel score of 6, but anticipates this would have been reflected by others. On the Bartel ADL Index page, dated 18-08-98, Mrs Lake's score is 9 (i.e. better)(page 373 of 443).

Point 22

Dr Barton should be asked to clarify if the use of the statement 'I am happy for nursing staff to confirm death' was a routine blanket statement added to patients notes upon their transfer to GWMH. This may already be apparent from the large number of medical records already examined. If Dr Barton only entered this statement into the notes of those patients considered likely to die, there is a paradox with Mrs Lake. Whilst I accept prognostication is difficult in elderly frail patients, if it were considered likely that Mrs Lake would die, it would seem unusual to note that she was for 'gentle rehabilitation', rather than for palliative

or terminal care for example. Noting that she was for 'gentle rehabilitation' is suggestive that there was at least a possibility of some improvement as opposed to none at all.

Dr Barton highlights that Mrs Lake had undergone the trauma of a fractured neck of femur, a significant operation in consequence, had heart failure and a possible myocardial infarction. Dr Barton should be asked to state why, given that she considers the latter two such significant factors, she did not record them in the medical notes when Mrs Lake was transferred on 18th August 1998. Whilst I understand that a fall and surgery would increase morbidity and mortality in the frail elderly' I am unaware of any evidence that a hospital transfer per se has an adverse impact on prognosis. Dr Barton should be asked to clarify the basis for this statement.

Point 24

Prior to her transfer to GWMH, Mrs Lake did not appear to be troubled with pain as a result of her fracture, operation, sacral sores or leg ulcers. The only documented pain was of chest pain, sometimes central, sometimes more towards the left side of her chest and/or shoulder. Relief was obtained either with GTN or codeine phosphate 30mg. Dr Barton should be asked to explicitly state if she took a pain history, and her rationale for commencing the Oramorph, rather than continuing with codeine phosphate.

Point 26

Dr Barton notes that Mrs Lake awoke 'very distressed and anxious, saying that she needed someone with her'. She states that 10mg of oramorph was given at 12.15am and that 'in view of the fact she was suffering from anxiety and distress

the oramorph would be appropriate.' In my experience it is not usual to prescribe an opioid to an anxious (and apparently delirious (page 388 of 443)) patient unless pain was specifically contributing to the anxiety or delirium. As Dr Barton considers morphine to be an appropriate treatment for anxiety per se, she should be asked to explicitly state the source, guidelines or authority that suggest this to be the case. It is of note that the morphine had little effect.

Point 27

Dr Barton states that 'Oramorph was also appropriate in view of Mrs Lake's history of congestive cardiac failure.' In my view, a *history* of congestive cardiac failure is not an appropriate additional reason to prescribe morphine. Of most relevance would be Mrs Lake's current physical state, but given that a thorough assessment does not appear to have been undertaken, it is unclear if she had any ongoing problems relating to congestive cardiac failure. Immediately prior to her transfer to GWMH, the Hasler notes do not appear to suggest she was experiencing problems related to congestive cardiac failure.

Whilst not commonplace, opioids are used for the relief of breathlessness associated with chronic heart failure. As I understand it, this is usually when all other more usual therapies have been optimised. In my opinion, if Dr Barton believed Mrs Lake to be experiencing symptoms as a result of congestive cardiac failure, a thorough assessment should have been undertaken and her current anti-failure treatment optimised or the addition of more effective anti-failure therapy instituted, obtaining advice from the local cardiologists as appropriate.

Dr Barton states that temazepam might have made Mrs Lake's heart failure worse. Whilst there are general concerns about the inappropriate use of

benzodiazepines such as temazepam as hypnotics in the frail elderly, I am not aware of any specific reasons why benzodiazepines like temazepam might worsen heart failure. Dr Barton should be asked to detail the evidence that forms the basis of this statement. Further, why, if Dr Barton had concerns regarding the use of temazepam in patients with heart failure, did she prescribe it Mrs Lake when she transferred to Dryad Ward?

Points 29 and 30

Given Dr Barton has no recollection of Mrs Lake together with the inadequate documentation, in my view the appropriateness of prescribing the diamorphine, hysocine and midazolam remains uncertain.

Dr Barton states that she was 'concerned that she [Mrs Lake] should have relief from the pain of her fractured hip and sacral ulcers and from her anxiety and distress which had been apparent overnight.' In my experience, two weeks after a hip fracture and its surgical repair, it would be unusual for there to be residual pain that would require morphine as analgesia. The Hasler physiotherapy notes dated 17-08-05 (page 18 of 181) state that Mrs Lake was 'mobilising with a zimmer frame with supervision and was managing well' and make no mention of pain. This is relevant as if there was significant residual pain from the hip fracture and its surgical repair, this would be most apparent on weight bearing and movement.

There had been no mention of pain due to her chronic leg ulcers or sacral ulcers, which had developed post-operatively, in the nursing notes made at Hasler or GWMH. Increasing pain from ulcers should prompt an examination, e.g. to exclude infection. Even then it would be unusual to prescribe morphine if weaker opioids had not been tried.

The reason for Mrs Lake becoming anxious and distressed at night is not clear. However, she had a number of disturbed nights at Hasler and whilst it is not documented exactly how the nursing staff supported Mrs Lake, it did not entail the administration of opioids or other sedatives.

Dr Barton states that 'opiates.... would also assist in relieving the pulmonary oedema from congestive cardiac failure.' In my opinion, if Dr Barton believed Mrs Lake to be experiencing symptoms due to congestive cardiac failure, a thorough assessment should have been undertaken and more usual therapies should have been utilised, e.g. diuretics, such as furosemide.

Point 31

Dr Barton states she has no recollection of events and in the absence of comprehensive notes, it is unclear to me how she could state that she would have been 'quite content that Oramorph should be given for the [chest] pain.' In my view, the appropriateness of the use of Oramorph can only be determined if the likely cause of the chest pain is known, and this would have required a thorough medical evaluation to have been undertaken.

Dr Barton states that 'there is no ECG available at the hospital and it would have been difficult to say if Mrs Lake had experienced another myocardial infarction but I anticipate that there was increasing cardiac failure.' If these serious developments in Mrs Lake's physical state were being considered, I would consider it essential that a thorough medical evaluation of Mrs Lake to have been undertaken as soon as possible. There is no evidence that this did occur, even though Dr Barton was on site (she reports she was due to chair a primary care group steering group meeting at GWMH at 12.30 p.m. [point 28]).

Intravenous opioids such as diamorphine are used to relieve chest pain from a myocardial infarction (a 'heart attack') and may be a helpful adjunct to intravenous diuretics (e.g. furosemide) and oxygen for the relief of associated pulmonary oedema. The nursing notes on the 19-08-98 at 11.50am suggest that chest pain and anxiety were the main problems, rather than breathlessness (page 394 of 443). This is relevant as shortness of breath is likely to be the *predominant symptom in congestive cardiac failure, particularly when acute and* severe. Nevertheless, the diamorphine, midazolam and hyoscine by syringe driver appear to have been prescribed by Dr Barton in response to Mrs Lake's poor night, rather than in response to her reports of chest pain.

Points 32 and 33

Dr Barton states that the Oramorph was unhelpful in relieving the chest pain over any prolonged period and that Mrs Lake was said to be very anxious. She is uncertain if she was informed of this at this time but in her view institution of the diamorphine and midazolam was entirely appropriate. As Dr Barton prescribed the syringe driver, she takes responsibility for its use. Dr Barton should be asked to state specifically the reasons she felt the diamorphine and midazolam were indicated. If this was because of cardiac failure she should be asked to clarify the source, guidelines or authority that suggest diamorphine and midazolam by subcutaneous infusion are considered appropriate treatment for cardiac failure over and above the more usual means of managing cardiac failure such as diuretic therapy.

Dr Barton should be asked to clarify, as she considered the use of diamorphine and midazolam appropriate to relieve Mrs Lake's symptoms, why they were not

prescribed as p.r.n. (as required) stat subcutaneous doses, either alone or alongside the syringe driver.

Point 35

Dr Barton states that the hyoscine would have assisted in reducing the pulmonary oedema and secretions consequent on Mrs Lake's heart failure. My understanding is that hysocine hydrobromide dries secretions from the salivary glands and major airways of the lung, but would be unlikely to provide any assistance in reducing pulmonary oedema due to congestive cardiac failure. Indeed, the use of hysocine hydrobromide is cautioned against in patients with heart problems. Dr Barton should be asked to clarify the source, guidelines or authority that suggest that hysocine hydrobromide is of assistance in reducing pulmonary oedema.

Points 36, 37 and 40

Dr Barton comments on Mrs Lake's 'distress' or 'stress' several times. However, in my view it is unclear what the possible source(s) of this distress and stress were and as such it is difficult to judge how appropriate it was to increase the dose of diamorphine.

Point 40

Dr Barton indicates that the use of the diamorphine, midazolam and hysocine were administered solely with the intention of relieving pain, anxiety and stress Mrs Lake was suffering, in conjunction with her congestive cardiac failure.

In my view, given Dr Barton's inability to recall Mrs Lake, the lack of a documented medical assessment and that chest pain rather than

breathlessness appeared to be the predominant symptom as recorded in the nursing notes, it remains unclear if Mrs Lake did have cardiac failure. Further, Dr Barton should be asked to comment on why, if she considered that congestive cardiac failure was such a significant factor in Mrs Lake's death, she recorded bronchopneumonia as the sole cause of death on the death certificate.

4. CONCLUSION

Dr Barton admits to poor note keeping and proactive prescribing due to time pressures. However, even with episodes considered potentially serious and significant by Dr Barton, no entry was made in the medical notes and it is unclear if Mrs Lake was medically assessed at all, even when she experienced chest pain that did not improve with Oramorph. Having read Dr Barton's statement regarding Ruby Lake, I believe that the main issues raised in my report (BJC/67), dated 23rd August 2005, remain valid and have not yet been satisfactorily addressed, for example:

- the reason for the prescription of morphine to Mrs Lake on transfer to Dryad Ward rather than continuation of the codeine
- given the lack of a thorough medical assessment there remains, in my view, inadequate justification for the prescription of diamorphine and midazolam by syringe driver on the 19th August 1998
- a thorough medical assessment of Mrs Lake should have been undertaken when she complained of chest pain, in order to identify possible cause(s) and appropriate treatment(s) to offer
- given the lack of a thorough medical assessment there remains reasonable doubt that Mrs Lake had irreversibly entered her terminal stage. For example, given Mrs Lake's intermittently raised temperature and subsequent

problems with respiratory tract secretions, it is possible that she was experiencing chest pain due to a chest infection and that antibiotics may have been an appropriate and effective treatment. Similarly, if it was confirmed on physical examination that she had congestive cardiac failure, it would have been much more appropriate to administer those drugs commonly indicated for this situation, e.g. diuretics.

It remains that Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Lake by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Lake by failing to adequately assess her physical state when she complained of chest pain, failing to take suitable and prompt action when necessary and if her physical state had deteriorated in a temporary or reversible way exposing her to the inappropriate use of diamorphine and midazolam in doses that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

Specific implications of the statement of Dr Barton regarding Mrs Lavender regarding my report (BJC/67), dated 123rd August 2005

1. Dr Barton's statement clarifies that she prescribed on the drug chart the syringe driver with diamorphine, midazolam and hyoscine in those dose ranges in response to Mrs Lake's poor night, i.e. *prior* to her complaining of chest pain; it was subsequently commenced later that day, after she complained of chest pain.
2. If Dr Barton is suggesting that the use of opioids were justified on the basis that Mrs Lake had heart failure, the report may need to be supplemented with information on the role of opioids in acute and chronic heart failure.

SUMMARY OF CONCLUSIONS

Mr Leslie Pittock was an 83 year old gentleman with a long recurrent history of severe depression resistant to treatment. This was complicated by drug induced parkinsonism and subsequent mental and physical frailty and dependency. His admission to the Gosport War Memorial Hospital Mental health beds on the 29th November and transfer to then medical beds on the 5th January 1997 was the end point of these chronic disease process. He continues to deteriorate and dies on the23rd January 1997

The major problem in assessing Mr Pittock's care is the lack of documentation. Good Medical practice (GMC 2001) states that "good clinical care must include an adequate assessment of the patient's condition, based on history and symptoms and if necessary an appropriate examination".... "In providing care you must keep clear accurate legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any other drugs or other treatments prescribed". The major gaps in the written notes, the lack of evidence of appropriate examinations, use of unusual drug regimes without adequate documentation in the medical notes, changes in prescription without proper documentation, all represent poor clinical practice clinical practice to the standards set by the General Medical Council. However, by itself, these do not prove that the medical or nursing care provided to Mr Pittock was sub-optimal, negligent or criminally culpable.

In my view the drug management as Gosport was sub-optimal. There was no written justification at any stage for the high doses of Diamorphine and Midazolam written up in the drug charts and subsequently prescribed to Mr Pittock. The notes and the drug charts leave confusion as to whether at one stage there may have been three syringe drivers being used. The dose of Nozinan may have been prescribed by verbal prescription and not written up in the drug chart. Combinations of the higher than standard doses of Diamorphine and Midazolam, together with the Nozinan were very likely to have caused excessive sedation and may have shortened his life by a short period of time, that in my view would have been no more than hours to days. However, this was a dying man, the family appeared to have been appropriately involved and the patient did eventually die without distress on 24th January. While his care is sub-optimal I cannot prove it beyond reasonable doubt to be negligent or criminally culpable

1. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to his death against the acceptable standard of the day. Where appropriate, if the care is felt to be sub-optimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

2. ISSUES

2.1. Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day.

2.2. If the care is found to be suboptimal what treatment should normally have been proffered in this case.

2.3. If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups.

3. CURRICULUM VITAE

Code A

Version 2 of complete report 31st January 2005 – Leslie Pittock

Code A

Code A

Code A

Code A

Code A

Code A

Code A

Code A

4. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Leslie Pittock.

[2] Full set of medical records of Leslie Pittock on CD-ROM.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Commission for Health Improvement Investigation Report on *Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital* (July 2002).

[6] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

5 CHRONOLOGY/CASE ABSTRACT. *(The numbers in brackets refer to the page of evidence)*

5.1. Mr Leslie Pittock had a very long history of depression as clearly set out in a summary (13). In 1959 he had reactive depression, it occurred again in 1967. In 1979 he had agitation and in 1988 agitated depression.

5.2. He had a further long admission with agitated depression in 1992 (8) complicated by an episode of cellulitis (30). This culminated in an admission to long-term residential care in January 1993 (34). He had further admissions to hospital under the care of the psychiatric team including June 1993 (37) when some impaired cognition was noted. In 1995 there was a home visit for further psychiatric problems (42).

5.3. In 1995 (44) there was a change in behaviour; loss of weight and increased frailty was noted. He was falling at the residential home. He was expressing grief, frustrations and aggression. At this time his psychiatric medications included Diazepam, Temazepam, Thioridazine, Sertraline, Lithium, and Codanthrusate for constipation. His other problems were hypothyroidism and Parkinsonism with a tremor. (Note: this was not Parkinson's disease but tremor, rigidity and akinesia which occurs similar to Parkinson's disease but as a result of long-term anti-psychotic medication).

5.4. On 29th November 1995 he was admitted under the psychiatrist Dr Banks (46) to Gosport War Memorial Elderly Mental Health beds. His mental test score was documented at 8/10 (50). He was discharged back to residential home on 24th October (46) with a continued diagnosis of depression (56). However, his very poor mobility and shuffling gate was noted (57).

5.5. On 13th December 1995 he was re-admitted (62) to mental health beds at the Gosport War Memorial under Dr Banks stating "everything is horrible". He was verbally aggressive to the staff and was not mobilising and staying in bed all day. He felt hopeless and suicidal. (62).

5.6. On 22nd December, diarrhoea started and he also had chest symptoms. It was thought he had a chest infection, and was treated with Erythromycin (64). On 27th December he was "chesty, not himself", and his bowels were causing concern. The physiotherapist noted that he had signs in his chest (65). A second course of a different antibiotic (Cephalosporin) was prescribed (81). The nursing

'cardex documents that he started becoming faecally incontinent on 20th December and then had further episodes of diarrhoea (140). It is also noted that by 1st January (147) he was drowsy with very poor fluid intake.

5.7. On 2nd January 1996 Dr Lord, consultant geriatrician was asked to see (66) and on 3rd January he was noted to be clinically deteriorating with poor food intake (66), albumin of 27 (67). An abdominal x-ray on 27th December describes possible "pseudo-obstruction" (116). This is a condition when the large bowel fails to work and starts to dilate, usually in patients who have multiple illnesses including Parkinsonism, electrolyte imbalance, infections, antibiotics and other drugs. Prognosis is often poor and depends on resolving the underlying causes.

5.8. On 4th January 1996 Mr Pittock is seen by Dr Lord, Consultant Geriatrician who noted severe depression, total dependency, catheterisation, lateral hip pressure sores and hypoproteinaemia. (67) He states that the patient should be moved to a long-stay bed at the Gosport War Memorial Hospital and that his residential home place should be given up as he was unlikely to return. On 5th January he is transferred to Dryad Ward for "long-term care" (151). Dr Lord also states (5M) "Mrs Pittock is aware of the poor prognosis".

5.9. Medical notes after transfer (13M and 15M). On 5th January a basic summary of the transfer is recorded, on the 9th January increasing anxiety and agitation is noted and the possibility of needing opiods is raised. The nurses cardex on 9th said that he is sweaty and has "generalised pain" (25M). On 10th January a medical decision is recorded "for TLC". In the medical discussion (13M) with the wife also apparently agrees "for TLC". I am not sure of the signature of 10th January in the medical notes (13M). The nursing cardex records they commenced Oramorph and that Mrs Pittock is aware of the poor outcome (25M).

5.10. The 15th January the nursing notes document that a syringe driver has been commenced (25M) and by the evening the patient is unresponsive (26M). However on 16th January there is some agitation when being attended to and Haloperidol is added to the syringe driver (26M). On the 17th the patient remains tense and agitated,(27M) the nursing cardex states that Dr Barton attended, reviewed and altered the dosage of medication. The syringe driver is removed at 15.30 hours and the notes say "two drivers" (27M).

5.11. The next medical note is on 18th January, eight days after previous note on 10th January. This states further deterioration, subcut

analgesia continues..... try Nozinan. On 20th January the nursing notes state that Dr Briggs was contacted regarding the drug regime and there was a verbal order to double the Nozinan and omit the Haloperidol (28M). This is confirmed in the medical notes on 20th January (15M). The medical notes on 21st January state "much more settled", respiratory rate of 6 per minute, not distressed and on 24th January the date of death is verified by Staff Nurse Martin in the medical notes (15M).

Note: Nozinan is a major tranquilliser similar to Chlorpromazine but more sedating. It is usually used for patients with schizophrenia and because of its sedation is not usually used in the elderly, though it is not completely contraindicated. Used subcutaneously in palliative care for nausea and vomiting at a dose of 25 – 200 mgs for 24 hours although British National Formulary, 39 Page 14, states that 5 – 25 mgs for 24 hours can be effective for nausea and vomiting with less sedation.

5.12. **Drug Chart Analysis:**

On 5th January at transfer (16M), Mr Pittock is written up for the standard drugs that he was on in the mental health ward including his Sertraline and Lithium (for his depression) Diazepam (for his agitation) Thyroxine for his hypothyroidism. The drug chart also had Diamorphine 40 – 80 mgs subcut in 24 hours, Hyoscine 200 – 400 micrograms subcut in 24 hours and Midazolam 20 – 40 mgs subcut in 24 hours. Midazolam 80 mg subcut in 24 hours written up but not dated and never prescribed. (18M)

5.13. On 10th January, Oramorph 10 mgs per 5 mls is written up for 2.5 mls four hourly and prescribed on the evening of 10th and the morning of the 11th. On the 11th Oramorph 10 mgs per 5 mls is written up to be given 2 mls 4 hourly 4 times a day with 5 mls to be given last thing at night. This is then given regularly between 11th and up to early morning on 15th January. This is a total daily dose of 26 mgs of morphine (19M).

5.14. Diamorphine 80 – 120 mgs subcut in 24 hours is written up on 11th January "as required" as is Hyoscine 200 – 400 micrograms in 24 hours, Midazolam 40 – 80 mgs in 24 hours. 80 mgs of Diamorphine together with 60 mgs of Midazolam are then started by syringe driver on the morning of the 15th January and re-started on both the mornings of the 16th and 17th January. (18M). On 16th January Haloperidol 5 mgs – 10 mgs subcutaneous for 24 hours is written up, prescribed over 24 hours on both 16th and 17th. I am not clear if this

was mixed in the other syringe driver or was the "second pump" referred to in the nursing cardex. (20M and 27M)

Diamorphine 120 mgs subcut in 24 hours is then prescribed on 18th January, together with Hyoscine 600 mgs subcut in 24 hours. The drug charts (20M) show this starting on the morning of 17th January and at 08.30 hours. If this correct there may have been up to three syringe drivers running, one with Diamorphine 80 mgs, one with Diamorphine 120 mgs in and one with the Haloperidol. The reason for this confusion needs clarification.

"The subsequent drug charts all appear to be missing for the final 6 days, however the nursing notes (27M, 28M and 29) suggest that there was a fairly constant prescription of 120 mgs of Diamorphine 24 hours, Midazolam 80 mgs 24 hours, Hyoscine 1200 mgs, Haloperidol 20 mgs and Nozinan 50 mgs. On the 20th there was no Haloperidol and the Nozinan was increased 100 mgs a day. This is still the prescription on 23rd January (27M).

6 TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

6.1 This section will consider if there are any actions so serious they might amount to gross negligence or any unlawful acts, or deliberate unlawful killing in the care of Mr Leslie Pittock. Also if the actions or omissions by the medical team, nursing staff or attendant GP's contributed to the demise of Mr Pittock, in particular, whether beyond reasonable doubt, the actions or omissions more than minimally, negligibly or trivially contributed to death.

I will also consider whether Mr Leslie Pittock received the proper standard of care and treatment from the medical and nursing staff including identifying any actions or omissions by the medical team, nursing team or attendant GP's that contributed to the demise of Mr Leslie Pittock.

6.2 In particular I will discuss a) whether Mr Pittock had become terminally ill and if so whether symptomatic treatment was *appropriate and b) whether the treatment provided was then* appropriate.

6.3 Mr Pittock has an unfortunate long history of depression, which had become more difficult and complex to manage and increasingly distressing in terms of his agitation related to his depressive symptomatology.

6.4 He had many treatments including high level drug treatment over many years and many episodes of electro convulsive treatment (ECT).

6.5 The complex and unresolved psychiatric problem led to a requirement to move to a residential accommodation in 1993. However he had further relapses and problems in 1995. A change occurred by September 1995 where the residential home was now noticing weight loss, increasing frailty and falls. Although a subsequent admission only came to the conclusion that he was depressed I have no doubt that his terminal decline was starting from that time.

6.6 By October 1995 he had extremely poor mobility and a shuffling gate. When re-admitted in December is aggressive, essentially immobile and extremely mentally distressed alongside his increasing physical frailty.

6.7 It is impossible in retrospect to be absolutely certain what was causing his physical as well as his mental decline. It may be that he was now developing cerebrovascular disease on top of his long standing drug induced Parkinsonism together with his persistent and profound depression agitation. It is not an uncommon situation for people with long standing mental and attendant physical problems, to enter a period of rapid decline without a single new diagnosis becoming apparent.

6.8 His deterioration is complicated by a probable chest infection (64, 81), which does not respond particularly well to appropriate antibiotic and physiotherapy treatment. He also has bowel complications attendant on all his other medical and drug treatment (116).

6.9 Dr Banks, psychiatric service asked Dr Lord, Consultant Geriatrician, to see the patient on 2nd January and he is actually seen on 4th January 1996. Dr Lord describes a very seriously ill gentleman. His comments that a long-stay bed will be found at the Gosport War Memorial and that he is unlike to return to his residential bed, reflect the fact that it was probably in his mind that this gentleman was probably terminally ill.

6.10 Mr Pittock is then transferred to Dryad Ward and is apparently seen by Dr Barton. A short summary of his problems is written in the notes but no physical examination, if undertaken, is documented.

It is normal clinical practice when accepting a patient to a new inpatient environment to undertake and record a basic physical examination. This will form a baseline for future management and a clinical record for other members of staff. The lack of a record of any examination, if undertaken, would be poor clinical practice.

6.11 It remains clear from the nursing record that he remains extremely frail with very little oral intake on 7th January (25M). When seen again by Dr Barton on 9th, there is the first note suggesting that Opiates may be an appropriate response to his physical and mental condition.

6.12 It is my view that this gentleman by this stage had come to the end point of a series of mental and physical conditions and that his problems were now irreversible. He was in considerable mental distress and had physical symptoms partly related to that and partly related to other medical problems. In my view he was dying and terminal care with a symptomatic approach was appropriate.

6.13 On the 10th Oramorph was started. Oramorph and Diamorph are particularly used for pain in terminal care. The nursing notes document that he had some pain; but most of his problems appeared to be restlessness, agitation and mental distress. However, despite the lack of serious pain, morphine like drugs are widely used and believed to be useful drugs in supporting patients in the terminal phase of the restlessness and distress that surrounds dying. I would not criticise the use of Oramorph in conjunction with his other psychiatric medication at this stage.

6.14 The decision that he was now terminally ill and for symptomatic relief appears to have been made appropriately with both the family and the ward staff and there was no disagreement with this decision.

This is indicated in the medical notes by the comment "poor TLC" (13M) together with the statement that it was discussed with the wife "for TLC" (note TLC= tender loving care). Beyond the statement in the medical notes that the patient was "for TLC" there is no specific justification given for the Oramorph in particular to be started. The notes are at best very thin and sparse and good medical practice (GMC 2001) states that "good clinical care must include an adequate assessment of the patients condition, based on the history and symptoms and, if necessary, an appropriate examination"..... "in providing care you must, keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the

information given to patients and any drugs or other treatments provided". The lack of information in the written notes, as documented in this report, represents poor clinical practice to the standards set by the General Medical Council.

The Drug Chart analysis (para. 5.12) described Diamorphine, Hyoscine and Midazolam all written up to be prescribed with a dosage range. This is quite common clinical practice, the aim of which is to allow the nursing team to have some flexibility in the management of a patient needing symptom control at the end of their life without having to call a doctor to change the drug charts every time a change in dosage is needed to maintain adequate palliation. However, there seems no rationale for writing up the dose of Midazolam at 80 mgs separate from the prescription above for 40 – 80 mgs.

6.15 The dose of Oramorph given from the early morning of 15th January was 26 mgs of morphine a day (see paragraph 1.14) (19M). On the 15th a syringe driver is started containing 80 mgs Diamorphine and 60 mgs of Midazolam. If a straight conversion is being given from Morphine to Diamorphine then you normally halve the dose i.e. 26 mgs of Oramorphine might be replaced by 13 mgs of Diamorphine (Wessex protocol). If you are increasing the dose because of breakthrough agitational pain then it would be normal to increase by 50% each day, some clinicians might increase by 100%. This would suggest that the maximum dose of Diamorphine to replace the stopped Oramorphine might be up to a maximum of 30 mgs of Diamorphine in 24 hours. Starting 80 mgs of Diamorphine is approximately three times of the dose that could conventionally be argued for.

As individuals response to Morphine or Diamorphine can be extremely difficult to predict, this is why clinicians will usually start with a low dose, then increase, with regular and close review to assess the patients response and to find a balance between pain, symptom relief and excessive doses. The main side effects of excessive dosage would be depression of respiration and consciousness. No justification is provided in the notes for starting at approximately 3 times the dose that could be conventionally argued for.

I believe the dose of Oramorph originally prescribed between 11th and 15th January was appropriate, however, no justification is given within the notes for originally writing up the higher than usual doses of Diamorphine and Midazolam on 11th January, the same time as the Oramorph was started, nor indeed is any rationale

made in the medical or nursing notes, the decision to commence the syringe driver on the 15th January. This lack of medical documentation is poor clinical practice.

Where clinicians significantly deviate from standard clinical practice, it is poor clinical practice not to document that decision clearly. It is very unwise from a medico legal perspective.

6.16 Midazolam was also started at a dose of 60 mgs per 24 hours. The main reason for using this is terminal restlessness and it is widely used subcutaneously in doses from 5 – 80 mgs per 24 hours for this purpose. Although 60 mgs is within current guidance, many believe that elderly patients need a lower dose of 5 – 20 mgs per 24 hours (Palliative Care, Welsh J, Fallon M, Keeley PW. Brocklehurst Text Book of Geriatric Medicine, 6th Edition, 2003, Chapter 23 pages 257-270). This would again suggest that the patient was being given a higher dose of Midazolam then would usually be required for symptom relief. Where clinicians significantly deviate from standard clinical practice, it is poor clinical practice not to document that decision clearly. It is very unwise from a medico legal perspective.

The nursing notes documented anxiety, agitation and generalised pain for which the Midazolam and the strong opioids (Oramorph and Diamorphine) were started. Midazolam is often used for the restlessness of terminal care and although Oramorphine and Diamorphine are usually used for severe pain, in clinical practice it is often used as well for the severe restlessness of terminal care. One study of patients on a long stay ward (Wilson J.A et.al. Palliative Medicine 1987:149-153) found that 56% of terminally ill patients on a long-stay ward receive opioid analgesia. Hyoscine is also prescribed in terminal care to deal with excess secretions which can be distressing for both patient and carers. I believe this was appropriately prescribed and given.

6.17 Diamorphine is compatible with Midazolam and can be mixed in the same syringe driver. Based on the evidence suggesting unusually high dosage of these medications being used I have considered whether there was evidence in the notes of any drug complications, in particular whether giving three times the normal starting dose for both Diamorphine and Midazolam together caused excessive sedation or other side effects might be considered gross negligence or an unlawful act. I was only able to find two pieces of evidence. The first was a statement in the nursing notes (26M) that by the evening that the syringe driver was started, the patient was unresponsive. The aim of palliative

care is to provide symptom relief not possible over sedation leading to unconsciousness. However, this did not continue and Mr Pittock was noted to be more alert and agitated again on the 16th.

Secondly on the 21st January (15M) a respiratory rate of 6 per minute is noted suggesting some possible respiratory depression.

6.18 A further drug, Nozinan, a sedating major tranquilliser is added to the drug regime, 50 mgs a day on the 18th January and increased to 100 mgs a day on the 20th January. Though this is within the therapeutic range in palliative care, 25 – 200 mgs a day when it is used for nausea and vomiting, the BNF advises 5 – 20 mgs a day and that the drug should be used with care in the elderly because of sedation.

The rationale for starting Nozinan appears to be the fact that the patient had become unsettled on Haloperidol (a different sort of major tranquilliser) and Nozinan is more sedating that Haloperidol. A verbal order to increase the dose of Nozinan from 50 to 100 mgs is documented in the medical notes (M15). This suggests that the 100 mgs was not actually written up within the Drug Charts, which if true, would be poor clinical practice. The absence of the drug charts makes this harder to determine.

6.19 The prediction of how long a terminally ill patient would live is virtually impossible and even palliative care experts show enormous variation (Higginson I.J. and Constantini M. Accuracy of Prognosis Estimates by 4 Palliative Care Teams: A prospective cohort study. BMC Palliative Care 2002 1:21). The combination of the high doses of Diamorphine, the high doses of Midazolam and the high doses of Nozinan are in my view likely to have caused excessive sedation beyond the need the symptom control in this dying man. In my view the medication is likely, but not beyond reasonable doubt, to have shortened life. However, I would have expected this to have been by no more than hours to a few days had a lower dose of all, or indeed any, of the drugs been used instead.

7. OPINION

7.1 Mr Leslie Pittock was an extremely ill, frail and dependent gentleman on his admission to Gosport War Memorial Hospital and was at the end point of a chronic disease process of depression and drug related side effects that had gone back for very many years.

7.2 The major problem in assessing Mr Pittock's care is the lack of documentation. Good Medical practice (GMC 2001) states that "good clinical care must include an adequate assessment of the patient's condition, based on history and symptoms and if necessary an appropriate examination".... "In providing care you must keep clear accurate legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any other drugs or other treatments prescribed". The major gaps in the written notes, the lack of evidence of appropriate examinations, use of unusual drug regimes without adequate documentation in the medical notes, changes in prescription without proper documentation, all represent poor clinical practice clinical practice to the standards set by the General Medical Council. However, by itself, these do not prove that the medical or nursing care provided to Mr Pittock was sub-optimal, negligent or criminally culpable.

7.3 In my view the drug management as Gosport was sub-optimal. There was no written justification at any stage for the high doses of Diamorphine and Midazolam written up in the drug charts and subsequently prescribed to Mr Pittock. The notes and the drug charts leave confusion as to whether at one stage there may have been three syringe drivers being used. The dose of Nozinan may have been prescribed by verbal prescription and not written up in the drug chart. Combinations of the higher than standard doses of Diamorphine and Midazolam, together with the Nozinan were very likely to have caused excessive sedation and may have shortened his life by a short period of time, that in my view would have been no more than hours to days. However, this was a dying man, the family appeared to have been appropriately involved and the patient did eventually die without distress on 24th January. While his care is sub-optimal I cannot prove it beyond reasonable doubt to be negligent or criminally culpable.

8 LITERATURE/REFERENCES

1. Good Medical Practice, General Medical Council 2002
2. Withholding withdrawing life, prolonging treatments: Good Practice and decision making. General Medical Council 2002.
3. Palliative Care, Welsh J, Fallon M, Keeley PW. Brocklehurst Text Book of Geriatric Medicine, 6th Edition, 2003, Chapter 23 pages 257-270.
4. The treatment of Terminally Ill Geriatric Patients, Wilson JA, Lawson, PM, Smith RG. Palliative Medicine 1987; 1:149-153.
5. Accuracy of Prognosis, Estimates by 4 Palliative Care Teams: A Prospective Cohort Study. Higginson IJ, Costantini M. BMC Palliative Care 2002:1:129

9. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

10. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature:_____ Date: _____

CONTENTS

This report is based on the following document:

2.1 Job Description for Clinical Assistant Post to the Geriatric Division in Gosport as provided to me by the Hampshire Constabulary (February 2005).

2.2 Statement of Dr Jane Barton re Leslie Pittock as provided to me by Hampshire Constabulary (April 2005). Appendix 1

2.3 Statement of Dr Jane Barton as provided to me by Hampshire Constabulary (February 2005). Appendix 2

2.4 Report regarding Leslie Pittock (BJC/ 71) Dr D Black 2005.

3. COMMENTS

3.1 Comments on Job Description (2.1)

3.1.1 This confirms the Clinical Assistant is responsible for a maximum of 46 patients and confirms that all patients are under the care of a named Consultant Physician who would take overall responsibility for their medical management. A Clinical Assistant should take part in the weekly consultant ward rounds.

3.1.2 A specific responsibility is the writing up of the original case notes and ensuring the follow up notes are kept up to date and reviewed regularly.

3.1.3 The post is for five sessions a week i.e. is half what a full time doctor would commit to the post. However, the time to be spent in the unit is not specified as the time is allowed to be "worked flexibly".

3.1.4 There appears to be some confusion between the statements in the job summary, that "patients are slow stream or slow stream for

rehabilitation but holiday relief and shared care patients are admitted" and the statement in the previous sentence "to provide 24 hour medical care to the long stay patients in Gosport". The job description appears to be confusing patients for rehabilitation with long stay patients.

3.1.5 There is no comment on the medical cover to be provided when the post holder is unavailable for out of hours or longer period of leave such as holidays. Lack of explicit cover might explain some gaps in the notes.

3.2 Report on the statement of Dr Jane Barton re Leslie Pittock (2.2).

The comments refer by paragraph to the statement, and by paragraph to the report (BJC/ 71)

3.2.1 I have read the statement of Dr Jane Barton as provided to me by the Hampshire Constabulary (April 2005). Appendix 1.

3.2.2.Paragraph 7. I agree that Mr Pittock was admitted to Mulberry Ward on 14th September 1995. Paragraph 5.4 my report (BJC/71) incorrectly stated 29th November 1995. Paragraph 10 of my report (BJC/71) I incorrectly assumed that Dr Lord was male and refers to "him" in paragraph 6.9.

3.2.3 Paragraph 13. Does imply that an external examination of Mr Pittock's pressure areas may have been undertaken. However, as set out in Paragraph 6.10 of my report (BJC/71) no general physical examination is otherwise recorded to have taken place.

3.3 Report on the Statement of Dr Jane Barton as provided to me by the Hampshire Constabulary (2.3):

3.3.1Page 1 paragraph 3: States that she works eight general practice surgery sessions. It is my understanding that most full time General Practitioners work eight or nine sessions. This suggests to me that she is undertaking a full time General Practitioner job and a half time community hospital job. Despite the fact the job description says that the job can be worked flexibly, an opinion should be obtained from an experience General Practitioner as to whether this workload is actually deliverable within a reasonable working week.

3.3.2 Page 1 paragraph 4: The job description states 46 beds, Dr Barton states 48 beds. The CHI report says 44 beds (20 on Dryad and 24 on Daedalus) Dr Barton uses the phrase "continuing care for long stay elderly patients". The job description also referred to slow stream or slow stream rehabilitation as well as holiday relief and shared care patients. There may have been confusion between staff in terms of the objectives of individual patient management.

3.3.3 Page 1 paragraph 5: This statement is incorrect as the post of Clinical Assistant is not a training post but a service post in the NHS. The only medical training grade posts are pre-registration house officers, senior house officers, specialist registrars and GP registrars.

3.3.4 Page 1 paragraph 5: States that she and her partners had decided to allocate come of the sessions to "out of hours aspects of the post". This would appear to be a local arrangement of the contractual responsibilities: it needs to be clarified if this was agreed with the Portsmouth and South East Hampshire Health Authority. This would influence how much time was expected to be provided for the patients and influence the pressure on Dr Barton to deliver the aspects of care provided.

3.3.5 Page 2 paragraph 3: This does confirm that there were consultants responsible for all the patients under the care of Dr. Barton. Thus a consultant should always have been available for discussing complex or difficult management decisions. However,(page 3 paragraph 1) , in my view it would be completely unacceptable of the Trust to have left Dr Barton with continuing medical responsibilities for the inpatients of Gosport Hospital without consultant supervision and regular ward rounds. This would be a serious failure of responsibility by the Trust in its governance of patients and in particular failings and in my view the Trust would need to take part of the responsibility for any clinical failings.

3.3.6 Page 3 paragraph 3: This again suggests that Dr Barton was trying to provide her half time responsibilities by fitting the work around her full time responsibilities as a General Practitioner. She suggests 5 patients were admitted each week, implying approximately 250 admissions and discharges a year. With a bed occupancy around 80%, this would suggest an average length of stay of 5 – 6 weeks. However, CHI state the actual figures were somewhat less, 1997/98 were 169 FCE's for Dryad and Daedalus and 197 FCE's in 1998/99. A new patient assessment including history and examination, writing up the notes, drug charts, talking to the nurses, talking to any relatives present and undertaking blood tests if these had to be taken by a doctor rather than any other staff, would take a maximum of 60 minutes.

Page 5 paragraph 2: The patients who were genuinely long stay or continuing care do not need to be reviewed medically every day, nor would a medical record be made daily. Indeed with average length of stay of six or more weeks, it is clear that many patients were genuinely long-stay patients and one would expect them to be medically reviewed no more than once a week and any medical comments to be no more than once a week. However, whenever patients' physical or mental state has changed and they are reviewed by a doctor, it would be normal practice to always make a comment in the notes. Patients who are in rehabilitation and making a good progress, then review and

comments in the notes once or twice a week would also be the norm.

It is my view that with less than 200 FCE's and a total of 44 inpatients, then this should be satisfactorily managed by somebody working half time as a Clinical Assistant with regular consultant supervision.

3.3.7 Page 4 paragraph 2: This suggests that Dr Barton is stating that she takes personal responsibility for most changes in medication, rather than it being a nursing decision.

