REPORT

regarding

ELSIE LAVENDER (BJC/30)

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

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mrs. Lavender was a frail 83 year old with significant medical problems. She was admitted to the Royal Naval Hospital, Hasler, Gosport, following a fall down her stairs, following which she found it difficult to walk or move her hands or wrists. She complained of pain across her shoulders and down her arms. A hypoglycaemic episode (low blood sugar) was considered a possible cause of her fall. She was seen by Dr Tandy 11 days later who documented some improvement in her mobility and abnormal neurological findings. Her conclusion was that Mrs Lavender had suffered a brain stem stoke and she was transferred to Gosport War Memorial Hospital, Daedalus Ward for rehabilitation.

During this admission, the medical care provided by Dr Barton was suboptimal: there was a failure to keep clear, accurate, and contemporaneous patient records; there was inadequate assessment of Mrs Lavender's condition, in particular her pain; symptoms and signs that warranted an examination were not acted upon (e.g. search for a possible infection due to raised white cell count, increased blood sugars and insulin requirements; a neurological examination due to her increasing back pain, urinary retention; and faecal incontinence). The morphine prescribed for Mrs Lavender's pains, may have been inappropriate (the type of pains she had may not have been that responsive to opioids) or excessive (as the dose was increased or as her kidney function deteriorated) and the possible role this may have had in her deterioration was not considered. Treatments were continued that may have aggravated her condition (e.g. the diuretic). Ultimately Mrs Lavender was prescribed doses of diamorphine and midazolam that were excessive for her needs.

If it were that Mrs Lavender had naturally entered the terminal phase of her life, at best Dr Barton could be seen as a doctor who whilst failing to keep clear, accurate, and contemporaneous patient records had in good faith been attempting to allow Mrs Lavender a peaceful death, albeit with what appears to

be an inappropriate and excessive use of medication due to a lack of sufficient knowledge. However, in my opinion, based on the medical and nursing records, there is reasonable doubt that Mrs Lavender had definitely entered her terminal stage. Given this doubt, at worst, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Lavender by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Lavender by not carefully assessing the possible causes of her decline that may have been reversible with appropriate treatment (e.g. antibiotics for an infection, stopping the diuretics, reducing the dose of morphine) and unnecessarily exposing her to possibly inappropriate and excessive doses of morphine and ultimately excessive doses of diamorphine and midazolam that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

2. INSTRUCTIONS

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

3. ISSUES

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

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

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

4. BRIEF CURRICULUM VITAE

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 and was the inaugural Secretary for the Science Committee of the Association for Palliative Medicine of Great Britain and Ireland. 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 15,500 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 Elsie Lavender (BJC-30).

[2] Set of medical records on paper of Elsie Lavender (JR-11A).

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

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

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

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

[7] Portsmouth Health Care NHS Trust Policies:

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

ii) Prescription Writing Policy (July 2000).

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

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

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

[8] General Medical Council, Good Medical Practice (October 1995).

[9] British National Formulary (BNF). Section on Prescribing in Terminal Care (March 1995).

[10] British National Formulary (BNF). Section on Prescribing in the

Elderly (March 1995).

[11] Medical report regarding Elsie Lavender (BJC/30) Dr James Gillespie.

6. CHRONOLOGY/CASE ABSTRACT

Events at the Royal Naval Hospital

Mrs Elsie Lavender, an 83 year old widow who lived alone, was admitted on the 5th February 1996 to the Royal Naval Hospital, Hasler, Gosport under the care of Surgeon Commander Taylor, following a fall down her stairs at home. Mrs Lavender had no recollection of the fall but a pool of blood was found at the top of her stairs (page 154 of 695) and she was found at the bottom. She sustained a full thickness (down to the bone) laceration to her forehead that required suturing and a more superficial one to her right shin (page 145 of 695). She complained of pain in both shoulders, but not initially of neck or back pain (page 141 of 695). She reported that she was unable to move her right fingers. When examined by the casualty officer her cervical spine was apparently normal (page 141 of 695), she was tender over the right shoulder and upper left arm (page 143 of 695) and although able to move her right fingers the strength was reduced (graded 3/5; active movement against gravity (but not resistance)) The plantar reflex (elicited by firmly stroking up along the outer edge of the sole of the foot and across the base of the toes) was abnormal in her right foot as it was 'up-going', i.e. the big toe ± other toes extend upwards, when normally they flex downwards (page 145 of 695). This suggests damage to the nerves responsible for muscle movements somewhere along their path from the brain and down the spinal cord. X-rays of her chest, skull and both shoulders were performed. All were regarded as normal (page 145 of 695). In his report, Dr Gillespie states that the chest X-ray was essentially

