June 19th 2006

DRAFT REPORT
regarding
HELENA SERVICE (BJC/72 and JR/16)



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AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

- 1. SUMMARY OF CONCLUSIONS
- 2. INSTRUCTIONS
- 3. ISSUES
- 4. BRIEF CURRICULUM VITAE
- 5. DOCUMENTATION
- 6... CHRONOLOGY/CASE ABSTRACT
- 7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE
- 8. OPINION
- 9. LITERATURE/REFERENCES
- 10. EXPERTS' DECLARATION
- 11. STATEMENT OF TRUTH

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 midazolamwas 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

Dr Andrew Wilcock MB ChB, FRCP, DM, Reader in Palliative Medicine and Medical Oncology, University of Nottingham and Honorary Consultant Physician, Nottingham University Hospitals NHS Trust.

Trained in general medicine, including experience in health care of the elderly (acute medicine and rehabilitation) prior to specialising in Palliative Medicine, working in Specialist Palliative Care Units in Nottingham and Oxford. Appointed to present post as Senior Lecturer in 1995. Promoted to Reader in 2001. Carries out research in pain, breathlessness and exercise capacity. Regularly lectures on national and international courses. Palliative care prescribing advisor to the British National Formulary (2002-). Expert reviewer for Prodigy national palliative care guidelines for general practitioners. Joint author of the international Palliative Care Formulary that has sold over 90,000 copies, and the 3rd edition of Symptom Management in Advanced Cancer, with Dr Robert Twycross. Previously Chair of the Mid-Trent Cancer Services Network Palliative Care Group, Nottingham

Cancer Centre Palliative Care Group, inaugural Secretary for the Science Committee of the Association for Palliative Medicine of Great Britain and Ireland and member of the National Institute for Clinical Excellence-Lung Cancer Guidelines Development Group.

Operates the international Palliative Medicine mailbase mailing list and coowns and edits www.palliativedrugs.com that publishes the Palliative Care Formulary on the internet. With 21,000 members it is the largest Palliative Care resource of its kind. Provisional Member of the Expert Witness Institute.

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 Gouncil, 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 History was unavailable on admission because her hearing aid wrist. 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, burnetanide 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 (PaO₂ 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 11.2x10⁹/L (neutrophils 8.2x10⁹/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 13.3x10⁹/L (neutrophils 10.1x10⁹/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 45-90micromot/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, burnetamide 1mg once a day, aspirin 75mg once a day, allopurinol 100mg at night and digoxin 125microgram once a day (page 263 of 401). 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 $\sqrt{\sqrt{}}$ (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 burnetamide, 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 thieridazine. 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 isdetermined, 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 liewithin 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:	D - 4	
Signature.	Date:	
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