3.3.8 Page 9 paragraph 2: An individual doctor must take responsibility for their prescribing however I would agree that consultants should also take responsibility for ensuring patients under their care were having appropriate medical management. It does appear that there was a consultant responsible for all patients in both Dryad and Daedalus Ward.

4. Conclusions

4.1. Having read all the documents provided by Hampshire Constabulary, the only changes I would wish to make in my expert report are in paragraphs 5.4. to change the date to the 14th September; in paragraph 6.9 to change "his" to "her"; and in paragraph 6.10 to state that no physical examination, apart from possible examination of pressure areas, is documented.

REPORT

regarding

LESLIE PITTOCK (BJC/71)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mr Pittock was a frail 82 year old man admitted to Mulberry Ward, Gosport War Memorial Hospital due to depression. He was withdrawn, agitated and irritable and required the help of two others to mobilise. Despite the admission and a reduction or discontinuation in some of his medication, his low mood and poor mobility persisted. He developed a chest infection and urinary retention. After about three weeks in hospital, his condition remained poor and he started to develop pressure sores. Mr Pittock was referred to Dr Lord, Consultant Geriatrician, for a medical review and was subsequently transferred to Dryad Ward.

During this admission, the medical care provided by Dr Barton fell short of a good standard of clinical care as defined by the General Medical Council that included the lack of clear note keeping, adequate assessment of the patient and providing treatment that was excessive to a patients' needs. The reason for the prescription of drugs was not clear. If pain was a problem, it was not recorded or assessed. Most significantly, the dose range of diamorphine prescribed for the 'as required' syringe driver, and the dose finally administered (80mg), far exceeded that generally considered to be an appropriate starting dose (10–15mg) based on Mr Pittock's existing opioid usage.

Mr Pittock was described as tense and agitated several times following the syringe driver being commenced. In this regard the use of midazolam, haloperidol and levomepromazine could be seen as justified. However, an assessment of the possible causes of his agitation should have been carried out. This would have included considering if drugs, such as the diamorphine, were a possible contributing factor to his agitation. At the very least, given that

diamorphine in a dose that is excessive to a patients needs can cause agitation and confusion, it should have prompted a review of the appropriateness of Mr Pittock's dose of diamorphine.

There appears little doubt that Mr Pittock was 'naturally' coming to the end of his life. At best, Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mr Pittock a peaceful death, albeit with what appears to be an excessive use of diamorphine due to a lack of sufficient knowledge.

It is my opinion however, that given the lack of documentation to the contrary, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mr Pittock by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mr Pittock by unnecessarily exposing him to excessive doses of diamorphine that could have resulted in a worsening of his agitation. Dr Barton's response to this was to further increase Mr Pittock's dose of diamorphine. Despite the fact that Mr Pittock was dying 'naturally', it is difficult to exclude completely the possibility that a dose of diamorphine that was excessive to his needs may have contributed more than minimally, negligibly or trivially to his death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

2. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to his death against the acceptable standard of the day. Where appropriate, if the care is felt to be suboptimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

3. ISSUES

3.1 Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

3.2 If the care is found to be suboptimal what treatment should normally have been proffered in this case?

3.3 If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

4. BRIEF CURRICULUM VITAE

Code A

Code A

5. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Leslie Pittock, including the death certificate.

[2] Full set of medical records of Leslie Pittock on CD-ROM.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Commission for Health Improvement Investigation Report on Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital (July 2002).

[6] *Palliative Care Handbook Guidelines on Clinical Management*, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

[7] Portsmouth Health Care NHS Trust Policies:

i) Control of Administration of Medicines by Nursing Staff Policy (January 1997).

ii) Prescription Writing Policy (July 2000).

iii) Policy for Assessment and Management of Pain (May 2001).

iv) *Compendium of Drug Therapy Guidelines, Adult Patients* (1998).

v) Draft Protocol for Prescription Administration of Diamorphine by Subcutaneous Infusion, Medical Director (December 1999).

vi) Medicines Audit carried out by the Trust referred to as Document 54 on page 52 in the Chi Report (reference 6).

[8] General Medical Council, Good Medical Practice (October 1995).

[9] British National Formulary (BNF). Section on Prescribing in Terminal Care (March 1995).

[10] British National Formulary (BNF). Section on Prescribing in the Elderly (March 1995).

6. CHRONOLOGY/CASE ABSTRACT

Events at the Gosport War Memorial Hospital, Mulberry Ward, 13th December 1995 until 5th January 1996

Mr Leslie Pittock, an 82 year old man who lived in Hazeldene residential home was admitted on the 13th December 1995 to Mulberry Ward, Gosport War Memorial Hospital under the care of Dr Banks, consultant in old age psychiatry (pages 62 of 181). He was depressed and reported feeling hopeless and suicidal. He had been verbally aggressive towards his wife and the staff at the residential home. He was staying in bed all day and not eating well (pages 62 and 125 of 181). He was known to Dr

Banks having suffered from chronic depression for over 30 years resulting in multiple admissions to hospital. He also had an underactive thyroid gland and problems with constipation (page 62 of 181). His medication consisted of sertraline 100mg once a day, lithium carbonate 400mg once a day, thioridazine 50mg four times a day, diazepam 10mg twice a day, temazepam 10mg at night, thyroxine 50microgram once a day, magnesium hydroxide 10ml at night and codanthrusate 2 capusles at night (pages 62 and 88 of 181). Examination revealed him to be withdrawn, a little agitated and irritable. He had a slight tremor on moving, a shuffling gait and required the help of two others to mobilise (page 63 of 181). It was considered that depression was his main problem (page 63 of 181).

Over the next few days he experienced a fall and problems with diarrhoea. His laxatives were discontinued and an abdominal x-ray carried out. This revealed distension of the large bowel with only a small gas bubble seen in the region of the rectum. The report concluded that these features could represent distal large bowel obstruction but as there was no faecal residue, the changes may be due to pseudo-obstruction (page 116 of 181). His low mood and poor mobility persisted. As thioridazine can cause Parkinsonism (i.e. a collection of features similar to those seen in patients with Parkinson's disease, e.g. difficulty initiating movements, rigidity, tremor etc.) the dose was reduced to 25mg four times a day and procyclidine 5mg twice a day was commenced (page 64 of 181). Procyclidine is an antimuscarinic drug that can help with Parkinsonism.

After about one week, on the 22nd December 1995 he was found to have a chest infection and erythromycin, an antibiotic, was commenced (page 64 of 181). On review by Dr Banks on the 27th December 1995, Mr Pittock

was noted to be 'chesty, poorly, abusive and not himself at all' (page 65 of 181). As he had not responded to the erythromycin, another antibiotic, cefaclor was commenced and the procyclidine was discontinued. He had been catheterised for urinary retention the week before (page 65 of 181). Microbiology tests of his sputum revealed a pseudomonas infection (page 112 of 181). A chest x-ray showed no evidence of focal lung disease (page 116 of 181). It was decided to reassess his mood once his medical problems had been addressed.

After about three weeks in hospital, on the 2nd January 1996 it was reported that he remained poorly, lethargic, his skin was breaking down and he was now nursed on a Pegasus bed. He was reported to be asking 'why don't you let me die?' (page 65 of 181). Blood test results on the 2nd January 1996 were mostly normal. There was a raised white blood cell count. $15.7x10^9$/L, due to an increase in neutrophils, $14.4x10^9$/L, in keeping with an infection (page 114 of 181). Liver enzymes were mildly abnormal with raised alkaline phosphastase of 110 IU/L, AST (aspartate aminotransferase) of 127 IU/L and a low albumin of 27g/L (upper limit of normal 95, 40 and lower limit of 37 respectively)(page 85 of 181). Rather than attribute his deterioration purely to his depression, Mr Pittock was referred to a geriatrician to see if any medical problems were contributing to his decline (page 65 of 181). A referral letter was written in the notes to Dr Lord, Consultant Geriatrician, on the 2nd January 1996 that noted Mr Pittock's mobility had deteriorated drastically during his admission and although his chest infection was now improving, he remained bed bound, expressing the wish to die. It also noted Mr Pittock's complaints of intermittent abdominal pain (page 66 of 181).

When reviewed by Dr Banks on the 3rd January 1996, it was again noted that Mr Pittock was deteriorating, with a poor food intake and some breaks in his skin (page 66 of 181). In case undesirable effects of some of his medication were contributing to his decline, the diazepam was reduced to 2mg three times a day and the thioridazine and temazepam discontinued (pages 67 and 81 of 181).

He was seen by Dr Lord on the 4th January 1996. She listed Mr Pittock's problems as 'chronic resistant depression – very withdrawn, completely dependent (Bartell 0), catheter by-passing, superficial ulceration of left buttock and hip, and hyoproteinaemic'. She suggested high protein drinks, bladder washouts twice a week, dressing to his skin ulcers and transfer to a long stay bed. Dr Lord felt his residential home place could be given up as he was unlikely to return (page 67 of 181). In the typed letter of the 8th January 1996, that summarised this review, Dr Lord stated that Mr Pittock's prognosis was poor and that he was unlikely to return to Hazeldene Rest Home (page 5 of 49).

Events at Gosport War Memorial Hospital, Dryad Ward, 5th January 1996 to 24th January 1996

On transfer to Dryad Ward on the 5th January 1996, the medical notes record Mr Pittock's problems as consisting of 'immobility, depression, a broken sacrum with small superficial areas of the right buttock, a dry lesion on his left ankle and both heels suspect. Catheterised, transfers with hoist, may help to feed himself. Long standing depression on lithium and sertraline' (page 13 of 49). Mr Pittock's medication was continued unchanged on transfer: sertraline 50mg twice a day, lithium carbohydrate

400mg at night, diazepam 2mg three times a day, thyroxine 50microgram once a day and daktacort cream (page 16 of 49). The nursing notes suggest that Mr Pittock settled into the ward well and went on to detail his pressure sores (page 25 of 49).

On the 8th January, a pain relief preparation 'arthortec' one tablet twice a day, containing a non-steroidal anti-inflammatory drug, diclofenac, was commenced and continued until the 10th January 1996 (page 16 of 49).

On the 9th January 1996 the medical notes entry reads 'painful right hand held in flexion, try *hot water* (this should be clarified as the handwriting is difficult to decifer). *Also increasing anxiety and agitation,?sufficient* diazepam, ?needs opiates' (page 13 of 49). The nursing notes record that *he was very sweaty but was apyrexial (temperature not elevated)* and that Mr Pittock stated that he had generalised pain (page 25 of 49).

On the 10th January 1996, oramorph (morphine solution, 10mg/5ml) 2.5ml (5mg) every four hours was prescribed but none given until the 11th January (page 17 of 49). Possibly also on the 10th January, diamorphine 40–80mg and hyoscine (hydrobromide) 200–400microgram SC (subcutaneous) in 24 hours were also prescribed (page 17 of 49). These were not used on the 10th or 11th January, and the drug chart appears to have been rewritten sometime on the 11th January (pages 18 and 19 of 49). The diamorphine was rewritten as 80–120mg along with hyoscine (hydrobromide) 200–400microgram and midazolam 40–80mg SC (subcutaneous) in 24 hours. The nursing notes for this day record 'Condition remains poor. Seen by Dr Tandy and Dr Barton. To commence on oramorph 4 hourly. This evening Mrs Pittock seen and is aware of poor condition. To stay in long stay bed' (page 25 of 49).

On the 11th January 1996 the diazepam was increased from 2mg to 5mg three times a day and the oramorph given as 5mg every 4 hours, with 10mg at night until the morning of the 15th January 1996 (page 19 of 49). On the 12th January 1996, the sertraline and lithium carbonate were discontinued.

On the 13th January 1996 the nursing notes record 'Catheter bypassing. Mr Pittock appears distress, suby g washout given. However, catheter continues to bypass heavily. Catheter removed, tip of same looks very mucky...' (page 25 of 49).

A medical notes entry on the 15th January 1996 summarises 'For TLC (tender loving care). Discussed with wife, agrees in view of the poor quality for TLC' (page 13 of 49). A syringe driver was commenced at 08.25am on the 15th January containing diamorphine 80mg, hyoscine hydrobromide, 400microgram and midazolam 60mg SC over 24 hours (pages 18,25,26 of 49). The nursing notes for that day detail 'Seen by Dr Barton. Syringe driver commenced....' and at 19.00pm 'Daughter informed of father's deterioration during the afternoon. Now unresponsive. Unable to take fluids and diet. Pulse strong and regular' (page 26 of 49).

On the 16th January 1996 haloperidol 5–10mg SC over 24 hours was prescribed (page 20 of 49) with Mr Pittock receiving haloperidol 5mg on the 16th January 1996 and 10mg on the 17th January 1996. The nursing notes entry reads 'Condition remains very poor. Some agitation was noticed when being attended to. Seen by Dr Barton. Haloperidol 5–10mg to be added to the driver' (page 26 of 49).

On the 17th January 1996, the dose of diamorphine was increased to 120mg and the midazolam to 80mg SC over 24 hours and both then

remained unchanged for the remainder of Mr Pittock's life. The dose of hyoscine hydrobromide was increased twice on the 17th January to 600microgram then 1200micrograms SC over 24 hours; as was the dose of haloperidol, increasing to 10mg and then to 20mg SC over 24 hours (pages 6, 7 and 20 of 49). The dose of hyoscine hydrobromide then remained unchanged for the remainder of Mr Pittock's life. There are several entries in the nursing notes on the 17th January: (09.00am) 'Seen by Dr Barton, medication increased 08.25am as patient remains tense and agitated. Chest very 'bubbly'. Suction required frequently this morning. Patient bed bathed, mouth care tolerated well. Skin marking easily despite hourly turning and use of Pegasus mattress and remains distressed on turning.' (14.30pm) 'Seen by Dr Barton, medication reviewed and altered. Syringe driver renewed at 15.35pm (two drivers).....Daughter informed of deterioration.' (20.30pm) 'Further deterioration in already poor condition. Appears more settled although still aware of when he is being attended to....' (page 27 of 49).

On the 18th January 1996 the medical notes report 'further deterioration, SC (subcutaneous) analgesia continues, difficulty controlling symptoms, try nozinan' (levomepromazine) (page 15 of 49). This was commenced at a dose of 50mg SC over 24 hours (page 6 of 49). The nursing notes report 'poorly condition, continues to deteriorate.....' (page 27 of 49). Wife has visited for most of the day. Appears comfortable in between attention. Oral suction given with some effect' (page 28 of 49).

On the 19th January 1996 the nursing notes read 'A marked deterioration in an already poorly condition.....Breathing very intermittent, colour poor' (page 28 of 49). On the 20th January 1996 the medical notes entry reads

'Has been unsettled on haloperidol in syringe driver. Discontinue and change to higher dose nozinan, increase nozinan 50→100mg in 24 hours (verbal order)' (pages 6, 7 and 15 of 49). The nursing notes for the 20th January 1996 read 'Mrs Pittock and both daughters have visited. Dr Brigg contacted regards to regime. Verbal order taken to double nozinan and omit haloperidol. Syringe driver recharged at 18.00hours. Appears comfortable at time of report...' (page 28 of 49).

On the 21st January 1996, the medical notes entry reads 'Much more settled. Quiet breathing. Respiratory rate 6 per minute. Not distressed, continue' (page 15 of 49). Nursing entry for this day reads 'Very settled today' (page 28 of 49). On the 22nd January 1996 the nursing notes record 'poorly but very peaceful' (page 29 of 49). On the 23rd January 1996, the nursing notes record 'Poorly condition remains unchanged, has remained peaceful' (page 29 of 49). An untimed entry then reads 'Patients condition deteriorated suddenly at 01.40am and Mr Pittock died at 01.45am' (page 29 of 49). A verification of death entry was made in the medical notes (page 15 of 49).

On the death certificate, cause of death was given as 1a Bronchopneumonia.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Syringe drivers, diamorphine, midazolam, haloperidol, levomepromazine (nozinan) and hyoscine hydrobromide

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24hours. Indications for its use include swallowing difficulties or a comatose patient. In the

United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF number 29 (March 1995)). Others sometimes suggested dividing by 2 or 3 depending on circumstance (Wessex protocol). Hence, 60mg of morphine taken orally a day could equate to a daily dose of 20 or 30mg of diamorphine SC. It is usual to prescribe additional doses for use 'as required' in case symptoms such as pain breakthrough. The dose is usually 1/6th of the 24hour dose. Hence for someone receiving 30mg of diamorphine in a syringe driver over 24hours, a breakthrough dose would be 5mg. One would expect it to have a 2–4hour duration of effect, but the dose is often prescribed to be given hourly if required. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in

their terminal phase would generally aim to find a dose that improves the patients' symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg a day. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (March 1995) recommends 20–100mg SC over 24hours. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated every 24hours if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24hours, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4hours, and it may need to be given more frequently. As an active metabolite of midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

Haloperidol is an antipsychotic. It is frequently used in syringe drivers for its antipsychotic and anxiolytic effects in patients with terminal delirium/agitation or as an anti-emetic. Compared to other antipsychotics, like levomepromazine, it is less sedative but can cause more problems with extrapyramidal effects and should be used with caution in patients with parkinsonism or Parkinson's disease. Extrapyramidal effects include parkinsonism, acute dystonia, acute akathesia and tardive dyskinesia. Parkinsonism consists of tremor, rigidity and slowing of movements; acute dystonia is spasm of muscles including those involving the eyes, head,

neck, trunk and limbs. They are usually abrupt in onset and associated with anxiety; acute akathesia is a form of restlessness of the muscles in which the person is compelled to move or change position and is associated with variable degrees of patient distress; tardive dyskinesia typically presents as involuntary chewing movements of the face and orofacial muscles.

A typical starting dose of haloperidol for an adult is 3–5mg a day with an upper dose range of 10–30mg orally or SC. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (March 1995) recommends 5–30mg SC over 24hours. The Wessex protocol suggests a range of 1.5–3mg up to three times a day orally. It is usual to prescribe additional doses for use 'as required' often in the dose range of 2.5–5mg SC. The dose is often prescribed so that it can be given hourly if required.

Levomepromazine is an antipsychotic. It is frequently used in syringe drivers for its antipsychotic and anxiolytic effects in patients with terminal delirium/agitation or as an anti-emetic. It is more sedative than haloperidol.

A typical starting dose of levomepromazine for an adult is 50mg SC over 24 hours, with an upper dose range of 300mg SC. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (March 1995) recommends 50–200mg SC over 24hours. The Wessex protocol suggests a range of 25–200mg SC over 24hours. It is usual to prescribe additional doses for use 'as required' often in the dose range of 6.25–25mg SC. The dose is often prescribed so that it can be given hourly if required.

Hyoscine hydrobromide is an antimuscarinic drug most commonly given to reduce excessive saliva or retained secretions ('death rattle'). It also has

anti-emetic, antispasmodic (smooth muscle colic) and sedative properties. Repeated administration can lead to cummulation and this can occasionally result paradoxically in an agitated delirium, highlighted in both in the BNF and the Wessex protocol (page 41). It is usually given in a dose of 600–2400micrograms SC over 24hours (BNF (March 1995)). or 400–600micrograms as a stat SC dose. The Wessex protocol gives a dose range of 400–1200micrograms over 24hours.

The titration of the dose of analgesic, antipsychotic or sedative medication is guided by the patients symptom control needs. The number and total dose of 'as required' doses required over a 24hour period are calculated and this guides the increase necessary in the regular dose of the drugs in the syringe driver in a way that is proportional to the patients needs. The ideal outcome is the relief of the symptoms all of the time with no need for additional 'as required' doses. In practice, this can be difficult to achieve and the relief of the symptoms for the majority of the time along with the use of 1–2 'as required' doses over a 24hour period is generally seen as acceptable.

ii) The principle of double effect.

The principle of double effect states that:

'If measures taken to relieve physical or mental suffering cause the death of a patient, it is morally and legally acceptable provided the doctor's intention is to relieve the distress and not kill the patient.'.

This is a universal principle without which the practice of medicine would be impossible, given that every kind of treatment has an inherent risk. Many discussions on the principle of double effect have however, involved the use of morphine in the terminally ill. This gives a false impression that

the use of morphine in this circumstance is a high risk strategy. When correctly used (i.e. in a dose appropriate to a patient's need) morphine does not appear to shorten life or hasten the dying process in patients with cancer. Although a greater risk is acceptable in more extreme circumstances, it is obvious that effective measures which carry less risk to life will normally be used. Thus, in an extreme situation, although it may occasionally be necessary (and acceptable) to render a patient unconscious, it remains unacceptable (and unnecessary) to cause death deliberately. As a universal principle, it is also obvious that the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

8. OPINION

Events at Gosport War Memorial Hospital, Mulberry Ward 13th December 1995 to 5th January 1996

Mr Pittock was an 82 year old man who suffered from chronic depression. Deterioration in his mental and physical state led to his admission for assessment on Mulberry Ward under the care of Dr Banks. Examination revealed him to be depressed and withdrawn and a little agitated and irritable. He had signs of Parkinsonism which may have been due to undesirable effects of his medication. Despite a reduction in his medication his situation failed to improve. He developed a chest infection that required two different sorts of antibiotic to treat. Despite this, his physical deterioration and poor mental state continued. Rather than attribute his deterioration purely to depression, Mr Pittock was appropriately referred to a geriatrician, Dr Lord. It was documented that

his mobility had deteriorated drastically during his admission and that he had become bedbound, was complaining of intermittent abdominal pain and expressing the wish to die. His diazepam was reduced and thioridazine and temazepam discontinued, but still Mr Pittock failed to improve. Dr Lord's review indicated that Mr Pittock's prognosis was poor and that he was unlikely to return to Hazeldene Rest Home. This implies that his transfer to Dryad Ward was for terminal care. There are no issues relating to the standard of care or treatment proferred to Mr Pittock during his admission to Mulberry Ward.

Events at Gosport War Memorial Hospital, Dryad Ward 5th January 1996 to 24th January 1996

Compared to the notes during Mr Pittock's stay on Mulberry Ward, infrequent entries in the medical notes during his stay on Dryad Ward make it difficult to closely follow Mr Pittock's progress over the last three weeks of his life. There are seven entries taking up just one and a half pages in length. In summary and in approximate chronological order, Mr Pittock was prescribed Arthrotec, a non-steroidal anti-inflammatory drug. There was no record or assessment of pain in the medical notes, but the nursing notes recorded that he stated that he had generalised pain. He later complained of a painful right hand held in flexion for which *?hot water* (to be clarified) was suggested. Increasing anxiety and agitation were also noted. Dr Barton queried whether he was receiving sufficient diazepam or required opiates. The possible cause of his painful right hand held in flexion is not documented in the medical notes.

The Arthrotec was discontinued after two days and he was commenced on morphine regularly. It is not clear from the notes what pain this was prescribed for, why the Arthrotec was stopped or why a 'weak' opioid like codeine was not felt appropriate. On the same day, a syringe driver was prescribed containing diamorphine 40–80mg and hyoscine (hydrobromide) 200–400microgram in 24hours to be used 'as required'. This was never given but when the drug chart was rewritten, apparently the next day, the dose range of diamorphine was increased to 80–120mg and midazolam 40–80mg added without reason.

His diazepam was increased on the 11th January 1996 and his sertraline and lithium carbonate discontinued on 12th January 1996 both without reason. On the 13th January 1996 the nursing notes record Mr Pittock to appear distressed. It is unclear if this was related to his urinary catheter bypassing or was more generalised.

On the 15th January 1996 a syringe driver was commenced containing diamorphine 80mg, hyoscine hydrobromide 400micrograms and midazolam 60mg. The indication for this is not clear. Once the syringe driver was commenced he became unresponsive and his family informed.

On the 16th January 1996 the nursing notes stated that he was agitated when being attended to. Haloperidol 5mg was prescribed and administered, although there was no entry in the medical notes. On the 17th January 1996 the dose of diamorphine was increased to 120mg, the haloperidol to 10mg (subsequently 20mg), the midazolam to 80mg and the hyoscine hydrobromide to 600microgram (subsequently 1200microgram). No reason is given in the medical notes, although the

nursing notes report Mr Pittock to be tense and agitated and have a very 'bubbly' chest.

The medical notes entry on the 18th January 1996 report symptoms were difficult to control but does not specify which symptoms. Levomepromazine was then commenced at a dose of 50mg SC over 24hours. On the 20th January 1996 an entry in the medical notes report Mr Pittock to be unsettled and the dose of levomepromazine was increased from 50 to 100mg and the haloperidol was then discontinued. Thereafter Mr Pittock appeared to be settled until his death in the early hours of the 24th January 1996. Given the nature of Mr Pittock's decline and problems with respiratory tract secretions, bronchopneumonia appears to be the most likely cause of his death, as stated on the death certificate.

Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

The overall care given to Mr Pittock whilst on Mulberry Ward, Gosport War Memorial Hospital was not substandard.

The medical care provided by Dr Barton to Mr Pittock following his transfer to Dryad Ward, Gosport War Memorial Hospital is suboptimal when compared to the good standard of practice and care expected of a doctor outlined by the General Medical Council (Good Medical Practice, General Medical Council, October 1995, pages 2–3) with particular reference to:

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs including, where necessary, an appropriate examination

- in providing care you must keep clear, accurate, and contemporaneous patients records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs, or appliances that serve patients' needs
- in providing care you must be willing to consult colleagues.

Specifically:

i) The notes relating to Mr Pittock's transfer to Dryad Ward are inadequate. On transfer from one service to another, a patient is usually reclerked highlighting in particular the relevant history, examination findings and any planned investigations to be carried out.

ii) Pain is the most likely reason for prescribing the non-steroidal anti-inflammatory drug (Arthrotec). However, pain was not documented in the notes, nor was any pain assessed.

iii) Mr Pittock's painful right hand held in flexion does not appear to have been appropriately assessed. From its description it may have been tetany causing carpopedal spasm and the common causes of this should have been considered, e.g. a low serum calcium or magnesium deficiency. Less likely is a dystonia but given that some of his medications could cause extrapyramidal effects (see technical background) this possibility should also have been considered. As hypocalcaemia is reported to cause mood disturbance such as anxiety and agitation, it would have been particularly relevant to consider.

iv) It should be clarified why Dr Barton felt Mr Pittock needed opioids. From the medical notes, it appears to relate to his increasing anxiety and agitation. This

is not an appropriate indication for the use of opioids. If opioids were being suggested for his painful hand, this would also be inappropriate. The medical notes state no other pain. The nursing notes do state he had generalised pain, but the lack of a full pain assessment makes it difficult to know what pain this represented; for example, was it related to muscle and/or joint stiffness from immobility, his pressure sores or abdomen?

v) It is not clear from the medical notes the indication for which the morphine was commenced. If it was for pain then this should have been documented and assessed. It was a reasonable starting dose for someone of his age and morphine is used in palliative care for generalised pain related to muscle or joint stiffness due to immobility or painful pressure sores.

vi) It is not clear what the indications were for prescribing the syringe driver on the 10th January 1996 and for the medications it contained. It is not usually necessary to utilise the SC route unless a patient is unwilling or unable or to take medications orally (e.g. difficulty swallowing, nausea and vomiting). From the drug chart Mr Pittock did not appear to have these problems (page 18 of 49). No instructions were given on the drug chart on when the syringe driver should be commenced, how this would be decided and by whom. The dose of diamorphine was initially written as a dose range of 40–80mg, only to be subsequently rewritten the next day as 80–120mg without explanation of why a higher dose range was necessary. Based on Mr Pittock's existing opioid dose, all of the doses of diamorphine are likely to be excessive for his needs. Given his total dose of oramorph (morphine solution) of 30mg in 24hours, an appropriate dose of diamorphine using a 1:2 or the more usual 1:3 dose conversion ratio, would have been 10–15mg in 24hours. There is no justification given for

this in the medical notes. Similarly, the indications for including the hyoscine hydrobromide and midazolam should have been documented. The dose range of midazolam of 40–80mg would generally be seen as excessive for someone of Mr Pittock's age. However, taking into account he was a long term user of benzodiazepines, a higher than usual starting dose would likely be necessary.

vii) The dose of diazepam was increased on the 11th January 1996 with no mention of this in the medical notes.

viii) The sertraline and lithium carbonate were discontinued on the 12th January 1996 with no mention of this in the medical notes. It was unclear if this was on the advice of the psychogeriatricians or not; my understanding is that sertraline should not be discontinued abruptly as this is associated with a withdrawal syndrome that can include anxiety, agitation and delirium. A gradual withdrawal of lithium is also advised (BNF).

ix) A syringe driver was ultimately commenced on the 15th January 1996. It is not documented why it had become necessary to give these medications via a syringe driver. Mr Pittock appeared to have been taking his oral medications and the medical entry noted that he 'will eat and drink'. There was no mention in the medical or nursing notes of pain, retained secretions, agitation or anxiety that day. If he was more drowsy and unable to take his medication it would have been reasonable, particularly if he required morphine for pain relief. However, taking into account Mr Pittock's dose of morphine, the starting dose of diamorphine (80mg) was likely to be excessive for his needs as detailed above. The reasons for including the hyoscine hydrobromide (400microgram) and midazolam (60mg) over 24hours were not documented. The dose of midazolam of 60mg over 24hours is an above average starting

dose for somebody of Mr Pittock's age (see technical issues). He had however, been on long term benzodiazepines and in these patients a larger than usual starting dose may be necessary.

x) On the 16th January 1996 the nursing notes reported some agitation when Mr Pittock was being attended to. Haloperidol 5mg SC over 24hours was added to the syringe driver. Haloperidol is a reasonable part of the approach to treating delirium or terminal agitation in someone of Mr Pittock's age. It should be given with caution, given Mr Pittock's parkinsonism, as it can cause extrapyramidal effects (see technical issues). However, it is not clear from the notes that his agitation had been assessed and hence the possible underlying causes of the agitation considered. Drugs (or their withdrawal) are one of the common causes of agitation or terminal restlessness. Of particular relevance to Mr Pittock, these would include the use of opioids, particularly in inappropriate and excessive doses, hyoscine hydrobromide and benzodiazepines (Wessex Protocol, pages 30, 34). It is possible that a reduction in the dose of diamorphine may have helped Mr Pittock's agitation.

xi) On the 17th January 1996 the dose of diamorphine was increased to 120mg and the midazolam to 80mg SC over 24hours with no reason given in the notes. The nursing notes suggest that Mr Pittock remained tense and agitated. There is no documentation that a medical assessment was undertaken to determine whether his being 'tense' related to muscle and joint stiffness, possible extrapyramidal effects from the haloperidol or that other causes of agitation had been considered. Again, rather than increase the diamorphine, a reduction may have been more appropriate. Similarly, the discontinuation or reduction in the dose of haloperidol, or substitution for

an antipsychotic with a lower risk of causing extrapyramidal effects, e.g. levomepromazine, may have been appropriate.

The nursing notes suggest that Mr Pittock was 'bubbly' due to retained secretions and this appears to be the reason for the hyoscine hydrobromide dose being increased twice in one day from 400 to 600microgram then to 1200microgram SC over 24hours.

xii) The medical notes entry on the 18th January 1996 suggested that Mr Pittock's symptoms were difficult to control but did not document which symptoms. Levomepromazine 50mg SC over 24hours was commenced. This is an appropriate drug to use for terminal agitation when haloperidol is insufficient. The dose is in keeping with that recommended by the BNF and the Wessex Protocol. However, it would have been usual to substitute it for the haloperidol rather than use it concurrently.

If the care is found to be suboptimal what treatment should normally have been preferred in this case?

In relation to the above:

Issue i (lack of clear documentation that an adequate assessment has taken place)

A medical assessment usually consists of information obtained from the patient or others (the history) and the findings of a physical examination that is documented in a structured fashion. Although the history can be restricted to the most salient points, it is unusual to omit relevant sections, e.g. past medical history, drug history, etc.) and given Mr Pittock's medical problems, in

my view, a general examination should have been undertaken and documented.

Reclerking of a patient when a different medical team takes over responsibility of care, helps to ensure that they are aware of the patient's current problems, relevant medical history and physical condition. If new problems subsequently develop, and abnormal physical findings are found on examination, it can be helpful for the doctor when considering the differential diagnosis and management to know if the findings are really new or old. A clear assessment and documentation of subsequent medical care are particularly useful for on-call doctors who may have to see a patient whom they have never met for a problem serious enough to require immediate attention.

Issue ii (lack of adequate assessment and documentation of Mr Pittock's pain and use of Arthrotec).

There should have been an adequate assessment of the patients' condition. If Mr Pittock complained of pain, this should have been noted and attempts made to assess as a minimum the site, severity, aggravating/relieving factors and likely cause of the pain. This is undertaken in order to identify the most likely underlying cause of the pain. Different pain relieving approaches can be helpful for some pains and not others. Knowledge of the cause of the pain thus provides a rational basis to how the pain is managed. Without a documented pain assessment I am unable to comment on the appropriateness of the use of Arthrotec.

The prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issue iii (lack of adequate assessment and documentation of Mr Pittock's painful right hand)

There should have been an adequate assessment of the patients' condition. If a patient is experiencing what sounds like tetany (painful muscle spasms), the possible causes of this should be considered and appropriate investigations carried out. As a minimum, in my view, blood levels of calcium should have been measured, as if low, simple replacement of calcium could have improved a distressing symptom. It would be a reasonable course of action to be taken by all but the junior of doctors.

Issue iv (possible inappropriate use of opioids for Mr Pittock's anxiety and agitation)

It should be clarified for what reason Dr Barton was considering the use of opioids. Opioids are not indicated for the relief of anxiety and agitation per se. The prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issue v (lack of adequate documentation regarding the use of oral morphine/lack of adequate assessment and documentation of Mr Pittock's pain)

There should be clear documentation in the medical notes of why and when the morphine was commenced. If it were for pain, attempts should have been made to assess as a minimum the site, severity, aggravating/relieving factors and likely cause of the pain.

Issue vi (lack of adequate documentation regarding the prescription of the syringe driver 'as required' on 10th January/ prescription of treatment that may exceed the patients' needs)

There should have been clear documentation in the medical notes as to why a syringe driver was prescribed 'as required'. It is unusual to prescribe a syringe driver 'as required' especially containing drugs with a range of possible doses. This is because of the inherent risks that would arise from a lack of clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing a drug as a range, particularly a wide range, is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. It is not usual in my experience for such decisions to be left for nurses to make alone.

If there were concerns that a patient may experience, for example, episodes of pain, anxiety or agitation, it would be much more usual, and indeed seen as good practice, to prescribe appropriate doses of morphine/diamorphine, diazepam/midazolam and levomepromazine respectively that could be given intermittently 'as required' orally or SC. This allows a patient to receive what they need, when they need it, and guides the doctor in deciding if a regular dose is required, the appropriate starting dose and subsequent dose titration.

The daily dose of diamorphine 40mg–80mg, rewritten one day later as 80–120mg is not justified at all in the notes. It is likely to be excessive for Mr Pittock's needs. An appropriate dose of diamorphine would have been 10–15mg in 24hours. Doses of opioids excessive to a patient's needs are associated with an increased risk of drowsiness, delirium, nausea and vomiting and respiratory depression.

The reasons for the inclusion of midazolam and hyoscine hydrobromide in the syringe driver should also have been documented. Decisions made and the prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issues vii and viii (lack of adequate documentation regarding the change in medication)

There should be clear documentation in the medical notes of why the diazepam was increased and the sertraline and lithium carbonate were discontinued. Decisions made and the prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issue ix (lack of adequate documentation regarding the prescription of the syringe driver on 15th January/prescription of treatment that may exceed the patients' needs)

There should be clear documentation in the medical notes of why the syringe driver was commenced containing those drugs. In particular, why a dose of diamorphine, that exceeded his current opioid requirements was justified. An appropriate dose of diamorphine would have been 10–15mg in 24hours. Doses of opioids excessive to a patient's needs are associated with an increased risk of drowsiness, delirium, nausea and vomiting and respiratory depression. Decisions made and the prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issue x (lack of adequate assessment and documentation of Mr Pittock's agitation)

There should have been an adequate assessment of Mr Pittock's agitation. This would have included considering, as a minimum, if any of the common causes of agitation were possibly contributing to his agitation (e.g. as listed in the Wessex protocol pages 30, 34). The assessment should have been documented in the medical notes. Such an approach should have allowed consideration if drugs (or their withdrawal) were a possible contributory factor to Mr Pittock's agitation. In particular, whether the dose of opioid was appropriate and not excessive to his needs.

Issue xi (lack of adequate documentation regarding the change in dose of drugs in the syringe driver on the 17th January 1996)

There should be clear documentation in the medical notes as to why the dose of diamorphine was increased to 120mg, the midazolam to 80mg SC over 24hours and the hyoscine hydrobromide dose increased twice from 400 to 600 microgram then to 1200microgram SC over 24hours.

Issue xii (lack of adequate assessment and documentation of Mr Pittock's symptoms, willingness to consult colleagues)

If symptoms are 'difficult to control', this should prompt an adequate (re)assessment to carefully (re)consider the possible contributing factors to ensure that all reasonable steps had been taken to attend to any underlying causes as appropriate.

If, despite the initial management plan, symptoms are 'difficult to control', it would also be seen as good practice for a doctor to seek additional

information or advice. There is no documentation in the notes that suggests that Dr Barton did this, for example, seeking additional information or advice from the Wessex protocol, one of the consultants, another colleague or a member of the palliative care team.

If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

Dr Barton had a duty to provide good palliative and terminal care and an integral part of this is the relief of pain and other symptoms to ensure the comfort of the patient. In doing so, as in every form of medical care provision, she would be expected to demonstrate a good standard of practice and care. In this regard, Dr Barton fell short of a good standard of clinical care as defined by the GMC (Good Medical Practice, General Medical Council, October 1995 pages 2–3) with particular reference to a lack of clear note keeping, adequate assessment of the patient, providing treatment that was excessive to the patients' needs and willingness to consult colleagues.

Most significantly, the dose range of diamorphine prescribed for the 'as required' syringe driver, and the dose finally administered (80mg), far exceeded that generally considered to be an appropriate starting dose (10–15mg) given Mr Pittock's existing opioid usage. It is unclear how Dr Barton determined or justified this dose. A dose of diamorphine excessive to Mr Pittock's needs would be associated with an increased risk of drowsiness, confusion, agitation, nausea and vomiting and respiratory depression.

Mr Pittock was described as tense and agitated several times following the syringe driver being commenced. This may have been due to a number of reasons, e.g. his depression, the developing pneumonia or a terminal

agitation. In this regard the use of midazolam, haloperidol and levomepromazine could be seen as justified. However, an assessment of the possible causes of his agitation should have been carried out, particularly if seen as difficult to manage. This would have included considering if drugs, such as the diamorphine, were a possible contributing factor to his agitation. At the very least, it should have prompted a review of the appropriateness of Mr Pittock's dose of diamorphine.

In patients with cancer, the use of diamorphine and other sedative medications (e.g. midazolam, haloperidol, levomepromazine) when appropriate for the patients needs, do not appear to hasten the dying process. This has not been examined in patients dying from other illnesses to my knowledge, but one would have no reason to suppose it would be any different. The key issue is whether the use and the dose of diamorphine and other sedatives are *appropriate* to the patients needs. In situations where they are inappropriate or excessive to the patients needs, it would be difficult to exclude with any certainty that they did not contribute more than minimally, negligibly or trivially to the death of the patient. Although the principle of double effect could be invoked here (see technical issues), it remains that a doctor has a duty to apply effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose of strong opioid that was *appropriate* and not excessive for a patient's needs.

