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

Dr Andrew Wilcock MB ChB, FRCP, DM, Reader in Palliative Medicine and Medical Oncology, University of Nottingham and Honorary Consultant Physician, Nottingham City Hospital 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 Palliative Care Formulary that has sold over 30,000 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 co-owns and edits www.palliativedrugs.com that publishes the Palliative Care Formulary on the internet. With over 16,400 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] 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 x 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: _____