normal but that the skull x-ray was missing from the x-ray packet. Given the severity of the fall and uncertain nature of its cause, Mrs Lavender was admitted under the medical team for observation and investigation. Her past medical history revealed her to be an insulin dependent diabetic for many years, asthmatic, registered blind and to have atrial fibrillation (an irregular heart rhythm). She had been admitted 11 months earlier following a collapse most likely due to hypoglycaemia (low blood sugar) (page 479 of 695). A neurological examination carried out by the medical senior house officer reported normal tone, power 4/5 (active power against gravity and resistance (but reduced from normal)) in her arms and legs, and 'can move fingers and thumb' (page 152 of 695). No sensory deficit is recorded, but this may reflect a cursory examination; previously reduced sensation in Mrs Lavender's hands and feet had been found in keeping with damage to her nerves, most likely from her diabetes (pages 48, 295 of 695). Reflexes were recorded as normal in both her arms. In her legs, her knee reflexes were normal, both ankle reflexes were absent and her right plantar reflex was up-going (page 152 of 695). Results of blood tests suggested an iron-deficiency anaemia with a haemoglobin of 9.7g/dl. There were no other signs or symptoms suggestive of chronic blood loss. White cell and platelet counts were normal (page 154 of 695). Her son reported that recently her blood sugars had been on the low side and she had experienced a very low sugar one month earlier (hypoglycaemic episode) that required treatment by the district nurses (page 154 of 695). Hypoglycaemia was thus considered a possible cause of her fall (page159 of 695).

On the 6th February, Mrs Lavender complained of pain in right arm. Examination revealed tenderness over the bone and muscles of the arm

and her hands were swollen (page 155 of 695). Later that day, she developed a raised temperature and was commenced on antibiotics empirically, as no obvious source of infection was found (page 156 of 695). Mrs Lavender temperature settled and she received 2 weeks of antibiotics, finishing on 19th February 1996 (page 687 of 695). On the 7th February, she complained of left shoulder/upper arm pain (page 156 of 695). On the 8th February, she was seen by the physiotherapist who noted that Mrs Lavender would not make any voluntary active movement when requested due to pain in both shoulders. When the physiotherapist moved her arms for her (passive/assisted movement) there was a full range of movement in both shoulders. She was only able to stand with the help of two others and took a few steps only. The physiotherapist concluded that the pain in the shoulders was a major problem (page 157 of 695). She was prescribed coproxamol 2 tablets every 6 hours and dihydrocodeine 30mg every four hours as required (page 690 of 695). The use of both of these analgesics was very variable. The most taken in one day was on the 12th February when 3 doses of coproxamol and 2 doses of dihydrocodeine were given (page 690 of 695).

Entries on the 9th and the 12th February report that pain in the arms/shoulders continued (page 158 of 695). Her blood sugars were low and her dose of insulin was reduced. A repeat haemoglobin on the 12th February was 10.1g/dl, platelet and white cell counts were normal (but the lymphocyte count reduced at 1.21×10^9/L)(page 205 of 695). Biochemistry revealed a low sodium 132mmol/l (lower limit 134mmol/l), total protein 60g/l (lower limit 63g/l) albumin 30g/l (lower limit 39g/l) and a raised urea 9.3mmol/l (upper limit 6.1mmol/l), alkaline phosphatase 401IU/l (upper limit

126IU/l) and gamma-glutamyl transferase 139IU/l (upper limit 78IU/l)(page 179 of 695). Apart from the haemoglobin, alkaline phosphatase and gamma-glutamyl transferase (latter two not tested) the remaining haematological and biochemical abnormalities were present at least 11 months earlier (pages 175 and 183 of 695).

On the 13th February she was referred for a geriatrician review and was seen by Dr Tandy, Consultant in Geriatrics on the 16th February 1996 (pages 159 and 162 of 695). In the letter summarising that assessment, Dr Tandy noted that Mrs Lavender complained of weakness in both her hands and difficulty standing since her fall along with pain across her shoulders and down her arms. Mrs Lavender felt that the mobility was starting to improve in her hands. She had stood with the help of the physiotherapist but was still requiring two nurses to help transfer (page 5 of 103). The iron-deficiency anaemia and long-standing stress incontinence were noted (page 5 of 103).

Examination by Dr Tandy confirmed weakness of both hands and wrists, (power of 4/5; active power against gravity and resistance (but reduced from normal))(page 163 of 695). Sensation to light touch was reduced in the right hand in the area supplied by the median nerve (thumb, index, middle and adjacent half of the ring finger) that Dr Tandy considered due to long-standing entrapment of the median nerve at the level of the wrist (carpel tunnel syndrome). Reflexes were generally reduced and her ankle jerks were absent. Her plantar reflex was up-going on the left but not the right (page 163 of 695 and page 5 of 103). *This is opposite to what was found before.*

Dr Tandy was under the impression that Mrs Lavender's neck (cervical spine) had been x-rayed and assumed this was normal. This is incorrect, Mrs Lavender had had only skull, shoulder and chest x-rays. Dr Tandy's assessment was that she had most likely experienced a brain stem stroke leading to her fall (page 163 of 695 and page 5 of 103). Atrial fibrillation is a risk factor for stroke as small blood clots can form in the heart that then travel to the brain to cause a stroke. Dr Tandy placed Mrs Lavender on the waiting list for transfer to Gosport War Memorial Hospital for rehabilitation to try and get her home (page 164 of 695).

Physiotherapy and medical entries on the 20th February 1996 noted that Mrs Lavender's upper limb function was improving as she was starting to feed herself (but not able to use cutlery) but that she still complained of shoulder pain. Mrs Lavender still required the help of two people to stand and could not use a walking aid because of hand weakness. Iron was prescribed for her anaemia (pages 165 and 166 of 695).