There appears little doubt that Mr Pittock was 'naturally' coming to the end of his life. His death was in keeping with a progressive irreversible physical

decline, documented over several weeks by different medical teams, accompanied in his terminal phase by a pneumonia. At best, Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mr Pittock a peaceful death, albeit with what appears to be an excessive use of diamorphine. This may have been due to an apparent lack of sufficient knowledge, illustrated, for example, by the prescription and use of doses of diamorphine by syringe driver that were inappropriately large for Mr Pittock's circumstances and did not reflect his current opioid requirements; the reliance on large dose ranges of diamorphine by syringe driver rather than a fixed dose along with the provision of smaller 'as required' doses that would allow Mr Pittock's needs to guide the dose titration; and a lack of consideration that the opioids may have been aggravating his agitation. It is my opinion however, that given the lack of documentation to the contrary, Dr Barton could also be seen as a doctor who breached the duty of care she owed to Mr Pittock by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mr Pittock by unnecessarily exposing him to excessive doses of diamorphine that could have resulted in a worsening of his agitation. Dr Barton's response to this was to further increase Mr Pittock's dose of diamorphine. Despite the fact that Mr Pittock was dying 'naturally', it is difficult to exclude completely the possibility that a dose of diamorphine that was excessive to his needs may have contributed more than minimally, negligibly or trivially to his death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

9. LITERATURE/REFERENCES

British National Formulary 29 (March 1995).

Prescribing in Terminal Care, pages 12–15.

British National Formulary 47 (March 2004).

Good Medical Practice, General Medical Council, October 1995, pages 2–3.

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition

'Wessex Protocol' Salisbury Palliative Care Services May 1995.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: Code A Date: 25th April 2005

DRAFT REPORT

regarding

STATEMENT OF DR JANE BARTON

RE: LESLIE PITTOCK (BJC/71)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. INSTRUCTIONS

To examine and comment upon the statement of Dr Jane Barton re: Leslie Pittock. In particular, if it raises issues that would impact upon any expert witness report prepared.

2. DOCUMENTATION

This Report is based on the following documents:

[1] Statement of Dr Jane Barton RE: Leslie Pittock as provided to me by Hamsphire police (signed and dated 3-3-05).

[2] Statement of Dr Jane Barton as provided to me by Hampshire police (undated).

[3] Report regarding Leslie Pittock (BJC/71) Dr A Wilcock, 25th April 2005.

3. COMMENTS

Having compared and contrasted the above documentation, I make the following comments that in my view may be relevant. They are in the order in which they arise in the Statement of Dr Jane Barton RE: Leslie Pittock.

Points 3 and 4

In the statement of Dr Jane Barton, Dr Barton outlines that in 1998, the demands on her time were such that firstly her note keeping suffered in consequence and that the medical records did not set out each and every review with a full assessment of a condition of a patient at any given point. Secondly, in relation to prescribing she felt obliged to adopt a policy of proactive prescribing. In the statement Dr Jane Barton RE: Leslie Pittock, Dr Barton states that this also applied to 1996.

Point 13

Dr Barton states that given the very considerable interval of time she now has no real recollection of Mr Pittock. Given the lack of adequate documentation in the medical records, subsequently a number of the points she makes are based on what she believed she would have done (e.g. points 15, 18, 21, 23, 24, 25, 29, 31, 34, 41, 42).

Point 16

Dr Barton clarifies that the illegible words in the medical notes entry of the 9th of January 1996 were not '*try hot water*' but 'try arthrotec'. It remains unclear what assessment Dr Barton made of Mr Pittock's painful hand, the possible cause(s) of it and therefore why arthrotec was deemed an appropriate treatment.

Point 18

Dr Barton highlights that the arthrotec was prescribed on the 8th January 1996 prior to her entry regarding the pain in Mr Pittock's hand on the 9th January 1996. She states she does not know if the date is an error or she had seen him the previous day and prescribed the arthrotec, and made a substantive note the following day.

She also states that she noted Mr Pittock had increased anxiety and agitation and raised the possibility that it might be necessary to increase the diazepam and prescribe opiates. Dr Barton should be asked to clarify exactly why she felt the opioids were indicated. In my view opioids are not indicated for the primary relief of anxiety or distress.

Point 19

Dr Barton states that Dr Tandy noted Mr Pittock's dementia. I think this should be depression. Mr Pittock's depression was a major problem and well documented. However, dementia was not previously mentioned anywhere in his medical records.

Point 21

Dr Barton states that she prescribed oramorph for Mr Pittock on the 10th January 1996, 'no doubt in consequence of liasing with Dr Tandy at the time of the ward round'. She indicates that it would have been for the relief of pain, anxiety and distress. Dr Barton does not clarify which pain this refers to. In my view opioids are not indicated for the primary relief of anxiety or distress.

Dr Barton also states that she proactively wrote up a prescription for diamorphine and a dose range of 40–80mg subcutaneously over 24hours, together with the 200–400microgram of hyoscine and 20–40microgram of midazolam. She states that 'we were concerned that the oramorph might be insufficient and that further medication should be available just in case he needed it'. Dr Barton does state who 'we' refers to, clarifies the basis for the concern that the oramorph might be insufficient, nor justifies why that dose of diamorphine was considered necessary. Dr Barton should be asked to explain why, given her stated concern, 'as required' oral or SC doses of (dia)morphine or a benzodiazepine (e.g. diazepam/midazolam) were not considered appropriate.

Point 23

Dr Barton states that the following day she rewrote the proactive prescription for the hyoscine, diamorphine and midazolam, with the latter two drugs at a slightly greater level than had been written the previous day, i.e. diamorphine 80–120mg and midazolam 40–80mg. Dr Barton states that she would have been concerned that although it was not necessary to administer the medication at that stage, Mr Pittock's pain, anxiety and distress might develop significantly and that appropriate medication should be available to relieve this if necessary. I do not understand the logic behind this explanation. Mr Pittock had not required the syringe driver prescribed from the day before and so Dr Barton would have no way at all of knowing or in anyway anticipating that an even greater level of these two drugs would be necessary.

Points 24, 25 and 26

Dr Barton states that she believes she would have seen Mr Pittock on Monday 15th January 1996 and that she may have been told that his condition had deteriorated considerably over the weekend and 'he appeared to be experiencing marked agitation and restlessness and to be in significant pain and distress'. She anticipates that due a lack of time she did not make a clinical entry in the notes but that diamorphine 80mg, midazolam 60mg and hyoscine hydrobromide 400microgram were commenced via syringe driver at 08.25am that day.

Dr Barton has not described why she considered a syringe driver to have become necessary when Mr Pittock appeared to have been taking his oral medications. There was no mention in the nursing notes of pain, retained secretions, agitation or anxiety that day. Dr Barton does not state for what pain

the diamorphine was used. Dr Barton states that she 'tried to judge the medication, including the increase in the level of opiates, to ensure that there was appropriate and necessary relief of his (Mr Pittock's) condition, whilst not administering an excessive level, and to ensure that this relief was established rapidly and maintained through the syringe driver'. These are reasonable aims. However, Dr Barton does not illustrate in a clear way how the dose of diamorphine was determined and it would be helpful for Dr Barton to specifically state on what basis a dose of 80mg was selected.

She states that she had to take into account the fact that the lithium and sertraline with their additional sedative effects had previously been discontinued and that he would have developed some tolerance to the oral regime. Dr Barton should be asked to clarify which aspects of Mr Pittock's oral regime she believes tolerance would have developed to. Tolerance to a drug means that over time an increasing dose would be required to have the same effect. It is likely he would have developed tolerance to benzodiazepines as he had been a long-term user of diazepam. As such it would be seen as reasonable to use a larger than usual starting dose of the midazolam particularly when taking the discontinuation of the lithium and sertraline into account. However, as Mr Pittock had only been receiving opioids for four days, tolerance is unlikely to have developed and would not in my view be an acceptable reason to justify such a relatively large increase in his opioid dose.

Points 28 and 29

On the 16th January 1996, Dr Barton states that 'Mr Pittock's condition remained very poor and that there had been some agitation when he was being attended to. It would appear therefore that the medication commenced the

previous day had been largely successful in relieving Mr Pittock's condition, but not entirely. At the same time, it would seem that Mr Pittock's pain, distress and agitation had been such that he was indeed tolerant to the medication given, including the level of diamorphine I felt appropriate'. I do not understand fully Dr Barton's final sentence and she should be asked to clarify exactly what she means by it.

It remains unclear if Dr Barton assessed the cause of Mr Pittock's agitation and considered the possible underlying cause(s). Of particular relevance to Mr Pittock would be drugs (or their withdrawal) particularly the use of opioids, hyoscine hydrobromide and benzodiazepines (e.g. midazolam).

Whilst haloperidol is a reasonable part of the approach to treating delirium for terminal agitation, its use should not be a substitute for considering other causes of agitation that may need to be addressed.

Point 31

On the 17th January 1996 Dr Barton states that due to Mr Pittock being tense and agitated she increased the level of his diamorphine to 120mg. She states this was with the specific aim of relieving the agitation. Dr Barton should be asked to state on what basis, recommendation or guidelines she was using diamorphine for the specific aim of relieving agitation. Diamorphine is not indicated for the relief of agitation and is not mentioned as a treatment for such in contemporary guidelines such as the Wessex Protocol or the BNF Prescribing in Palliative Care section. Again from the medical, nursing notes and Dr Barton's statement it remains unclear if an assessment of the possible causes of his agitation was undertaken. Increasing the haloperidol to 10mg and

the hyoscine to 600microgram were reasonable steps based on his agitation and retained respiratory secretions.

Points 34 and 35

Dr Barton states that in the entry dated the 18th January 1996 she noted 'difficulty controlling symptoms, try nozinan' (levomepromazine). Which symptoms were difficult to control are not specified but Dr Barton believes that it was for Mr Pittock's agitation. Haloperidol was increased to 20mg and levomepromazine 50mg was added to the syringe driver. Increasing the dose of antipsychotic medication for terminal agitation is reasonable but Dr Barton should be asked to explain why the levomepromazine was given in addition to the haloperidol rather than substituted for it. It remains unclear if Dr Barton undertook an assessment of Mr Pittock's agitation.

Point 36

Dr Barton states that the nursing notes record that Mr Pittock appeared comfortable in between attentions. She infers from this that he had adequate relief from symptoms but would experience pain, distress and agitation when receiving care. Dr Barton should be asked to clarify why if this was the case the syringe driver not modified again; why smaller doses of the diamorphine, midazolam, levomepromazine or haloperidol and hyoscine hydrobromide were not prescribed 'as required' to be administered prior to turning Mr Pittock; and if, given that the symptoms were difficult to control, whether she sought advice?

Points 38, 39 and 40

Dr Barton states that 'Dr Briggs would have been advised of Mr Pittock's condition and the drug regimen. The only modification was in the antipsychotic medication (levomepromazine), it would seem that Dr Briggs did not consider the general regimen to be inappropriate.....'. Dr Briggs should be asked for his view of this.

4. CONCLUSION

Dr Barton admits to poor note keeping and proactive prescribing due to time pressures in 1996. Even with significant episodes in Mr Pittock's care however, no entry was made. Having read Dr Barton's statement regarding Mr Pittock, I believe that the main issues raised in my report (BJC 71), dated 24th April 2005, remain valid and have not yet been satisfactorily addressed due to a lack of clarity regarding:

- the nature of Mr Pittock's pain and its possible cause(s)
- the justification for the proactive prescribing of a syringe driver containing *diamorphine, hyoscine and midazolam 'just in case he needed it'*
- the lack of use of 'as required' doses of the above drugs instead of, or subsequently, alongside the syringe driver
- the basis for Dr Barton's use of diamorphine specifically for the relief of agitation
- the lack of assessment of the possible cause(s) of Mr Pittock's agitation
- how the dose of diamorphine Mr Pittock ultimately received (80mg) was calculated in a way that can be clearly related to his existing dose of opioid
- given the difficulty of controlling the symptoms, whether Dr Barton sought advice.

As some of the above points relate directly to Dr Barton's knowledge of the management of pain and other symptoms in a palliative care setting it would be helpful if she could state what specific training she had received in relation to

this. In particular, where she obtained her understanding from with regards to the indications for the use of morphine/diamorphine, the phenomenon of tolerance to opioids, the methods of determining an appropriate dose of diamorphine given a patients oral morphine dose and what prescribing guidelines she was aware of and/or followed.

Specific implications of the statement of Dr Barton regarding Mr Pittock regarding my report (BJC 71), dated 24th April 2005

Dr Barton's statement clarifies that the 'arthrotec' (and not 'hot water') was prescribed for Mr Pittock's painful right hand held in flexion. This relates to specific issue ii (pages 23 and 28) in my report.

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DRAFT REPORT

regarding

ROBERT WILSON (BJC/55)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mr Wilson was a 74 year old man who was admitted to hospital after falling over and fracturing the greater tuberosity of his left humerus. He had multiple serious medical problems; alcohol-related cirrhosis leading to liver failure and encephalopathy, heart failure and kidney failure. Other problems included early dementia, depression and a high level of dependency. Although the care he received at Queen Alexander Hospital led to Mr Wilson being mentally more alert and returned his kidney function to normal, he continued to become increasingly oedematous despite the re-introduction of his diuretic therapy which was considered due to heart failure. The pain he experienced from his fracture progressively improved as anticipated and during his time at Queen Alexander Hospital, his daily analgesic requirements reduced from the equivalent of 20mg to 3mg of oral morphine. Nevertheless, given the time it takes for a fracture to heal, it was not surprising that pain on movement was still present at the time of his transfer. There are no concerns regarding the care proffered to Mr Wilson at the Queen Alexander Hospital.

On transfer to Dryad Ward, the care proffered to Mr Wilson by Dr Barton and Dr Knapman fell short of a good standard of clinical care as defined by the GMC (Good Medical Practice, General Medical Council, July 1998 pages 2–3) with particular reference to a lack of clear note keeping, adequate assessment of the patient (Dr Barton and Dr Knapman) and providing treatment that could be excessive to the patients needs (Dr Barton). No pain assessment was carried out on Mr Wilson, but his only regular analgesic, paracetamol, was discontinued and prescribed p.r.n. (as

required). Instead of his usual codeine 15–30mg p.r.n., approximately equivalent to morphine 1.5–3mg, he was prescribed morphine 5–10mg p.r.n. for pain relief. He received two doses of 10mg (a total of 20mg/24h) and the next day commenced on regular morphine 10mg every 4h and 20mg at night. In total he received 50mg of morphine in this 24h period, representing a larger dose than that he received in the initial 24h after his fracture. This is against the general expectation that pain from a fracture would have been improving over time and, without a clearly documented pain assessment, it is difficult to justify. However, the impact of this dose of morphine on Mr Wilson is impossible to judge because he deteriorated rapidly in the early hours of the 16th October 1998. The nature of his rapid decline and subsequent death were in keeping with worsening heart failure with or without a sudden event such as a heart attack. This, combined with his liver failure, could easily have precipitated his terminal decline. His reduced level of consciousness could have been due to a hepatic coma precipitated by the morphine or by a reduced level of blood oxygen secondary to the excess fluid on the lungs (pulmonary oedema) due to the heart failure. Later that day a syringe driver was commenced containing diamorphine 20mg/24h and increased over the next 48h to 60mg/24h, equivalent to oral morphine 120–180mg/24h. This increase in dose appears difficult to justify, as Mr Wilson was not reported to be distressed by pain, breathlessness or the secretions and was likely to be excessive for his needs. However, because heart and liver failure could also have led to a reduced level of consciousness, in my opinion, it is difficult to state with

any certainty that the doses of morphine or diamorphine he received would have contributed more than minimally, negligibly or trivially to his death

2. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to his death against the acceptable standard of the day. Where appropriate, if the care is felt to be suboptimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

3. ISSUES

3.1 Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

3.2 If the care is found to be suboptimal what treatment should normally have been proffered in this case?

3.3 If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

4. BRIEF CURRICULUM VITAE

Code A

Code A

5. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Robert Wilson, including the medical certificate of cause of death.

[2] *Full set of medical records of Robert Wilson on CD-ROM.*

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Hampshire Constabulary Summary of Care of Robert Wilson.

[6] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); also referred to as the 'Wessex Protocols.'

[6] *Portsmouth Health Care NHS Trust Policies:*

i) Control of Administration of Medicines by Nursing Staff Policy (January 1997).

ii) Prescription Writing Policy (July 2000).

iii) Policy for Assessment and Management of Pain (May 2001).

iv) Compendium of Drug Therapy Guidelines, Adult Patients (1998).

v) Draft Protocol for Prescription Administration of Diamorphine by Subcutaneous Infusion, Medical Director (December 1999).

vi) Medicines Audit carried out by the Trust referred to as Document 54 on page 52 in the Chi Report (reference 6).

[7] General Medical Council, Good Medical Practice (July 1998).

[8] British National Formulary (BNF). Section on Prescribing in Terminal Care (March 1998).

[9] British National Formulary (BNF). Section on Prescribing in the Elderly (March 1998).

[10] Statement of Dr Jane Barton as provided to me by Hampshire

Constabulary (undated).

[11] Statement of Dr Jane Barton RE: Robert Wilson, 19th May 2005.

[12] Draft Report regarding Statement of Dr Jane Barton RE: Robert Wilson (BJC/55), Dr A Wilcock, 18th January 2006.

[13] Draft overview of Robert Wilson (BJC/55), Dr A Wilcock, 24th November 2005.

[14] Report regarding Robert Wilson, Dr J Marshall, April 2006.

6. CHRONOLOGY/CASE ABSTRACT

Events at Queen Alexander Hospital, September 21st–October 14th 1998

Mr Wilson, a 74 year old man, who lived at home with his wife, was seen in Accident and Emergency on the evening of the 21st September 1998 (page 157 of 642). He had been drinking alcohol and had fallen onto his left shoulder. An x-ray revealed a fracture of the greater tuberosity of the left humerus with 'some displacement' of the fragment (pages 141 and 157 of 642). For pain relief he received morphine 10mg IV (as cyclimorph) at 20.45h; followed by a prescription for morphine 10mg IV at 21.00h, it is unclear if this was given, as a time of administration is not stated (page 157 of 642). His fracture was managed with immobilisation using a sling and analgesia (page 159 of 642). It was necessary to admit Mr Wilson as there was no one at home (his wife was on holiday in Plymouth) and he was feeling nauseated (page 159 of 642).

On the 22nd September 1998, he received 2 kapake (co-codamol 30/500; each tablet containing codeine phosphate 30mg, paracetamol 500mg) at 07.00h. It is unclear if he was receiving this regularly or p.r.n. 'as required'. He was noted to be confused at times (page 161 of 642). Vomiting was a problem and he reported that this normally happened after he had been drinking 'so much alcohol' (page 161 of 642). Mr Wilson was reviewed in fracture clinic where it is reported that he was not keen to undergo surgical fixation of the fracture (page 141 of 642). (He subsequently changed his mind, although by the time of his orthopaedic review on the 6th October 1998, he had again decided against surgery, but was, in any case, then considered unsuitable for surgery (pages 161 and 333 of 642)). As Mr Wilson felt unwell, was vomiting and unsteady on his feet, it became clear that he would not be able to manage at home and he was transferred to Dickens Ward (page 163 of 642).

Mr Wilson was fully clerked at 02.00h on the 23rd September 1998 (page 165 of 642). He reported an increasing cough for the past 6 months, productive of white sputum; vomiting associated with dizziness/vertigo and tingling in the left hand (page 165 of 642). Mr Wilson was known to have alcohol-related liver disease; he had been admitted 18 months earlier with epigastric pain, vomiting and pitting oedema (swelling). Investigations revealed liver cirrhosis, liver failure and fluid in the abdomen (ascites). He received diuretics (water tablets) and vitamins and told to abstain from alcohol (pages 165, 253 and 465 of 642). Mr Wilson's current medication consisted of spironolactone

100mg once a day, furosemide 40mg once a day (both water tablets) thiamine 100mg once a day (a vitamin) and multivitamins (page 110 and 166 of 642). He lived in a house with his second wife and was usually independent. He smoked 40 cigarettes a day until 3 years ago and drank six double whiskies a day (page 166 of 642). Examination revealed his left arm to be painful on palpation and on movement. He was able to move his fingers, had normal sensation to light touch and pulses were present. There was dullness to percussion and crackles at the base of his left lung. Routine blood investigations, a chest x-ray (I could find no comment or report in the notes) and an ECG (electrocardiogram; with inverted T waves in leads II, III and V1 suggestive of poor blood supply to the heart) were undertaken (pages 167, 301 of 642). Mr Wilson was initially for resuscitation in the event of an unexpected cardiorespiratory arrest (page 168 of 642). It was noted that his pain relief was unsatisfactory despite the co-codamol and he was prescribed morphine 2–5mg IV every 4h p.r.n. (pages 106 and 168 of 642). His other medication now consisted of cyclizine 50mg PO/IV p.r.n. (an anti-emetic), paracetamol 1g p.r.n., codeine phosphate 30mg p.r.n., furosemide 40mg once a day, spironolactone 100mg once a day, thiamine 100mg once a day, multivitamins 1 tablet once a day, chlordiazepoxide 15mg four times a day (a benzodiazepine given as a course in a reducing dose to manage alcohol withdrawal) (pages 106, 110, 113 of 642).

Blood test results from the 23rd September 1998 revealed abnormal liver function: bilirubin 67micromol/L (normal 3–20micromol/L), alkaline

phosphatase 120IU/L (normal 30–95IU/L), aspartate aminotransferase (AST) 91IU/L (normal 12–40IU/L), gamma-glutamyl transferase (GGT) 102IU/L (normal 4–45IU/L), albumin 25g/L (normal 37–50g/L) (page 209 of 642). None of these findings were new; abnormal liver function was present 18 months earlier (page 129 of 642). Kidney function was also abnormal: urea 11mmol/L (normal 3–7.6mmol/L), creatinine 178micromol/L (normal 60–120micromol/L) (page 209 of 642). This appeared to be a new finding, not present 18 months earlier (page 195 of 642).

Mr Wilson's analgesic requirements varied over his time at Queen Alexandra Hospital. Between the 23rd and 24th of September 1998, the pain seemed severe and he received three doses of morphine (5mg, 2.5mg and 2.5mg) IV/SC, five doses of codeine 30mg and one dose of paracetamol PO (pages 25 and 106 of 642). Mr Wilson was reviewed early on the morning of 24th September 1998 because of pain in the left arm and reduced forearm sensation. He was discussed with the orthopaedic team and although the pain persisted, it appeared to improve and the left limb pulse, colour and function were monitored regularly and remained satisfactory (pages 25 and 169 of 642).

On the 25th September 1998 he commenced co-dydramol 2 tablets four times a day regularly, providing a daily dose of dihydrocodeine 80mg and paracetamol 4g; together with senna and magnesium hydroxide as laxatives (page 114 of 642). He continued on this regimen until the 30th September 1998 when he was prescribed paracetamol alone (page 114 of 642). The discontinuation of the dihydrocodeine appeared to be in

response to his drowsiness (page 171 of 642). He took the paracetamol erratically, although fairly regularly in the days leading up to his transfer to Dryad Ward on the 14th October 1998 (pages 114 and 115 of 642). Additional analgesia was intermittently required; morphine 2.5mg IM on the 3rd and 5th October 1998 (page 107 of 642) and codeine 30mg, each time as a single dose, on the 8th, 9th, 12th and 13th of October 1998 (page 107 of 642).

A full blood count dated 25th September 1998 was abnormal with a haemoglobin of 10.5g/dL (normal 13–18g/dL), white cell count of 15.1x10^9/L (normal 4–11x10^9/L) due to an increase in neutrophils, platelets 133x10^9/L (normal 150–400x10^9/L) and a mean corpuscular volume (MCV) of 113.4fL (normal 80–96fl) (page 239 of 642). A repeat blood test on the 25th September 1998 also revealed worsening kidney function with urea 17.8mmol/L and creatinine 246micromol/L (pages 170 and 207 of 642). This was acted upon on the 28th September 1998. It was considered due to dehydration; the water tablets furosemide and spironolactone were discontinued and he was given intravenous fluids (page 170 of 642).

On the 27th September 1998, Mr Wilson's second wife returned from holiday and made it clear that she would not be able to care for him in his present condition. The staff explained the concerns about his poor nutritional intake and improving his pain relief. His wife informed the staff that Mr Wilson frequently had nothing to eat all day (page 12 of 642). The pain remained 'bad' in the arm although at night time he was

reported to appear comfortable with regular analgesia (pages 27 and 28 of 642).

On the 29th September 1998, Mr Wilson's first wife visited and expressed concern to the staff about Mr Wilson's low mood. There was friction between Mr Wilson's first wife and children and his second wife whom they considered neglectful of Mr Wilson (page 12 of 642). Because Mr Wilson had not passed urine all day he was catheterised and had a residual volume of 600ml (page 13 of 642). It was noted that he was able to lift his left arm quite well without any pain (page 28 of 642). His resuscitation status was changed to not for resuscitation in the event of an unexpected cardiorespiratory arrest because of his liver failure, kidney failure, poor quality of life and poor prognosis (page 171 of 642).

On the 30th September 1998, Mr Wilson's kidney function had improved with urea 14.4micromol/L and creatinine 165micromol/L (page 171 and 199 of 642). He was noted to be drowsy but did not have a flap (one sign of hepatic encephalopathy; see technical issues) and his temperature was normal. The top of his left arm was oedematous and weeping in small areas (page 14 of 642). The sedative drugs chlordiazepoxide and dihydrocodeine were discontinued (pages 113 and 114 of 642). Mr Wilson had pain in the neck and his arm, had a restless night but was unable to express his needs (pages 29 and 30 of 642).

On the 1st October 1998 it was recorded that his left arm was 'painful+++ on movement' but 'not complaining of pain at rest' (page 30 of 642).

On the 2nd October 1998, Mr Wilson was noted to be very sleepy but to be awake at night. He was noted to be oedematous (swelling of the tissues due to retained fluid) and to have crackles in his chest. These are signs of excess fluid and the IV fluids were discontinued. He was referred to the psychogeriatricians as he was very withdrawn and depressed (page 172 of 642). Mr Wilson expressed that he was desperate for sleep, but was awake at night and asleep during day (page 15 of 648). It was considered that he would require long term care (page 172 of 642). His arm remained painful on movement (page 30 of 642).

Between the 4th and 6th October 1998, Mr Wilson's level of sleepiness improved but pain was still present in his left arm on movement. He was reviewed at the fracture clinic, who advised physiotherapy (pages 31, 32, 173, 174 and 333 of 642). He was not tolerating the sling and so the arm was elevated on pillows (page 16 of 642). Blood tests revealed that Mr Wilson's urea and creatinine had returned to normal (page 201 of 642). On the 4th October 1998 at 23.10h he refused to take oral analgesia and had morphine 2.5mg IM with good effect (page 31 of 642). A further dose of morphine 2.5mg IM was given at 02.00h on the 5th October 1998, as Mr Wilson refused paracetamol, stating that it didn't help (page 32 of 642). On the 6th October 1998, he was reported

to have had a comfortable afternoon but at night that the prescribed analgesia had only a small effect on his arm pain (page 33 of 642).

On the 7th October 1998 he was reported to be brighter, more talkative and eating and drinking more. He walked a short distance with help and expressed the wish to return home (pages 17 and 174 of 642). At night he was reported as uncomplaining (page 33 of 642).

On the 8th October he was reviewed by Dr Lusznat, consultant in old age psychiatry. She noted that Mr Wilson had been sleepy, withdrawn, low in mood with disturbed nights but that he was now eating and drinking well and his mood had improved. Examination found him still to be low in mood, admitting that there was no point in living. He was fully orientated in place, partially orientated in time and had mildly impaired short-term memory, scoring 24/30 on the mini-mental state examination. She noted him to be obese with his left arm in a sling, his left hand grossly swollen and bruised and marked oedema of both legs. Dr Lusznat considered that Mr Wilson may have developed an early dementia which could be alcohol related, or alternatively, an early Alzheimer's or vascular dementia. In addition she considered him depressed and commenced him on the sedative antidepressant trazadone 50mg at night (pages 114 and 118 of 642). Because of the gross oedema, diuretics were recommenced by Dr Ravi, this time as spironolactone 50mg twice a day and bendrofluazide 2.5mg once a day (pages 114 and 176 of 642). At night, the nurses requested stronger analgesia for Mr Wilson and codeine phosphate 30mg p.r.n. was prescribed (pages 35 and 107 of 642).

On the 9th October 1998, his urinary catheter was removed (page 35 of 642). On the 10th October 1998, it was noted that Mr Wilson was a bit brighter and that the swelling in his left arm seemed better (page 177 of 642).

The pain remained variable; on the 11th October 1998 co-dydramol 2 tablets p.r.n. were also prescribed but never administered (pages 35 and 107 of 642). His pain was reported as 'quite bad' but his night was comfortable with regular analgesia (page 35 and 36 of 642). Despite the improvement in his level of alertness and nutritional intake, Mr Wilson's Barthel score (activity level) was still reduced (13 on the 23rd September, 7 on the 11th October 1998)(page 69 of 642).

On the 12th October, it was noted that Mr Wilson 'remains in a lot of pain when being cared for' and had a restless night (page 36 of 642).

On the 13th October 1998, it was noted that Mr Wilson was still very oedematous and his weight was increasing (suggesting increasing fluid retention) and the diuretic furosemide 80mg was commenced (pages 36, 114, 115, 177 and 178 of 642). His weight had progressively increased during his admission from 103.9kg on 27th September 1998 to 114.3kg on 14th October (pages 61, 63, 65 of 642). As he still needed both nursing and medical care it was noted that a 'short spell in long term NHS bed would be appropriate'. Mr Wilson's limbs were considered at high risk of breakdown (his right foot was about to breakdown) due to the oedema caused by heart failure and low protein. He was also considered at high risk of self neglect and injury if he

started to take alcohol again (page 21 of 642). There were no complaints of any pain (page 36 and 37 of 642).

On the 14th October 1998, an entry at 05.00h records that Mr Wilson had had a peaceful night, slept well with no complaints of pain. He was later moved to Dryad Ward at Gosport War Memorial Hospital (pages 37, 177 and 178 of 642). The transfer letter indicated that Mr Wilson was being transferred for continuing nursing care until his arm was healed; that he still had a lot of pain in his arm and difficulty moving it and that his oedematous legs due to heart failure and low protein were at high risk of breaking down. His regular medication was listed but not his codeine 15–30mg p.r.n. (page 81 of 642).

Events at Gosport War Memorial Hospital, Dryad Ward, 14th–18th October 1998

14th October 1998

An entry in the medical notes records that Mr Wilson was transferred to Dryad Ward Continuing Care, his fractured left humerus on the 27th August 1998 (an incorrect date, already acknowledged by Dr Barton) and his past medical history of alcohol problems, recurrent oedema and CCF (congestive cardiac failure). It was noted that he needed help with ADL (activites of daily living) required hoisting, was continent and had a Barthel score of 7. The plan was for 'gentle mobilisation' (page 179 of 642).

He was prescribed furosemide 80mg once a day, spironolactone 50mg twice a day, bendrofluazide 2.5mg once a day, trazadone 50mg once a day, thiamine 100mg once a day, multivitamins 1 tablet once a day, magnesium

hydroxide 10ml twice a day and senna 2 tablets once a day (pages 260 and 261 of 642). The regular paracetamol was discontinued and prescribed p.r.n. instead, although he never received any (page 258 of 642). On the daily review section of the drug chart, 'Regular prescription' was crossed out and replaced with 'p.r.n.' and morphine solution 5–10mg prescribed every 4h p.r.n. (page 262 of 642). He never received a 5mg dose; but 10mg at 14.45h and 23.45h on the 14th October 1998. Although undated, Dr Barton anticipates that on the 14th October 1998, she also prescribed diamorphine 20–200mg SC/24h, hyoscine hydrobromide 200–800microgram SC/24h and midazolam 20–80mg SC/24h (page 262 of 642). The nursing summary for the 14th October 1998 notes 'seen by Dr Barton. Oramorph 10mg in 5ml given (page 265 of 642). His Barthel score was 4 (page 273 of 642). The nursing care plan for 'requires assistance to settle at night' noted that morphine 10mg was given for pain relief (page 278 of 642).

15th October 1998

There was no entry in the medical notes, but Mr Wilson was prescribed morphine 10mg every 4h and 20mg at night. In total he was given 50mg of morphine over the next 24h (page 261 of 642). The nursing summary notes recorded that this was for pain in his left arm and that Mr Wilson's wife was seen by Sister Hamblin who explained that his 'condition is poor' (page 265 of 642). The nursing care plan for 'requires assistance to settle at night' reported that Mr Wilson settled and slept well with morphine 20mg given at 12 midnight but that his condition had deteriorated overnight 'very chesty

and difficulty in swallowing medications, incontinent of urine++'. Morphine 10mg was given at 06.00h (page 278 of 642).

16th October 1998

An entry in the medical notes was made by Dr Knapman, one of Dr Barton's partners. He notes 'declined overnight with shortness of breath. On examination bubbly, weak pulse, unresponsive to spoken orders. Oedema++ in arms and legs. Diagnosis ?silent MI (myocardial infarction; heart attack, silent indicating without pain), ?decreased liver function. Dr Knapman prescribed an additional dose of furosemide 80mg PO (pages 179 and 261 of 642). Mr Wilson received this extra dose once only on the 16th October 1998.

The nursing summary notes record 'seen by Dr Knapman a.m. as deteriorated overnight. Increase furosemide to 80mg daily (although he was already on furosemide 80mg daily; page 260 of 642), for all nursing care. Wife informed of visit this morning' (page 265 of 642). A later entry notes 'p.m. patient very bubbly chest this p.m., syringe driver commenced 20mg diamorphine, 400micrograms hyoscine hydrobromide. Explained to family reason for driver. Wife informed of patient's continued deterioration, has been to visit' (page 265 of 642). The syringe driver was commenced at 16.10h (page 262 of 642).

The nursing care plan for 'requires assistance to settle at night' noted 'has been on syringe driver since 16.30h. Diamorphine 20mg and hyoscine 400microgram. A little bubbly at approximately 22.30h when repositioned/pad changed. More secretions – pharyngeal - during the night

but Robert hasn't been distressed. Appears comfortable' (page 278 of 642).

17th October 1998

An entry in the medical notes was made (according to Dr Barton's statement) by Dr Peters, one of her partners 'comfortable but rapid deterioration. Nursing staff to verify death if necessary' (page 179 0f 642).

The nursing summary notes for the morning recorded '05.15h hyoscine increased to 600microgram as oropharyngeal secretions increasing overnight. Diamorphine 20mg' (unchanged) (page 265 of 642). A later entry noted 'p.m. Slow deterioration in already poor condition. Requiring suction very regularly – copious amounts suctioned. Syringe driver renewed at 15.50h with diamorphine 40mg, midazolam 20mg, hyoscine 800micrograms. Mrs Wilson visited again this evening and is aware that his condition is poorly' (pages 265 and 266 of 642). The drug chart confirms the times and changes in the medication (page 262 of 642).

The nursing care plan 'requires assistance to settle at night' notes '05.15h hysocine increased to 600microgram as secretions increased. During day diamorphine 40mg and hyoscine increased to 800microgram, midazolam 20mg added. Night: noisy secretions but not distressing Robert. Suction given as required during night. Appears comfortable, hot at times' (page 278 of 642).

18th October 1998

The nursing summary notes record 'further deterioration in already poor condition. Wife has remained overnight. Seen by Dr Peters who spoke to Mrs Wilson. Syringe driver renewed at 14.50h with diamorphine 60mg, midazolam 40mg and hyoscine 1200microgram. Continues to require regular suction. His children have also visited' (page 266 of 642). A later entry notes 'p.m. All care has been given. Oral suction has been required and performed. Condition continues to deteriorate' (page 266 of 642). The drug chart confirms the times and changes in the medication (page 262 of 642).

The nursing care plan for 'requires assistance to settle at night' records 'Suctioned at 22.30h for large amounts of sputum. Patient died peacefully at 23.40h (page 278 of 642). Confirmation of death is recorded in the nursing summary notes and in the medical notes by the nursing staff (pages 179 and 266 of 642).

The cause of death was given as '1a (*Disease or condition directly leading to death*) Congestive cardiac failure, 1b (*Other disease or condition, if any, leading to 1a*) Renal failure and 2 (*Other significant conditions contributing to the death but not related to the disease or condition causing it*) Liver failure. The approximate interval between onset and death was given as 2 years for each of the above.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Syringe drivers, diamorphine, midazolam and hyoscine hydrobromide

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24h. Indications for its use include swallowing difficulties or a comatose patient. In the United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF 35, March 1998). Others sometimes suggest dividing by 2 or 3 depending on circumstance (Wessex protocol). Hence, 60mg of morphine taken orally a day could equate to a daily dose of 20 or 30mg of diamorphine SC. It is usual to prescribe additional doses for use 'as required' in case symptoms such as pain breakthrough. The dose is usually 1/6th of the 24h dose. Hence for someone receiving 30mg of diamorphine in a syringe driver over 24h, a breakthrough dose would be 5mg. One would expect it to have a 2–4h duration of effect, but the dose is often prescribed to be given hourly as required. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in their terminal phase would generally aim to find a dose that improves the patients' symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg a day. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (BNF 35, March 1998) recommends 20–100mg SC over 24h. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated every 24h if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24h, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4h, and it may need to be given more frequently. As an active metabolite of midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

Hyoscine hydrobromide is an antimuscarinic drug most commonly given to reduce excessive saliva or retained secretions ('death rattle'). It also has

anti-emetic, antispasmodic (smooth muscle colic) and sedative properties. Repeated administration can lead to cummulation and this can occasionally result paradoxically in an agitated delirium, highlighted in both in the BNF and the Wessex protocol (page 41). It is usually given in a dose of 600–2400microgram SC over 24h (BNF 35, March 1998) or 400–600microgram as a stat SC dose. The Wessex protocol gives a dose range of 400–1200microgram over 24h.

The titration of the dose of analgesic or sedative medication is guided by the patients symptom control needs. The number and total dose of p.r.n. doses needed over a 24h period are calculated and this guides the increase necessary in the regular dose of the drugs in the syringe driver in a way that is proportional to the patients needs. The ideal outcome is the relief of the symptoms all of the time with no need for additional p.r.n. doses. In practice, this can be difficult to achieve and the relief of the symptoms for the majority of the time along with the use of 1–2 'as required' doses over a 24h period is generally seen as acceptable.

ii) The principle of double effect

The principle of double effect states that:

'If measures taken to relieve physical or mental suffering cause the death of a patient, it is morally and legally acceptable provided the doctor's intention is to relieve the distress and not kill the patient.'

This is a universal principle without which the practice of medicine would be impossible, given that every kind of treatment has an inherent risk. Many discussions on the principle of double effect have however, involved the use

of morphine in the terminally ill. This gives a false impression that the use of morphine in this circumstance is a high risk strategy. When correctly used (i.e. in a dose *appropriate* to a patient's need) morphine does not appear to shorten life or hasten the dying process in patients with cancer. Although a greater risk is acceptable in more extreme circumstances, it is obvious that effective measures which carry less risk to life will normally be used. Thus, in an extreme situation, although it may occasionally be necessary (and acceptable) to render a patient unconscious, it remains unacceptable (and unnecessary) to cause death deliberately. As a universal principle, it is also obvious that the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

iii) Hepatic (liver) encephalopathy

Hepatic encephalopathy is a life-threatening condition that arises when toxic substances, usually removed by the liver, cumulate in the blood (e.g. ammonia). It causes confusion, disorientation, abnormal neurological signs, loss of consciousness and death. It is common in patients with chronic liver disease/cirrhosis who binge drink or develop an acute infection. It can also be precipitated by, for example:

- gastrointestinal bleeding
- constipation (increases nitrogen-containing compounds)
- dehydration (cumulation of nitrogen-containing compounds, e.g. urea)
- electrolyte imbalances (e.g. low levels of potassium)

- drugs such as sedatives (e.g. opioid analgesics) or diuretics (via dehydration ± low potassium)
- reduced levels of oxygen (hypoxia).

Symptoms of hepatic encephalopathy range from minor changes in personality, energy levels and cognition to deep coma. There may be inappropriate behaviour, lack of interest in personal grooming, mood swings and poor judgment. The patient may be less alert than usual and develop new sleep patterns. Movement and speech may be slow and laboured.

As the disease progresses, patients become confused, drowsy, and disoriented. The breath and urine acquires a sweet, musky odour. The hands shake, the outstretched arms flap ('liver flap') and the patient may lapse into unconsciousness. Agitation occasionally occurs. Seizures are uncommon.

Confusion, disorientation, and other signs of impaired brain function strongly suggest encephalopathy in patients known to have liver disease. Management consists, when possible, of treating reversible causes, removing or avoiding precipitating factors, improving liver function and decreasing the body's production of toxic substances. For example, non-essential medications are discontinued, antibiotics, enemas or laxatives are used to decrease the production of ammonia by bacteria in the intestine and dietary protein intake is reduced.

Encephalopathy may be reversible if the responsible factor is identified and removed or treated. Patients whose condition is the result of chronic liver disease may recover completely after the underlying cause is corrected. However, those with chronic liver failure often die in hepatic coma.

8. OPINION

Events at Queen Alexander Hospital, September 21st–October 14th 1998

Mr Wilson was a 74 year old man with alcohol-related cirrhosis and liver failure. He had fallen after drinking alcohol and fractured the greater tuberosity of his left humerus which showed 'some displacement' of the fragment. Other problems around the time of his initial admission were vomiting, unsteadiness on his feet, vertigo and intermittent confusion, also likely to be related directly or indirectly to alcohol. I note that Dr Marshall considers hepatic encephalopathy a likely explanation for some of Mr Wilson's problems (see technical issues).

Blood tests confirmed liver failure as noted previously. However, on this admission his kidney function was also abnormal, most likely related to dehydration. Urinary retention may also have contributed. Further, liver failure can also compromise the blood supply to the kidneys leaving them more prone to damage from insults such as dehydration. On receiving intravenous fluids and discontinuing his diuretics, Mr Wilson became increasingly oedematous. This can be a direct consequence of severe liver failure, which results in a low level of protein in the blood stream; this in turn allows fluid to be drawn out of the blood stream and into, for example, the subcutaneous tissues or abdomen, resulting in oedema or ascites respectively. Because the blood volume is reduced the kidneys retain more water, creating a vicious circle. Increasing oedema would also occur as a consequence of heart failure which was considered a problem for Mr Wilson. His heavy smoking would have increased his risk of heart problems (his ECG was suggestive of a reduced blood supply to the heart)

and alcohol can directly damage the heart. The chest X-ray film or report should be sought, as this may also provide evidence of heart failure. The fluids were stopped and although the diuretics were recommenced his weight (and hence fluid retention) continued to increase. By the time of his transfer, he was receiving a larger dose of diuretic than on admission and his weight had increased by about 10kg, equivalent to about 10L of (additional) retained fluid.

During his admission, Mr Wilson did improve with regard to his level of alertness. He was more talkative and eating and drinking more. There may be several reasons for this improvement; abstinence from alcohol, discontinuation of sedative drugs; correction of his dehydration and better nutritional intake. Nevertheless it was considered likely that he had an alcohol-related early dementia, a depression and he remained dependent on others for his care.

I note that the orthopaedic team considered surgical fixation of the displaced tuberosity, only to ultimately decide against this, based on Mr Wilson's wishes and clinical condition. I am not an expert in orthopaedics, nor have I seen the X-rays and thus I am unsure to what extent the 'some displacement' of the fragment could impact upon the anticipated clinical course of the fracture I describe below. If this aspect of the case is considered important, the opinion of an orthopaedic surgeon should be obtained. However, it is my general understanding that pain from this sort of a fracture can initially be severe enough to require strong opioids. Subsequently, the main approaches for pain relief would be immobilisation and weak opioids as proffered to Mr Wilson. Movement is likely to

aggravate the pain until the fracture begins to heal, a process that can take several weeks and not be fully complete for 12 weeks (although there is wide variation). Nevertheless, one would anticipate that Mr Wilson's pain would improve so that he was pain-free when the limb was at rest, followed by a progressive improvement in the movement-related ('incident') pain. Attempting to provide sufficient analgesia to manage incident pain can be difficult; the dose of opioid required to fully relieve the pain on movement can be excessive for the patient whom for the majority of the time is resting and pain free. Typically in this situation the patient becomes increasingly drowsy as the dose of opioid increases.

Thus, it was not unusual that Mr Wilson initially had severe pain and he received at least one and possibly two doses of morphine 10mg IV in the Accident and Emergency department. The dose of morphine the BNF recommends for acute pain varies with the route of administration: 10mg (15mg for heavier patients) SC or IM, and one quarter to one half of this dose if given IV (i.e. up to 7.5mg IV in heavier patients). Although Mr Wilson was heavy (about 100kg) he also had severe liver failure and it would have been prudent in my opinion to have used smaller doses, as he was subsequently prescribed (e.g. 2.5–5mg morphine IV/SC). Mr Wilson was treated with a sling and initially prescribed analgesia to be given as required; the most he received in one day was on the 24th September 1998 consisting of morphine (total of 5mg IV/SC), codeine (total 90mg) and paracetamol 1g. The oral morphine equivalent of this combination of morphine and codeine is approximately 20mg. Subsequently he was prescribed co-dydramol 8 tablets a day regularly (a total of dihydrocodeine

80mg; the oral morphine equivalent is approximately 8mg). This was discontinued after 6 days as Mr Wilson was drowsy, leaving him just on paracetamol. It is possible that the dihydrocodeine could have been aggravating his hepatic encephalopathy and he did subsequently improve. However, he had also been receiving chlordiazepoxide, a sedative benzodiazepeine, which was discontinued at the same time.

The reports regarding Mr Wilson's level of comfort did vary. This may relate to varying levels of activity causing movement-related pain or his depressed mood. His pain also appeared more bothersome at night. This is not unusual and thought partly due to there being less happening at night to distract the persons' attention away from the pain. Whatever the cause, there were times when the paracetamol alone appeared ineffective or inadequate for Mr Wilson's analgesic requirements and a small number of additional doses of morphine and codeine were administered. However, this never exceeded morphine 2.5mg IM (last dose on the 5th October 1998) or codeine 30mg in one day, an oral morphine equivalent of 3–5mg. Given this infrequent use of additional analgesia, in my opinion, the approach to Mr Wilson's analgesia was reasonable. Although the transfer letter noted 'still has a lot of pain in his arm and difficulty moving' overall his analgesic requirements had reduced over the course of his admission; over the 48h prior to his transfer his only analgesia was paracetamol 1g four times a day along with only one additional dose of codeine 30mg each day. Further, the nursing daily summary notes for the 13th October 1998 reported no complaints of pain from Mr Wilson, and the entry dated the 14th October 1998, the day of his transfer, noted that Mr Wilson had had a

peaceful night, slept well with no complaints of pain. I have no concerns regarding the care proffered to Mr Wilson at the Queen Alexander Hospital. Although Dr Marshall suggests that high dose vitamins IV and lactulose should also have been considered, I note that he also concludes that Mr Wilson's care at Queen Alexander Hospital was 'not perfect but very reasonable'.

Events at Dryad Ward, 14th October–18th October 1998.

Infrequent entries in the medical notes during Mr Wilson's stay on Dryad Ward make it difficult to closely follow his progress over the last four days of his life. There are three entries prior to the confirmation of death taking up less than one page in length. In summary and in approximate chronological order, Mr Wilson was admitted to Dryad Ward for 'gentle mobilisation'. There was a brief history but no pain assessment or examination documented in the medical notes. The transfer letter listed his regular medication, but omitted to note that he was also prescribed codeine phosphate 15–30mg p.r.n. Mr Wilson's regular medication was continued largely unchanged on Dryad Ward, but his regular paracetamol was discontinued and made p.r.n. If pain was considered such a problem for Mr Wilson, it unclear why his only regular analgesic was discontinued. He was prescribed morphine solution 5–10mg p.r.n. for pain relief. As required analgesics are sometimes written as a choice of two doses that cover a small dose range, but the effect of the smaller dose is generally evaluated first and it is unclear why this did not happen; Mr Wilson received two doses of 10mg on the day of his arrival on Dryad Ward.

Although Mr Wilson was transferred for 'gentle mobilisation' it is of concern that on the day of his transfer he was also prescribed diamorphine 20–200mg SC/24h, hyoscine hydrobromide 200–800microgram/24h and midazolam 20–80mg SC/24h. There appeared to be no immediate indication for the prescription of these drugs in these dose ranges. In particular, the dose range of diamorphine, equivalent to 40–600mg of oral morphine/24h, in my opinion, contains doses that would likely be excessive to Mr Wilson's needs.

On the day following his admission Mr Wilson was commenced on regular oral morphine 10mg every 4h and 20mg at night. The nursing summary notes recorded that this was for pain in his left arm. In total he received 50mg of morphine in this 24h period, representing a larger dose than he received in the initial 24h after his fracture. This is against the general expectation that pain from a fracture would have been improving over time and, without a clearly documented pain assessment, it is difficult to justify. He had required two p.r.n.s of morphine in the previous 24h and this generally suggests regular analgesia is required. However, as the total dose he received was 20mg/24h, in my opinion an equivalent dose, i.e. morphine 2.5mg every 4h and 5mg at night (20mg/day) would have been most prudent.

However, the impact of this dose of morphine on Mr Wilson is impossible to judge. He deteriorated rapidly in the early hours of the 16th October 1998 becoming 'very chesty, difficulty in swallowing medications and incontinent of urine'. When reviewed later that day by Dr Knapman it was noted that he had declined overnight with shortness of breath, he was 'bubbly' (retained

secretions causing noisy breathing), had a weak pulse and was not able to respond. The doctor made a clinical diagnosis of a silent (i.e. without chest pain) myocardial infarction and decreased liver function. As an additional dose of furosemide 80mg was given, this suggests that the doctor considered pulmonary oedema (fluid in the lungs) was responsible for his shortness of breath. The nature of his rapid decline and subsequent death could be in keeping with worsening heart failure precipitated by a sudden event such as a myocardial infarction. His reduced level of consciousness could have been due to hepatic encephalopathy precipitated by the morphine or by a reduced level of blood oxygen secondary to the pulmonary oedema. A respiratory rate and oxygen saturation level were not recorded in Mr Wilson and it is difficult to comment further regarding respiratory depression. Very rarely, pulmonary oedema has been reported following an opioid overdose, mainly in IV drug users; to my knowledge, there has been only one published case of possible opioid-induced pulmonary oedema in a patient with cancer following a rapid escalation in the dose of morphine given IV (200mg → 2,000mg/24h increased over 6 days for unrelieved pain). It is generally associated with the rapid administration of a dose large enough to cause sudden onset respiratory depression and hypoxia. There may also be release of the chemical histamine in the lungs. Both hypoxia and histamine cause the blood vessels in the lung to become leaky, resulting in pulmonary oedema. However, in my opinion, this is unlikely to have been a contributing factor to Mr Wilson's pulmonary oedema, partly because there was no such problem when he received the largest and most rapidly administered dose of

morphine (10mg IV) at the time of his fracture. Further, Mr Wilson had documented increasing fluid retention and heart failure which would put him at risk of a sudden deterioration leading to pulmonary oedema. This, combined with his liver failure, could easily have precipitated his terminal decline. It would have been appropriate to have excluded an abnormal heart rate or rhythm as a cause of his heart failure as this may have been reversible; there was no record of his pulse rate at the time of his deterioration and it is difficult to comment further. However, as Mr Wilson had most likely entered a terminal decline, providing symptom relief 'comfort' measures only was appropriate. If he was distressed by the breathlessness, this could still have included giving oxygen and trying to reduce the pulmonary oedema with diuretics IV, nitrates sublingual/IV and opioids IV. Mr Wilson was described as unresponsive to commands and only given an increased dose of diuretic PO rather than IV, suggesting that he may not have been that distressed. However, the fact he took the diuretic PO does suggest he was at that time conscious enough to swallow tablets.

At 16.10h on the 16th October 1998, a syringe driver was commenced containing diamorphine 20mg/24h, equivalent to oral morphine 40–60mg/24h and hyoscine hydrobromide 400microgram/24h. Although the hyoscine was most likely to be for the secretions, there is no entry relating to the syringe driver in the medical notes and the indication for the use of the diamorphine is not documented in the nursing notes. It is unclear if the nursing staff contacted Dr Barton or the duty doctor before the syringe driver was commenced as was 'the usual way' indicated by Dr Barton in her

statement. It may have been simply to replace the dose of oral morphine he had been prescribed and if the comfort of a patient is in doubt in the terminal stage, this could be seen as reasonable. However, it is subject to the same comments as the oral dose and, thus, in my opinion, diamorphine 10mg/24h CSCI would have been a more reasonable dose. It is of note that despite the pharyngeal secretions, Mr Wilson was not distressed by them and appeared comfortable. This suggests that he was unconscious.

On the 17th October 1998, because of the secretions, the hysocine was increased to 600microgram/24h at 05.15h. Despite this, copious amounts of secretions were suctioned. This further suggests that the secretions were due to pulmonary oedema and as such, if Mr Wilson was distressed by the secretions, diuretics IV/SC should have been considered because hyoscine hydrobromide would have little chance of improving the pulmonary oedema. The syringe driver was changed at 15.50h with an increased dose of hyoscine hydrobromide 800microgram/24h and diamorphine 40mg/24h, equivalent to oral morphine 80–120mg/24h and midazolam 20mg/24h added. It was reported that the secretions were noisy but not apparently distressing Mr Wilson. Thus, although diamorphine and midazolam are used to relieve the sensation of breathlessness in the terminal stage, it is unclear from the medical or nursing notes why it was necessary in Mr Wilson's case to increase the diamorphine or add the midazolam.

Mr Wilson continued to require regular suctioning and at 14.50h on the 18th October 1998, the hysocine hydrobromide was increased to 1200microgram/24h. There were no reports that Mr Wilson was intolerant of this regular suctioning, which can be an unpleasant stimulus as it entails

the insertion of a catheter into the back of the throat; this again suggests that Mr Wilson was likely to be unconsciousness and unaware. It is thus unclear from the medical or nursing notes why it was considered necessary, and by whom, to further increase the diamorphine to 60mg/24h, equivalent to oral morphine 120–180mg/24h and the midazolam to 40mg/24h. There were no reports of Mr Wilson being distressed because of the secretions or pain and as such it is unclear why his dose of diamorphine was trebled over a 48h period.

The cause of death was given as 1a. congestive cardiac failure which is in keeping with his terminal decline. 1b. was given as renal failure, present for a period of 2 years, this is inaccurate; his renal impairment at Queen Alexander Hospital resolved completely with appropriate therapy. 1c. was given as liver failure, which was an important contributing factor to his death.

Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

The medical provided by Dr Barton and Dr Knapman to Mr Wilson following his transfer to Dryad Ward, Gosport War Memorial Hospital is suboptimal when compared to the good standard of practice and care expected of a doctor outlined by the General Medical Council (General Medical Practice, General Medical Council, July 1998, page 2–3) with particular reference to:

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs and, if necessary, an appropriate examination

- in providing care you must keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs, or appliances that serve patients' needs.

Specifically:

i) There was insufficient assessment and documentation of Mr Wilson's physical state and pain on his transfer to Dryad Ward on the 14th October 1998.

ii) Mr Wilson was prescribed doses of oral morphine initially p.r.n. and subsequently regularly, likely to be excessive to his needs. On the day of his transfer he was also prescribed doses of diamorphine to be given by syringe driver p.r.n. in a range that would likely be excessive to his needs.

iii) There was insufficient assessment and documentation of Mr Wilson's clinical condition when he deteriorated on the 16th October 1998.

iv) Mr Wilson subsequently received doses of diamorphine over the last 48h of his life that were likely to be excessive to his needs.

If the care is found to be suboptimal what treatment should normally have been proffered in this case?

Issue i (lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate and contemporaneous patient records).

Mr Wilson's admission to Dryad Ward was accompanied by the minimum of medical notes. A medical assessment usually consists of information

obtain from the patient ± others, the existing medical records (the history), and the findings of a relevant physical examination documented in a structured fashion. Although the history can be restricted to the most salient points, it is unusual to omit relevant sections, e.g. past medical history, drug history, etc. When a new medical team takes over the day-to-day care of a patient with serious medical problems, a physical examination is warranted to inform the ongoing management of those medical problems and to also provide a base line for future comparison. This allows monitoring of changes for the better or worse. A clear assessment and documentation of medical care is also particularly useful for on-call doctors who may have to see a patient, whom they have never met, for a problem serious enough to require immediate attention.

There was no pain assessment that would help to justify why his only regular analgesic was discontinued and why morphine rather than his usual codeine was prescribed p.r.n.

Issue ii (in providing care you must prescribe only the treatment, drugs or appliances that serve patients needs).

Mr Wilson was prescribed doses of oral morphine p.r.n. and subsequently regularly that were likely to have been excessive to his needs. In general, if regular paracetamol is considered insufficient, then a weak opioid such as codeine would be considered appropriate. It is known from the Queen Alexander Hospital that Mr Wilson had recently required, at most, only one dose of codeine 30mg a day, thus maintaining its use p.r.n. rather than giving it regularly would have been most appropriate in my opinion. If it

were considered necessary to give it regularly, a reasonable dose would be codeine 30mg 4 times a day (120mg/day). Some doctors do prescribe small doses of morphine instead of a weak opioid when paracetamol is inadequate. In this case, a comparable dose would be morphine 2.5mg p.r.n. or 2.5mg every 4h (15mg/24h).

Generally, if ≥2 p.r.n. doses are consistently required in a 24h period, this suggests that regular analgesia is indicated. The total amount of p.r.n. given also guides the amount of analgesia likely to be required on a regular basis. The patient's age, kidney and liver function (as in Mr Wilson's case) may also need to be taken into account. Thus, because Mr Wilson received 10mg x 2 p.r.n. doses (20mg/24h), if it was considered necessary to give him regular analgesia, a reasonable starting dose would have been morphine 2.5mg every 4h (15mg/day). Because of his liver failure, the effect of this dose would need to have been evaluated over the next 24–48h.

The prescription of a syringe driver containing diamorphine, midazolam and hyoscine hydrobromide p.r.n. for a patient transferred for 'general mobilisation' is not usual in my experience, particularly with such a wide dose range. This is because of the inherent risk that would arise from a lack of clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing a drug as a range, particularly a wide range, is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. It is not usual in my experience for such decisions to be left for

nurses to make alone. If there were concerns that a patient may experience, for example, episodes of pain, anxiety or agitation, it would be much more usual, and indeed seen as good practice, to prescribe appropriate doses of morphine/diamorphine or diazepam/midazolam respectively, which could be given p.r.n. PO or SC. This allows a patient to receive what they need, when they need it, and guides the doctor in deciding if a regular dose is required, the appropriate starting dose and subsequent dose titration. The wide dose range of diamorphine 20–200mg/24h is not justified at all in the notes. As already indicated, even the lower end of this dose range may have been excessive for Mr Wilson's needs. Doses of opioids excessive to a patients needs are associated with an increase risk of drowsiness, delirium, nausea and vomiting and respiratory depression.

Issue iii (lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate and contemporaneous patient records). Generally, when a patient's clinical condition changes for the worse, a thorough medical assessment should be carried out to ascertain the possible cause(s) in order to identify if they are reversible with appropriate treatment. The assessment will consist of the history, examination and appropriate investigation. With regards to the entry made by Dr Knapman on the 16th October 1998, following the rapid deterioration in Mr Wilson's condition, even basic observations have not been recorded including, for example, temperature, pulse rate/rhythm, blood pressure and auscultation of heart and breath sounds (although noisy secretions can impede useful

auscultation). These observations should have been undertaken, particularly as Dr Knapman considered that Mr Wilson had possibly experienced a serious event such as a myocardial infarction. It should be clarified on what basis Dr Knapman satisfied himself that Mr Wilson's condition was terminal rather than due to a potentially reversible complication, e.g. cardiac arrhythmia, chest infection. That said, in my opinion, given Mr Wilson's combination of severe liver failure and heart failure this rapid deterioration was most likely to be a terminal event and, as such, it was appropriate to focus his care on comfort measures.

From the description, it was likely that Mr Wilson had developed an acute worsening of his pulmonary oedema. As such, oxygen, intravenous diuretics, nitrates and opioids could all have been appropriate therapies, particularly if Mr Wilson was experiencing difficulty in breathing. The only treatment proffered to Mr Wilson was an additional dose of oral furosemide and the reason for this should be clarified. For example, IV furosemide may not have been available but IV diamorphine would have been. Did this less optimal approach to treating pulmonary oedema reflect that Mr Wilson was not particularly aware/distressed by his situation, because of being semiconscious or unconscious? When diamorphine is used for acute pulmonary oedema, it is usually given IV. It works by dilating the veins, reducing the amount of blood returning to the heart, reducing the heart's workload. Other drugs are more effective at this, e.g. nitrates, and some would use these in preference to opioids. However, I am not a cardiologist and if this aspect of the case is considered important then the opinion of a cardiologist should be sought.

Issue iv (providing treatment that serves the patients needs).

Mr Wilson received doses of diamorphine over the last 48h of his life that were likely to be excessive to his needs. It is not clear who decided to start the syringe driver later on the day of his deterioration, the drugs it should contain and the doses to use. There was no entry relating to the syringe driver in the medical notes and the indication for the use of the diamorphine is not documented in the nursing notes and this should be clarified. It may have been simply to replace the dose of regular oral morphine and, if the comfort of a patient is in doubt in their terminal stage, this could be seen as reasonable. However, given the comments in issue ii relating to an appropriate dose of oral morphine, in my opinion, diamorphine 10mg SC/24h would have been an appropriate dose.

Over the next two days the hyoscine was increased in an attempt to improve the secretions, and this would not be unusual. However, given that his situation was suggestive of pulmonary oedema, other measures would have been more likely to help, e.g. furosemide IV, IM, SC. Despite the secretions being noisy and requiring frequent suctioning, Mr Wilson did not appear distressed and this suggests that he was unconscious. Given the apparent lack of distress, it is unclear why it was considered necessary to increase the diamorphine to 40mg then 60mg SC/24h. This is equivalent to oral morphine 120–180mg/24h and, in my opinion, would have been likely to be excessive to his needs. The combination of diamorphine and midazolam are used to relieve the sensation of breathlessness in the terminal stage, but I can find no reports of Mr Wilson being distressed

because of breathlessness (or pain) and thus it is difficult to justify why his dose of diamorphine was trebled over a 48h period.

If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

Dr Barton and her partners had a duty to provide a good standard of practice and care that would include good palliative and terminal care. In this regard Dr Barton and Dr Knapman fell short of a good standard of clinical care as defined by the GMC (Good Medical Practice, General Medical Council, July 1998 pages 2–3) with particular reference to a lack of clear note keeping, adequate assessment of the patient (Dr Barton and Dr Knapman) and providing treatment that could be excessive to the patients needs (Dr Barton).

The dose of oral morphine prescribed for Mr Wilson's arm pain both p.r.n. and regularly were likely to be excessive for his needs. As a result, the initial dose of diamorphine 20mg/24h would also likely to be excessive to his needs. The subsequent increase in the dose of diamorphine to 60mg/24h over the following 48h was not obviously justified. Mr Wilson was likely to be unconscious; he was not reported to be distressed by pain, the secretions or his breathing and he appeared to tolerate regular suctioning. A dose of diamorphine excessive to Mr Wilson's needs would be associated with an increased risk of drowsiness, confusion, agitation, nausea and vomiting and respiratory depression.

In patients with cancer, the use of diamorphine and other sedative medications (e.g. midazolam) when appropriate for the patient's needs, do

not appear to hasten the dying process. This has not been examined in patients dying from other illnesses to my knowledge, but one would have no reason to suppose it would be any different. The key issue is whether the use and the dose of diamorphine and other sedatives were *appropriate* to the patient's needs. Although the principle of double effect could be invoked here (see technical issues), it remains that a doctor has a duty to employ effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose opioid that was *appropriate* and not excessive for a patients needs.

Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate and contemporaneous patient records, had been attempting to allow Mr Wilson a peaceful death, albeit with what appears to be an apparent lack of sufficient knowledge, illustrated, for example, by the reliance on large dose range of diamorphine by a syringe driver rather than a fixed dose along with the provision of smaller p.r.n. doses that would allow Mr Wilson's needs to guide the dose titration. Dr Barton could also be seen as a doctor who breached the duty of care she owed to Mr Wilson by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mr Wilson by unnecessarily exposing him to receiving excessive doses of diamorphine.

However, Mr Wilson had significant medical problems. His clinical condition was not stable in that his oedema and thus heart failure were worsening over his time in Queen Alexander Hospital, despite the

reintroduction of diuretic therapy. In this regard an acute deterioration in Mr Wilson's heart failure would not have been that unusual, whether or not precipitated by a myocardial infarction, and his death was in keeping with severe heart failure and liver failure which combined to cause a rapid irreversible physical decline. Although the dose of morphine may well have contributed to his reduced level of consciousness, either directly or by precipitating a hepatic coma, it is difficult to say with any certainty that the dose of morphine he received would have contributed more than minimally, *negligibly or trivially to his death because the heart and liver failure could* also have done this. Similarly, although the doses of diamorphine used were likely to have been excessive to his needs, it is difficult to say with any certainty that the dose of diamorphine he received would have contributed more than minimally, negligibly or trivially to his death, because drowsiness/unconsciousness, the one feature of excess opioid seen in this case, is also a feature of the terminal stage of heart failure and liver failure.

9. LITERATURE/REFERENCES

British National Formulary 35 (March 1998):

- Prescribing in terminal care, pages 12–15
- Prescribing for the elderly, pages 16–17

Good Medical Practice, General Medical Council July 1998, pages 2–3

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition 'Wessex Protocol' Salisbury Palliative Care Services May 1995.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: _____ Date: _____

Version 2 of complete report 19th November 2005 – Robert Wilson

SUMMARY OF CONCLUSIONS

Mr Robert Wilson a 74 year old gentleman with known severe alcoholic liver disease who was admitted with a complex and painful fracture of the left upper humerus. His physical condition deteriorates at first in hospital, with alteration in mental state, renal impairment and subsequent gross fluid retention. He then starts to improve and is transferred to the Gosport War Memorial Hospital for further assessment and possible rehabilitation or continuing care. He is started on regular oral strong opiate analgesia for pain in his left arm and rapidly deteriorates and dies within 5 days of admission.

There is weakness in the documentation of his condition, in particular on the admission to the Gosport War Memorial Hospital on 14th October, and on the15th October when the regular oral strong opiate analgesia is commenced. If clinical examinations were undertaken they have not been recorded. General Medical Practice (GMC2001) states that "good clinical care must include adequate assessment of the patient's condition, based on the history and symptoms and if necessary an appropriate examination"..... "in providing care you must provide clear, accurate, legible and contemporaneous patient records which must report the relevant clinical findings, the decisions made, the information given to the patient and any drugs or other treatments provided". The lack of clinical examination on admission and on the day of 15th October when the decision was made to start regular strong oral opiate analgesia represents poor clinical practice to the standards set by the General Medical Council.

It is my belief that the prescription of a total of 50 mgs of Oramorphine on the 15th October following the 20 mgs that were given on the 14th October was not an appropriate clinical response to the pain in Mr Wilson's left arm. In my view this dose of analgesia formed a major contribution to the clinical deterioration that occurred over the 15th-16th October, in particular, his rapid mental state deterioration. In my view this treatment was negligent, and more than minimally contributed to the death of Mr Robert Wilson on 19th October.

1. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to his death against the acceptable standard of the day. Where appropriate, if the care is felt to be sub-optimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

2. ISSUES

2.1. Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day.

2.2. If the care is found to be suboptimal what treatment should normally have been proffered in this case.

2.3. If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups.

3. CURRICULUM VITAE

Code A

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Code A

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Code A

Code A

4. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Robert Wilson (BJC/55)

[2] Operation Rochester Briefing Document Criminal Investigation Summary.

[3] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[4] Commission for Health Improvement Investigation Report on Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital (July 2002).

[5] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

5. **CHRONOLOGY/CASE ABSTRACT.** (The numbers in brackets refer to the page of evidence).

5.1. Robert Wilson a 74 year old gentleman in 1998 attended Queen Alexandra Hospital, Portsmouth A&E Department on the 21st September 1998 (125-127) with a fracture of the left femoral head and tuberosity (169).

5.2. Mr Wilson had suffered many years before with Malaria and Diphtheria (143) but was first noticed to be abusing alcohol at the time of an endoscopy in 1994 (313). In 1997 he was admitted to

hospital with a fall, epigastric pain and was found to have evidence of severe alcoholic liver disease (129). During the 1997 admission, an ultra sound showed a small bright liver compatible with cirrhosis and moderate ascites (129). His Albumin was very low at 19 (150) and a bilirubin was 48 (129). All these are markers of serious alcoholic liver disease with a poor long term prognosis. His weight was 100 kgs (152). There is no record of follow up attendance.

5.3. When he attends A&E it is originally intended to offer him an operation on his arm, which he refuses. However, he is kept in A&E overnight for observation (161-2). It becomes apparent by the next day that he is not well, is vomiting (163) and he is needing Morphine for pain (11). His wife is on holiday (11) and it is not thought possible for him to go home so he is transferred on 22nd September to the Care of the Elderly team at the Queen Alexandra Hospital (163).

5.4. The day after admission he is no longer thought fit enough to have an operation on his arm, although he would now be prepared to. He is recognised to have been an extremely heavy drinker with considerable oedema and abdominal distension on admission (167). He has abnormal blood tests on admission including a mild anaemia of 10.5 with a very raised mean cell volume of 113 and his platelet count is reduced at 133 (239). Five days later his haemoglobin has fallen to 9.7 and the platelet count has fallen to 123 (237). There are no further full blood counts in the notes, although his haemoglobin was normal with haemoglobin of 13 in 1997 (241).

5.5. He is noted to have impaired renal function with a Urea of 6.7 and a Creatinine of 185 on admission (209) and on 25th September Urea of 17.8 and a Creatinine of 246 (203). He is started on intravenous fluids on 27th September (12) and his renal function then continues to improve so that by the 7th October both his Urea and Creatinine are normal at 6.1 and 101 (199).

5.6. His liver function is significantly abnormal on admission and on 29th his albumin is 22, his bilirubin 82 (he would have been clinically jaundice) there is then little change over his admission. On the 7th October is albumin is 23 and his bilirubin also 82 (199). His AST is 66 (171).

5.7. His vomiting within 24 hours of admission may have been due to alcohol withdrawal but he had also been given Morphine for pain (11). He is started on a Chlordiazepoxide regime (11) as standard

management plan to try and prevent significant symptoms of alcohol withdrawal. This has some sedative effects as well.

5.8. His physical condition in hospital deteriorates at first. He is noted to have considerable pain for the first 2 – 3 days, he is found to have extremely poor nutritional intake and has eaten little at home (12). His renal function deteriorates as documented above. He is communicating poorly with the nursing staff (28) and is restless at night on 30th September (30). His Barthel deteriorates from 13 on 23rd September to 3 on the 2nd October (69), his continued nutritional problems are documented by the dietician on 2nd October (16). In the nursing cardex he is vomiting, he has variable communication problems, he is irritable and cross on 1st October (30). On 4th October (16) his arm is noted to be markedly swollen and very painful and it is suggested he needs Morphine for pain (31). The following day he knocks his arm and gets a laceration (16).

5.9. There is ongoing communication with his family which is complicated by inter-family relationships between his first wife's family and his current wife. The plan by 6th October is that he will need nursing home care when he leaves hospital and his Barthel at this stage is 5 (16) (69). However on the 5th the nursing cardex note that he is starting to improve (32) although, he remains catheterised and has been faecally incontinent on occasion.

5.10. On 7th October is now more alert and is now telling the staff that he wishes to return home (17). The nursing staff notes that he is now much more adamant in his opinions (33). However on 8th he had refused to wash for 2 days (18). He is then reviewed at the request of the medical staff by a psycho-geriatrician. The opinion is that he has early dementia, which may be alcohol related and depression. He is noted to be difficult to understand with a dysarthria (117-118). He is started on Trazodone as an antidepressant and as a night sedative, he is still asking for stronger analgesics on 8th October (35). The letter also mentions (429) rather sleepy and withdrawn..... his nights had been disturbed.

5.11. On the 9th October an occupational therapy assessment is difficult because he is reluctant to comply and a debate occurs about whether he is capable of going home (19). By the 12th October (21) his Barthel has improved to 7 (69) so Social Services say that he no longer fits their criteria for a nursing homeand he should now be considered for further rehabilitation (21). The nursing cardex notes that his catheter is out (35) he is eating better but he

still gets bad pain in his left arm (36). His arms, hands and feet are noted to be significantly more swollen on 12th October (36). His weight has now increased from 103 kgs on 27th September to 114 kgs by 14th October (61,63). However his Waterlow score remains at "high risk" for all his admission (71). A decision is made to transfer him for possible further rehabilitation, although the medical review on 13th October states in view of the medical staff and because of his oedematous limbs, he is at high risk of tissue breakdown. He is also noted to be in cardiac failure with low protein and at very high risk of self neglect and injury if he starts to take alcohol again. He currently needs 24 hour hospital care (21).

5.12. On 14th October he is transferred to Draed Ward and the notes (179) say "for continuing care". The notes document the history of fractured humerus, his alcohol problem, current oedema and heart failure. No examination is documented. The notes state that he needs help with ADL, he is incontinent, Barthel 7, he lives with his wife and is for gentle rehabilitation. I am unable to read four words. The single word on the line above incontinence, two words after lives with wife (this may be a street address) and the word in front of gentle mobilisation.

5.13. The next medical notes (179) are on 16th October and state that he had declined overnight with shortness of breath. On examination he is reported to have a weak pulse, unresponsive to spoken orders, oedema plus plus in arms and legs. The diagnosis is "? silent MI, ? liver function" and the treatment is to increase the Frusemide. The nursing cardex for 14th October confirms he was seen by Dr Barton, that Oramorphine 10 mgs was given and he was continent of urine. On 15th October the nursing notes 9265) state commenced Oramorphine 10 mgs 4 hourly for pain in left arm, poor condition is explained to wife. On 16th on the nursing cardex he is "seen by Dr Knapman am as deteriorated overnight, increased Frusemide". However I find some possible confusion with the nursing care plan (278), this states for 15th October, settled and slept well, Oramorphine 20 mgs given 12 midnight with good effect, Oramorphine 10 mgs given 06.00 hours. Condition deteriorated overnight, very chesty and difficulty in swallowing medications. Then on 16th it states has been on syringe driver since 16.30 hours. As will be seen from the analysis of the drug chart, Mr Wilson received the Oramorph at midnight on 15th and then 06.00 hours Oramorph on 16th. The first clinical deterioration is on the night of 15th – 16th October not the night of the 14th – 15th October.

5.14. The next medical note is on 19th October which notes that he had been comfortable at night with rapid deterioration (179) and death is later recorded at 23.40 hours and certified by Staff Nurse Collins. The nursing cardex mentions a bubbly chest late pm on 16th October (265). On the 17th Hyoscine is increased because of the increasing oropharyngeal secretions (265). Copious amounts of fluid are being suctioned on 17th. He further deteriorates on 18th and he continues to require regular suction (266). The higher dose of Diamorphine on the 18th and Midazolam is recorded in the nursing cardex (266).

5.15. Two Drug Charts; The first is the Queen Alexandra drug chart (106-116). This records the regular laxatives, vitamins and diuretics given for his liver disease. The reducing dose of Chlordiazepoxide stops on 30th September for his alcohol withdrawal and the Trazodone started for his mild depression and night sedation. In terms of pain management Morphine, slow IV or subcutaneous 2.5 – 5 mgs written up on the prn side and 5 mgs given on 23rd September and 2.5 mgs twice on 24th September. Morphine is also written up IM 2 – 5 mgs on 3rd October and he receives 2.5 mgs on 3rd and 2.5 mgs on 5th. He is also written up for prn Codeine Phosphate and receives single doses often at night up until 13th October but never needing more than 1 dose a day after 25th September. Regular Co-dydramol starts on 25th September until 30th September when it is replaced by 4 times a day regular Paracetamol which continues until his transfer.

In summary, his pain relief for the last week in the Queen Alexandra is 4 times a day Paracetamol and occasional night time dose of Codeine Phosphate.

5.16. The second drug chart is the drug chart of the Gosport War Memorial Hospital (258-263). His diuretics, anti-depressant, vitamins and laxatives are all prescribed regularily. The regular Paracetamol is not prescribed but is written up on the as required (prn) after the drug chart. This is never given. Regular prescriptions also contains Oramorphine 10 mgs in 5 mls to be given 10 mgs 4 hourly, starting on 15th October (261). 10 mgs is given at 10 am, 2pm and 6 pm on 15th, 6am, 10 am and 2 pm on 16th. A further dose of 20 mgs at night given at 10 pm is given at 10 pm on 15th October. Although these prescriptions are dated 15th October it is not clear if they were written up on the 14th or 15th.

5.17. On a further sheet of this drug chart (262) regular prescription has been crossed out and prn written instead. Oramorphine, 10 mgs in

5 mls, 2.5 – 5 mls 4 hourly is then prescribed on this sheet. It is not dated but it would appear 10 mgs is given at 2.45 on 14th October and 10 mgs at midnight on 14th October. Further down this page Diamorphine 20 – 200 mgs subcut in 24 hours from Hyoscine 200 – 800 micrograms subcut in 24 hours, Midazolam 20 – 80 mgs subcut in 24 hours are all prescribed. It is not clear what date these were written up. The first prescription is 16th October and the 20mls of Diamorphine with 400 micrograms of Hyoscine are started at 16.10. On 17th October, 20 mgs of Diamorphine, 600 micrograms of Hyoscine are started at 5.15 and the notes suggest that what was left in the syringe driver at that stage was destroyed (262). At 15.50 hours on 17th October, 40 mgs, 800 mgs of Hyoscine and 20 mgs of Midazolam are started and on 18th 60 mgs of Diamorphine, 1200 micrograms of Hyoscine (a new prescription has been written for the Hyoscine) and 40 mgs of Midazolam are started in the syringe driver at 14.50 and again the notes suggest the remainder that was previously in the syringe driver is destroyed.

6. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

6.1. This section will consider whether there were any actions so serious that they might amount to gross negligence or any unlawful acts, or deliberate unlawful killing in the care of Robert Wilson. Also whether there were any actions or omissions by the medical team, nursing staff or attendant GP's that contributed to the demise of Robert Wilson, in particular, whether beyond reasonable doubt, the actions or omissions more than minimally, negligibly or trivially contributed to death.

6.2. The principle underlying medical problem in Mr Wilson is his alcoholic liver disease. There is no doubt that he had hepatocellular failure based on long-standing alcohol abuse, with evidence at least back to his admission in 1997 where he has evidence of portal hypertension giving him a significant ascites. He also at that stage had a low albumin and a persistently raised bilirubin, hall-markers of a poor medium to long-term prognosis.

6.3. The presenting problem on admission was his complex fracture of his left upper arm, which ideally would have had an operative repair. First he refuses this, and then by the time he agrees it his physical status has significantly deteriorated to a point that he was not fit for an anaesthetic. He gets continual pain from this arm throughout his admission. His admission treatment is strong opiate analgesia; this is then replaced by regular oral mild opiate analgesia and finally by regular Paracetamol supplemented by

mild oral opiate analgesia (Codeine Phosphate) at night. There is no doubt though that he does have continuing pain from this arm.

6.4. His health deteriorates for at least the first 7 – 8 days after his admission. He develops impaired renal function; there is evidence of change in mental state with comments on poor communication, sleepiness, irritability and restlessness, and "dysarthria". There are a number of possibilities for this. The first possibility is that he is having alcohol withdrawal, combined with the sedative effect of Chlordiazepoxide to prevent marked symptoms of alcohol withdrawal delirium. The psycho-geriatrician wonders if he has alcohol related dementia plus some depression. I believe it is very likely that he has early hepatic encephalopathy, a change in mental state that goes with hepatic failure. This includes disturbed consciousness with sleep disorder, personality change and intellectual deterioration. It is often precipitated by acute events including gastro-intestinal blood loss and drugs, in particular opiates. There is evidence of other deterioration in his liver function including a reduced platelet count suggesting an enlarged spleen due to portal hypertension, his bilirubin which is significantly higher than his previous admission and his persistent very low albumin. His haemoglobin does fall during admission. It is possible that he has had a small gastro-intestinal bleed at some stage but this is not pursued.