A repeat full blood count on the 21st February revealed an increased haemoglobin of 11.0g/dl (normal) and a fall in her platelet count to $120x10^9/l$ (lower limit $150x10^9/l$). This result was signed, but not dated by one of the medical team (page 201 of 695). There is no entry in the notes commenting upon this result.

Over the course of Mrs Lavender's admission her blood sugars remained variable, either too high or too low, and the dose of insulin had to be altered several times (pages 665, 666, 660, 659 and 687, 689, 681, 682 of 695).

Events at Gosport War Memorial Hospital

Mrs Lavender was transferred to Daedalus Ward, Gosport War Memorial Hospital on the 22nd February 1996, under the care of Dr Lord. The Royal Naval Hospital nursing transfer form noted that Mrs Lavender's medication consisted of digoxin 125microgram once a day (for her atrial fibrillation), co-amilofruse (frusemide 40mg and amiloride 5mg) 1 tablet once a day (a diuretic or 'water tablet'), salbutamol inhaler 2 puffs four times a day, becotide inhaler, 2 puffs twice a day, mixtard insulin 24 units in the morning, 12 units in the evening and iron sulphate 200mg twice a day (page 71 of 103). She was however, also still taking coproxamol 2 tablets or dihydrocodeine 30mg as required, and had taken a total of 2 coproxamol and 30mg of dihydrocodeine on the 21st February 1996 (page 684 of 695). Mrs Lavender required minimal assistance with feeding but full assistance with her hygiene needs. There were ulcers on both legs dressed every other day. Her pressure areas were intact although the skin over the buttocks was red (page 71 of 103).

There are six entries in the medical notes that cover a period of 13 days, taking up just over one page in length (pages 44 and 45 of 103). They are brief and make events difficult to follow in any depth. What follows is a record of events summarised from the medical notes, summary notes and nursing care plan.

The entry in the medical notes dated 22nd February 1996, reads 'Transferred to Daedalus Ward, GWMH. PMH (past medical history) fall at home from the top to the bottom of the stairs, laceration on head. Leg ulcers, severe incontinence needs a catheter. IDDM (insulin dependent diabetes mellitus) needs mixtard insulin bd (twice a day), regular series

B.S. (blood sugars), transfers with 2, incontinence of urine, help to feed and dress. Bartell 2. Assess general mobility. ?suitable rest home, if home found for cat' (page 45 of 103). Pain was not mentioned nor assessed in the medical notes. In the summary notes, it was noted that Mrs Lavender experienced pain in her arms and shoulders (page 91 of 103). Her medication was continued unchanged (pages 65, 66, 67 of 103), apart from an increase in the dose of dihydrocodeine to 60mg to be taken as required (page 65 of 103).

The medical notes entry on the 23rd February 1996 reported that Mrs Lavender was catheterised the previous night and that there was some residual urine. The summary notes report that 750ml of urine was drained in the first hour (page 91 of 103) and the nursing care plan reports that one litre or more of urine was drained within 1½ hours after catheterisation (page 75 of 103). This suggests that Mrs Lavender was in urinary retention with 'overflow' incontinence of urine. Blood and protein was found in the urine and trimethoprim (an antibiotic) prescribed for a presumed urinary tract infection (pages 45, 67 and 91 of 103). It is unclear if a sample of urine was sent for microbiology; I could find no results in the notes. Blood for routine haematology and biochemistry testing was taken on 23rd February 1996 (page 91 of 103). The blood count revealed a further drop in the platelet count ($36x10^9$/L)(page 58 of 103). It was commented on the results form that as it was a very small sample, the validity of the platelet count was in question and an early repeat was suggested (page 58 of 103). The main findings of the biochemistry testing were a low sodium at 133mmol/L (stable; probably due to her diuretic therapy) and a raised alkaline phosphatase at 572 IU/L (increasing). As the

alkaline phosphatase can be increased in liver or bone problems, identifying the liver or bone isoenzyme can help differentiate between the two. The isoenzyme test was 'to follow' but I can find no result in the notes (pages 41 and 42 of 103). However, the recent finding of a raised gamma-glutamyl transferase suggests it was more likely liver.

On the 24th February 1996 the summary sheet reports that pain was not controlled properly by DF118 (the dihydrocodeine). Mrs Lavender had received four doses of dihydrocodeine 60mg on the 23rd February and one dose at 06.03 on the 24th February 1996 (page 65 of 103). She was seen by Dr Barton and commenced on MST 10mg twice a day (pages 67 and 91 of 103). MST is a slow release formulation containing morphine. There is no medical notes entry on the 24th February 1996 that details the pain problem or the commencement of the morphine.

No additional dihydrocodeine was requested by/offered to Mrs Lavender on the 25th February (she only had two further doses, one on the afternoon of the 3rd March and one on the morning of the 5th March 1996), but the summary sheet entry at 19.00 hours on the 25th February reports that Mrs Lavender appears to be in more pain, screaming "my back" when moved but uncomplaining when not (page 92 of 103).