6.5. Despite all of this, there is a an improvement in his condition recorded in both his better functioning on the ward with the nursing staff, his greater alertness and communication improvement. The fact that his catheter can be removed and he becomes continent and that his overall measured functional status through the Barthel score improves to a point that Social Services will no longer place him in a nursing home, although he clearly needs nursing care. However, his weight dramatically increases by 11 kgs during his admission and this will be almost entirely fluid retention going to his abdomen, legs and potentially his chest. This is not adequately managed medically.

6.6. He is transferred on 14th October for ongoing assessment, possible rehabilitation and decisions about long-term care arrangements. No examination has been recorded on admission by the medical staff. Not even a basic clinical examination has been undertaken which appears to me to be poor clinical practice to the standards set by the General Medical Council.

6.7. The only management that is really needed at this stage is to continue the management that was ongoing from the Queen

Alexandra Hospital while gently addressing the fluid balance problems. However the regular oral analgesics that he was on are not written up regularly, no explanation is given for this. Strong opioid analgesia is written up and two doses of 10 mgs Oramorphine are given on the day of transfer, the 14th October. At the Queen Alexandra Hospital the single doses on the 3rd and 5th October has been at 2.5 mgs. Regular Oramorphine to a total dose of 50 mgs is then given on the 15th October. It is now being given regularly and it is not clear whether the original intention to give it regularly was from the admission on the 14th, though the prescription is clearly written and starts at 10 am on 15th. There is no documentation in the nursing or medical notes to suggest the patient was seen by a doctor on 15th where the decision to start the regular dose of Morphine appears to be made.

6.8. The decision to give regular Morphine at this dose on 15th October is crucial to the future understanding of this case. "*.....the effects of hepatitis or cirrhosis on drug deposition range from impaired to increased drug clearance in an unpredictable fashion..... the oral availability for high first class drugs such as Morphine.....is almost double in patients with cirrhosis compared to those with normal liver function. Therefore the size of the oral dose of such drugs should be reduced in this setting" (Harrison).* In my view the decision to give regular oral doses of high oral doses of strong opiates on 15th was negligent. The appropriate use of weaker analgesics had not been used, though these had controlled his symptoms the previous week in the Queen Alexandra Hospital. The dose of Morphine used, particularly in the presence of severe liver disease, was very likely to have serious implications.

6.9. By the 16th October there has been a very significant clinical deterioration overnight and Mr Wilson is examined by a doctor. He is noted to be unwell and unresponsive to spoken orders. While it is possible that Mr Wilson has gone into heart failure to frank left ventricular failure due to his salt and water retention documented previously, the unresponsiveness makes it almost certain in my view that he is either now unresponsive because of a direct cerebral effect of the Morphine or he is being precipitated again into Hepatic Encephalopathy. The situation may or may not have been reversible but he is probably now entering a period of irreversible terminal decline. However, it would have been appropriate to have obtained senior medical opinion as to whether other management should be considered. In my view, the failure to obtain senior medical opinion was poor clinical practice.

6.10. He is no longer able to take oral medication and as the clinical decision has been made that he is now in terminal decline he is started on a syringe driver containing Diamorphine and Hyoscine. Diamorphine, Hyoscine (and Midazolam) are all compatible in the same syringe driver. Hyoscine is particularly useful for patients with a large amount of secretion as is documented in this case. When starting Diamorphine in a syringe driver it is conventional to do it at a dose of 2 to 1 i.e. half the dose of Diamorphine in the syringe driver than was being given orally. On 15th October 50 mgs in total of Oramorphine was prescribed, it was reasonable to start 20 mgs in the syringe driver on 16th October. The dose of Diamorphine is increased on both 17th and 18th and Midazolam is started on 17th. Apart from comments about secretions in the nursing cardex, there is no rationale for the increase in dose of Diamorphine or the addition of Midazolam provided in either the medical or nursing notes. It is not clear whether the decision to increase the dose is a medical or nursing decision. I have indicated in section 5 that there are significant problems with the use of the drug chart in Gosport which seems to have been used in an irregular fashion.

6.11. It is my view the regular prescription and dosage of Oramorphine was unnecessary and inappropriate on 15th October and in a patient with serious hepatocellular dysfunction was the major cause of the deterioration, in particular in mental state, on the night of 15th and the 16th. In my view it is beyond reasonable doubt that these actions more than minimally contributed to the death of Mr Wilson.

7. OPINION

7.1. Mr Robert Wilson is a 71 year old gentleman with known severe alcoholic liver disease who was admitted with a complex and painful fracture of the left upper humerus. His physical condition deteriorates at first in hospital, with alteration in mental state, renal impairment and subsequent gross fluid retention. He then starts to improve and is transferred to the Gosport War Memorial Hospital for further assessment and possible rehabilitation or continuing care. He is started on regular oral strong opiate analgesia for pain in his left arm and rapidly deteriorates and dies within 5 days of admission.

7.2. There is weakness in the documentation of his condition, in particular on the admission to the Gosport War Memorial Hospital on 14th October, and on the15th October when the regular oral strong opiate analgesia is commenced. If clinical examinations were undertaken they have not been recorded. General Medical Practice (GMC2001) states that "good clinical care must include adequate assessment of

the patient's condition, based on the history and symptoms and if necessary an appropriate examination"..... "in providing care you must provide clear, accurate, legible and contemporaneous patient records which must report the relevant clinical findings, the decisions made, the information given to the patient and any drugs or other treatments provided". The lack of clinical examination on admission and on the day of 15th October when the decision was made to start regular strong oral opiate analgesia represents poor clinical practice to the standards set by the General Medical Council.

7.3. It is my belief that the prescription of a total of 50 mgs of Oramorphine on the 15th October following the 20 mgs that were given on the 14th October was not an appropriate clinical response to the pain in Mr Wilson's left arm. In my view this dose of analgesia formed a major contribution to the clinical deterioration that occurred over the 15th-16th October, in particular, his rapid mental state deterioration. In my view this treatment was negligent, and more than minimally contributed to the death of Mr Robert Wilson on 19th October.

8 LITERATURE/REFERENCES

1. Good Medical Practice, General Medical Council 2002
2. Withholding withdrawing life, prolonging treatments: Good Practice and decision making. General Medical Council 2002.
3. Palliative Care, Welsh J, Fallon M, Keeley PW. Brocklehurst Text Book of Geriatric Medicine, 6th Edition, 2003, Chapter 23 pages 257-270.
4. The treatment of Terminally Ill Geriatric Patients, Wilson JA, Lawson, PM, Smith RG. Palliative Medicine 1987; 1:149-153.
5. Accuracy of Prognosis, Estimates by 4 Palliative Care Teams: A Prospective Cohort Study. Higginson IJ, Costantini M. BMC Palliative Care 2002:1:129
6. The Palliative Care Handbook. Guidelines on Clinical Management, 3rd Edition. Salisbury Palliative Care Services, May 1995.
7. Diseases of the Liver and Biliary System. Sheila Sherlock and James Dooley. 9th Edition Oxford 1993.
8. Harrisons Principles of Internal Medicine. Kesper, Braunwald, Fauci, Hauser, Longo, Jameson. 16th Edition New York 2005 (page 19).

9. EXPERTS' DECLARATION

Version 2 of complete report 19th November 2005 – Robert Wilson

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters, which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report, which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

10. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: _____ Date: _____

CONTENTS

1. **INSTRUCTIONS**

To examine and comment upon the statement of Dr Jane Barton re Robert Wilson. In particular, it raises issues that would impact upon any expert witness report prepared.

2. **DOCUMENTATION**

This report is based on the following document:

2.1 Job Description for Clinical Assistant Post to the Geriatric Division in Gosport as provided to me by the Hampshire Constabulary (February 2005).

2.2 Statement of Dr Jane Barton re Robert Wilson as provided to me by Hampshire Constabulary (November 2005). Appendix 1

2.3 Statement of Dr Jane Barton as provided to me by Hampshire Constabulary (February 2005). Appendix 2

2.4 Report regarding Robert Wilson (BJC/ 55) Professor D Black 2005.

3. **COMMENTS**

3.1 Comments on Job Description (2.1)

3.1.1 This confirms the Clinical Assistant is responsible for a maximum of 46 patients and confirms that all patients are under the care of a named Consultant Physician who would take overall responsibility for their medical management. A Clinical Assistant should take part in the weekly consultant ward rounds.

3.1.2 A specific responsibility is the writing up of the original case notes and ensuring the follow up notes are kept up to date and reviewed regularly.

3.1.3 The post is for five sessions a week i.e. is half what a full time doctor would commit to the post. However; the time to be spent in the unit is not specified as the time is allowed to be "worked flexibly".

3.1.4 There appears to be some confusion between the statements

in the job summary, that "patients are slow stream or slow stream for rehabilitation but holiday relief and shared care patients are admitted" and the statement in the previous sentence "to provide 24 hour medical care to the long stay patients in Gosport". The job description appears to be confusing patients for rehabilitation with long stay patients.

3.1.5 There is no comment on the medical cover to be provided when the post holder is unavailable for out of hours or longer period of leave such as holidays. Lack of explicit cover might explain some gaps in the notes.

3.2 Report on the statement of Dr Jane Barton re Robert Wilson (2.2).

3.2.1. I agree with paragraph 20 of Dr Barton's statement. Thus the final paragraph of 5.15 in my report should read "... a day paracetamol and fairly regular doses of Codeine Phosphate at night.

3.2.2. The words mentioned in paragraph 5.12 of my report that I was unable to read are: hoisting...Sarisbury Green.....plan.

3.2.3 Paragraph 9 of Dr Barton's statement says 'Diamorphine', but I believe the drug chart states 'Morphine'

3.2.2 These alterations do not effect the conclusions in my report.

3.3 Report on the Statement of Dr Jane Barton as provided to me by the Hampshire Constabulary (2.3):

3.3.1Page 1 paragraph 3: States that she works eight general practice surgery sessions. It is my understanding that most full time General Practitioners work eight or nine sessions. This suggests to me that she is undertaking a full time General Practitioner job and a half time community hospital job. Despite the fact the job description says that the job can be worked flexibly, an opinion should be obtained from an experienced General Practitioner as to whether this workload is actually deliverable within a reasonable working week.

3.3.2 Page 1 paragraph 4: The job description states 46 beds, Dr Barton states 48 beds. The CHI report says 44 beds (20 on Dryad and 24 on Daedalus) Dr Barton uses the phrase "continuing care for long stay elderly patients". The job description also referred to slow stream or slow stream rehabilitation as well as holiday relief and shared care patients. There may have been confusion between staff in terms of the objectives of individual patient management.

3.3.3 Page 1 paragraph 5: This statement is incorrect as the post of Clinical Assistant is not a training post but a service post in the NHS. The only medical training grade posts are pre-registration house officers, senior house officers, specialist registrars and GP registrars.

3.3.4 Page 1 paragraph 5: States that she and her partners had decided to allocate come of the sessions to "out of hours aspects of the post". This would appear to be a local arrangement of the contractual responsibilities: it needs to be clarified if this was agreed with the Portsmouth and South East Hampshire Health Authority. This would influence how much time was expected to be provided for the patients and influence the pressure on Dr Barton to deliver the aspects of care provided.

3.3.5 Page 2 paragraph 3: This does confirm that there were consultants responsible for all the patients under the care of Dr. Barton. Thus a consultant should always have been available for discussing complex or difficult management decisions. However,(page 3 paragraph 1) , in my view it would be completely unacceptable of the Trust to have left Dr Barton with continuing medical responsibilities for the inpatients of Gosport Hospital without consultant supervision and regular ward rounds. This would be a serious failure of responsibility by the Trust in its governance of patients and in particular failings and in my view the Trust would need to take part of the responsibility for any clinical failings.

3.3.6 Page 3 paragraph 3: This again suggests that Dr Barton was trying to provide her half time responsibilities by fitting the work around her full time responsibilities as a General Practitioner. She suggests 5 patients were admitted each week, implying approximately 250 admissions and discharges a year. With a bed occupancy around 80%, this would suggest an average length of stay of 5 – 6 weeks. However, CHI state the actual figures were somewhat less, 1997/98 were 169 FCE's for Dryad and Daedalus and 197 FCE's in 1998/99. A new patient assessment including history and examination, writing up the notes, drug charts, talking to the nurses, talking to any relatives present and undertaking blood tests if these had to be taken by a doctor rather than any other staff, would take a maximum of 60 minutes.

Page 5 paragraph 2: The patients who were genuinely long stay or continuing care do not need to be reviewed medically every day, nor would a medical record be made daily. Indeed with average length of stay of six or more weeks, it is clear that many patients were genuinely long-stay patients and one would expect them to be medically reviewed no more than once a week and any medical comments to be no more than once a week. However, whenever patients' physical or mental state has changed and they are reviewed by a doctor, it would be normal practice to always make a

comment in the notes. Patients who are in rehabilitation and making a good progress, then review and comments in the notes once or twice a week would also be the norm.

It is my view that with less than 200 FCE's and a total of 44 inpatients, then this should be satisfactorily managed by somebody working half time as a Clinical Assistant with regular consultant supervision.

3.3.7 Page 4 paragraph 2: This suggests that Dr Barton is stating that she takes personal responsibility for most changes in medication, rather than it being a nursing decision.

3.3.8 Page 9 paragraph 2: An individual doctor must take responsibility for their prescribing however I would agree that consultants should also take responsibility for ensuring patients under their care were having appropriate medical management. It does appear that there was a consultant responsible for all patients in both Dryad and Daedalus Ward.

4. Conclusions

4.1. Having read all the documents provided by Hampshire Constabulary, I would wish to make minor changes to my expert report.

4.2. I agree with paragraph 20 of Dr Barton's statement. Thus the final paragraph of 5.15 in my report should read "... a day paracetamol and fairly regular doses of Codeine Phosphate at night.

4.3. The words mentioned in paragraph 5.12 of my report that I was unable to read are: hoisting...Sarisbury Green.....plan

4.4. Paragraph 9 of Dr Barton's statement says 'Diamorphine', but I believe the drug chart states 'Morphine'

4.5. These alterations do not effect the conclusions in my report

APPENDIX 1

Wilson/ Barton statements Version 1 21st November 2005

APPENDIX 2

29

Code A

Code A

Code A

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DRAFT REPORT

regarding

Patient Name Robert Wilson (Ref No. BJC/55)

PREPARED BY: Professor R Baker.....

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

I have studied the copies of the records provided to me by Hampshire Constabulary in order to consider three issues – the certified cause of death, the prescription of opiates and sedatives, and whether Mr Wilson fell into the category of patients who might have left hospital alive.

With respect to death certification, I have concluded that the certificate was inaccurate in that Mr Wilson did not have renal failure, and had liver dysfunction but not failure. He probably did have heart failure, although I believe the initiation of opiate medication was an important factor in leading to death.

With respect to the prescription of opiate drugs, I have concluded, on the evidence available to me, that the initiation of opiate medication on transfer to Dryad ward was inappropriate; I have also concluded that the starting dose was too high. The prescription of hyoscine and midazolam was justified by the use of opiates.

With respect to leaving hospital alive, I have concluded that Mr Wilson was in the category of patients who might have left hospital alive if he had not been commenced on opiate medicate on transfer to Dryad ward.

1. INSTRUCTIONS

I have been asked to provide a statement of evidential use that could be used in the event of criminal proceedings arising from the case of Mr Robert Wilson.

2. ISSUES

I was asked to address three questions:

1. Certified cause of death. In this case, was the certified cause of death supported by the medical history of the patient?
2. Prescription of opiates and sedatives. In the case of Mr Wilson was his prescribing in accordance with his clinical need?
3. Leaving hospital alive. In my statement (080904) I had referred to patients who were administered opiates and eventually died who may have recovered and left hospital had they not received this medication. The issue to be addressed was whether, in my opinion, Mr Wilson fell into this category.

3. BRIEF CURRICULUM VITAE

Code A

Code A

4. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Mr Robert Wilson, provided to me by Hampshire Constabulary.

[2] A copy of my report dated 08 September 2004.

[3] The Palliative Care Handbook Guidelines on clinical management fourth edition, of the Portsmouth Healthcare NHS Trust, Portsmouth Hospitals NHS Trust, and the Rowans (Portsmouth Area Hospice), 1998.

5. CHRONOLOGY/CASE ABSTRACT (prepared by Hampshire Constabulary) *The numbers in square brackets[ ] refer to the page of evidence.*

1.1. Robert Wilson a 74 year old gentleman in 1998 attended Queen Alexandra Hospital, Portsmouth A&E Department on the 21st September 1998 [125-127] with a fracture of the left humerus and tuberosity [169].

1.2. Mr Wilson had suffered many years before with Malaria and Diphtheria [143] but was first noticed to be abusing alcohol at the time of an endoscopy in 1994 (313). In 1997 he was admitted to hospital with a fall, epigastric pain and was found to have evidence of severe alcoholic liver disease [129]. During the 1997 admission, an ultra sound showed a small bright liver compatible with cirrhosis and moderate ascites [129]. His Albumin was very low at 19 [150] and a bilirubin was 48 [129]. All these are markers of serious alcoholic liver disease with a poor long term prognosis. His weight was 100 kgs [152]. There is no record of follow up attendance.

1.3. When he attends A&E in September 1998 with a fracture of his left humerus it is originally intended to offer him an operation on his arm, which he refuses. However, he is kept in A&E overnight for observation [161-2]. It becomes apparent by the next day that he is not well, is vomiting [163] and he is needing Morphine for pain [11]. His wife is on holiday [11] and it is not thought possible for him to go home so he is transferred on 22nd September 1998 to the Care of the Elderly team at the Queen Alexandra Hospital [163].

1.4. The day after admission he is no longer thought fit enough to have an operation on his arm, although he would now be prepared to. He is recognised to have

been an extremely heavy drinker with considerable oedema and abdominal distension on admission [167]. He has abnormal blood tests on admission including a mild anaemia of 10.5 with a very raised mean cell volume of 113 and his platelet count is reduced at 133 [239]. Five days later his haemoglobin has fallen to 9.7 and the platelet count has fallen to 123 [237]. There are no further full blood counts in the notes, although his haemoglobin was normal with haemoglobin of 13 in 1997 [241].

1.5. He is noted to have impaired renal function with a Urea of 6.7 and a Creatinine of 185 on admission (209) and on 25th September Urea of 17.8 and a Creatinine of 246 [203]. He is started on intravenous fluids on 27th September [12] and his renal function then continues to improve so that by the 7th October both his Urea and Creatinine are normal at 6.1 and 101 [199].

1.6. His liver function is significantly abnormal on admission and on 29th his albumin is 22, his bilirubin 82 (he would have been clinically jaundiced) there is then little change over his admission. On the 7th October is albumin is 23 and his bilirubin also 82 [199]. His AST is 66 [171].

1.7. His vomiting within 24 hours of admission may have been due to alcohol withdrawal but he had also been given Morphine for pain [11]. He is started on a Chlordiazepoxide regime [11] as standard management plan to try and prevent significant symptoms of alcohol withdrawal. This has some sedative effects as well.

1.8. His physical condition in hospital deteriorates at first. He is noted to have considerable pain for the first 2 – 3 days, he is found to have extremely poor nutritional intake and has eaten little at home [12]. His renal function deteriorates as documented above. He is communicating poorly with the nursing staff [28] and is restless at night on 30th September [30]. His Barthel deteriorates from 13 on 23rd September to 3 on the 2nd October [69], his continued nutritional problems are documented by the dietician on 2nd October [16]. In the nursing cardex he is reported as vomiting, having variable communication problems, and being irritable and cross on 1st October [30]. On 4th October [16] his arm is noted to be markedly swollen and very painful and it is suggested he needs Morphine for pain [31]. The following day he knocks his arm and gets a laceration [16].

1.9. There is ongoing communication with his family which is complicated by inter-family relationships between his first wife's family and his current wife. The plan by 6th October is that he will need nursing home care when he leaves hospital and his Barthel at this stage is 5 [16] [69]. However on the 5th the nursing cardex notes that he is starting to improve [32], although he remains catheterised and has been faecally incontinent on occasion.

1.10. On 7th October is now more alert and is now telling the staff that he wishes to return home [17]. The nursing staff notes that he is now much more adamant in his opinions [33]. However on 8th he had refused to wash for 2 days [18]. He is then reviewed at the request of the medical staff by a psycho-geriatrician. The opinion is that he has early dementia, which may be alcohol related, and is also depressed. He is noted to be difficult to understand with a dysarthria [117-118]. He is started on Trazodone as an antidepressant and as a night sedative, he is still

asking for stronger analgesics on 8th October [35]. The letter also mentions [429] rather sleepy and withdrawn..... his nights had been disturbed.

1.11. On the 9th October an occupational therapy assessment is difficult because he is reluctant to comply and a debate occurs about whether he is capable of going home [19]. By the 12th October [21] his Barthel has improved to 7 [69] so Social Services say that he no longer fits their criteria for a nursing home and he should now be considered for further rehabilitation [21]. The nursing cardex notes that his catheter is out [35] and he is eating better but he still gets bad pain in his left arm [36]. His arms, hands and feet are noted to be significantly more swollen on 12th October [36]. His weight has now increased from 103 kgs on 27th September to 114 kgs by 14th October [61, 63]. However his Waterlow score remains at "high risk" for all his admission [71]. A decision is made to transfer him for possible further rehabilitation, although the medical review on 13th October states in view of the medical staff and because of his oedematous limbs, he is at high risk of tissue breakdown. He is also noted to be in cardiac failure with low protein and at very high risk of self neglect and injury if he starts to take alcohol again. He currently needs 24 hour hospital care [21].

1.12. On 14th October he is transferred to Dryad Ward and the notes [179] say "for continuing care". The notes document the history of fractured humerus, his alcohol problem, recurrent oedema and heart failure. No examination is documented. The notes state that he needs help with ADL, he is incontinent, Barthel 7, he lives with his wife and is for gentle rehabilitation.

1.13. The next medical notes [179] are on 16th October and state that he had declined overnight with shortness of breath. On examination he is reported to have a weak pulse, unresponsive to spoken orders, oedema plus plus in arms and legs. The diagnosis is "? silent MI, ? liver function" and the treatment is to increase the Frusemide. The nursing cardex for 14th October confirms he was seen by Dr Barton, that Oramorphine 10 mgs was given and he was continent of urine. On 15th October the nursing notes [265] state commenced Oramorphine 10 mgs 4 hourly for pain in left arm, poor condition is explained to wife. According to the cardex on 16th he is "seen by Dr Knapman am as deteriorated overnight, increased Frusemide".

1.14. (possible confusion with the nursing care plan [278], this states for 15th October, settled and slept well, Oramorphine 20 mgs given 12 midnight with good effect, Oramorphine 10 mgs given 06.00 hours. Condition deteriorated overnight, very chesty and difficulty in swallowing medications. Then on 16th it states has been on syringe driver since 16.30 hours. As will be seen from the analysis of the drug chart, Mr Wilson received the Oramorph at midnight on 15th and then 06.00 hours Oramorph on 16th. The first clinical deterioration is on the night of 15th – 16th October not the night of the 14th – 15th October.)

1.15. The next medical note is on 19th October which notes that he had been comfortable at night with rapid deterioration [179] and death is later recorded at 23.40 hours and certified by Staff Nurse Collins. The nursing cardex mentions a bubbly chest late pm on 16th October [265]. On the 17th Hyoscine is increased because of the increasing oropharyngeal secretions [265]. Copious amounts of fluid are being suctioned on 17th. He further deteriorates on 18th and he continues to require regular suction [266]. The higher dose of Diamorphine on

the 18th and Midazolam is recorded in the nursing cardex [266].

1.16. Two Drug Charts: The first is the Queen Alexandra drug chart [106-116]. This records the regular laxatives, vitamins and diuretics given for his liver disease. The reducing dose of Chlordiazepoxide stops on 30th September for his alcohol withdrawal and the Trazodone started for his mild depression and night sedation. In terms of pain management Morphine, slow IV or subcutaneous 2.5 – 5 mgs written up on the prn side and 5 mgs given on 23rd September and 2.5 mgs twice on 24th September. Morphine is also written up IM 2 – 5 mgs on 3rd October and he receives 2.5 mgs on 3rd and 2.5 mgs on 5th. He is also written up for prn Codeine Phosphate and receives single doses often at night up until 13th October but never needing more than 1 dose a day after 25th September. Regular Co-dydramol starts on 25th September until 30th September when it is replaced by 4 times a day regular Paracetamol which continues until his transfer.

In summary, his pain relief for the last week in the Queen Alexandra is 4 times a day Paracetamol and occasional night time dose of Codeine Phosphate.

1.17. The second drug chart is the drug chart of the Gosport War Memorial Hospital [258-263]. His diuretics, anti-depressant, vitamins and laxatives are all prescribed regularly. The regular Paracetamol is not prescribed but is written up on the as required (prn) after the drug chart. This is never given. Regular prescriptions also contains Oramorphine 10 mgs in 5 mls to be given 10 mgs 4 hourly, starting on 15th October [261]. 10 mgs is given at 10 am, 2pm and 6 pm on 15th, 6am, 10 am and 2 pm on 16th. A further dose of 20 mgs at night given at 10 pm is given at 10 pm on 15th October. Although these prescriptions are dated 15th October it is not clear if they were written up on the 14th or 15th.

1.18. On a further sheet of this drug chart [262] regular prescription has been crossed out and prn written instead. Oramorphine, 10 mgs in 5 mls, 2.5 – 5 mls 4 hourly is then prescribed on this sheet. It is not dated but it would appear 10 mgs is given at 2.45 on 14th October and 10 mgs at midnight on 14th October. Further down this page Diamorphine 20 – 200 mgs subcut in 24 hours from Hyoscine 200 – 800 micrograms subcut in 24 hours, Midazolam 20 – 80 mgs subcut in 24 hours are all prescribed. It is not clear what date these were written up. The first prescription is 16th October and the 20mls of Diamorphine with 400 micrograms of Hyoscine are started at 16.10. On 17th October, 20 mgs of Diamorphine, 600 micrograms of Hyoscine are started at 5.15 and the notes suggest that what was left in the syringe driver at that stage was destroyed [262]. At 15.50 hours on 17th October, 40 mgs, 800 mgs of Hyoscine and 20 mgs of Midazolam are started and on 18th 60 mgs of Diamorphine, 1200 micrograms of Hyoscine (a new prescription has been written for the Hyoscine) and 40 mgs of Midazolam are started in the syringe driver at 14.50 and again the notes suggest the remainder that was previously in the syringe driver is destroyed.

6. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

Figures in square brackets [ ] refer to page numbers of the notes.

I. Certified cause of death. In this case, was the certified cause of death supported by the medical history of the patient?

The certified cause of death was Ia congestive cardiac failure, Ib renal failure, II liver failure. The certifying doctor was Dr E.J. Peters.

Liver failure

Mr Wilson was known to have a poorly functioning liver. The primary diagnosis relating to his admission between 17/02/97 and 12/03/97 was alcoholic liver disease [129], and at that time he had abnormal liver function tests including low albumin level, and an ultrasound had shown a small liver, possibly cirrhotic, with marked ascites.

His liver function was also impaired at the time of admission in September 1998 [207, 199]. Jaundice does not seem to have been remarked upon in the notes relating to this admission. The working diagnosis during the admission in Queen Alexandra Hospital was active alcoholic hepatitis [171]. A hand written entry in the records dated 13/10/98 records results of blood tests taken 12/10/98 [178]. At that time, the bilirubin had fallen to 48 umol/L and the AST to 37 IU/L, although the alkaline phosphatase was 181 IU/L. I would tend to interpret these results as indicating some improvement. The notes do not record a diagnosis of liver failure although this diagnosis is mentioned on blood test forms [199, 213, 217]. The liver function tests, whilst abnormal, are not sufficiently abnormal to suggest fulminant liver failure. Diuretics can precipitate hepatic encephalopathy in patients with cirrhosis (Jones, 2003), but the hepatic encephalopathy was not diagnosed and the records do not include mention of the signs of encephalopathy. Mr Wilson was noted to have some depression and mildly impaired short term memory when assessed by Dr Luznat, the consultant in old age psychiatry on 08/10/98 [118, 119], and the nursing records indicate he was sleepy

and had poor speech on 29/09/98 [29], but these features were not sufficiently consistent, progressive or severe to suggest hepatic encephalopathy. The course of Mr Wilson's final illness was one of gradual if limited progress until transfer to Dryad ward, which tends to rule out the progressive development of encephalopathy due to liver failure.

Renal failure

Mr Wilson also had renal dysfunction. His creatinine reached 246 umol/l and his urea 17.8 mmol/l on 25/09/98 [213], but there was some improvement over the following days. On 30/09/98 his creatinine was 165 umol/l and his urea 14.4 mmol/l [203], and by the 05/10/98 his creatinine had fallen to 97 umol/l and his urea to 7.5 mmol/l [201]. The results on the 05/10/98 were within the normal range, and remained so on 07/10/98 and 13/10/98 [178]. The improvement in renal function appears to have occurred following the temporary withdrawal of diuretics and the institution of intravenous fluids [170, 89] on 28/09/98.

Congestive cardiac failure

The note on admission to Dryad ward records the problems of 'alcohol problems', recurrent oedema, and CCF (congestive cardiac failure). Heart failure is a syndrome rather than a specific disease, that is, it is a collection of symptoms and signs that can be caused by several different diseases. Congestive cardiac failure is a term that is less commonly used today. It can mean different things to different doctors (Fry and Sandler, 1993), and may indicate right ventricular failure to some doctors, left ventricular failure to others, or failure of both ventricles to others. Mr Wilson had ankle, leg and sacral oedema which may have been explained by right heart failure (the low albumin level secondary to the alcoholic liver disease and poor nutrition would also have played a role in causing the oedema), although he did not have a raised jugular venous pressure [166] when admitted to Queen Alexandra Hospital. He did have 'crackles' in the lung bases especially the left, and this might have been a

feature of left heart failure [166]. Diagnosis of cardiac failure on clinical grounds alone is difficult (Khunti et al, 2000).

The notes indicate that Mr Wilson suffered from retention of fluid leading to swelling of his arm [174] and legs [81, 129, 118, 265]. Potential explanations for heart failure in Mr Wilson's case include ischaemic heart disease and alcohol induced cardiomyopathy. He was treated with high doses of diuretics at his admission in 1997, specifically spironolactone 100mgs daily and frusemide 80 mgs daily [129]. During the admission in 1997, his weight declined from around 103kgm to around 93 kgm, suggesting that the diuretics had produced a satisfactory diuresis [367, 369]. In contrast, in 1998, his weight rose from 103 kgms on 27/09/98 [65] to 114 kgm on 14/10/98 [61], despite continued treatment with diuretics. This suggests that his cardiovascular status may have declined between the admissions in 1997 and 1998.

The medical notes on transfer to Dryad on 14/09/98 do not mention the need for additional treatment of the congestive cardiac failure [179]. Diuretics were continued, and Oramorph 10mg was prescribed, doses being given that day at 14.45 pm and 23.45 pm [262, 265]. However, there was no mention of pain at all in the medical records [179] and therefore the indications for Oramorph are unclear. Oramorph 10mg 4 hourly was commenced on 15/10/98, the first dose being given at 10.00 am, six doses being given up to 14.00 on 16/10/98. Mr Wilson was seen the next morning by Dr Knapman as he had declined overnight with shortness of breath. On examination he was reported as bubbling, had a weak pulse, unresponsive to spoken orders, and had oedema ++ in the arms and legs. The possibility of a silent myocardial infarct was raised (although not investigated), and the history of reduced liver function noted. The dose of frusemide was doubled. These notes indicate that Dr Knapman thought that congestive failure was an important factor in explaining Mr Wilson's condition. However, the fact that the deterioration coincided with the regular administration of Oramorph points to an alternative explanation, namely the side effects of opiate

medication. The side effects would include sedation leading to lack of responsiveness, and reduced ability to expectorate which could explain the 'bubbling' respiration.

In the afternoon of 16/10/98, the nursing staff noted that Mr Wilson was 'very bubbly', and that diamorphine by syringe driver had been commenced [265]. The dose began at 16.10 pm, and the prescription was written by Dr Barton [262]. The bubbly chest may have been explained by morphine. Hyoscine was also prescribed by syringe driver, midazolam being added on 17/10/98, the dose of diamorphine being increased to 40 mgs on 17/10/98 [278], and on the 18/10/98 to 60mgs [262].

2. Prescription of opiates and sedatives. In the case of Mr Wilson was his prescribing in accordance with his clinical need?

Mr Wilson was receiving soluable paracetamol four times daily from 30/09/98 until the morning of 14/10/98, prior to his transfer to Dryad ward [114, 115]. He had received 2.5-5mg morphine on 23-24/09/98 and 2.5mg on 3/10/98 and 5/10/98 [106.107], and he had also received codydramol until the paracetamol had been started. Although he did have pain throughout his stay in Queen Alexandra Hospital, it appears to have been reasonably well controlled by 13/10/98. The nursing record indicates that he had no complaints about pain on 13/10/98. nor on the morning of 14/10/98 [37]. Neither the medical or nursing records from Dryad ward mention an increase in pain later on the 14/10/98 [179, 265], although the nursing notes on 15/10/98 state that the Oramorph was for pain in the arm. On the information contained in the records, therefore, the commencement of Oramorph was not adequately justified.

The commencement of subcutaneous diamorphine on 16/10/98 followed a decline in Mr Wilson's condition, the cause of which was not clear [179]. The nursing records mention that the reason for commencing diamorphine by syringe driver was explained to the family, but the reason itself is not recorded in the records. An alternative approach to the decline on 16/10/98 would have been to stop the Oramorph and

observe whether Mr Wilson improved. For some reason which cannot be found in the records, it had been concluded that Mr Wilson was not going to recover and that terminal care was the appropriate course of action. Hyoscine was also prescribed, and I assume the intention was to control secretions. The dose of hyoscine was increased in accordance with the problems caused by the secretions (which were recorded as 'copious' on 17/10/98 [265]). The dose of diamorphine was increased, and midazolam was added, although the records do not explain the reasons for these prescribing decisions.

2. Leaving hospital alive. In my statement (080904) I had referred to patients who were administered opiates and eventually died who may have recovered and left hospital had they not received this medication. The issue to be addressed was whether, in my opinion, Mr Wilson fell into this category.

The comment referred to from my statement (080904) is:

As made clear in the report, I became concerned about aspects of care at Gosport War Memorial Hospital, including aspects of the care provided by Dr Barton. I concluded that it was probable that a small number of patients who had been given opiates and had died might, if they had not been given opiates, have sufficiently recovered to be discharged from hospital eventually. An attitude or culture of limited hope and expectations of recovery appeared to have existed at the hospital. I was unable to identify when this culture had first gained hold at the hospital and it may have existed before Dr Barton's appointment in 1988. In addition, I have not identified the underlying motivations responsible for this culture.

When Mr Wilson was transferred from Queen Alexandra Hospital to Dryad ward, he was in need of nursing and medical care and at risk of falling until fully mobilised. A short spell in a long term NHS bed was regarded as appropriate when he was reviewed on the ward round on 13/10/98 [177,178]. He appeared to be making some progress,

with improved renal function, less pain, and improvement in some of the measures of liver function [178]. He still had significant problems, however, including difficulty in moving and oedema [81]. Nevertheless, the Queen Alexandra Hospital records do not indicate that death was expected in the near future – with appropriate care, gradual mobilisation was anticipated. Yet shortly after admission to Dryad ward, he was commenced on regular Oramorph.

8. OPINION

1. Certified cause of death. In this case, was the certified cause of death supported by the medical history of the patient?

In my opinion, Mr Wilson had liver dysfunction but not full blown failure. His liver dysfunction did not cause death. In the presence of other life-threatening conditions, the liver dysfunction may impair the ability to recover, and it would have been reasonable to mention on the death certificate that Mr Wilson had chronic liver disease. The cause of his liver disease – alcohol – was not mentioned on the ceritificate.

Mr Wilson did not have renal failure. He did have abnormal blood test results after his admission to hospital, but these improved with rehydration. Mr Wilson probably did have cardiac failure. There may have been other conditions as well. Haemoglobin estimations during his admission to Queen Alexandra Hospital had indicated mild anaemia. If this condition had deteriorated, the heart failure would also have become worse. However, I think this is rather unlikely since he was being closely observed in Queen Alexandra Hospital and signs of increasing anaemia would almost certainly have been recognised. Evidence of bleeding would have been noted if it had occurred. There is no convincing evidence in the records to

confirm a diagnosis of myocardial infarction such as history of chest pain, raised cardiac enzymes or ECG evidence. One could also speculate about possible occurrence of some unsuspected condition. However, despite all these speculations, it has to be acknowledged that his decline was associated with the regular administration of morphine, and was responded to by administration of diamorphine by syringe driver. The reason for commencing Oramorph is not recorded in the medical notes [179]; in particular, the reasons for not using a non-opiate drug for pain relief are not given. Even if Mr Wilson did have pain from the fracture that was not controlled by paracetamol, regular does of 10mg of oral morphine would not have been the appropriate treatment. Other non-opiate or weak opiate medication should have been used first. If these medications had failed to adequately reduce the pain, a low dose of morphine (2.5-5mg) as had been used in the early days of his admission might have been reasonable. Although Mr Wilson did have congestive cardiac failure, therefore, his death would have been hastened by opiate administration and the path to death may well have been initiated by the commencement of Oramorph on 14/10/98.

It is important to note that the general standard of completion of death certificates is unsatisfactory. For example, in a review of 1000 counterfoils of certificates in one teaching hospital in 1999-2000, only 55% of certificates had been completed to a minimally accepted standard (Swift and West, 2002). Of the remaining certificates, 25% had incomplete data, in 11% the part II section had been used inappropriately, and 9% were illogical or inappropriate. In her third report from the Shipman Inquiry, Dame Janet Smith observed: *A further problem with the current system is that the quality of certification is poor. Doctors receive little training in death certification.* (paragraph 17, page 4, Shipman Inquiry). The standard of completion

of the death certificate in Mr Wilson's case should therefore be regarded as fairly typical. Although Mr Wilson did not have renal failure, the history of recent abnormal renal function tests prompted use of this diagnosis; the mention of liver failure was probably a convenient way of describing the impaired liver function.

2. Prescription of opiates and sedatives. In the case of Mr Wilson was his prescribing in accordance with his clinical need?

The records do not contain information to explain why opiates were commenced. On the basis of the records alone, therefore, the prescribing of opiates was not indicated. The sedative midazolam was prescribed to accompany the diamorphine in the syringe driver, although the reason for the addition of midazolam is not given in the medical or nursing records.

The Palliative Care Handbook, fourth edition, published by the Portsmouth Healthcare NHS Trust, Portsmouth Hospitals NHS Trust and the Rowans (Portsmouth Area Hospice) in 1998 reproduces the WHO analgesic ladder in which step 1 (mild pain) involves the use of non opioids such as paracetamol, step 2 (moderate pain) weak opioids such as cocodamol [codeine and paracetamol], and step 3 (severe pain) strong opioids such as morphine. In Mr Wilson's case, medication for pain moved from step 1 to step 3 without any explanation. Hyoscine hydrobromide 0.4-2.4 mg over 24 hours by syringe driver is recommended in the Handbook for reducing secretions and is noted to be an excellent sedative. Midazolam 5-60mg over 24 hours is described as a sedative, higher doses to be used only for terminal sedation. The Handbook also indicates that a total daily dose of 30mg of morphine would be equivalent to 10mg of diamorphine by syringe driver in 24 hours.

The Handbook recommends starting morphine at a low dose and increase gradually according to need. This policy was applied in Queen Alexandra Hospital when occasional low (2.5-5mg) doses of morphine were needed early in Mr Wilson's admission. On Dryad ward, however, the starting dose was 10mg; on the 15/10/98 he had three doses of 10mg, and one at 10 pm of 20mgs (the time of this dose appears to be 22.00 hrs in the prescription record but is given as 24.00 hrs in the nursing record). This is a significant amount of opiate, more than would have been indicated even if step 2 of the WHO analgesic ladder had been tried first, and I would have expected sedation and drowsiness to occur.

My September 1998 copy of the British National Formulary (BNF; issue 36) notes that morphine 'may precipitate coma in hepatic impairment (reduce dose or avoid but many such patients tolerate morphine well); reduce dose or avoid in renal impairment' (page 201). It also states that in palliative care these cautions should not necessarily be a deterrent to the use of opioids.

The use of hyoscine to reduce secretions is common practice. Opiates can suppress the cough reflex, which reduces the ability to clear secretions (Schug and Cardwell, 2003). It also occurs in people who are too weak to expectorate effectively (Twycross and Lack, 1990). Midazolam, a benzodiazepine sedative, can be added to hyoscine if repeated administration of hyoscine leads to an agitated or confused state.

3. Leaving hospital alive. In my statement (080904) I had referred to patients who were administered opiates and eventually died who may have recovered and left hospital had they

not received this medication. The issue to be addressed was whether, in my opinion, Mr Wilson fell into this category.

In judging whether Mr Wilson might, if Oramorph had not been initiated on transfer to Dryad ward, eventually left Gosport War Memorial Hospital, several qualifications must be made. I am reliant on the hospital records only; records are often incomplete and I have not sought or obtained any information directly from the doctors, nurses, other staff or relatives who were involved in caring for Mr Wilson in the last days of his life. It is also difficult to predict with certainty the course of recovery that a patient will follow, especially when the patient is elderly and has a complex mix of several serious clinical problems, as did Mr Wilson. In addition to deterioration of existing conditions, new and unexpected problems can arise, including for example myocardial infarction [179]. It is also impossible to be certain about the degree of recovery, and whether the patient would have been fit for discharge to their own home or whether residential or nursing accommodation would be required. Bearing these qualifications in mind, in my opinion, Mr Wilson did fall into the category of patients who might have left hospital alive if the Oramorph had not been commenced on transfer to Dryad ward.

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10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.

7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: _____ Date: _____

SUMMARY OF CONCLUSIONS

Mrs Elsie Lavender was an 84 year-old lady admitted to the Haslar Hospital on 5th February 1996 following a fall and then transferred to Gosport War Memorial Hospital on 26th February 1996. She had long-standing problems with diabetes, a peripheral neuropathy, poor eyesight and registered blind. After admission she is found to be doubly incontinent, totally dependent with a probable quadriplegia, constant pains down her shoulders and arms and is found to have serious and unexplained abnormalities in various blood tests.

In the Gosport War Memorial Hospital, she fails to make any improvement, deteriorates with a bed sore that eventually becomes black and blistered. She receives pain relief and palliation for her deteriorating physical condition including subcutaneous Diamorphine and Midazolam and dies on 6th March 1996.

The expert opinion is:

Mrs Elsie Lavender provides an example of a very complex and challenging problem in geriatric medicine. It included multiple medical problems and increasing physical dependency causing very considerable patient distress. Several doctors, including Consultants, failed to make an adequate assessment of her medical condition.

The major problems in this lady's case are the apparent lack of medical assessment and the lack of documentation. Good Medical Practice (GMC 2001) states that "good clinical care must include an adequate assessment of the patient's condition, based on the history and symptoms and if necessary an appropriate examination"..... "in providing care you must, keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed". "Good clinical care must include – taking suitable and prompt action necessary"... "referring the patient to another practitioner, when indicated"..... "in providing care you must – recognise and work within the limits of your professional competence...."..... "prescribe drugs or treatments, including repeat prescriptions, only where you have adequate knowledge of the patients health and medical needs". The major gaps in the written notes, as documented in my report, represent poor clinical practice to the standards set by the General Medical Council. In this case, I believe that the overall episode of medical care provided between Haslar and Gosport Hospital was negligent in that an inadequate assessment and diagnosis of this lady's conditions was made. If it was, it was never recorded. The lack of any examination at Gosport, the lack of any comment on the abnormal blood test make it impossible to decide if the care she subsequently received was sub optimal, negligent or criminally culpable. It seems likely to me that she had several serious illnesses, which were probably unlikely to be reversible, and therefore, she was entering the terminal phase of her life at the point of admission to Gosport Hospital.

However, without proper assessment or documentation this is impossible to prove either way.

The initial symptomatic management of her terminal illness was appropriate. The prescription of the Diamorphine on the 26th February (never given) and the excessive doses of medication used in the final 36 hours was, in my view, sub optimal drug management. These may have been given with the intention of shortening life at the final phase of her terminal illness. However, I am unable to satisfy myself beyond reasonable doubt this did hasten death by anything other than a short period of time (hours to a few days).

1. *INSTRUCTIONS*

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be sub-optimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

2. ISSUES

2.1. Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day.

2.2. If the care is found to be suboptimal what treatment should normally have been proffered in this case.

2.3. If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups.

3. CURRICULUM VITAE

Code A

Code A

Code A

Code A

Code A

Version 4 of complete report 19th March 2005 – Elsie Lavender

Code A

Code A

Code A

Code A

4. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Elsie Lavender

[2] Full set of medical records of Elsie Lavender on CD-ROM.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Hampshire Constabulary Summary of Care of Elsie Lavender

[6] Commission for Health Improvement Investigation Report on Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital (July 2002).

[7] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

[8] Medical report prepared by Dr James Gillespie

5 CHRONOLOGY/CASE ABSTRACT. (The numbers in brackets refer to the page of evidence, the numbers with 'H' in front are the Haslar notes, 'M' in front are the microfilm notes).

5.1. The Gosport notes record that Mrs Lavender was a insulin dependent diabetes mellitus since the1940's (53). She is referred to the Diabetic Service because of more troublesome hypoglycaemia in 1984 (65). In 1985 she is known to have a mild peripheral neuropathy (73). Her weight in 1988 is 85 kgs (73) and in 1987 her weight is 89 kgs (77). By 1988 she has very poor eyesight (47M). She is also documented to have high blood pressure in 1986 (29).

5.2. Elsie Lavender was admitted to Haslar hospital on 5th February 1996 through A&E having had a fall at home (H15, H16). She is recorded as having right shoulder tenderness (H25) is moving all four limbs and her cervical spine is thought to be normal, written as (CX spine√) (H16). The notes record that x-rays were taken of her skull and both shoulders (H24). In a subsequent neurological examination, she is noted to have reduced power 3/5, cannot move her right fingers and has an extensor right plantar (H24). A Barthel on the 5th (H631) is recorded as 5/20.

Her past medical history is noted as insulin dependent, diabetes mellitus for 54 years (age 29) appendicectomy and a hysterectomy. She is noted to have previous collapses in the past (H47) but without weakness, although her clerking in 1995 (H48) suggested that she might have had some sensory loss and a mild diabetic peripheral neuropathy. Her Barthel in 1995 was 14/20 (H495) and she was able to mobilise at that stage with a walking stick (H497). She had diabetes, eye disease, was registered blind in 1988 (H 97). She had hypoglycaemic episodes going back many years (H 71) and pneumonia in 1985 (H317).

On transfer to the ward, both her legs are noted to be weak 4/5 (H35) no sensory loss is noted. The notes also state she does not normally go upstairs and her bed is downstairs (H29). However, her son stated that a large pool of blood was found at the top of the stairs (H37). She apparently goes out once a week with her son is forgetful but not confused (H39).

Following admission, she is seen by a physiotherapist (157) who notes pain in both shoulders, can only stand with two people and is now having to be fed, washed and dressed, when previously independent.

No further neurological examination is recorded by the Haslar medical team and she is referred to Dr Lord on 13th February (H159). Dr Lord sees her and confirms that she still has bilateral weakness of both arms and legs (H163) and finds that her left plantar is extensor (H163) confirmed in his letter (H253) but is not sure about the right plantar which has previously been found to be extensor.

The importance of this finding is that it suggests that she has a bilateral neurological event in the brain, brain stem or spinal cord somewhere above the thoracic spine.

Dr Lord records "probable brain stem CVA"..... "she has had her neck x-rayed, I assume it was normal" (H167).
I was unable to find any x-ray request recorded in the notes for a cervical spine, nor any reports of an x-ray of a cervical spine or indeed reports on the x-rays that were recorded as being requested (i.e. the skull and shoulder x-rays).

Dr Lord notes her mild anaemia of 9.7 with an MCV of 76.5 (H17) and says that he will consider investigation into anaemia later (H164). Abnormal blood tests are also available in the notes on 9th February (H609) an albumin of 32, a Gamma GT 128 and Alkaline Phosphatase of 362. No investigations are done to determine whether these are a hepatic effect of her diabetes or a mixture of problems with the a raised alkaline phosphatase potentially coming from a fracture.

On the 20th February Mrs Lavender is again seen by a physiotherapist (H165), her bilateral shoulder pain is again documented and she needs two to transfer. Reviewing her drug charts (H684 and H690) she receives regular analgesia comprising Co-proxamol and Dihydrocodeine all through her admission.

5.3. The medical notes in Gosport (45M) 22nd February 1996 state that she "fell at home from the top to the bottom of the stairs and had lacerations on her head". It also states that she has severe incontinence and leg ulcers. Once in Gosport there is no rigorous clerking of the patient and no examination recorded. In some of the nursing cardex there is a series of assessments confirming that this lady is highly dependent. She has no mobility and bed rest is maintained all through her stay (100 -101). She has leg ulcers both legs (107 - 109). She is catheterised throughout, although there is no suggestion that she had a catheter prior to her admission to hospital (111). She has a sacral bed sore noted; "a red and broken sacrum on 21st February" (115) and this progresses to a black and blistered bed sore on the 27th February (115). She is thought to be constipated on a assessment, then continually leaks faeces throughout her admission (119).

5.4. Barthel is documented at 4/20 on 22nd February (165) (i.e. grossly dependent). Her mental test score is normal 10/10 on the same date (165). Lift handling score (171) also confirms high dependency.

5.5. Investigation tests reported on 23rd February 1996 find that she has a normal haemoglobin of 12.9 with a slightly reduced mean cell volume of 75.6 and gross thrombocytopenia (a low platelet count) of 36,000 (57M). The report on the film (58M) shows that this is a highly abnormal full blood count with distorted red blood cells and polychromasia. A repeat blood film is suggested. This is repeated on 27th February (57M) and thrombocytopenia is now even lower at 22,000. The urea is normal at 7.1 on 23rd February but has increased and is abnormal at 14.6 on 27th February (187). Her alkaline phosphatase is 572 (over 5 times the upper limit of normal) her albumin is low at 32 (187). No comment is made on any of these significantly abnormal blood tests in any of the Gosport notes, though the low platelet count is noted in nursing summary on 23rd February (151). The platelet count had been normal at 161 on admission to the Haslar (H17).

5.6. An MSU (59M) sent on 5th February showed a heavy growth of strep faecalis there are no other MSU or other blood culture results in the notes.

5.7. Medical progression (documented on pages 45M and 46M) is of catheterisation and treatment for a possible U.T.I on 23rd February. On 26th February, a statement that the patient is not so well and the family were seen regarding progress. Nursing cardex reports (153) a meeting with the son occurred on the 24th February and state "son is

happy for us just to make Mrs Lavender comfortable". "Syringe driver explained".

5.8. The medical notes on 5th March say deteriorated further, in some pain, therefore start subcutaneous analgesia. On 6th March "analgesia commenced, comfortable overnight I am happy for the night staff to confirm death". It is then confirmed at 21.28 hours on 6th March.

5.9. The nursing care plan first mentions significant pain on 27th February (95) and describes pain on most days up until 5th March where the pain is uncontrolled and the patient is distressed, at which point a syringe driver is commenced (97). On 6th March pain is controlled.

5.10. **Drug management in Gosport.** I shall concentrate on the use of analgesia. Throughout the patient received appropriate doses of insulin, Co-amilofruse (a diuretic), Digoxin, Iron and steroid inhalers up unto the last twelve hours. She also received a course of Trimethoprim (an antibiotic) between 23rd and 27th February.

5.11. Morphine slow release (MST) (67M)was started at 10 mgs bd on the 24th February and is given until 26th February when MST 20 mgs bd (145)is started, this continues until the 3rd March. On 4th March Oramorph 30 mgs bd is written up and given during 4th March (139). On 5th March Diamorphine is written up 100 – 200 mgs subcut in 24 hours (137). 100 mgs is prescribed and started at 08.30 in the morning, together with Midazolam 40 mgs (137) (61M). Midazolam had been written up at 40 – 80 mgs subcut in 24 hours. Diamorphine and Midazolam pump is filled at 09.45 hours (61M) on 6th March together with another 40 mgs of Midazolam.

5.12. When admitted into hospital Dihydrocodeine PRN for pain had been written up together Hyoscine. Diamorphine 80 – 160 mgs subcut in 24 hours was written up on 26th February together with Midazolam 40 – 80 mgs in 24 hours subcut, but these drugs were never prescribed (141).

5.13. The notes document (for example page 65M) Dr Lord was the consultant responsible for this patient although the patient only appears to have been seen medically at any stage by Dr Barton, and a different consultant Dr Tandy saw the patient in the Haslar Hospital.

6. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

6.1. This section will consider whether there were any actions so serious that they might amount to gross negligence or any unlawful acts, or deliberate unlawful killing in the care of Elsie Lavender. Also whether there were any actions or admissions by the medical team, nursing staff or attendant GP's that contributed to the demise of Mrs Lavender, in particular, whether beyond reasonable doubt, the actions or omissions more than minimally, negligibly or trivially contributed to death.

6.2. In particular I have discussed:
a) Her medical conditions
b) Whether she had become terminally ill during her admission
c) Whether the treatment that was then provided was appropriate.

6.3. Mrs Lavender had a number of serious underlying medical conditions. The most serious of which was her insulin dependent diabetes mellitus going back to the 1940's complicated by hypoglycaemia's, which had led, to falls on previous occasions, peripheral neuropathy which may also contribute to falls and with a combination of diabetes and other processes she had become registered blind. She also had documented frailty prior to admission, for example, already having moved her bed downstairs with an exercise tolerance of 10 yards with a stick. Her son was documented to do her shopping (11). However, she was still living alone, was only documented to have stress incontinence (11) and was cognitively intact (MTS 10/10) (165).

6.4. She was then admitted to Haslar Hospital having had a fall, which was from the top to the bottom of the stairs. No explanation is given as to how she was at the top of the stairs, if she was already set up with her bed downstairs at home. Following this she is documented both at the assessment at Haslar Hospital and then on admission to Gosport Hospital as being severely dependent. She cannot use her arms properly, her hands and wrists are noted to be weak and she cannot stand and walk, she is so incontinent she needs a catheter and she has continual faecal leakage. Barthel is 4/10. I believe this lady was misdiagnosed and had quadriplegia from a high cervical Spinal cord injury secondary to her fall. This diagnosis appears to have been missed by all the doctors who saw her. Although the A&E notes in Haslar state "cervical spine normal" (H18), presumably on clinical, not x-ray, grounds. Also Dr Tandy mistakenly believes she had her neck x-rayed and it was normal (H163). No-one checks this statement is correct.

6.5. Other on-going serious medical problems have also not been explained. She has a documented low platelet count on admission to Gosport, which on repeat is extremely low and at a level that makes life threatening bleeding at any time quite probable. The blood film is also highly abnormal which suggests that there is now some systemic illness going on, probably involving this lady's bone marrow. In the absence of infection or a likely drug culprit, then cancer involving the bone marrow would be a possibility. She also has a very rapidly rising alkaline phosphatase, which suggests either liver, or bone pathology. No other information is now available that would help me clarify this further.

I would have expected that these very abnormal blood tests would have been reviewed and commented on by the doctor in charge of the case. There is no point in undertaking investigations if the results are ignored. The blood results appear to be complex to interpret and I would have expected a clinical assistant or General Practitioner to have taken advice from the consultant in charge of the case as to their relevance and whether further action was required. If further discussion did take place or the results were properly looked at, this is simply not recorded in the notes.

6.6. Other evidence that this lady was frail and ill is provided by the pressure sore which appears to deteriorate during admission and a low albumin documented on admission.

6.7. In my view this lady received a negligent medical assessment in both Haslar and Gosport. In particular she was not examined on admission to Gosport, or if she was it was not documented in the notes. Thus no medical explanation beyond the "possible brain stem CVA" is made. This would not explain all her physical symptoms, or her profound neurological deficit. Also no medical diagnosis was made for pain that she continually complained of down her arms, which again would fit with a high cervical Spinal cord fracture or similar injury. Also, no attempt was made to determine why this lady had a very low platelet count and rising alkaline phosphatase. Without making an adequate medical assessment it is impossible to plan appropriate management. The lack of an adequate medical assessment and adequate documentation make it very difficult to be certain as to what treatment should normally have been given.

Good medical practice (GMC, 2001) states that "good clinical care must include an adequate assessment of the patient's

condition, based on the history and symptoms, and if necessary, an appropriate investigation".... "In providing care you must , keep clear, accurate, legible and contemporaneous patient records, which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed". The major gaps in the written notes as described above represents poor clinical practice to the standard set by the General Medical Council.

6.8. There can be no doubt though that the family, Dr Barton and the nursing staff all recognised this lady was seriously ill. Although the doctors fail to come to a diagnosis and therefore could not determine whether there was any treatable underlying problem. Evidence for this is that there was already discussion, within 2 days of admission, with the family about prognosis for recovery and how best to manage her illness. A syringe driver was already being discussed with the family on 24th February. Indeed all the markers of illness I have found, suggest this lady was very seriously ill.

6.9. Even if a high cervical Spinal cord fracture had been diagnosed, the potential for neurosurgical intervention in an elderly lady with diabetes is low and treatment with prolonged immobilisation has a very high mortality rate in itself. The unexplained low platelet count also suggests other significant serious pathology, which was never diagnosed, and on top of this we have somebody who needs all care and has leg ulcers and pressure sores. In my view, there were only two options open at this stage, **a)** to get a further specialist opinion or **b)** treat symptomatically and provide palliative care.

6.10. In view of the complexity of the medical problems, it would have been wise and appropriate to have obtained a further specialist opinion, probably from the consultant in charge of the case before deciding this lady was definitely terminally ill. I can see no evidence in the notes that this was considered.

If there was a failure to obtain further specialist opinion I believe this would be poor clinical practice to the standards set by the General Medical Council.

It was appropriate though to provide pain relief for someone who was both apparently in pain and distressed with loss of totally bodily function. To start MST at a normal low dose on the 24th February was appropriate.

6.11. If the pain was not resolved, increasing the dose to 20 mgs bd on both the 26th February adding the Oramorph 30 mgs bd on 4th March were all appropriate symptomatic responses.

6.12. An unusually large dose of Diamorphine (80 – 160 mgs subcut in 24 hours) is written up on the 26th February on the PRN (as required prescriptions) section of the drug chart. Midazolam 80 mgs subcut is also written up PRN. Although never prescribed, there is no justification in the notes for why such an apparently large dose of Diamorphine was written to be given if needed.

6.13. I have little doubt this lady was moving to a terminal phase of her illness by the 5th March. There had been no improvement in her quadriplegia, she remained faecally incontinent, the nursing cardex documents increasing pain, her platelet count has fallen further and her urea has doubled to 14.6 (187). At this stage a decision to start Diamorphine 100 mgs once a day subcutaneously and 40 mgs once a day Midazolam is made.

6.14. Midazolam is widely used subcutaneously in doses from 5 – 80 mgs for 24 hours and is particularly used for terminal restlessness. The dose of Midazolam used was 40 mgs for 24 hours, which is within current guidance, although many believe that elderly patients may need a lower dose of 5 – 20 mgs per 24 hours. (Palliative Care. Chapter 23 in Brocklehurst Text Book of Geriatric Medicine, 6th Edition 2003).

6.15. The Diamorphine was specifically prescribed for pain and is commonly used for pain in terminal care, Diamorphine is compatible with Midazolam and can be mixed in the same syringe driver. The dose of Diamorphine actually prescribed was 100 mgs in 24 hours. At that time Mrs Lavender was receiving 60 mgs a day of Oramorphine. Diamorphine subcutaneously is usually given at a maximum ratio of 1:2 (i.e. up to 30 mgs of Diamorphine in 24 hours for 60 mgs of Oramorphine). (Wessex Guidelines). However her pain was not controlled and it would be appropriate to give a higher dose of the Diamorphine. Conventionally this would be 50% greater than the previous days; (Wessex Guidelines) some people might give up to 100%. Thus a starting dose of Diamorphine of 45 – 60 mgs in 24 hours would seem appropriate. Mrs Lavender actually was prescribed a minimum dose of 100 mgs of Diamorphine, in my view excessive.

6.16. Diamorphine is compatible with Midazolam and can be used in the same syringe driver. It is documented above though that she

received a high dose of Midazolam and an excessive, and in my view, inappropriately large dose of Diamorphine. Together these drugs are likely to have caused excessive sedation and respiratory depression. However there is no evidence in the notes to prove these complications occurred.

6.17. Mrs Lavender is documented to be comfortable on the 6th and dies approximately 36 hours after the Midazolam and Diamorphine pumps were started.

The prediction of how long a terminally ill patient will live is virtually impossible and even Palliative Care experts show enormous variation (Higginson I J and Costantini M. Accuracy of Prognosis Estimates by 4 Palliative Care teams: A prospective cohort study. BMC Palliative Care 2002 1:1.)

6.18. The doses of Midazolam and Diamorphine used were in my opinion excessively high and may have been prescribed with the intention of deliberately shortening the terminal phase of her life. However, I can not find evidence to satisfy myself the standard of "beyond reasonable doubt", they had the definite effect of shortening her life in more than a minor fashion of a few hours to a few days.

7. OPINION

7.1. Mrs Elsie Lavender provides an example of a very complex and challenging problem in geriatric medicine. It included multiple medical problems and increasing physical dependency causing very considerable patient distress. Several doctors, including Consultants, failed to make an adequate assessment of her medical condition.

7.2. The major problems in this lady's case are the apparent lack of medical assessment and the lack of documentation. Good Medical Practice (GMC 2001) states that "good clinical care must include an adequate assessment of the patient's condition, based on the history and symptoms and if necessary an appropriate examination"..... "in providing care you must, keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed". "Good clinical care must include – taking suitable and prompt action necessary"... "referring the patient to another practitioner, when indicated"..... "in providing care you must – recognise and work within the limits of your professional competence...."..... "prescribe drugs or treatments, including repeat prescriptions, only where you have adequate knowledge of the patients health and medical needs". The major gaps in the written notes, as

documented in my report, represent poor clinical practice to the standards set by the General Medical Council. In this case, I believe that the overall episode of medical care provided between Haslar and Gosport Hospital was negligent in that an inadequate assessment and diagnosis of this lady's conditions was made. If it was, it was never recorded. The lack of any examination at Gosport, the lack of any comment on the abnormal blood test make it impossible to decide if the care she subsequently received was sub optimal, negligent or criminally culpable. It seems likely to me that she had several serious illnesses, which were probably unlikely to be reversible, and therefore, she was entering the terminal phase of her life at the point of admission to Gosport Hospital. However, without proper assessment or documentation this is impossible to prove either way.

7.3. The initial symptomatic management of her terminal illness was appropriate. The prescription of the Diamorphine on the 26th February (never given) and the excessive doses of medication used in the final 36 hours was, in my view, sub optimal drug management. These may have been given with the intention of shortening life at the final phase of her terminal illness. However, I am unable to satisfy myself beyond reasonable doubt this did hasten death by anything other than a short period of time (hours to a few days).

8 LITERATURE/REFERENCES

1. Good Medical Practice, General Medical Council 2002
2. Withholding withdrawing life, prolonging treatments: Good Practice and decision making. General Medical Council 2002.
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9. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.

2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
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4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report, which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

10. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature:_____ Date: _____

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REPORT

regarding

ELSIE LAVENDER (BJC/30)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mrs. Lavender was a frail 83 year old with significant medical problems. She was admitted to the Royal Naval Hospital, Hasler, Gosport, following a fall down her stairs, following which she found it difficult to walk or move her hands or wrists. She complained of pain across her shoulders and down her arms. A hypoglycaemic episode (low blood sugar) was considered a possible cause of her fall. She was seen by Dr Tandy 11 days later who documented some improvement in her mobility and abnormal neurological findings. Her conclusion was that Mrs Lavender had suffered a brain stem stoke and she was transferred to Gosport War Memorial Hospital, Daedalus Ward for rehabilitation.

During this admission, the medical care provided by Dr Barton was suboptimal: there was a failure to keep clear, accurate, and contemporaneous patient records; there was inadequate assessment of Mrs Lavender's condition, in particular her pain; symptoms and signs that warranted an examination were not acted upon (e.g. search for a possible infection due to raised white cell count, increased blood sugars and insulin requirements; a neurological examination due to her increasing back pain, urinary retention; and faecal incontinence). The morphine prescribed for Mrs Lavender's pains, may have been inappropriate (the type of pains she had may not have been that responsive to opioids) or excessive (as the dose was increased or as her kidney function deteriorated) and the possible role this may have had in her deterioration was not considered. Treatments were continued that may have aggravated her condition (e.g. the diuretic). Ultimately Mrs Lavender was prescribed doses of diamorphine and midazolam that were excessive for her needs.

If it were that Mrs Lavender had naturally entered the terminal phase of her life, at best Dr Barton could be seen as a doctor who whilst failing to keep clear, accurate, and contemporaneous patient records had in good faith been attempting to allow Mrs Lavender a peaceful death, albeit with what appears to

be an inappropriate and excessive use of medication due to a lack of sufficient knowledge. However, in my opinion, based on the medical and nursing records, there is reasonable doubt that Mrs Lavender had definitely entered her terminal stage. Given this doubt, at worst, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Lavender by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Lavender by not carefully assessing the possible causes of her decline that may have been reversible with appropriate treatment (e.g. antibiotics for an infection, stopping the diuretics, reducing the dose of morphine) and unnecessarily exposing her to possibly inappropriate and excessive doses of morphine and ultimately excessive doses of diamorphine and midazolam that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

2. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be suboptimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

3. ISSUES

3.1 Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day?

3.2 If the care is found to be suboptimal what treatment should normally have been proffered in this case?

3.3 If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

4. BRIEF CURRICULUM VITAE

Code A

5. DOCUMENTATION

This Report is based on the following documents:

[1] Set of medical records on paper and CD-ROM of Elsie Lavender (BJC-30).

[2] Set of medical records on paper of Elsie Lavender (JR-11A).

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Commission for Health Improvement Investigation Report on Portsmouth Health Care NHS Trust at Gosport War Memorial Hospital (July 2002).

[6] Palliative Care Handbook Guidelines on Clinical Management, Third Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

[7] Portsmouth Health Care NHS Trust Policies:

i) Control of Administration of Medicines by Nursing Staff Policy (January 1997).

ii) Prescription Writing Policy (July 2000).

iii) Policy for Assessment and Management of Pain (May 2001).

iv) Compendium of Drug Therapy Guidelines, Adult Patients (1998).

v) Medicines Audit carried out by the Trust referred to as Document 54 on page 52 in the Chi Report (reference 6).

[8] General Medical Council, Good Medical Practice (October 1995).

[9] British National Formulary (BNF). Section on Prescribing in Terminal Care (March 1995).

[10] British National Formulary (BNF). Section on Prescribing in the

Elderly (March 1995).

[11] Medical report regarding Elsie Lavender (BJC/30) Dr James Gillespie.

6. CHRONOLOGY/CASE ABSTRACT

Events at the Royal Naval Hospital

Mrs Elsie Lavender, an 83 year old widow who lived alone, was admitted on the 5th February 1996 to the Royal Naval Hospital, Hasler, Gosport under the care of Surgeon Commander Taylor, following a fall down her stairs at home. Mrs Lavender had no recollection of the fall but a pool of blood was found at the top of her stairs (page 154 of 695) and she was found at the bottom. She sustained a full thickness (down to the bone) laceration to her forehead that required suturing and a more superficial one to her right shin (page 145 of 695). She complained of pain in both shoulders, but not initially of neck or back pain (page 141 of 695). She reported that she was unable to move her right fingers. When examined by the casualty officer her cervical spine was apparently normal (page 141 of 695), she was tender over the right shoulder and upper left arm (page 143 of 695) and although able to move her right fingers the strength was reduced (graded 3/5; active movement against gravity (but not resistance)) The plantar reflex (elicited by firmly stroking up along the outer edge of the sole of the foot and across the base of the toes) was abnormal in her right foot as it was 'up-going', i.e. the big toe ± other toes extend upwards, when normally they flex downwards (page 145 of 695). This suggests damage to the nerves responsible for muscle movements somewhere along their path from the brain and down the spinal cord. X-rays of her chest, skull and both shoulders were performed. All were regarded as normal (page 145 of 695). In his report, Dr Gillespie states that the chest X-ray was essentially

normal but that the skull x-ray was missing from the x-ray packet. Given the severity of the fall and uncertain nature of its cause, Mrs Lavender was admitted under the medical team for observation and investigation. Her past medical history revealed her to be an insulin dependent diabetic for many years, asthmatic, registered blind and to have atrial fibrillation (an irregular heart rhythm). She had been admitted 11 months earlier following a collapse most likely due to hypoglycaemia (low blood sugar) (page 479 of 695). A neurological examination carried out by the medical senior house officer reported normal tone, power 4/5 (active power against gravity and resistance (but reduced from normal)) in her arms and legs, and 'can move fingers and thumb' (page 152 of 695). No sensory deficit is recorded, but this may reflect a cursory examination; previously reduced sensation in Mrs Lavender's hands and feet had been found in keeping with damage to her nerves, most likely from her diabetes (pages 48, 295 of 695). Reflexes were recorded as normal in both her arms. In her legs, her knee reflexes were normal, both ankle reflexes were absent and her right plantar reflex was up-going (page 152 of 695). Results of blood tests suggested an iron-deficiency anaemia with a haemoglobin of 9.7g/dl. There were no other signs or symptoms suggestive of chronic blood loss. White cell and platelet counts were normal (page 154 of 695). Her son reported that recently her blood sugars had been on the low side and she had experienced a very low sugar one month earlier (hypoglycaemic episode) that required treatment by the district nurses (page 154 of 695). Hypoglycaemia was thus considered a possible cause of her fall (page159 of 695).

On the 6th February, Mrs Lavender complained of pain in right arm. Examination revealed tenderness over the bone and muscles of the arm

and her hands were swollen (page 155 of 695). Later that day, she developed a raised temperature and was commenced on antibiotics empirically, as no obvious source of infection was found (page 156 of 695). Mrs Lavender temperature settled and she received 2 weeks of antibiotics, finishing on 19th February 1996 (page 687 of 695). On the 7th February, she complained of left shoulder/upper arm pain (page 156 of 695). On the 8th February, she was seen by the physiotherapist who noted that Mrs Lavender would not make any voluntary active movement when requested due to pain in both shoulders. When the physiotherapist moved her arms for her (passive/assisted movement) there was a full range of movement in both shoulders. She was only able to stand with the help of two others and took a few steps only. The physiotherapist concluded that the pain in the shoulders was a major problem (page 157 of 695). She was prescribed coproxamol 2 tablets every 6 hours and dihydrocodeine 30mg every four hours as required (page 690 of 695). The use of both of these analgesics was very variable. The most taken in one day was on the 12th February when 3 doses of coproxamol and 2 doses of dihydrocodeine were given (page 690 of 695).

Entries on the 9th and the 12th February report that pain in the arms/shoulders continued (page 158 of 695). Her blood sugars were low and her dose of insulin was reduced. A repeat haemoglobin on the 12th February was 10.1g/dl, platelet and white cell counts were normal (but the lymphocyte count reduced at 1.21×10^9/L)(page 205 of 695). Biochemistry revealed a low sodium 132mmol/l (lower limit 134mmol/l), total protein 60g/l (lower limit 63g/l) albumin 30g/l (lower limit 39g/l) and a raised urea 9.3mmol/l (upper limit 6.1mmol/l), alkaline phosphatase 401IU/l (upper limit

126IU/l) and gamma-glutamyl transferase 139IU/l (upper limit 78IU/l)(page 179 of 695). Apart from the haemoglobin, alkaline phosphatase and gamma-glutamyl transferase (latter two not tested) the remaining haematological and biochemical abnormalities were present at least 11 months earlier (pages 175 and 183 of 695).

On the 13th February she was referred for a geriatrician review and was seen by Dr Tandy, Consultant in Geriatrics on the 16th February 1996 (pages 159 and 162 of 695). In the letter summarising that assessment, Dr. Tandy noted that Mrs Lavender complained of weakness in both her hands and difficulty standing since her fall along with pain across her shoulders and down her arms. Mrs Lavender felt that the mobility was starting to improve in her hands. She had stood with the help of the physiotherapist but was still requiring two nurses to help transfer (page 5 of 103). The iron-deficiency anaemia and long-standing stress incontinence were noted (page 5 of 103).

Examination by Dr Tandy confirmed weakness of both hands and wrists, (power of 4/5; active power against gravity and resistance (but reduced from normal))(page 163 of 695). Sensation to light touch was reduced in the right hand in the area supplied by the median nerve (thumb, index, middle and adjacent half of the ring finger) that Dr Tandy considered due to long-standing entrapment of the median nerve at the level of the wrist (carpel tunnel syndrome). Reflexes were generally reduced and her ankle jerks were absent. Her plantar reflex was up-going on the left but not the right (page 163 of 695 and page 5 of 103). *This is opposite to what was found before.*

Dr Tandy was under the impression that Mrs Lavender's neck (cervical spine) had been x-rayed and assumed this was normal. This is incorrect, Mrs Lavender had had only skull, shoulder and chest x-rays. Dr Tandy's assessment was that she had most likely experienced a brain stem stroke leading to her fall (page 163 of 695 and page 5 of 103). Atrial fibrillation is a risk factor for stroke as small blood clots can form in the heart that then travel to the brain to cause a stroke. Dr Tandy placed Mrs Lavender on the waiting list for transfer to Gosport War Memorial Hospital for rehabilitation to try and get her home (page 164 of 695).

Physiotherapy and medical entries on the 20th February 1996 noted that Mrs Lavender's upper limb function was improving as she was starting to feed herself (but not able to use cutlery) but that she still complained of shoulder pain. Mrs Lavender still required the help of two people to stand and could not use a walking aid because of hand weakness. Iron was prescribed for her anaemia (pages 165 and 166 of 695).

A repeat full blood count on the 21st February revealed an increased haemoglobin of 11.0g/dl (normal) and a fall in her platelet count to $120x10^9/l$ (lower limit $150x10^9/l$). This result was signed, but not dated by one of the medical team (page 201 of 695). There is no entry in the notes commenting upon this result.

Over the course of Mrs Lavender's admission her blood sugars remained variable, either too high or too low, and the dose of insulin had to be altered several times (pages 665, 666, 660, 659 and 687, 689, 681, 682 of 695).

Events at Gosport War Memorial Hospital

Mrs Lavender was transferred to Daedalus Ward, Gosport War Memorial Hospital on the 22nd February 1996, under the care of Dr Lord. The Royal Naval Hospital nursing transfer form noted that Mrs Lavender's medication consisted of digoxin 125microgram once a day (for her atrial fibrillation), co-amilofruse (frusemide 40mg and amiloride 5mg) 1 tablet once a day (a diuretic or 'water tablet'), salbutamol inhaler 2 puffs four times a day, becotide inhaler, 2 puffs twice a day, mixtard, insulin 24 units in the morning, 12 units in the evening and iron sulphate 200mg twice a day (page 71 of 103). She was however, also still taking coproxamol 2 tablets or dihydrocodeine 30mg as required, and had taken a total of 2 coproxamol and 30mg of dihydrocodeine on the 21st February 1996 (page 684 of 695). Mrs Lavender required minimal assistance with feeding but full assistance with her hygiene needs. There were ulcers on both legs dressed every other day. Her pressure areas were intact although the skin over the buttocks was red (page 71 of 103).

There are six entries in the medical notes that cover a period of 13 days, taking up just over one page in length (pages 44 and 45 of 103). They are brief and make events difficult to follow in any depth. What follows is a record of events summarised from the medical notes, summary notes and nursing care plan.

The entry in the medical notes dated 22nd February 1996, reads 'Transferred to Daedalus Ward, GWMH. PMH (past medical history) fall at home from the top to the bottom of the stairs, laceration on head. Leg ulcers, severe incontinence needs a catheter. IDDM (insulin dependent diabetes mellitus) needs mixtard insulin bd (twice a day), regular series

B.S. (blood sugars), transfers with 2, incontinence of urine, help to feed and dress. Bartell 2. Assess general mobility. ?suitable rest home, if home found for cat' (page 45 of 103). Pain was not mentioned nor assessed in the medical notes. In the summary notes, it was noted that Mrs Lavender experienced pain in her arms and shoulders (page 91 of 103). Her medication was continued unchanged (pages 65, 66, 67 of 103), apart from an increase in the dose of dihydrocodeine to 60mg to be taken as required (page 65 of 103).

The medical notes entry on the 23rd February 1996 reported that Mrs Lavender was catheterised the previous night and that there was some residual urine. The summary notes report that 750ml of urine was drained in the first hour (page 91 of 103) and the nursing care plan reports that one litre or more of urine was drained within 1½ hours after catheterisation (page 75 of 103). This suggests that Mrs Lavender was in urinary retention with 'overflow' incontinence of urine. Blood and protein was found in the urine and trimethoprim (an antibiotic) prescribed for a presumed urinary tract infection (pages 45, 67 and 91 of 103). It is unclear if a sample of urine was sent for microbiology; I could find no results in the notes. Blood for routine haematology and biochemistry testing was taken on 23rd February 1996 (page 91 of 103). The blood count revealed a further drop in the platelet count ($36x10^9$/L)(page 58 of 103). It was commented on the results form that as it was a very small sample, the validity of the platelet count was in question and an early repeat was suggested (page 58 of 103). The main findings of the biochemistry testing were a low sodium at 133mmol/L (stable; probably due to her diuretic therapy) and a raised alkaline phosphatase at 572 IU/L (increasing). As the

alkaline phosphatase can be increased in liver or bone problems, identifying the liver or bone isoenzyme can help differentiate between the two. The isoenzyme test was 'to follow' but I can find no result in the notes (pages 41 and 42 of 103). However, the recent finding of a raised gamma-glutamyl transferase suggests it was more likely liver.

On the 24th February 1996 the summary sheet reports that pain was not controlled properly by DF118 (the dihydrocodeine). Mrs Lavender had received four doses of dihydrocodeine 60mg on the 23rd February and one dose at 06.03 on the 24th February 1996 (page 65 of 103). She was seen by Dr Barton and commenced on MST 10mg twice a day (pages 67 and 91 of 103). MST is a slow release formulation containing morphine. There is no medical notes entry on the 24th February 1996 that details the pain problem or the commencement of the morphine.

No additional dihydrocodeine was requested by/offered to Mrs Lavender on the 25th February (she only had two further doses, one on the afternoon of the 3rd March and one on the morning of the 5th March 1996), but the summary sheet entry at 19.00 hours on the 25th February reports that Mrs Lavender appears to be in more pain, screaming "my back" when moved but uncomplaining when not (page 92 of 103).

On the 26th February 1996, the medical notes reported 'not so well over weekend. Family seen and well aware of prognosis and treatment plan. Bottom very sore, needs Pegasus mattress, institute SC (subcutaneous) analgesia if necessary' (page 45 of 103). The summary notes report that Dr Barton increased the MST to 20mg twice a day (page 92 of 103). At 14.30 hours they note Mrs Lavender's son and his wife were seen by Dr Barton '...prognosis discussed. Son is happy for us to just make Mrs

Lavender comfortable and pain free, syringe driver explained' (page 92 of 103). Mrs Lavender was prescribed on the 'as required' section of the drug chart a syringe driver containing diamorphine 80–160mg and midazolam 40–80 mg (page 65 of 103). There was no explanation in the medical or nursing notes of why it was that Mrs Lavender's prognosis was apparently limited. This dose of diamorphine approximately equates to a 6–12-fold increase in Mrs Lavender's dose of morphine. It was however, never used. The summary sheet noted that due to a high blood sugar, Mrs Lavender's dose of insulin had to be increased (pages 62 and 92 of 103).