On the 26th February 1996, the medical notes reported 'not so well over weekend. Family seen and well aware of prognosis and treatment plan. Bottom very sore, needs Pegasus mattress, institute SC (subcutaneous) analgesia if necessary' (page 45 of 103). The summary notes report that Dr Barton increased the MST to 20mg twice a day (page 92 of 103). At 14.30 hours they note Mrs Lavender's son and his wife were seen by Dr Barton '...prognosis discussed. Son is happy for us to just make Mrs

Lavender comfortable and pain free, syringe driver explained' (page 92 of 103). Mrs Lavender was prescribed on the 'as required' section of the drug chart a syringe driver containing diamorphine 80–160mg and midazolam 40–80 mg (page 65 of 103). There was no explanation in the medical or nursing notes of why it was that Mrs Lavender's prognosis was apparently limited. This dose of diamorphine approximately equates to a 6–12-fold increase in Mrs Lavender's dose of morphine. It was however, never used. The summary sheet noted that due to a high blood sugar, Mrs Lavender's dose of insulin had to be increased (pages 62 and 92 of 103).

The full blood count was repeated on the 27th February 1996 and revealed a further fall in the platelet count 22 x 10^9/L, an increased white blood cell count 13 x 10^9/L, due to an increase in neutrophils (10.8 x 10^9/L) and a normal haemoglobin 12.5g/dL (page 57 of 103). The biochemistry tests for renal function were also repeated on the 27th February 1996. The urea and creatinine had both increased, to 14.6mmol/L and 120micromol/L respectively, in keeping with a deterioration in kidney function (page 42 of 103). There is no mention of these results in the medical notes and no further investigation or consideration for the causes of the low platelet count, raised white cell count or deteriorating renal function. On the 27th February 'painful shoulders and upper arms' became part of the nursing plan (page 84 of 103). An entry reports 'analgesia administered, fairly effective' (page 84 of 103).

On the 29th February 1996, the summary sheet noted that due to a high blood sugar, Mrs Lavender received an additional dose of human actrapid insulin (pages 62 and 92 of 103). Mrs Lavender received two doses in all, before the prescription was crossed off (page 62 of 103).

Entries in the 'painful shoulders and upper arms' nursing care plan each day between 28th February and 4th March 1996 seem to suggest that the pain was mainly on movement and on the 2nd and 3rd of March it was described as 'slight' (page 83 of 103).

Nursing care plan notes from 1st March to the 6th March 1996 reported leakage of faecal fluid, despite rectal digital examination (excluding faecal impaction), suppositories and a manual evacuation (pages 85 and 87 of 103).

There is no mention of pain in the summary notes or medical notes again until the 4th March 1996. The summary notes reported 'Patient complained of pain and having extra analgesia p.r.n (as required). Oramorph sustained release tablets dose increased to 30mg b.d. (twice a day) by Dr Barton (pages 62 and 92 of 103). The Oramorph SR tablets are a different brand of slow release morphine, similar to MST. There is no medical notes entry on the 4th March 1996 that details the pain problem or the increase in the morphine. In the nursing plan notes, the entry for the 4th March 1996 reads 'seen by physio- exercises:- 3 turns of head to right + 5 neck retractions every 2 hours. Elsie needs reminding. Analgesia increased' (page 83 of 103).

The next entry in the medical notes, on the 5th March 1996, reads 'Has deteriorated over the last few days. Not eating or drinking. In some pain, therefore start SC analgesia. Let family know' (page 45 of 103). The summary note entry for the 5th March 1996 reads 'patients pain uncontrolled, very poor night. Syringe driver commenced 5th March 1996 at 09.30 hours, containing diamorphine 100mg and midazolam 40mg...' (page 92 of 103). Both drugs were written as a range, i.e. diamorphine

100–200mg and midazolam 40–80mg; although neither dose needed adjusting (page 65 of 103). A dose of diamorphine 100mg approximately equates to a 5-fold increase in Mrs Lavender's dose of morphine. The nursing care plan notes 'pain uncontrolled, patient distressed, syringe driver commenced 09.30, son informed' (page 83 of 103).

On the 6th March 1996 the medical notes entry reads 'Further deterioration. SC analgesia commenced. Comfortable and peaceful. I am happy for nursing staff to confirm death' (page 45 of 103). The summary sheet entry for the 6th March 1996 reads 'seen by Dr Barton. Medication other than through syringe driver discontinued as patient unrousable' (page 93 of 103). The next entries in the medical notes and summary sheet were at 21.28 hours, the pronunciation of Mrs Lavenders death (pages 45 and 93 of 103). I am advised that on the death certificate, the cause of death was stated as 1a Cerebrovascular accident and 2 Diabetes Mellitus.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Syringe drivers, diamorphine and midazolam

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

Diamorphine is a strong opioid that is ultimately converted to morphine in the body. In the United Kingdom, it is used in preference to morphine in syringe drivers as it is more soluble, allowing large doses to be given in very small volumes. It is indicated for the relief of pain, breathlessness and cough. The initial daily dose of diamorphine is usually determined by dividing the daily dose of oral morphine by 3 (BNF number 29 (March 1995)). Others sometimes suggested dividing by 2 or 3 depending on circumstance (Wessex protocol). Hence, 60mg of morphine taken orally a day could equate to a daily dose of 20 or 30mg of diamorphine SC. It is usual to prescribe additional doses for use 'as required' in case symptoms such as pain breakthrough. The dose is usually 1/6th of the 24hour dose. Hence for someone receiving 30mg of diamorphine in a syringe driver over 24hours, a breakthrough dose would be 5mg. One would expect it to have a 2–4 hour duration of effect, but the dose is often prescribed to be given hourly if required. As the active metabolites of morphine are excreted by the kidneys, caution is required in patients with impaired kidney function.

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in their terminal phase would generally aim to find a dose that improves the patient's symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg a day. A

smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated every 24hours if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24hours, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4hours, and it may need to be given more frequently. As an active metabolite of midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

ii) The principle of double effect.

The principle of double effect states that:

'If measures taken to relieve physical or mental suffering cause the death of a patient, it is morally and legally acceptable provided the doctor's intention is to relieve the distress and not kill the patient.'

This is a universal principle without which the practice of medicine would be impossible, given that every kind of treatment has an inherent risk. Many discussions on the principle of double effect have however, involved the use of morphine in the terminally ill. This gives a false impression that the use of morphine in this circumstance is a high risk strategy. When correctly used (i.e. in a dose appropriate to a patient's need) morphine does not appear to shorten life or hasten the dying process in patients with cancer. Although a greater risk is acceptable in more extreme circumstances, it is obvious that effective measures which carry less risk to

life will normally be used. Thus, in an extreme situation, although it may occasionally be necessary (and acceptable) to render a patient unconscious, it remains unacceptable (and unnecessary) to cause death deliberately. As a universal principle, it is also obvious that the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

8. OPINION

Mrs Lavender was a frail 83 year old with insulin dependent diabetes mellitus who was admitted following a serious fall from the top to the bottom of her stairs. Initially, it was considered likely that the fall was due to a hypoglycaemic episode (low blood sugar). She was at risk of hypoglycaemia as her blood sugars had recently been running low. Following the fall, Mrs Lavender complained of pain across her shoulders and down her arms and was unable to use her hands or to stand. Examination confirmed weakness in the right hand and an 'up going' plantar reflex in her right foot. Investigations revealed iron deficiency anaemia. Pain in her shoulder and arms continued, although there had been some improvement in the use of her hands by the time Dr Tandy saw her (11 days after admission). On examination she found weakness of both hands and wrists and an 'up going' plantar reflex in the left foot. Dr Tandy's opinion was that Mrs Lavender had suffered a brain stem stroke. Mrs Lavender's diabetes and atrial fibrillation would increase her risk of having a stroke. In my current practice I no longer see patients who are admitted with a stroke and Dr Tandy's experience will be greater than mine. However, given that Mrs Lavender had recently experienced a severe fall, I am unsure how certain one could be in attributing all of Mrs

Lavender's symptoms and signs as being caused by a brain stem stroke, particularly as her neurological findings could also be in keeping with cervical spinal cord and nerve root trauma sustained in the fall down the stairs. I would have thought it prudent whatever the findings on the initial examination of the cervical spine in casualty to have obtained a cervical spine X-ray. Whatever the cause of her fall, when considering Mrs Lavender's pain, it is my opinion that:

1. Mrs Lavender's pain across her shoulders and into her arms was most likely to be related to her fall.
2. Her pain was likely to be a 'mixed' pain; that is originating from damage to muscles and soft tissues (e.g. ligaments) of the neck and, possibly from impingement on the nerve roots and spinal cord within the cervical spine. Muscle and nerve injury pain respond poorly to strong opioids.
3. As her injuries healed over subsequent weeks, it is reasonable to expect that the pain would also settle. As such, failure of the pain to settle or any worsening of the pain should, in my view, prompt a careful reassessment that includes appropriate investigation, e.g. a cervical spine imaging (given her neurological findings) and certainly the area of the spine causing Mrs Lavender to scream out in pain "my back" (page 92 of 103). I am unable to find in the notes which part of her back this pain was.

Events at Gosport War Memorial Hospital

Infrequent entries in the medical notes make it difficult to closely follow Mrs Lavender's progress over the last two weeks of her life. There are six entries, taking up just over one page in length.

Mrs Lavender's most relevant problems during her stay, in summary and in approximate chronological order, appear to have consisted of weak hands and

wrists, poor mobility, pain in her shoulders and arms that was mainly on movement for which she went on to receive increasing doses of morphine; urinary retention and a probable urinary tract infection; a falling platelet count; being generally 'unwell'; increased blood sugars and insulin requirements; increasing white cell count, deteriorating renal function; leakage of faecal fluid; worsening of her pain and further deterioration. A syringe driver was then commenced with doses of diamorphine and midazolam sufficient to render her unresponsive until she died 36 hours later. Her cause of death was registered as cerebrovascular accident. A lack of assessment and documentation make the validity of this difficult to comment upon, but her final deterioration as outlined in the nursing and medical notes does not appear in my opinion to be typical of a cerebrovascular accident. Based on the sequence of events and biochemical and haematological findings, it seems more likely that her immobility resulting from her fall, led to an infection. Given that Mrs Lavender had suffered a recent accident that may have contributed in some way to her death, it is usual practice to discuss such deaths with the coroner.

There is a lack of documentation to demonstrate that there had been an adequate assessment of many of the problems Mrs Lavender had through the undertaking of an appropriate history, physical examination and investigation.