The full blood count was repeated on the 27th February 1996 and revealed a further fall in the platelet count 22 x 10^9/L, an increased white blood cell count 13 x 10^9/L, due to an increase in neutrophils (10.8 x 10^9/L) and a normal haemoglobin 12.5g/dL (page 57 of 103). The biochemistry tests for renal function were also repeated on the 27th February 1996. The urea and creatinine had both increased, to 14.6mmol/L and 120micromol/L respectively, in keeping with a deterioration in kidney function (page 42 of 103). There is no mention of these results in the medical notes and no further investigation or consideration for the causes of the low platelet count, raised white cell count or deteriorating renal function. On the 27th February 'painful shoulders and upper arms' became part of the nursing plan (page 84 of 103). An entry reports 'analgesia administered, fairly effective' (page 84 of 103).

On the 29th February 1996, the summary sheet noted that due to a high blood sugar, Mrs Lavender received an additional dose of human actrapid insulin (pages 62 and 92 of 103). Mrs Lavender received two doses in all, before the prescription was crossed off (page 62 of 103).

Entries in the 'painful shoulders and upper arms' nursing care plan each day between 28th February and 4th March 1996 seem to suggest that the pain was mainly on movement and on the 2nd and 3rd of March it was described as 'slight' (page 83 of 103).

Nursing care plan notes from 1st March to the 6th March 1996 reported leakage of faecal fluid, despite rectal digital examination (excluding faecal impaction), suppositories and a manual evacuation (pages 85 and 87 of 103).

There is no mention of pain in the summary notes or medical notes again until the 4th March 1996. The summary notes reported 'Patient complained of pain and having extra analgesia p.r.n (as required). Oramorph sustained release tablets dose increased to 30mg b.d. (twice a day) by Dr Barton (pages 62 and 92 of 103). The Oramorph SR tablets are a different brand of slow release morphine, similar to MST. There is no medical notes entry on the 4th March 1996 that details the pain problem or the increase in the morphine. In the nursing plan notes, the entry for the 4th March 1996 reads 'seen by physio- exercises:- 3 turns of head to right + 5 neck retractions every 2 hours. Elsie needs reminding. Analgesia increased' (page 83 of 103).

The next entry in the medical notes, on the 5th March 1996, reads 'Has deteriorated over the last few days. Not eating or drinking. In some pain, therefore start SC analgesia. Let family know' (page 45 of 103). The summary note entry for the 5th March 1996 reads 'patients pain uncontrolled, very poor night. Syringe driver commenced 5th March 1996 at 09.30 hours, containing diamorphine 100mg and midazolam 40mg...' (page 92 of 103). Both drugs were written as a range, i.e. diamorphine

100–200mg and midazolam 40–80mg; although neither dose needed adjusting (page 65 of 103). A dose of diamorphine 100mg approximately equates to a 5-fold increase in Mrs Lavender's dose of morphine. The nursing care plan notes 'pain uncontrolled, patient distressed, syringe driver commenced 09.30, son informed' (page 83 of 103).

On the 6th March 1996 the medical notes entry reads 'Further deterioration. SC analgesia commenced. Comfortable and peaceful. I am happy for nursing staff to confirm death' (page 45 of 103). The summary sheet entry for the 6th March 1996 reads 'seen by Dr Barton. Medication other than through syringe driver discontinued as patient unrousable' (page 93 of 103). The next entries in the medical notes and summary sheet were at 21.28 hours, the pronunciation of Mrs Lavenders death (pages 45 and 93 of 103). I am advised that on the death certificate, the cause of death was stated as 1a Cerebrovascular accident and 2 Diabetes Mellitus.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Syringe drivers, diamorphine and midazolam

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24hours. Indications for its use include swallowing difficulties or a comatose patient. In the United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF number 29 (March 1995)). Others sometimes suggested dividing by 2 or 3 depending on circumstance (Wessex protocol). Hence, 60mg of morphine taken orally a day could equate to a daily dose of 20 or 30mg of diamorphine SC. It is usual to prescribe additional doses for use 'as required' in case symptoms such as pain breakthrough. The dose is usually 1/6th of the 24hour dose. Hence for someone receiving 30mg of diamorphine in a syringe driver over 24hours, a breakthrough dose would be 5mg. One would expect it to have a 2–4 hour duration of effect, but the dose is often prescribed to be given hourly if required. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in their terminal phase would generally aim to find a dose that improves the patient's symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg a day. A

smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated every 24hours if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24hours, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4hours, and it may need to be given more frequently. As an active metabolite of midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

ii) The principle of double effect.

The principle of double effect states that:

'If measures taken to relieve physical or mental suffering cause the death of a patient, it is morally and legally acceptable provided the doctor's intention is to relieve the distress and not kill the patient.'

This is a universal principle without which the practice of medicine would be impossible, given that every kind of treatment has an inherent risk. Many discussions on the principle of double effect have however, involved the use of morphine in the terminally ill. This gives a false impression that the use of morphine in this circumstance is a high risk strategy. When correctly used (i.e. in a dose appropriate to a patient's need) morphine does not appear to shorten life or hasten the dying process in patients with cancer. Although a greater risk is acceptable in more extreme circumstances, it is obvious that effective measures which carry less risk to

life will normally be used. Thus, in an extreme situation, although it may occasionally be necessary (and acceptable) to render a patient unconscious, it remains unacceptable (and unnecessary) to cause death deliberately. As a universal principle, it is also obvious that the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

8. OPINION

Mrs Lavender was a frail 83 year old with insulin dependent diabetes mellitus who was admitted following a serious fall from the top to the bottom of her stairs. Initially, it was considered likely that the fall was due to a hypoglycaemic episode (low blood sugar). She was at risk of hypoglycaemia as her blood sugars had recently been running low. Following the fall, Mrs Lavender complained of pain across her shoulders and down her arms and was unable to use her hands or to stand. Examination confirmed weakness in the right hand and an 'up going' plantar reflex in her right foot. Investigations revealed iron deficiency anaemia. Pain in her shoulder and arms continued, although there had been some improvement in the use of her hands by the time Dr Tandy saw her (11 days after admission). On examination she found weakness of both hands and wrists and an 'up going' plantar reflex in the left foot. Dr Tandy's opinion was that Mrs Lavender had suffered a brain stem stroke. Mrs Lavender's diabetes and atrial fibrillation would increase her risk of having a stroke. In my current practice I no longer see patients who are admitted with a stroke and Dr Tandy's experience will be greater than mine. However, given that Mrs Lavender had recently experienced a severe fall, I am unsure how certain one could be in attributing all of Mrs

Lavender's symptoms and signs as being caused by a brain stem stroke, particularly as her neurological findings could also be in keeping with cervical spinal cord and nerve root trauma sustained in the fall down the stairs. I would have thought it prudent whatever the findings on the initial examination of the cervical spine in casualty to have obtained a cervical spine X-ray. Whatever the cause of her fall, when considering Mrs Lavender's pain, it is my opinion that:

1. Mrs Lavender's pain across her shoulders and into her arms was most likely to be related to her fall.
2. Her pain was likely to be a 'mixed' pain; that is originating from damage to muscles and soft tissues (e.g. ligaments) of the neck and, possibly from impingement on the nerve roots and spinal cord within the cervical spine. Muscle and nerve injury pain respond poorly to strong opioids.
3. As her injuries healed over subsequent weeks, it is reasonable to expect that the pain would also settle. As such, failure of the pain to settle or any worsening of the pain should, in my view, prompt a careful reassessment that includes appropriate investigation, e.g. a cervical spine imaging (given her neurological findings) and certainly the area of the spine causing Mrs Lavender to scream out in pain "my back" (page 92 of 103). I am unable to find in the notes which part of her back this pain was.

Events at Gosport War Memorial Hospital

Infrequent entries in the medical notes make it difficult to closely follow Mrs Lavender's progress over the last two weeks of her life. There are six entries, taking up just over one page in length.

Mrs Lavender's most relevant problems during her stay, in summary and in approximate chronological order, appear to have consisted of weak hands and

wrists, poor mobility, pain in her shoulders and arms that was mainly on movement for which she went on to receive increasing doses of morphine; urinary retention and a probable urinary tract infection; a falling platelet count; being generally 'unwell'; increased blood sugars and insulin requirements; increasing white cell count, deteriorating renal function; leakage of faecal fluid; worsening of her pain and further deterioration. A syringe driver was then commenced with doses of diamorphine and midazolam sufficient to render her unresponsive until she died 36 hours later. Her cause of death was registered as cerebrovascular accident. A lack of assessment and documentation make the validity of this difficult to comment upon, but her final deterioration as outlined in the nursing and medical notes does not appear in my opinion to be typical of a cerebrovascular accident. Based on the sequence of events and biochemical and haematological findings, it seems more likely that her immobility resulting from her fall, led to an infection. Given that Mrs Lavender had suffered a recent accident that may have contributed in some way to her death, it is usual practice to discuss such deaths with the coroner.

There is a lack of documentation to demonstrate that there had been an adequate assessment of many of the problems Mrs Lavender had through the undertaking of an appropriate history, physical examination and investigation.

Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day?

The medical care provided by Dr Barton to Mrs Lavender following her transfer to Gosport War Memorial Hospital, Daedalus Ward is suboptimal when compared to the good standard of practice and care expected of a doctor outlined by the General Medical Council (General Medical Council, Good Medical Practice, October 1995, pages 2–3) with particular reference to:

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs including, where necessary, an appropriate examination; providing or arranging investigations or treatment where necessary; taking suitable and prompt action when necessary; referring the patient to another practitioner when indicated
- in providing care you must keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs or appliances that serve the patients' needs.

Specifically:

i) The notes relating to Mrs Lavender's transfer to Daedalus Ward are inadequate. On transfer from one service to another, a patient is usually re-clerked highlighting in particular the relevant history, examination findings and planned investigations to be carried out.

ii) The cause of Mrs Lavender's urinary retention was not assessed.

iii) Mrs Lavender was treated for a urinary tract infection with the antibiotic trimethoprim. Neither a diagnostic urine specimen nor a check urine specimen (to see if the infection had cleared) were sent for microbiology. It is therefore unclear if the urinary tract infection was successfully treated or not. This should have been considered when Mrs Lavender was noted to be 'not so well' (see point v).

iv) There is a lack of medical notes relating to the pain or its assessment and the commencement of morphine (MST 10mg) twice a day on the 24th February 1996.

v) On the 26th February 1996 the medical notes report Mrs Lavender to be 'not so well over weekend'. There is a lack of detail that explains in what way she was not so well. There are no records that an appropriate history, examination or investigations had been undertaken to try and determine the reason for Mrs Lavender feeling less well. Instead, without any assessment of the pain, the MST was increased to 20mg twice a day and a syringe driver prescribed to be used 'as required' that contained diamorphine and midazolam in doses that would be excessive to Mrs Lavenders needs.

vi) Blood tests from the 27th February 1996 revealed a low platelet count and deteriorating kidney function. There is no mention of this in the medical notes, and no action was taken.

vii) On the 29th February 1996 there is no mention in the medical notes that Mrs Lavender's blood sugars were high requiring additional doses of insulin. The fact that this could have been due to an untreated infection does not appear to have been considered.

Despite entries in the nursing care plan and summary sheets relating to Mrs Lavender's pain there is no mention of this in the medical notes.

viii) The nursing care plan reports leakage of faecal fluid. There is no mention of this problem in the medical notes or consideration of the possible significance of this symptom given Mrs Lavenders history of trauma.

ix) The morphine was increased again on the 4th March 1996. There is no pain assessment or entry in the medical notes that relates to this increase.

x) The entry in the medical notes of the 5th March reports that Mrs Lavender had deteriorated over the last few days. It is not clear in what way she had deteriorated. There is no history or examination that considers the possible reasons for her decline.

xi) Mrs Lavender's pain appeared poorly controlled on the night of the 4th March but there is no assessment of the pain in the medical notes prior to a syringe driver containing diamorphine 100mg and midazolam 40mg being commenced. The doses of diamorphine and midazolam used in response to Mrs Lavender's worsening pain, are excessive for her needs, even if it were considered that her pain was morphine responsive and she was dying from natural causes.

If the care is found to be suboptimal what treatment should normally have been proffered in this case?

Issue i (failure to take an adequate history and examination on transfer; failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed)

Upon her transfer to Daedalus Ward there should have been an adequate assessment of Mrs Lavender's condition based on the history and clinical signs and, if necessary, an appropriate examination. In my view there is inadequate documentation of Mrs Lavender's relevant history, in particular a lack of an assessment of her pain. As the Wessex guidelines (page 2) point out, an accurate pain assessment is essential both for diagnostic and therapeutic purposes. An assessment should have included as a minimum the noting of the site, severity, aggravating/relieving factors that together with a physical examination would help identify the most likely cause(s) of the

pain(s). This was important as it was likely that Mrs Lavender would have been experiencing several different types of pain as a result of her injury. There may have been soft tissue, muscle and nerve injury pains. Muscle and nerve injury pains are less likely to respond to opioid analgesics. This is highlighted in the Wessex protocol (page 3) 'remember some pains are opioid responsive, others are only opioid semi-responsive and need other approaches'.

There was no physical examination of Mrs Lavender on her transfer. This would be important to act as a baseline against which to compare any future changes. A thorough neurological examination would have been particularly important given the history of her fall, the possibility of a brain stem stroke being raised and the abnormal neurological findings mentioned in Dr Tandy's letter.

Issue ii (failure to adequately assess the patient's condition)

Urinary retention is rare in women and should have prompted an assessment to explore the possible causes of it in Mrs Lavender. Long-standing diabetes can cause damage to the nerves controlling bladder function and may have been responsible. Another cause of urinary retention is injury to the spinal cord. Given Mrs Lavender's history of a severe fall and complaints of back pain, in my opinion she should have been reassessed, including a careful neurological examination. This would have included assessment of anal tone and perineal sensation.

Issue iii (failure in providing or arranging investigations or treatment where necessary; taking suitable and prompt action when necessary; failure to adequately assess the patient's condition)

A urinary tract infection is sometimes treated 'blind' with antibiotics such as trimethoprim, without obtaining a sample of urine for microbiology. The risk with this practice is that the bacteria causing the infection may be resistant to the antibiotic. If there are reasons to doubt that the infection is responding to

treatment, e.g. patient remains unwell, urinary symptoms persist, then a urine specimen should be sent for microbiology testing and/or consideration given to changing the antibiotic.

Issues iv and ix (failure to adequately assess the patient's condition; failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed)

Given that Mrs Lavender's pain required frequent 'as required' doses of dihydrocodeine immediately after her transfer, it was reasonable to provide her with analgesia on a regular basis. An assessment of the pain should however have been done in order to determine the cause(s) of her pain(s) as this would influence the way the pain(s) were managed. For example, were non-drug methods such as positioning, massage, TENS (transcutaneous electrical nerve stimulation) appropriate? If drug measures were considered appropriate, and the pain was considered to be opioid responsive one option would have been to combine the use of paracetamol (step 1 analgesic) with the dihydrocodeine (step 2 analgesic) regularly. If reasonable doses of dihydrocodeine were not relieving the pain some practitioners may well commence a small dose of morphine as Dr Barton did. However, if the pain was not particularly opioid responsive, the dihydrocodeine or morphine may do little or nothing for the pain but could expose the patient to unwanted effects of opioids, e.g. drowsiness, delirium, nausea, vomiting etc. This is relevant, as given her traumatic fall, muscle or nerve injury pain that generally respond poorly to opioids may have been significant factors in Mrs Lavender's pain. Further, it was commented upon that Mrs Lavender was comfortable at rest, only to be in pain when moved (termed 'incident' pain). These can be difficult pains to manage, even if opioid responsive, as the dose of opioid required to improve the pain on movement can be excessive for the patient whom for the

majority of the time is resting and pain free. Typically in this situation the patient becomes increasingly drowsy as the dose of opioid increases.

Despite increasing the morphine dose, a thorough pain assessment was not carried out.

Issues v, vi and vii (failure to adequately assess the patient's condition; failing in providing or arranging investigations or treatment where necessary; taking suitable and prompt action when necessary; failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed; failure to prescribe only the treatment, drugs or appliances that serve the patients needs)

There was a failure to adequately assess and document clearly why Mrs Lavender was less well around the 26th February. This should have been based on a history, examination (e.g. temperature, chest) and findings of appropriate investigations (e.g. urine specimen for microbiology). Mrs Lavender was at increased risk of infection due to her immobility and diabetes, and this should have specifically been considered as a cause for her being less well. Other findings that pointed to the possibility of there being an infection, e.g. the raised blood sugars, increased insulin requirements, raised white cell count and falling platelet count do not appear to have been acted upon.

In the absence of a diagnosis that explained why Mrs Lavender was less well, it is unclear what information Dr Barton was in a position to give Mrs Lavender's son regarding his mother's situation and prognosis. Unless Mrs Lavender was clearly entering her terminal stage and was actively dying, it would have been appropriate to have made reasonable efforts to identify the cause of her feeling less well as it could have been treatable. Even if she were considered to be dying, it would be unusual to respond by prescribing a

syringe driver 'as required' that contained doses of diamorphine and midazolam that were excessive to her needs (see technical issues).

The causes of Mrs Lavender's low platelet count and deteriorating kidney function should have been considered in light of her overall situation. There are many causes of a fall in platelet count, and infection is one. It does not appear that Dr Barton discussed this finding (or Mrs Lavender's situation at any point) with a consultant or obtained advice specifically about the low platelet count from a haematologist. The decline in kidney function could have been due to a urinary tract infection not responding to the antibiotics and this should have been actively considered. Alternatively, as she was less well, she may have been drinking less and as a result had become dehydrated. Mrs Lavender's diuretic (water tablet) that could aggravate the situation was continued unchanged when stopping it should have been considered. With a deterioration in her kidney function, the possibility that cummulation of the metabolites of morphine could have been contributing to her decline was not considered.

Issue viii (failure to adequately assess the patient's condition)

There is no mention of the problem of faecal leakage in the medical notes. There are a number of possible reasons why Mrs Lavender may have been experiencing this, including her age, diabetes, immobility and diarrhoea. As it can also be caused by injuries to the brain or spinal cord, this symptom is significant given Mrs Lavenders history of a severe fall, her other symptoms and complaints of back pain. There should have been a neurological examination that would have included assessment of anal tone and perineal sensation.

Issue x (failure to adequately assess the patient's condition; failing in providing or arranging investigations or treatment where necessary; taking suitable and prompt action when necessary; failure to keep clear, accurate, and

contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed; failure to prescribe only the treatment, drugs or appliances that serve the patients needs)

Although Mrs Lavender was reported to have further declined, there was no clear documentation in what way this was. There should have been a search for the possible causes in case these were reversible. In particular, an infection should have been ruled out.

Given the expectation that the pain should improve as her injuries healed, a reason for the pain worsening on the evening of 4th March should have been sought. For example, were there new findings on examination? Had her neurology altered?

As the pain had got worse despite increasing the morphine, consideration should have been given to the fact that the pain was not responding to the morphine. This should have prompted an assessment of the causes of her pain and review of her treatment. If her pain was not responsive to morphine, was the amount she was taking too much? Was this playing a part in her deterioration?

Issue xi (failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed; failure to prescribe only the treatment, drugs or appliances that serve the patients needs)

The medication used in response to Mrs Lavender's worsening pain, detailed below, appears excessive for her needs, even if it were considered that her pain was morphine responsive and she was dying from natural causes. Medication to control symptoms is usually commenced at a starting dose appropriate to the patient (e.g. considering age, frailty etc.) and their particular

symptom control needs and titrated upwards only to control these symptoms without necessarily rendering the patient unresponsive. There is no justification given for how the doses of diamorphine and midazolam were determined for Mrs Lavender. Using a 1:2 or 1:3 dose conversion ratio to calculate the dose of subcutaneous diamorphine from her oral morphine dose, Mrs Lavender's dose should have been in the order of 20–30mg of diamorphine per day. A daily dose of diamorphine of 100mg (with scope to increase the dose to 200mg a day) is likely to be excessive for Mrs Lavender's needs and to cause drowsiness. Increasing doses of opioids excessive to a patients needs are also associated with an increasing risk of delirium, nausea and vomiting and respiratory depression. There are no clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing any drug as a range is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient should decide on and prescribe any change in medication. Such decisions should not be left to a nurse.

The daily dose of midazolam was prescribed as 40–80mg. There is no justification within the medical notes for the use of midazolam. Although the nursing care plan notes that Mrs Lavender was distressed, this appeared to relate to her uncontrolled pain. It is usual practice in this situation to concentrate on providing pain relief rather than on sedating the patient. If a patient is particularly distressed, small doses of sedative are sometimes given, but usually on an 'as required basis' whilst awaiting any changes made to the analgesia to become effective. In this regard, midazolam 2.5mg by intermittent SC injection would have been reasonable. The dose of 40mg of midazolam is likely to lead to drowsiness in a frail elderly patient. If Mrs

Lavender was considered to have muscle spasm, terminal agitation, or anxiety then a smaller daily dose such as 10mg may have sufficed. Again, there are no prescribing instructions on why, when and by how much the dose can be altered within this range and by whom.

If there were concerns that a patient may experience, for example, episodes of pain or anxiety, it would be much more usual, and indeed seen as good practice, to prescribe appropriate doses of morphine/diamorphine, or diazepam/midazolam respectively that could be given intermittently 'as required' orally or SC. This allows a patient to receive what they need, when they need it, and guides the doctor in deciding if a regular dose is required, the appropriate starting dose and subsequent dose titration.

In short, the diamorphine and midazolam appear to have been prescribed without sufficient safeguard in relation to altering the dosage and in a way that exceeded Mrs Lavender's needs. In regard to the latter, Mrs Lavender was unrousable after the syringe driver had been commenced and no alteration in the dose of diamorphine or midazolam was required.

If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

Dr Barton does not appear to have provided Mrs Lavender a good standard of clinical care as defined by the GMC (General Medical Council, Good Medical Practice, October 1995, pages 2–3).

Although it is possible that Mrs Lavender was dying 'naturally', it is also possible that her physical state had deteriorated in a temporary or reversible way and that she was not in her terminal phase. In this regard, there should have been a more thorough assessment and clearer documentation of the

possible contributing factors, such as an infection, to Mrs Lavender becoming 'less well'.

A failure to assess Mrs Lavender's pain correctly could have resulted in her receiving increasing doses of morphine for pain(s) that occurred mainly on movement and that were not fully opioid responsive (e.g. muscle and nerve injury pains). This may have provided little pain relief but exposed her to the adverse effects of opioids such as drowsiness. That this may have contributed to her further deterioration was not considered or acted upon. The effect of deteriorating kidney function on morphine metabolites that may have exacerbated the above was not considered or acted upon.

There were symptoms, signs and investigations in keeping with deteriorating kidney function, a possible infection and possible spinal cord injury that should have prompted a more thorough assessment of Mrs Lavender's condition, including a neurological examination.

In the absence of a thorough assessment that could confirm whether Mrs Lavender was likely to be experiencing a reversible or irreversible decline, it is difficult to know what could have been said to her son with any certainty. However, the prescribing of a syringe driver, even though never used, with large doses of diamorphine and midazolam to be used 'if required' appeared excessive and premature. The syringe driver started some days later also contained doses of diamorphine and midazolam that were excessive for Mrs Lavender's needs.

In patients with cancer, the use of diamorphine and midazolam when appropriate for the patients needs does not appear to hasten the dying process. This has not been examined in patients dying from other illnesses to my knowledge, but one would have no reason to suppose it would be any different. The key issue is whether the use and the dose of diamorphine and midazolam are *appropriate* to the patients needs. In situations where they are inappropriate or excessive to the patients needs, it would be difficult to exclude

with any certainty that they did not contribute more than minimally, negligibly or trivially to the death of the patient.

Although the principle of double effect could be invoked here (see technical issues), it remains that a doctor has a duty to apply effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose of strong opioid that was *appropriate* and not excessive for a patient's needs.

If it were that Mrs Lavender had naturally entered the terminal phase of her life, at best, Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mrs Lavender a peaceful death, albeit with what appears to be an inappropriate and excessive use of medication due to a lack of sufficient knowledge.

However, in my opinion, based on the medical and nursing records, there is reasonable doubt that she had definitely entered her terminal stage. Given this doubt, at worst, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Lavender by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Lavender by failing to adequately assess the cause of her pain and deterioration, failing to take suitable and prompt action when necessary and exposing her to inappropriate and/or excessive doses of diamorphine and midazolam that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

9. LITERATURE/REFERENCES

British National Formulary 29 (March 1995).

Prescribing in Terminal Care, pages 12–15.

British National Formulary 47 (March 2004).

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition

General Medical Council, Good Medical Practice, October 1995, pages 2–3.

'Wessex Protocol' Salisbury Palliative Care Services May 1995 pages 3–4, 30–31.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete professional opinion.

Signature: Code A Date: 1.5.05

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DRAFT REPORT

regarding

ENID SPURGIN (BJC/45)

PREPARED BY: Dr Andrew Wilcock MB ChB FRCP DM
Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mrs Spurgin was a relatively fit and independent 92 year old widow who lived alone. Whilst walking her dog, she fell and fractured her right hip which was surgically repaired using a dynamic hip screw on the 20th March 1999. Within hours of the surgery there was leakage from the wound and swelling of her right thigh to twice its normal size, causing discomfort and pain on palpation. It was considered most probable that she had developed a haematoma due to a bleeding vessel in the wound. Pain in Mrs Spurgin's hip/thigh on movement continued to be a problem noted by Dr Reid when he reviewed Mrs Spurgin on the 24th March 1999. Surgeon Commander Scott reviewed Mrs Spurgin but no specific comment was recorded in the medical notes regarding Mrs Spurgin's pain, no changes were made to her analgesia and on the 26th March 1999 she was transferred to Dryad Ward, Gosport War Memorial Hospital. With regards to the standard of care proffered to Mrs Spurgin in Haslar Hospital, the report of Mr Redfern raises several concerns.

During her admission to Dryad Ward, the medical care provided by Dr Barton and Dr Reid was suboptimal: there was a lack of clear, accurate, and contemporaneous patient records; inadequate assessment of Mrs Spurgin's condition; a lack of consultation with colleagues to seek appropriate advice and support; the use of diamorphine and midazolam in doses excessive to Mrs Spurgin's needs.

When Mrs Spurgin became less well, increasingly drowsy, dehydrated, agitated, spilling things and had a nightmare there was no medical assessment or even simple observations documented. Mrs Spurgin was

not anticipated to be dying and her symptoms and signs were in keeping with a potentially reversible septicaemia/toxaemia arising from an infection (the wound had become tender and inflamed despite the antibiotics) ± the effects of increasing blood levels of morphine metabolites due to dehydration. Potentially beneficial treatments (e.g. intravenous hydration, reduction in the dose of morphine, different antibiotics) were not proffered nor advice obtained from the orthopaedic team or a microbiologist. Instead a syringe driver containing diamorphine (equivalent to a 4–6 fold increase in her morphine dose) and midazolam was commenced. On a subsequent review by Dr Reid, as a result of finding Mrs Spurgin unresponsive, the diamorphine dose was halved, however the midazolam dose was doubled.

In short, Dr Barton in particular, but also Dr Reid, could be seen as doctors who breached the duty of care they owed to Mrs Spurgin by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Spurgin by failing to adequately assess her condition and taking suitable and prompt action when she complained of pain that appeared excessive to her situation and when her physical state deteriorated in what was a potentially reversible way. Instead the actions of Dr Barton and Dr Reid exposed Mrs Spurgin to the use of inappropriate doses of diamorphine and midazolam that would have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton and Dr Reid leave themselves open to the accusation of gross negligence.

2. INSTRUCTIONS

To examine the medical records and comment upon the standard of care afforded to the patient in the days leading up to her death against the acceptable standard of the day. Where appropriate, if the care is felt to be suboptimal, comment upon the extent to which it may or may not disclose criminally culpable actions on the part of individuals or groups.

3. ISSUES

3.1 Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day?

3.2 If the care is found to be suboptimal what treatment should normally have been proffered in this case?

3.3 If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

4. BRIEF CURRICULUM VITAE

Code A

Code A

5. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Enid Spurgin, including the medical certificate of cause of death.

[2] Full set of medical records of Enid Spurgin on CD-ROM.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

[4] Hampshire Constabulary Operation Rochester Guidance for Medical Experts.

[5] Hampshire Constabulary Summary of Care of Enid Spurgin.

[6] Palliative Care Handbook Guidelines on Clinical Management, Third

Edition, Salisbury Palliative Care Services (1995); Also referred to as the 'Wessex Protocols.'

[7] Portsmouth Health Care NHS Trust Policies:

i) Control of Administration of Medicines by Nursing Staff Policy (January 1997).

ii) Prescription Writing Policy (July 2000).

iii) Policy for Assessment and Management of Pain (May 2001).

iv) Compendium of Drug Therapy Guidelines, Adult Patients (1998).

v) Draft Protocol for Prescription Administration of Diamorphine by Subcutaneous Infusion, Medical Director (December 1999).

vi) Medicines Audit carried out by the Trust referred to as Document 54 on page 52 in the Chi Report (reference 6).

[8] General Medical Council, Good Medical Practice (July 1998).

[9] British National Formulary (BNF). Section on Prescribing in Terminal Care (September 1998).

[10] British National Formulary (BNF). Section on Prescribing in the Elderly (September 1998).

[11] Statement of Dr Jane Barton as provided to me by Hampshire Constabulary (undated).

[12] Statement of Dr Jane Barton RE. Enid Spurgin, 15th September 2005.

[13] Draft Report regarding Statement of Dr Jane Barton RE. Enid Spurgin (BJC/45), Dr A Wilcock, 5th January 2006.

[14] Draft overview of Enid Spurgin (BJC/45), Dr A Wilcock, 1st November 2005.

[15] Draft Report regarding Enid Spurgin, Mr D R M Redfern, 22nd January 2006.

6. CHRONOLOGY/CASE ABSTRACT

Events at Royal Haslar Hospital, 19th–26th March 1999

Mrs Spurgin, a 92 year old widow who lived alone, was admitted on the 19th March 1999 to Haslar Hospital having been pulled over by her dog onto her right hip resulting in a fracture (page 66 of 135).

Mrs Spurgin was considered 'basically well with no major medical problems' (page 68 of 135). Most of her past medical history was orthopaedic with fractures of her right patella, sternum (page 13 of 135), fifth metacarpal of her right hand (page 86 of 135), stress fracture left hip (page 37 of 51), crush fractures lumbar spine vertebrae (page 38 of 51), lumbar back ache, right hip pain, Pagets disease of the sacrum and right ilium, stress fracture right hip (page 44 of 51); a probable inferior myocardial infarction in 1989 (page 6 of 51), depression secondary to failing physical health in 1997 (page 171 of 175) and removal of a cataract in 1998 (page 153 of 175).

Mrs Spurgin's fracture was repaired surgically using a dynamic hip screw on the afternoon of the 20th March 1999 (page 75 of 135). Mrs Spurgin's pre-operative care raised concerns for the anaesthetist who reviewed her at 12.00h on the 20th March 1999 (page 68 of 135). On admission, she had been made 'nil by mouth' as she was possibly going to theatre the same day (page 68 of 135). This did not occur, but she remained nil by mouth and no intravenous fluids were administered. As a result Mrs Spurgin was likely to be dehydrated; she had not taken any fluid in nor passed urine for over 24h. The anaesthetist was also concerned Mrs Spurgin had received minimal analgesia and in addition to intravenous

fluids gave her morphine 2mg IV. On review 2h later the anaesthetist noted that Mrs Spurgin had passed urine, but also that she had hallucinated following the morphine (page 69 of 135). An outline of the sequence of events that led to Mrs Spurgin receiving inadequate fluid pre-operatively was given by Dr Woods (the SHO) later in the notes (page 80 of 135).

Mrs Spurgin's post-operative course was not straight forward. A review at 21.30h on the 20th March 1999 noted '+++ooze' (i.e. leakage) from the wound but only 40ml in the wound drain (page 69 of 135). Mrs Spurgin complained of discomfort in the leg and pain on palpation and her right thigh was noted to be twice the size of her left. It was considered most likely she had developed a haematoma. This is a collection of blood due to bleeding into the operation site. As the amount increases, the greater the swelling and, if in an enclosed space, the greater the pressure it exerts. The increasing pressure can lead to a compartment syndrome compressing blood vessels and damaging surrounding tissue and nerves (see technical issues). The reviewing doctor examined Mrs Spurgin with this in mind, noting two collections underneath the wound and checking the circulation and nerve function in the leg, which appeared to be satisfactory (page 79 of 135). The clinical impression formed by the doctor was that Mrs Spurgin may have a potential bleeding vessel in the wound (to explain why her leg had become rapidly so swollen), and that she was at risk of compartment syndrome (due to increasing pressure from the haematoma) and hypovolaemia (low blood volume; due to bleeding into the wound)(page 79 of 135). Mrs Spurgin's haemoglobin was reduced at 82g/L (normal range 105–160g/L), having being 122g/L on the day of admission

(page 67 of 135) which suggests she had lost a significant amount of blood as a result of the fracture, its repair and the bleed into the wound. Subsequently, Mrs Spurgin received a three unit blood transfusion on the 21st March 1999 which corrected her anaemia (haemoglobin 111g/L on 22nd March 1999; page 92 of 135).

On the 21st March 1999 concerns remained about Mrs Spurgin's hydration level due to her poor urine output. Her blood tests suggested that she was dehydrated (urea 13.3mmol/L, creatinine 136micromol/L; normal range 3.2–7.5 and 71–133 respectively; page 90 of 135). Her right hip was noted to be painful+++ and her thigh enlarged but there was no ooze from the wound (page 82 of 135). The nursing notes reported that Mrs Spurgin had a lot of pain on movement with a plan to give morphine before moving her (page 27 of 135).

On the 22nd and the 24th March 1999 Mrs Spurgin was reviewed on the wardround by Surgeon Commander Scott, whom I presume was the consultant responsible for her care. There was no specific mention of her painful swollen right thigh, but she was referred to Dr Lord for rehabilitation and a referral letter written in the notes (pages 82, 83 and 84 of 135). This noted that Mrs Spurgin was transfused with three units of blood, but 'has otherwise made a remarkable post-op recovery.' There is no mention of the haematoma, but it does go on to state '...she has proved quite difficult to get mobilised and her post-op rehabilitation may prove somewhat difficult. Additionally the quality of her skin, especially her lower legs is poor and at great risk of breaking down....' (page 83, 84 of 135). On the 23rd March 1999, the nursing notes reported that Mrs Spurgin had difficulty and pain++ with mobility (page 25 of 135).

Mrs Spurgin was reviewed by Dr Reid on the 24th March 1999 (pages 11 and 84 of 135). Dr Reid notes that Mrs Spurgin was '...previously well, but still in a lot of pain which is the main barrier to her mobilisation at present' and asked that her analgesia be reviewed. Dr Reid stated that he would be happy to take Mrs Spurgin to Gosport War Memorial Hospital provided that the orthopaedic team was satisfied that 'orthopaedically all is well with the right hip' (page 84 of 135). In his formal letter that followed, Dr Reid reported that prior to the fall Mrs Spurgin was 'very active and in good health' and repeated his concerns regarding Mrs Spurgin's hip, noting that 'the main problem was pain and swelling of the right thigh. Even a limited range of passive movement was painful. I was concerned about this and I would like to be reassured that all is well from an orthopaedic point of view' (page 11 of 135).

Surgeon Commander Scott reviewed Mrs Spurgin again on the 25th March 1999. It was noted that her right leg was increasingly swollen and that a haematoma had developed and broken down. It is unclear if 'broken down' relates to her wound breaking down as a result of the haematoma but dressing with jelonet and elevation were recommended (page 85 of 135). Commander Surgeon Scott considered that Mrs Spurgin could go to Gosport War Memorial Hospital but to warn them that her skin required great care (page 85 of 135). The nursing notes reported that Mrs Spurgin had had a settled evening and mobilised to the commode with two staff. Mrs Spurgin was transferred the following day on the 26th March 1999 (pages 25 and 26 of 135).

Mrs Spurgin's analgesia consisted of morphine and paracetamol p.r.n. 'as required'; she received morphine 5mg IM at 19.15h and 23.00h on the 20th

March 1999 and at 11.15h on the 21st March 1999 (page 38 of 135). Paracetamol 1G was taken on the following dates (number of doses): 19th (one); 21st (two), 22nd (two), 24th (one) and 25th March 1999 (one) (page 38 of 135).

Events at Dryad Ward, 26th March 1999 until 13th April 1999.

26th March 1999

The nursing transfer note written by Royal Haslar Hospital for Dryad Ward noted that Mrs Spurgin was mobile from bed to chair with two nurses and could walk short distances with a zimmer frame; she was continent during the day but occasionally incontinent at night; the skin on her lower legs was paper thin; her right lower leg was very swollen and needed elevating and there was a small break on the posterior aspect that had been steri-stripped. She needed encouragement with eating and drinking but could manage independently. No drugs were included as she was only on paracetamol p.r.n. 'as required' (page 20 of 175).

The medical note entry reports Mrs Spurgin's fracture of the right femur on the 19th March 1999, nil of significance in her past medical history and that she was non-weight bearing, had tissue paper skin and was not continent. The plan was to 'sort out her analgesia' (page 24 of 175).

The drug chart reveals that Mrs Spurgin was prescribed oral morphine (Oramorph) 5–10mg p.r.n. and also regularly: 5mg every 4h (at 06.00, 10.00, 14.00, 18.00h) and 10mg at 22.00h along with lactulose (a laxative) 10ml twice a day (pages 123 and 125 of 175).

Blood tests were undertaken which revealed a mild anaemia (haemoglobin 10.1g/dL; page 46 of 175) and elevated urea of 9.5mmol/L (normal 3.0–

7.6mmol/L; page 40 of 175). Swabs from her nose, throat, axillae, groins and wound, probably as a routine, were taken to screen for Methicillin resistant staphylococcus aureus (MRSA) and were all negative (pages 32 and 58 of 175).

The nursing summary notes record that Mrs Spurgin had been admitted 'for rehabilitation and gentle mobilisation.' Despite the information in the transfer letter from Haslar Hospital, on Dryad Ward her transferring had been difficult; Mrs Spurgin had complained of a lot of pain for which she was given oral morphine regularly 'with effect' (page 106 of 175). Her 'very dry tissue paper skin' in the lower legs, the small break on back of right calf, and her swollen legs were noted (page 106 of 175). A nursing care plan for Mrs Spurgin's wounds, specifies only that her right leg was swollen and oedematous (page 88 of 175). A handling profile reported pain in the right hip (page 102 of 175).

A nursing care plan was produced for 'Enid is experiencing a lot of pain on movement' and listed the nursing action as 'give prescribed analgesia and monitor effect; position comfortably and seek advice from physiotherapists regarding moving and mobilising' (page 84 of 175).

The nursing care plan for 'Enid requires assistance for settling for the night' noted that she used the slipper bed pan but had difficulty in moving; slept for long periods; Oramorph given as boarded for pain in hip' (pages 80 and 81 of 175).

The nursing summary for the night reported 'requires much assistance with mobility at present due to pain/discomfort. Oramorph 10mg given 23.15h and 5mg at 06.00h' (page 106 of 175).

27th March 1999

The nursing notes reported that it required two nurses to transfer Mrs Spurgin (page 114 of 175) and despite regular Oramorph, Mrs Spurgin was still in pain (page 84 of 175).

The drug chart shows that the regular oral morphine was increased to 10mg every 4h (at 06.00, 10.00, 14.00, 18.00h) and 20mg at 22.00h (page 125 of 175).

28th March 1999

The nursing notes reported that Mrs Spurgin had been vomiting with the Oramorph. Dr Barton advised to stop the Oramorph and Mrs Spurgin received metoclopramide (an anti-emetic) and codydramol for pain relief instead (pages 84 and 85 of 175).