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

The medical care provided by Dr Barton to Mrs Lavender following her transfer to Gosport War Memorial Hospital, Daedalus Ward is suboptimal when compared to the good standard of practice and care expected of a doctor outlined by the General Medical Council (General Medical Council, Good Medical Practice, October 1995, pages 2–3) with particular reference to:

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs including, where necessary, an appropriate examination; providing or arranging investigations or treatment where necessary; taking suitable and prompt action when necessary; referring the patient to another practitioner when indicated
- in providing care you must keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs or appliances that serve the patients' needs.

Specifically:

i) The notes relating to Mrs Lavender's transfer to Daedalus Ward are inadequate. On transfer from one service to another, a patient is usually re-clerked highlighting in particular the relevant history, examination findings and planned investigations to be carried out.

ii) The cause of Mrs Lavender's urinary retention was not assessed.

iii) Mrs Lavender was treated for a urinary tract infection with the antibiotic trimethoprim. Neither a diagnostic urine specimen nor a check urine specimen (to see if the infection had cleared) were sent for microbiology. It is therefore unclear if the urinary tract infection was successfully treated or not. This should have been considered when Mrs Lavender was noted to be 'not so well' (see point v).

iv) There is a lack of medical notes relating to the pain or its assessment and the commencement of morphine (MST 10mg) twice a day on the 24th February 1996.

v) On the 26th February 1996 the medical notes report Mrs Lavender to be 'not so well over weekend'. There is a lack of detail that explains in what way she was not so well. There are no records that an appropriate history, examination or investigations had been undertaken to try and determine the reason for Mrs Lavender feeling less well. Instead, without any assessment of the pain, the MST was increased to 20mg twice a day and a syringe driver prescribed to be used 'as required' that contained diamorphine and midazolam in doses that would be excessive to Mrs Lavenders needs.

vi) Blood tests from the 27th February 1996 revealed a low platelet count and deteriorating kidney function. There is no mention of this in the medical notes, and no action was taken.

vii) On the 29th February 1996 there is no mention in the medical notes that Mrs Lavender's blood sugars were high requiring additional doses of insulin. The fact that this could have been due to an untreated infection does not appear to have been considered.

Despite entries in the nursing care plan and summary sheets relating to Mrs Lavender's pain there is no mention of this in the medical notes.

viii) The nursing care plan reports leakage of faecal fluid. There is no mention of this problem in the medical notes or consideration of the possible significance of this symptom given Mrs Lavenders history of trauma.

ix) The morphine was increased again on the 4th March 1996. There is no pain assessment or entry in the medical notes that relates to this increase.

x) The entry in the medical notes of the 5th March reports that Mrs Lavender had deteriorated over the last few days. It is not clear in what way she had deteriorated. There is no history or examination that considers the possible reasons for her decline.

xi) Mrs Lavender's pain appeared poorly controlled on the night of the 4th March but there is no assessment of the pain in the medical notes prior to a syringe driver containing diamorphine 100mg and midazolam 40mg being commenced. The doses of diamorphine and midazolam used in response to Mrs Lavender's worsening pain, are excessive for her needs, even if it were considered that her pain was morphine responsive and she was dying from natural causes.

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

Issue i (failure to take an adequate history and examination on transfer; failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed)

Upon her transfer to Daedalus Ward there should have been an adequate assessment of Mrs Lavender's condition based on the history and clinical signs and, if necessary, an appropriate examination. In my view there is inadequate documentation of Mrs Lavender's relevant history, in particular a lack of an assessment of her pain. As the Wessex guidelines (page 2) point out, an accurate pain assessment is essential both for diagnostic and therapeutic purposes. An assessment should have included as a minimum the noting of the site, severity, aggravating/relieving factors that together with a physical examination would help identify the most likely cause(s) of the

pain(s). This was important as it was likely that Mrs Lavender would have been experiencing several different types of pain as a result of her injury. There may have been soft tissue, muscle and nerve injury pains. Muscle and nerve injury pains are less likely to respond to opioid analgesics. This is highlighted in the Wessex protocol (page 3) 'remember some pains are opioid responsive, others are only opioid semi-responsive and need other approaches'.

There was no physical examination of Mrs Lavender on her transfer. This would be important to act as a baseline against which to compare any future changes. A thorough neurological examination would have been particularly important given the history of her fall, the possibility of a brain stem stroke being raised and the abnormal neurological findings mentioned in Dr Tandy's letter.

Issue ii (failure to adequately assess the patient's condition)

Urinary retention is rare in women and should have prompted an assessment to explore the possible causes of it in Mrs Lavender. Long-standing diabetes can cause damage to the nerves controlling bladder function and may have been responsible. Another cause of urinary retention is injury to the spinal cord. Given Mrs Lavender's history of a severe fall and complaints of back pain, in my opinion she should have been reassessed, including a careful neurological examination. This would have included assessment of anal tone and perineal sensation.

Issue iii (failure in providing or arranging investigations or treatment where necessary; taking suitable and prompt action when necessary; failure to adequately assess the patient's condition)

A urinary tract infection is sometimes treated 'blind' with antibiotics such as trimethoprim, without obtaining a sample of urine for microbiology. The risk with this practice is that the bacteria causing the infection may be resistant to the antibiotic. If there are reasons to doubt that the infection is responding to

treatment, e.g. patient remains unwell, urinary symptoms persist, then a urine specimen should be sent for microbiology testing and/or consideration given to changing the antibiotic.

Issues iv and ix (failure to adequately assess the patient's condition; failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed)

Given that Mrs Lavender's pain required frequent 'as required' doses of dihydrocodeine immediately after her transfer, it was reasonable to provide her with analgesia on a regular basis. An assessment of the pain should however have been done in order to determine the cause(s) of her pain(s) as this would influence the way the pain(s) were managed. For example, were non-drug methods such as positioning, massage, TENS (transcutaneous electrical nerve stimulation) appropriate? If drug measures were considered appropriate, and the pain was considered to be opioid responsive one option would have been to combine the use of paracetamol (step 1 analgesic) with the dihydrocodeine (step 2 analgesic) regularly. If reasonable doses of dihydrocodeine were not relieving the pain some practitioners may well commence a small dose of morphine as Dr Barton did. However, if the pain was not particularly opioid responsive, the dihydrocodeine or morphine may do little or nothing for the pain but could expose the patient to unwanted effects of opioids, e.g. drowsiness, delirium, nausea, vomiting etc. This is relevant, as given her traumatic fall, muscle or nerve injury pain that generally respond poorly to opioids may have been significant factors in Mrs Lavender's pain. Further, it was commented upon that Mrs Lavender was comfortable at rest, only to be in pain when moved (termed 'incident' pain). These can be difficult pains to manage, even if opioid responsive, as the dose of opioid required to improve the pain on movement can be excessive for the patient whom for the

majority of the time is resting and pain free. Typically in this situation the patient becomes increasingly drowsy as the dose of opioid increases.
Despite increasing the morphine dose, a thorough pain assessment was not carried out.

Issues v, vi and vii (failure to adequately assess the patient's condition; failing in providing or arranging investigations or treatment where necessary; taking suitable and prompt action when necessary; failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed; failure to prescribe only the treatment, drugs or appliances that serve the patients needs)

There was a failure to adequately assess and document clearly why Mrs Lavender was less well around the 26th February. This should have been based on a history, examination (e.g. temperature, chest) and findings of appropriate investigations (e.g. urine specimen for microbiology). Mrs Lavender was at increased risk of infection due to her immobility and diabetes, and this should have specifically been considered as a cause for her being less well. Other findings that pointed to the possibility of there being an infection, e.g. the raised blood sugars, increased insulin requirements, raised white cell count and falling platelet count do not appear to have been acted upon.

In the absence of a diagnosis that explained why Mrs Lavender was less well, it is unclear what information Dr Barton was in a position to give Mrs Lavender's son regarding his mother's situation and prognosis. Unless Mrs Lavender was clearly entering her terminal stage and was actively dying, it would have been appropriate to have made reasonable efforts to identify the cause of her feeling less well as it could have been treatable. Even if she were considered to be dying, it would be unusual to respond by prescribing a

syringe driver 'as required' that contained doses of diamorphine and midazolam that were excessive to her needs (see technical issues).

The causes of Mrs Lavender's low platelet count and deteriorating kidney function should have been considered in light of her overall situation. There are many causes of a fall in platelet count, and infection is one. It does not appear that Dr Barton discussed this finding (or Mrs Lavender's situation at any point) with a consultant or obtained advice specifically about the low platelet count from a haematologist. The decline in kidney function could have been due to a urinary tract infection not responding to the antibiotics and this should have been actively considered. Alternatively, as she was less well, she may have been drinking less and as a result had become dehydrated. Mrs Lavender's diuretic (water tablet) that could aggravate the situation was continued unchanged when stopping it should have been considered. With a deterioration in her kidney function, the possibility that cummulation of the metabolites of morphine could have been contributing to her decline was not considered.

Issue viii (failure to adequately assess the patient's condition)

There is no mention of the problem of faecal leakage in the medical notes. There are a number of possible reasons why Mrs Lavender may have been experiencing this, including her age, diabetes, immobility and diarrhoea. As it can also be caused by injuries to the brain or spinal cord, this symptom is significant given Mrs Lavenders history of a severe fall, her other symptoms and complaints of back pain. There should have been a neurological examination that would have included assessment of anal tone and perineal sensation.

Issue x (failure to adequately assess the patient's condition; failing in providing or arranging investigations or treatment where necessary; taking suitable and prompt action when necessary; failure to keep clear, accurate, and

contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed; failure to prescribe only the treatment, drugs or appliances that serve the patients needs)

Although Mrs Lavender was reported to have further declined, there was no clear documentation in what way this was. There should have been a search for the possible causes in case these were reversible. In particular, an infection should have been ruled out.

Given the expectation that the pain should improve as her injuries healed, a reason for the pain worsening on the evening of 4th March should have been sought. For example, were there new findings on examination? Had her neurology altered?

As the pain had got worse despite increasing the morphine, consideration should have been given to the fact that the pain was not responding to the morphine. This should have prompted an assessment of the causes of her pain and review of her treatment. If her pain was not responsive to morphine, was the amount she was taking too much? Was this playing a part in her deterioration?