The drug chart shows that the last oral morphine dose was at 10.00h and that codydramol 2 tablets 4 times a day (a total of dihydrocodeine 80mg and paracetamol 4G/24h) were commenced at 18.00h and taken regularly until the 31st April 1999 (page 125 of 175). Metoclopramide (an anti-emetic) 10mg three times a day was also commenced and taken intermittently until the 11th April 1999 (page 134 of 175).

29th March 1999

The nursing notes recorded a request for Mrs Spurgin's analgesia to be reviewed (page 85 of 175) and a mobility evaluation indicated that she required two nurses to move around the bed, a hoist to get in and out of bed and was unable to walk (page 103 of 175).

The drug chart shows that senna (a laxative) 2 tablets at night were commenced and taken until the 10th April 1999 (page 134 of 175).

30th March 1999

The nursing notes record that the steristrips on Mrs Spurgin's surgery wound were removed. A dressing was applied to one small area near top that was oozing slightly (page 89 of 175).

31st March 1999

The nursing notes record that Mrs Spurgin was commenced on modified release morphine (MST) 10mg twice a day. She walked with the physiotherapist in the morning but was in a lot of pain (page 85 of 175). Oramorph 5mg was given for pain relief at 13.15h with 'not too much effect' (pages 85 and 123 of 175). Mrs Spurgin slept well (page 81 of 175). The drug chart records the commencement of MST 10mg twice a day until the 6th April 1999 (page 134 of 175).

1st April 1999

The nursing notes record that Mrs Spurgin was seen by the physiotherapist and that the recommendation was that she remain on her bed rather than in a chair over the Easter holiday but to walk with a zimmer frame once or twice a day (page 85 of 175). The physiotherapy report specifies that Mrs Spurgin should walk twice a day with a gutter frame (page 96 of 175). Mrs Spurgin was noted to have pain on movement (page 85 of 175). Her right hip wound was 'oozing large amounts of serous fluid

and some blood' from a hole in the wound 1–1.5cm long. This was steristripped but continued to ooze (page 81 of 175).

2nd April 1999

The nursing notes record that a different type of dressing (Granuflex) was applied to the wound on Mrs Spurgin's right calf as her leg was oedematous (swollen) (page 89 of 175).

3rd April 1999

The nursing notes record that the MST 10mg twice a day continued and that Mrs Spurgin continued to complain of pain on movement (page 85 of 175).

4th April 1999

A nursing care plan was commenced for Mrs Spurgin's right hip wound 'oozing serous fluid and blood. Steristrip in-situ at present' (pages 86 and 87 of 175). On the same day, the dressings were renewed, no new leakage was seen, the steristrip was intact and a dry dressing reapplied (page 87 of 175).

6th April 1999

The nursing notes record that swabs to test for the presence of infection were taken from the from right hip and right calf wounds. The dressing was removed off the hip wound and left uncovered. The calf wound was leaking and redressed (page 87 of 175). Subsequently, the calf wound cultured the bacterium staphylococcus aureus, sensitive to the antibiotics

erythromycin, flucloxacillin and penicillin. This result was available on the 9th April 1999 (page 52 of 175).

The nursing summary notes record that Mrs Spurgin was seen by Dr Barton and that the MST was increased to 20mg (page 106 of 175). Mrs Spurgin's nephew visited who offered to employ a live-in carer for when she was discharged home (as she was adamant about not going to a nursing home). Mrs Spurgin had been incontinent of urine a few times and the use of a catheter discussed (pages 106 and 107 of 175).

The drug chart shows the increase in the MST to 20mg twice a day which continued until 20.00h on the 11th April 1999 (page 134 of 175).

7th April 1999

The nursing notes reported that Mrs Spurgin's hip wound was red and inflamed and she was seen by Dr Barton and commenced on antibiotics (metronidazole 400mg and ciprofloxacin 500mg both twice a day)(pages 89 and 107 of 175). She was later reviewed by Dr Reid who noted that Mrs Spurgin was still in a lot of pain and very apprehensive. Her MST had been increased to 20mg twice a day yesterday. He prescribed flupenthixol and requested an X-ray of the right hip to be done, as movement was still quite painful and the right leg was 2 inches shorter than the left (page 24 of 175).

The drug chart shows prescriptions for a five day course of antibiotics (ciprofloxacin and metronidazole; page 134 of 175) and the flupenthixol 0.5mg twice a day, given until the 11th April 1999 (page 8 of 175).

8th April 1999

The nursing notes reported that Mrs Spurgin's wound was oozing slightly overnight but that the redness at the edges of the wound was subsiding (page 87 of 175).

9th April 1999

The nursing notes reported that Mrs Spurgin was to remain on bed rest until Dr Reid saw the X-ray of her hip (page 85 of 175). It was noted that Mrs Spurgin had spilt two drinks in bed and had had a nightmare early morning (page 81 of 175). Because of episodes of urinary incontinence and being 'very distressed when put on to commode earlier today' Mrs Spurgin agreed to have a catheter inserted at 19.30h which drained 500ml overnight (page 115 of 175).

10th April 1999

The nursing notes reported that the catheter was draining 'concentrated urine – small amount. Enid not drinking despite encouragement and help'. Mrs Spurgin spilt her drink prior to settling and had a 'very poor night (page 81 of 175).

11th April 1999

The nursing notes recorded that Mrs Spurgin 'appears to be leaning to the left. Does not appear to be as well and experiencing difficulty in swallowing. Stitch line inflamed and hard area. Complaining of pain on movement and around stitch line. Oramorph 5mg given at 07.15h' (pages 81, 85 and 123 of 175). Other entries report 'commenced antibiotics a few

days ago, wound not leaking today but hip feels hot and Enid complaining of tenderness all around site. Enid very drowsy and irritable' (page 87 of 175); 'Condition ill. Tolerating sips of oral fluids. Not anxious to be moved in any way. Did settle for long periods' (page 83 of 175). A bladder washout was performed due to leakage (I assume bypassing) of dark concentrated urine. It was flushed without problem and 'very little drainage' was noted at 17.00h (page 115 of 175).

The nursing summary notes record that Mrs Spurgin's nephew was telephoned at 19.10h as Enid's condition had deteriorated over the afternoon; '....She is very (the nurse's emphasis) drowsy - unrousable at times. Refusing food and drink and asking to be left alone. Site around wound in right hip looks red and inflamed and feels hot. Asked about her pain, Enid denies pain when left alone but complaining when moved at all. Syringe driver possibility discussed with nephew who is anxious that Enid be kept as comfortable as possible. He will telephone ward later this evening. Seen by Dr Barton to commence syringe driver' (page 107 of 175). However, in her statement, Dr Barton believes this last point refers to her seeing Mrs Spurgin on the morning of 12th April 1999.

12th April 1999

The nursing notes reported that Mrs Spurgin's condition 'remains ill. Urine very concentrated. Syringe driver satisfactory. Appears to be in some discomfort when attended to. Breathing very shallow' (page 83 of 175).

Mrs Spurgin was seen by Dr Reid who made an entry into the medical notes 'now very drowsy (since diamorphine infusion established) – reduce

to 40mg/24h – if pain recurs increase to 60mg. Able to move hip without pain but patient not rousable!' (Dr Reid's emphasis)(page 24 of 175).

The nursing summary notes also recorded the decisions taken on the wardround and that Mrs Spurgin's nephew had been spoken to and was aware of the situation (page 108 of 175).

The drug chart shows that Mrs Spurgin was prescribed, on the regular prescription part of the drug chart, diamorphine 20–200mg, midazolam 20–80mg, hyoscine (hydrobromide) 200–800microgram (marked p.r.n. in the margin) and cyclizine (an anti-emetic) 50–100mg (marked p.r.n. in the margin) all SC/24h (page 131 of 175). A syringe driver was commenced at 08.00h containing diamorphine 80mg/24h and midazolam 20mg/24h (page 131 of 175). It was altered at 16.40h to one containing a reduced dose of diamorphine 40mg/24h and an increased dose of midazolam 40mg/24h (page 131 of 175).

13th April 1999

An entry was made at 01.15h confirming that Mrs Spurgin had died (pages 24 and 83 of 175).

On the death certificate, the cause of death was given as 1a Cerebrovascular accident, with an onset of 48h prior to death.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Syringe drivers, diamorphine, midazolam and hyoscine hydrobromide

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24h. Indications for its use include swallowing difficulties or a comatose patient. In the United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF number 36 (September 1998)). Others sometimes suggest dividing by 2 or 3 depending on circumstance (Wessex protocol). Hence, 60mg of morphine taken orally a day could equate to a daily dose of 20 or 30mg of diamorphine SC. It is usual to prescribe additional doses for use 'as required' in case symptoms such as pain breakthrough. The dose is usually 1/6th of the 24h dose. Hence for someone receiving 30mg of diamorphine in a syringe driver over 24h, a breakthrough dose would be 5mg. One would expect it to have a 2–4h duration of effect, but the dose is often prescribed to be given hourly if required. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in their terminal phase would generally aim to find a dose that improves the patients' symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg a day. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (September 1998) recommends 20–100mg SC over 24h. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated every 24h if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24h, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4h, and it may need to be given more frequently. As an active metabolite of midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

Hyoscine hydrobromide is an antimuscarinic drug most commonly given to reduce excessive saliva or retained secretions ('death rattle'). It also has anti-emetic, antispasmodic (smooth muscle colic) and sedative properties.

Repeated administration can lead to cummulation and this can occasionally result paradoxically in an agitated delirium, highlighted in both in the BNF and the Wessex protocol (page 41). It is usually given in a dose of 600–2400microgram SC over 24h (BNF (September 1998)) or 400–600microgram as a stat SC dose. The Wessex protocol gives a dose range of 400–1200microgram over 24h.

The titration of the dose of analgesic or sedative medication is guided by the patients symptom control needs. The number and total dose of 'as required' doses needed over a 24h period are calculated and this guides the increase necessary in the regular dose of the drugs in the syringe driver in a way that is proportional to the patients needs. The ideal outcome is the relief of the symptoms all of the time with no need for additional 'as required' doses. In practice, this can be difficult to achieve and the relief of the symptoms for the majority of the time along with the use of 1–2 'as required' doses over a 24h period is generally seen as acceptable.

ii) The principle of double effect

The principle of double effect states that:

'If measures taken to relieve physical or mental suffering cause the death of a patient, it is morally and legally acceptable provided the doctor's intention is to relieve the distress and not kill the patient.'

This is a universal principle without which the practice of medicine would be impossible, given that every kind of treatment has an inherent risk. Many discussions on the principle of double effect have however, involved the use of morphine in the terminally ill. This gives a false impression that the use of morphine in this circumstance is a high risk strategy. When

correctly used (i.e. in a dose *appropriate* to a patient's need) morphine does not appear to shorten life or hasten the dying process in patients with cancer. Although a greater risk is acceptable in more extreme circumstances, it is obvious that effective measures which carry less risk to life will normally be used. Thus, in an extreme situation, although it may occasionally be necessary (and acceptable) to render a patient unconscious, it remains unacceptable (and unnecessary) to cause death deliberately. As a universal principle, it is also obvious that the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

iii) Compartment syndrome.

See also the report by Mr Redfern.

Thick layers of tissue called fascia separate groups of muscles in the leg into different compartments. There is limited scope for expansion within a compartment, and a significant swelling, such as a large haematoma, will lead to an increase in pressure, compressing the surrounding muscles, blood vessels and nerves. If the pressure builds sufficiently, the blood flow to the tissues is reduced and this can lead to permanent injury to the muscle and nerves. The hallmark symptom of compartment syndrome is severe pain that does not respond to elevation or pain medication. There may also be:

- tense, swollen and shiny skin overlying the limb
- severe pain when the muscle is moved actively or passively
- pain when the compartment is squeezed.

In more advanced cases, there may be:

- decreased sensation

- muscle weakness
- pallor of the skin.

8. OPINION

Events at Royal Haslar Hospital, 19th–26th March 1999

Mrs Spurgin was a relatively fit and independent 92 year old widow who lived alone. She underwent surgical repair of a fractured right hip using a dynamic hip screw. Mrs Spurgin's post-operative course was not straight forward; within hours of her surgery she had to be reviewed because of leakage from the wound and swelling of her right thigh to twice its normal size, causing discomfort and pain on palpation. It was considered most probable that she had developed a haematoma due to a bleeding vessel in the wound. A large haematoma can exert a pressure effect, compressing blood vessels and damaging surrounding tissue and nerves. The reviewing doctor appropriately examined Mrs Spurgin with this in mind, checking the circulation and nervous function in her leg, which appeared satisfactory. Pain in Mrs Spurgin's hip/thigh on movement continued to be recorded as a problem in the nursing notes and by Dr Reid when he reviewed Mrs Spurgin on the 24th March 1999. He considered the pain the main barrier to rehabilitation, asked for her analgesia to be reviewed and to be reassured that orthopaedically all was well with her hip. Surgeon Commander Scott reviewed Mrs Spurgin several times between the 22nd–25th March 1999 but no specific comment was recorded in the medical notes regarding Mrs Spurgin's pain, no changes were made to her analgesia but on the 25th March she was considered able to be transferred to Gosport War Memorial Hospital once a bed was available. Despite pain

being recorded as a problem, at no point did Mrs Spurgin receive regular analgesia; three doses of morphine given as required within the first 24h of her surgery and subsequently, only paracetamol as required, at most 2G in 24h. One explanation for this apparent discrepancy would be that Mrs Spurgin was relatively comfortable at rest and only experiencing significant pain on movement and/or weight bearing.

With regards to the standard of care proferred to Mrs Spurgin during her admission to Haslar Hospital, I am not experienced enough in orthopaedics to comment, but the report of Mr Redfern raises several concerns.

Events at Dryad Ward, 26th March 1999 until 13th April 1999.

Infrequent entries in the medical notes during Mrs Spurgin's stay on Dryad Ward make it difficult to closely follow her progress over the last eighteen days of her life. There are three entries prior to the confirmation of death, taking up one page in length. In summary and approximate chronological order, Mrs Spurgin was admitted to Dryad Ward for rehabilitation and gentle mobilisation. It was noted that Mrs Spurgin complained of a lot of pain on movement for which she was commenced on regular oral morphine. Despite this there was no mention of pain nor a formal pain assessment in the medical clerking. Mrs Spurgin initially was prescribed a total of 30mg/24h of oral morphine regularly. This was increased the next day to 60mg/24h and was the probable cause of her nausea and vomiting. The response to Mrs Spurgin's vomiting appears nonsensical; if it were that her pain was considered severe enough to warrant morphine regularly, the addition of a regular anti-emetic would be seen as an appropriate response. Instead the morphine was substituted for the weaker

analgesic codydramol. Because of continued pain on movement, the codydramol was substituted three days later for oral morphine again, now in a modified release preparation (MST) in a dose of 20mg/24h, subsequently increased to 40mg/24h. Mrs Spurgin's hip wound began to leak large amounts of serous fluid and blood. This initially improved with steristrips but on the 7th April 1999 it was red and inflamed and antibiotics (metronidazole and ciprofloxaxin) commenced. Although the use of antibiotics was appropriate for a possible wound infection, it was not, in my experience, a typical combination used for a post-operative wound infection. Dr Reid reviewed Mrs Spurgin and found that movement of the right leg was still painful. It was now 18 days after Mrs Spurgin's operation and a progressive improvement in pain and mobility can generally be anticipated. This was not the case for Mrs Spurgin and Dr Reid was concerned enough to ask for an X-Ray and it should be confirmed if this was undertaken or not and, if so, the result found. However, an orthopaedic assessment was not sought. Because Mrs Spurgin was 'apprehensive' Dr Reid commenced flupenthixol 0.5mg twice a day. I am unfamiliar with the use of flupenthixol (an antipsychotic) for managing anxiety in the elderly.

The pain on movement did not improve although Mrs Spurgin denied pain when left alone. Mrs Spurgin became less well; she spilt drinks and had a nightmare. She was noted to be very drowsy – unrousable at times, irritable, leaning to the left and experiencing difficulty in swallowing. The wound was inflamed, hot and tender. She was catheterised but drained only small amounts of concentrated urine. The exact cause of Mrs Spurgin's deterioration is unclear as no medical assessment was undertaken. Even simple observations like temperature, heart rate and blood pressure were not carried

out. However, in my opinion, her situation could be consistent with septicaemia from an infection despite her current antibiotics ± cummulation of morphine metabolites as she became dehydrated. Even in her statement, Dr Barton anticipates that Mrs Spurgin's drowsiness was a consequence of her infection (point 40).

On the 12th April 1999, a syringe driver was commenced containing diamorphine 80mg/24h. This is equivalent to oral morphine 160–240mg/24h and thus represents a 4–6 fold increase Mrs Spurgin's dose of morphine. There is no apparent justification for an increase of this magnitude in the dose of analgesia, and, in my opinion, was excessive to Mrs Spurgin's needs. This would explain why Dr Reid noted Mrs Spurgin to have been very drowsy since the diamorphine infusion was commenced (he states she was not rousable! (his emphasis)) and why he was able to move her hip without pain. The syringe driver also contained midazolam 20mg/24h, a dose likely to sedate a 92 year old. Given that the major risk of excessive opioid is respiratory depression, in an unrousable patient, it would have been reasonable for a doctor to have assessed respiratory function, e.g. respiratory rate and the level of oxygen saturation in the blood (pulse oximetry). If there was evidence of respiratory depression, discontinuation of the opioid and careful use of the opioid antagonist naloxone to partially reverse the effects of the opioid would have been indicated to rouse the patient and restore satisfactory ventilation. Even if naloxone was not deemed necessary, other practitioners would stop the opioid until the patient was more awake, and subsequently restart at a lower dose. Others may continue the opioid but at a lower dose. Although Dr Reid halved the diamorphine dose to 40mg/24h, this was still equivalent to oral morphine 80–120mg/24h, i.e. a 2–3 fold increase on Mrs Spurgin's previous

dose. In my opinion, given Mrs Spurgin's dose of oral morphine 40mg/24h, using a 2:1 or 3:1 conversion ratio, an appropriate starting dose of diamorphine would have been 15–20mg/24h. Further, there was a simultaneous increase in the midazolam to 40mg/24h, a dose that in my opinion would sedate a 92 year old. In this regard, despite the reduction in opioid, the increase in midazolam would have contributed to Mrs Spurgin remaining sedated until her death at 01.15h on the 13th April 1999.

The cause of death was given as a cerebrovascular accident. The clinical evidence on which this is based should be clarified. In her statement, Dr Barton suggests 'the reference to her leaning to the left raised the possibility that Mrs Spurgin might have had a cerebrovascular accident'. However, on its own, this is a non-specific finding which could occur in an elderly patient with a reduced level of consciousness due to any cause. If it were strongly considered that Mrs Spurgin had had a cerebrovascular accident, one would expect that this significant change in her clinical condition to have been recorded in the medical notes and accompanied by a medical assessment. In my opinion, the circumstances of Mrs Spurgin's deterioration and death are not typical of a cerebrovascular accident and thus there is a lack of sufficient supporting clinical evidence and certainty that a cerebrovascular accident was the most likely cause of her death.

Was the standard of care afforded to this patient in the days leading up to his death in keeping with the acceptable standard of the day?

The overall care given to Mrs Spurgin whilst at Haslar Hospital has raised concerns as detailed in the report by Mr Redfern.

The medical care provided by Dr Barton and Dr Reid to Mrs Spurgin following her transfer to Dryad Ward, Gosport War Memorial Hospital is suboptimal when compared to the good standard of practice and care expected of a doctor outlined by the General Medical Council (Good Medical Practice, General Medical Council, July 1998, pages 2–3) with particular reference to:

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs and, if necessary, an appropriate examination
- in providing care you must keep clear, accurate, and contemporaneous patients records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs, or appliances that serve patients' needs
- in providing care you must be willing to consult colleagues.

Specifically:

i) The notes relating to Mrs Spurgin's transfer to Dryad Ward are inadequate. On admission, a patient is usually clerked highlighting in particular the relevant history, examination findings, planned investigations and care plan.

ii) There was insufficient assessment and documentation of Mrs Spurgin's pain and its treatment.

iii) An orthopaedic opinion was not sought even when the pain did not improve with time or increasing doses of morphine that were associated with undesirable effects.

iv) An appropriate medical assessment was not undertaken when Mrs Spurgin deteriorated, becoming more drowsy and her wound more painful and inflamed.

v) Doses of diamorphine and midazolam that were excessive to her needs were administered.

If the care is found to be suboptimal what treatment should normally have been preferred in this case?

In relation to the above:

Issue i (lack of clear documentation that an adequate assessment has taken place)

A medical assessment usually consists of information obtained from the patient or others and existing medical records (the history), and the findings of a physical examination that is documented in a structured fashion. Although the history can be restricted to the most salient points, it is unusual to omit relevant sections, e.g. a basic physical examination, etc.

Clerking of a patient also provides a baseline for future comparison. If new problems subsequently develop, and abnormal physical findings are found on examination, it can be helpful for the doctor when considering the differential diagnosis and management to know if the findings are really new or old. A clear assessment and documentation of subsequent medical care are particularly useful for on-call doctors who may have to see a patient, whom they have never met, for a problem serious enough to require immediate attention.

Issue ii (lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate, and contemporaneous patients records which report drugs prescribed; prescribing only the treatment, drugs, or appliances that serve patients' needs)

Part of the plan outlined by Dr Barton was to sort out Mrs Spurgin's analgesia. Particularly when pain relief is considered such a prominent part of the care plan for a patient, it would be considered good practice to take and document a full pain history and undertake an appropriate examination. This is to help diagnose the most likely cause of the pain and thus guide a rational and appropriate management plan.

Dr Barton considered Mrs Spurgin unable to weight bear and that her pain to require regular morphine. This was in contrast to the transfer note, written on the same day of transfer, which recorded Mrs Spurgin to be mobile with help and requiring only p.r.n. 'as required' paracetamol. There is no documented history or examination which suggests that the possible reasons for this apparent increase in pain were considered. This is relevant, because, if increasing pain was associated with a wound infection for example, this would require appropriate antibiotics rather than morphine. Further, given that pain generally improves quickly and progressively in patients who have undergone surgical repair of their fractured neck of femur, the need to commence strong opioid analgesia for severe pain one week post-operatively should have been a particular prompt to have undertaken a thorough assessment.

It is unclear on what basis Dr Barton considered that regular morphine was necessary, rather than initially trying a regular weak opioid ± paracetamol. In general, practitioners progressively increase the strength of regular analgesia and the dose against the patients pain, in the order non-opioid (e.g.

paracetamol) → weak opioid (e.g. codeine) → strong opioid (e.g. morphine). Although some may omit the weak opioid step and go straight to a strong opioid, this usually involves a smaller initial dose of morphine (e.g. 20–30mg/24h). Although the starting dose of morphine and its increase prescribed by Dr Barton were in keeping with the BNF, in the context of omitting a regular weak opioid step and in view of Mrs Spurgin's advanced age, it would have been prudent in my opinion to have used a smaller dose. Mrs Spurgin's nausea and vomiting could be in keeping with the doses she received being excessive, although up to half of patients can experience nausea and vomiting when commencing morphine.

Issue iii (in providing care you must be willing to consult colleagues)

Because of Mrs Spurgin's nausea and vomiting, the morphine was discontinued and she received regular codydramol for about 3 days. However, because of persistent pain, Dr Barton recommenced a smaller dose of morphine. This was 11 days after Mrs Spurgin's operation and this level of pain and analgesic requirement should have prompted a search for the cause of the pain. In this regard there is no evidence that Dr Barton considered, examined Mrs Spurgin or documented the possible reasons why Mrs Spurgin's pain was so problematic, discussed her with Dr Reid or the orthopaedic team. Similarly, when the morphine was increased to 40mg/24h, 17 days after Mrs Spurgin's operation, neither Dr Barton nor Dr Reid contacted the orthopaedic team. An X-ray was apparently requested, but I am unable to ascertain if it was carried out.

Finally, it should be ascertained if the choice of ciprofloxacin and metronidazole for a post-operative (orthopaedic) wound infection was in

keeping with Trust guidelines, and, if not, why the advice of a microbiologist was not obtained.

Issue vi ((lack of clear documentation that an adequate assessment has taken place; lack of clear, accurate, and contemporaneous patients records which report drugs prescribed; in providing care you must be willing to consult colleagues)

Mrs Spurgin became less well, increasingly drowsy, dehydrated, agitated, spilling things and had a nightmare. When a patients' clinical condition changes for the worse, a thorough medical assessment should be carried out to ascertain the possible cause(s) and to identify if they are reversible with appropriate treatment. The assessment would consist of the history, examination and appropriate investigation. There is no assessment or even simple observations documented. This is relevant, as in my opinion, Mrs Spurgin was not anticipated to be dying and her symptoms and signs were in keeping with a potentially reversible septicaemia/toxaemia arising from an infection (the wound had become tender and inflamed despite the antibiotics) ± the effects of increasing blood levels of morphine metabolites; even though the morphine dose had not been increased, in dehydration morphine metabolites cumulate as if the dose of morphine had been increased. Intravenous hydration, reduction in the dose of morphine and different antibiotics may well have been of benefit to Mrs Spurgin and it should be ascertained why these were not considered appropriate. Particularly the latter, as in her statement, Dr Barton's appears to consider that an infection was contributing to Mrs Spurgin's drowsiness. For patients this unwell with an infection, particularly despite the existing use of antibiotics, the choice of

further antibiotic(s) would usually be made with the help of a microbiologist and modified subsequently based on results of wound, blood and urine cultures etc. There is no documentation to suggest that Dr Barton discussed Mrs Spurgin's management with Dr Reid, the orthopaedic team or a microbiologist before commencing a syringe driver containing diamorphine and midazolam.

Issue v (lack of clear, accurate, and contemporaneous patients records which report drugs prescribed; prescribing only the treatment, drugs, or appliances that serve patients' needs; willing to consult colleagues)

On the 12th April 1999, Dr Barton prescribed diamorphine 20–200mg, midazolam 20–80mg, hyoscine (hydrobromide) 200–800microgram (marked p.r.n. in the margin) and cyclizine (an anti-emetic) 50–100mg (marked p.r.n. in the margin) all SC/24h.

It is unusual that drugs to be given by syringe driver are prescribed 'as required' especially in a wide dose range. This is because of the inherent risks that would arise from a lack of clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For example, the lower dose range of diamorphine was 20mg/24h, but Mrs Spurgin was commenced on 80mg/24h. For these reasons, prescribing a drug as a range, particularly a wide range, is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication.

If there were concerns that a patient may experience, for example, episodes of pain, anxiety or agitation, it would be much more usual, and

indeed seen as good practice, to prescribe appropriate doses of morphine/diamorphine, diazepam/midazolam and other drugs that could be given intermittently 'as required' orally or SC alongside the fixed regular dose of analgesic. This allows a patient to receive what they need, when they need it and guides the doctor in subsequent dose titration of the regular dose of analgesic.

The wide dose range of diamorphine 20mg–200mg, is not justified at all in the notes and in my opinion includes doses excessive for Mrs Spurgin's needs. Doses of opioids excessive to a patient's needs are associated with an increased risk of drowsiness, delirium, nausea and vomiting and respiratory depression.

The equivalent subcutaneous dose of diamorphine is generally calculated by dividing the oral morphine dose by 2 or 3 (see technical issues). As Mrs Spurgin had been receiving oral morphine 40mg/24h, this is approximately equivalent to diamorphine 15–20mg/24h. A syringe driver was commenced containing diamorphine 80mg/24h, equivalent to oral morphine 160–240mg/24h, representing a 4–6 fold increase in Mrs Spurgin's dose of morphine. There is no justification for an increase of this magnitude in the dose of analgesia, and, in my opinion, was excessive to Mrs Spurgin's needs. *The syringe driver also contained without apparent justification, midazolam* 20mg/24h, a dose likely to sedate a 92 year old. As a result, Dr Reid found her unrousable and unresponsive to movement of her hip (a painful stimulus). Given the depth of her sedation, it would have been reasonable to have assessed her respiratory function, e.g. respiratory rate and the level of oxygen saturation in the blood (pulse oximetry), but this did not occur. In my opinion the syringe driver should have been discontinued and Mrs Spurgin's condition

monitored closely for evidence of respiratory depression, pain or agitation. Other practitioners may well choose to continue the opioid but at a lower dose as Dr Reid did. However, the dose he selected, diamorphine 40mg/24h, is equivalent to oral morphine 80–120mg/24h, i.e. still a 2–3 fold increase on Mrs Spurgin's previous dose. Further, there was a simultaneous increase in the midazolam to 40mg/24h, a dose that in my opinion would sedate a 92 year old, and was unjustified given that she was already unresponsive.

In her statement, Dr Barton makes the point that even 40mg of diamorphine was not seemingly successful in relieving Mrs Spurgin's pain as she was 'in some discomfort when attended to'. This, in my view, continues to underscore the point that the pain that Mrs Spurgin was experiencing on movement was not relieved by a dose of diamorphine that was associated with undesirable effects (i.e. sedation). This is unusual for someone who had undergone repair of a fractured neck of femur with a dynamic hip screw and reinforces the point that an orthopaedic review should have been sought.

If the care is found to be suboptimal to what extent may it disclose criminally culpable actions on the part of individuals or groups?

Both Dr Barton and Dr Reid had a duty to provide a good standard of medical practice and care. In this regard, Dr Barton and Dr Reid fell short of a good standard of clinical care as defined by the GMC (Good Medical Practice, General Medical Council, July 1998 pages 2–3) with particular reference to a lack of clear note keeping, adequate assessment of the patient, providing treatment that could be excessive to the patients' needs and willingness to consult colleagues.

In my view, Mrs Spurgin was not anticipated to be dying and very likely that her pain and subsequent deterioration were due to potentially reversible (and possibly preventable) causes that could be managed by the timely provision of hydration, a reduction in morphine dose and appropriate antibiotics. The pain was out of keeping with that usually seen in this situation, and failed to improve with time or increasing doses of morphine. Thus there were several prompts for both Dr Barton and Dr Reid to have sought an orthopaedic review.

Morphine and diamorphine are safe drugs when used correctly. The key issue is whether the use and the dose of diamorphine and other sedatives are *appropriate* to the patients' needs. Although some might invoke the principle of double effect (see technical issues), it remains that a doctor has a duty to apply effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose of strong opioid that was *appropriate* and not excessive for a patient's needs.

In short, Dr Barton in particular, but also Dr Reid, could be seen as doctors who breached the duty of care they owed to Mrs Spurgin by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Spurgin by failing to adequately assess her condition and taking suitable and prompt action when she complained of pain that appeared excessive to her situation and when her physical state deteriorated in what was a potentially reversible way. Instead the actions of Dr Barton and Dr Reid exposed Mrs Spurgin to inappropriate doses of diamorphine and midazolam that would have contributed more than minimally,

negligibly or trivially to her death. As a result Dr Barton and Dr Reid leave themselves open to the accusation of gross negligence.

9. LITERATURE/REFERENCES

British National Formulary 36 (September 1998).

Prescribing in Terminal Care, pages 11–14

Prescribing for the elderly, pages 15-16

Good Medical Practice, General Medical Council, July 1998, pages 2–3

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition

'Wessex Protocol' Salisbury Palliative Care Services May 1995.

10. EXPERTS' DECLARATION

1. I understand that my overriding duty is to the court, both in preparing reports and in giving oral evidence. I have complied and will continue to comply with that duty.
2. I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert are required.
3. I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.
4. I have drawn to the attention of the court all matters, of which I am aware, which might adversely affect my opinion.
5. Wherever I have no personal knowledge, I have indicated the source of factual information.
6. I have not included anything in this report which has been suggested to me by anyone, including the lawyers instructing me, without forming my own independent view of the matter.
7. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.
8. At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.
9. I understand that this report will be the evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

I confirm that insofar as the facts stated in my report are within my own knowledge I have made clear which they are and I believe them to be true, and the opinions I have expressed represent my true and complete *professional opinion.*

Signature: _____ Date: _____

From: Juliet StBernard (020 7189 5148)
Sent: 05 September 2007 13:05
To: 'Ellson, Sarah'
Cc: 'Tomlinson, Tamsin'
Subject: RE: Dr Barton

Hello,

I have now discussed with Peter and he is of the view that the defence should only be given three months to prepare their case.

He is of the view that if the defence require 6 months it will be for Adjudication to determine whether or not they can have it.

Juliet

From: Juliet StBernard Code A
Sent: 05 Sep 2007 10:07
To: 'Ellson, Sarah'
Cc: Tomlinson, Tamsin
Subject: RE: Dr Barton

Hello,

I will need to consult Peter and he is out of the office until this afternoon.

I have just checked with Adjudication and the first available date for a 8 week hearing in London is from 19 May 2007.

Juliet

From: Ellson, Sarah Code A
Sent: 04 Sep 2007 17:51
To: Juliet StBernard Code A
Cc: Tomlinson, Tamsin
Subject: Dr Barton

Just had a long and helpful call with Ian Barker at MDU in anticipation of protocol call.

I have brought him round from initial view that it might not be worth having call at this stage because it is too early to know the scope of the case. We both agree having a date to work to and being able to book Counsel will be helpful. They will be using Alan Jenkins and Tim Langdale QC.

The difficulty is that I have sketched out a timetable

- copy and disclose materials in possible cases asap (when we are preparing instructions

to Counsel)
- confirmation of cases to be issued shortly after our con (Oct/Nov) + poss nature of charges
- draft charges and any outstanding evidence by end of 2007

on this basis - which is still quite tight for us given that we will need to book a block of time with Counsel so he can review and advise - Code A says he would not be ready for a June hearing - he is saying more like September (he is equating the preparation time to a murder case and says 6 months would not be sufficient - I am not sure I agree the analogy and know the Criminal system obviously also tries to get cases on asap)

I need to know whether GMC are concerned to get this on as soon as possible or whether you would prefer to go for the September date for which we will get defence "buy in" and an agreed timetable. If we press for earlier we may face an application any time between now and May saying they are not and cannot be ready - if successful the case would leave a major gap in the GMC calendar and by then would cause re-listing problems. I am inclined to go for co-operation and certainty but know that the case ought to be heard as soon as possible. Service standards are in this case of no relevance but of course the principle is cases ought to be listed sooner rather than later. In the scheme of things a further 3 months would not be significant.

We will also be seeking a London listing but I did explain that there is limited space in London and other major cases might need to be listed in London. I think we will be asking for an 8 week listing which is only a guestimate but Ian agreed with my back of the envelope calculations.

Can you let me have the GMC view/instructions so that I can prepare for Thursday's call - thanks

Sarah Ellson | Partner
for Field Fisher Waterhouse LLP
dd: Code A | m: Code A

From: Juliet StBernard Code A
Sent: 06 September 2007 18:57
To: Peter Swain Code A
Subject: Dr Barton

Peter,

This case has been listed for 8 September 2008 for 40 days in London.

As you aware the defence wanted several months to prepare their case and we stated that 3 months was sufficient, due to our differing views Adjudication made the decision as to when the case should be listed.

Juliet

From: Bushra Ali (Code A
Sent: 06 September 2007 13:34
To: Bushra Ali (Code A); 'Ellson, Sarah'; ' Code A
Juliet StBernard Code A
Subject: RE: Dr Barton
Attachments: Dr Barton.doc

Dear All,

Following a request by the GMC the telecon minutes have been amended.

Please can I request for all parties to confirm their agreement with the amended minutes.

Many thanks,

Bushra

From: Bushra Ali (Code A
Sent: 06 September 2007 11:07
To: 'Ellson, Sarah'; Code A ; Juliet StBernard Code A
Subject: Dr Barton

Dear All,

Please find attached the minutes from today's telecon. Please don't hesitate to contact me if you wish to make any amendments.

Ahead of the next telecon on 24 January 2008, 11am, I attach the agenda and dial up details.

Best wishes,

Bushra

Bushra Ali
Adjudication Co-ordinator
General Medical Council
Tel: Code A

E/Committee/PCC/Listings/GMC Case Protocol stage 3 form

GMC Case Protocol - Stage 3 Telephone Conference
Sarah Ellson & Tamsin Tomlinson, Field Fisher Waterhouse
Ian Barker, Medical Defence Union
Juliet StBernard, Investigation Office
Bushra Ali, Adjudication Listings

Case: Dr Barton

Conference date: 6 September 2007, 10am

Areas to be covered

	Action	Outcome
1.	GMC to complete investigation	4 January 2008
2.	GMC to disclose evidence and final charge	18 January 2008
3.	Doctor to indicate timetable for preparation of defence GMC suggested 3 months preparation time however the defence requested more due to the complexity of the case, which the GMC did not challenge. The Investigation Officer asked Adjudication to make the decision. The telecon was adjourned and the Adjudication Manager was consulted, it was agreed that an extended preparation time will be allocated.	8 August 2008
4.	Agree timetable	GMC, Defence
5.	Provisional hearing date	8 September 2008 – 31 October 2008
6.	Time estimate	40 days

7.	Location of hearing	London
8.	Date of next telephone conference	24 January 2008, 11am

From: Juliet StBernard (Code A
Sent: 06 September 2007 18:30
To: Bushra Ali (Code A)
Cc: Code A; Tomlinson, Tamsin
Subject: RE: Dr Barton

Bushra,

This is a more accurate reflection.

Thanks Juliet

From: Bushra Ali (Code A
Sent: 06 Sep 2007 13:34
To: Bushra Ali (Code A); 'Ellson, Sarah'; Code A
Code A Juliet StBernard (020 7189 5148)
Subject: RE: Dr Barton

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Bushra

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Code A
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Best wishes,

Bushra

Bushra Ali
Adjudication Co-ordinator
General Medical Council
Code A

From: Juliet StBernard (Code A)
Sent: 06 September 2007 13:04
To: Bushra Ali Code A
Cc: 'Ellson, Sarah'; Code A
Subject: RE: Dr Barton

Bushra,

Thank for your reply.

I would be grateful if you could still update the minutes to reflect that it was the GMC's view that Adjudication should determine the defence preparation time due to our differing views, as this is very pertinent information.

Juliet

From: Bushra Ali (Code A
Sent: 06 Sep 2007 11:45
To: Juliet StBernard (Code A
Cc: 'Ellson, Sarah'; Code A
Subject: RE: Dr Barton

Dear Juliet,

As is also confirmed by my colleague Christine Haynes, who was also present on the telecon for training purposes: **after** Defence stated their case for why additional time needs to be allocated, the GMC raised no objections to the arguments put forward/the request for additional time.

At this point, I recall you stated that defence and the GMC had differing opinions and Adjudication needs to determine the time allowed, however, Defence responded by pointing out that at no point during the telecon has FFW expressed any objection to the case Defence has put forth, as FFW did not contest this either "GMC raised no objections" was noted in the minutes. Further to this, once I returned to the telecon to confirm Adjudication's decisions, Defence re-stated that FFW have expressed no objections to the Case for additional preparation time.

I hope this clarifies the minutes.

Many thanks,

Bushra

From: Juliet StBernard Code A
Sent: 06 September 2007 11:17
To: Bushra Ali (Code A
Cc: Code A Tomlinson, Tamsin
Subject: RE: Dr Barton

Hello Bushra,

I am concerned that you have stated in minutes that the GMC had no objections to the defence preparation time, whereas to clarify I recall saying that the GMC and the defence had differing views as the amount of time the defence could be allowed to prepare their case and it was for Adjudication to determine the amount of time that the would be allowed.

I would be grateful if you would amend the minutes to reflect this.

Thanks Juliet

From: Bushra Ali (Code A
Sent: 06 Sep 2007 11:07
To: 'Ellson, Sarah'; Code A Juliet StBernard
Code A
Subject: Dr Barton

Dear All,

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Ahead of the next telecon on 24 January 2008, 11am, I attach the agenda and dial up details.

Best wishes,

Bushra

Bushra Ali
Adjudication Co-ordinator
General Medical Council
Tel: Code A