Issue xi (failure to keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed; failure to prescribe only the treatment, drugs or appliances that serve the patients needs)

The medication used in response to Mrs Lavender's worsening pain, detailed below, appears excessive for her needs, even if it were considered that her pain was morphine responsive and she was dying from natural causes. Medication to control symptoms is usually commenced at a starting dose appropriate to the patient (e.g. considering age, frailty etc.) and their particular

symptom control needs and titrated upwards only to control these symptoms without necessarily rendering the patient unresponsive. There is no justification given for how the doses of diamorphine and midazolam were determined for Mrs Lavender. Using a 1:2 or 1:3 dose conversion ratio to calculate the dose of subcutaneous diamorphine from her oral morphine dose, Mrs Lavender's dose should have been in the order of 20–30mg of diamorphine per day. A daily dose of diamorphjne of 100mg (with scope to increase the dose to 200mg a day) is likely to be excessive for Mrs Lavender's needs and to cause drowsiness. Increasing doses of opioids excessive to a patients needs are also associated with an increasing risk of delirium, nausea and vomiting and respiratory depression. There are no clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing any drug as a range is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient should decide on and prescribe any change in medication. Such decisions should not be left to a nurse.

The daily dose of midazolam was prescribed as 40–80mg. There is no justification within the medical notes for the use of midazolam. Although the nursing care plan notes that Mrs Lavender was distressed, this appeared to relate to her uncontrolled pain. It is usual practice in this situation to concentrate on providing pain relief rather than on sedating the patient. If a patient is particularly distressed, small doses of sedative are sometimes given, but usually on an 'as required basis' whilst awaiting any changes made to the analgesia to become effective. In this regard, midazolam 2.5mg by intermittent SC injection would have been reasonable. The dose of 40mg of midazolam is likely to lead to drowsiness in a frail elderly patient. If Mrs

Lavender was considered to have muscle spasm, terminal agitation, or anxiety then a smaller daily dose such as 10mg may have sufficed. Again, there are no prescribing instructions on why, when and by how much the dose can be altered within this range and by whom.

If there were concerns that a patient may experience, for example, episodes of pain or anxiety, it would be much more usual, and indeed seen as good practice, to prescribe appropriate doses of morphine/diamorphine, or diazepam/midazolam respectively that could be given intermittently 'as required' orally or SC. This allows a patient to receive what they need, when they need it, and guides the doctor in deciding if a regular dose is required, the appropriate starting dose and subsequent dose titration.

In short, the diamorphine and midazolam appear to have been prescribed without sufficient safeguard in relation to altering the dosage and in a way that exceeded Mrs Lavender's needs. In regard to the latter, Mrs Lavender was unrousable after the syringe driver had been commenced and no alteration in the dose of diamorphine or midazolam was required.

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

Dr Barton does not appear to have provided Mrs Lavender a good standard of clinical care as defined by the GMC (General Medical Council, Good Medical Practice, October 1995, pages 2–3).

Although it is possible that Mrs Lavender was dying 'naturally', it is also possible that her physical state had deteriorated in a temporary or reversible way and that she was not in her terminal phase. In this regard, there should have been a more thorough assessment and clearer documentation of the

possible contributing factors, such as an infection, to Mrs Lavender becoming 'less well'.

A failure to assess Mrs Lavender's pain correctly could have resulted in her receiving increasing doses of morphine for pain(s) that occurred mainly on movement and that were not fully opioid responsive (e.g. muscle and nerve injury pains). This may have provided little pain relief but exposed her to the adverse effects of opioids such as drowsiness. That this may have contributed to her further deterioration was not considered or acted upon. The effect of deteriorating kidney function on morphine metabolites that may have exacerbated the above was not considered or acted upon.

There were symptoms, signs and investigations in keeping with deteriorating kidney function, a possible infection and possible spinal cord injury that should have prompted a more thorough assessment of Mrs Lavender's condition, including a neurological examination.

In the absence of a thorough assessment that could confirm whether Mrs Lavender was likely to be experiencing a reversible or irreversible decline, it is difficult to know what could have been said to her son with any certainty. However, the prescribing of a syringe driver, even though never used, with large doses of diamorphine and midazolam to be used 'if required' appeared excessive and premature. The syringe driver started some days later also contained doses of diamorphine and midazolam that were excessive for Mrs Lavender's needs.

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

with any certainty that they did not contribute more than minimally, negligibly or trivially to the death of the patient.

Although the principle of double effect could be invoked here (see technical issues), it remains that a doctor has a duty to apply effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose of strong opioid that was *appropriate* and not excessive for a patient's needs.

If it were that Mrs Lavender had naturally entered the terminal phase of her life, at best, Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mrs Lavender a peaceful death, albeit with what appears to be an inappropriate and excessive use of medication due to a lack of sufficient knowledge.

However, in my opinion, based on the medical and nursing records, there is reasonable doubt that she had definitely entered her terminal stage. Given this doubt, at worst, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Lavender by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mrs Lavender by failing to adequately assess the cause of her pain and deterioration, failing to take suitable and prompt action when necessary and exposing her to inappropriate and/or excessive doses of diamorphine and midazolam that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

9. LITERATURE/REFERENCES

British National Formulary 29 (March 1995).

Prescribing in Terminal Care, pages 12–15.

British National Formulary 47 (March 2004).

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition

General Medical Council, Good Medical Practice, October 1995, pages 2–3.

'Wessex Protocol' Salisbury Palliative Care Services May 1995 pages 3–4, 30–31.

10. EXPERTS' DECLARATION

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

11. STATEMENT OF TRUTH

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

Signature: Code A Date: 1.5.05