REPORT

regarding

Code A

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AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Code A was a frail 82 year old man admitted to Mulberry Ward, Gosport War Memorial Hospital due to depression. He was withdrawn, agitated and irritable and required the help of two others to mobilise. Despite the admission and a reduction or discontinuation in some of his medication, his low mood and poor mobility persisted. He developed a chest infection and urinary retention. After about three weeks in hospital, his condition remained poor and he started to develop pressure sores. Code A was referred to Dr Lord, Consultant Geriatrician, for a medical review and was subsequently transferred to Dryad Ward.

During this admission, the medical care provided by Dr Barton fell short of a good standard of clinical care as defined by the General Medical Council that included the lack of clear note keeping, adequate assessment of the patient and providing treatment that was excessive to a patients' needs. The reason for the prescription of drugs was not clear. If pain was a problem, it was not recorded or assessed. Most significantly, the dose range of diamorphine prescribed for the 'as required' syringe driver, and the dose finally administered (80mg), far exceeded that generally considered to be an appropriate starting dose (10–15mg) based on Code A existing opioid usage.

Code A was described as tense and agitated several times following the syringe driver being commenced. In this regard the use of midazolam, haloperidol and levomepromazine could be seen as justified. However, an assessment of the possible causes of his agitation should have been carried out. This would have included considering if drugs, such as the diamorphine, were a possible contributing factor to his agitation. At the very least, given that

diamorphine in a dose that is excessive to a patients needs can cause agitation and confusion, it should have prompted a review of the appropriateness of Code A dose of diamorphine.

There appears little doubt that Code A was 'naturally' coming to the end of his life. At best, Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Code A a peaceful death, albeit with what appears to be an excessive use of diamorphine due to a lack of sufficient knowledge.

It is my opinion however, that given the lack of documentation to the contrary, Dr Barton could be seen as a doctor who breached the duty of care she owed to Code A by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Code A by unnecessarily exposing him to excessive doses of diamorphine that could have resulted in a worsening of his agitation. Dr Barton's response to this was to further increase Code A dose of diamorphine. Despite the fact that Code A Code A was dying 'naturally', it is difficult to exclude completely the possibility that a dose of diamorphine that was excessive to his needs may have contributed more than minimally, negligibly or trivially to his death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

2. INSTRUCTIONS

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

3. ISSUES

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

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

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

4. BRIEF CURRICULUM VITAE

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] Full paper set of medical records of Code A including the death certificate.

[2] Full set of medical records of Code A on CD-ROM.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

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

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

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

[7] Portsmouth Health Care NHS Trust Policies:

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

ii) Prescription Writing Policy (July 2000).

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

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

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

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

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

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

[10] British National Formulary (BNF). Section on Prescribing in the Elderly (March 1995).

6. CHRONOLOGY/CASE ABSTRACT

Events at the Gosport War Memorial Hospital, Mulberry Ward, 13th December 1995 until 5th January 1996

Code A an 82 year old man who lived in Hazeldene residential home was admitted on the 13th December 1995 to Mulberry Ward, Gosport War Memorial Hospital under the care of Dr Banks, consultant in old age psychiatry (pages 62 of 181). He was depressed and reported feeling hopeless and suicidal. He had been verbally aggressive towards his wife and the staff at the residential home. He was staying in bed all day and not eating well (pages 62 and 125 of 181). He was known to Dr

Banks having suffered from chronic depression for over 30 years resulting in multiple admissions to hospital. He also had an underactive thyroid gland and problems with constipation (page 62 of 181). His medication consisted of sertraline 100mg once a day, lithium carbonate 400mg once a day, thioridazine 50mg four times a day, diazepam 10mg twice a day, temazepam 10mg at night, thyroxine 50microgram once a day, magnesium hydroxide 10ml at night and codanthrusate 2 capusles at night (pages 62 and 88 of 181). Examination revealed him to be withdrawn, a little agitated and irritable. He had a slight tremor on moving, a shuffling gait and required the help of two others to mobilise (page 63 of 181). It was considered that depression was his main problem (page 63 of 181).

Over the next few days he experienced a fall and problems with diarrhoea. His laxatives were discontinued and an abdominal x-ray carried out. This revealed distension of the large bowel with only a small gas bubble seen in the region of the rectum. The report concluded that these features could represent distal large bowel obstruction but as there was no faecal residue, the changes may be due to pseudo-obstruction (page 116 of 181). His low mood and poor mobility persisted. As thioridazine can cause Parkinsonism (i.e. a collection of features similar to those seen in patients with Parkinson's disease, e.g. difficulty initiating movements, rigidity, tremor etc.) the dose was reduced to 25mg four times a day and procyclidine 5mg twice a day was commenced (page 64 of 181). Procyclidine is an antimuscarinic drug that can help with Parkinsonism.

After about one week, on the 22nd December 1995 he was found to have a chest infection and erythromycin, an antibiotic, was commenced (page 64 of 181). On review by Dr Banks on the 27th December 1995, Code A

was noted to be 'chesty, poorly, abusive and not himself at all' (page 65 of 181). As he had not responded to the erythromycin, another antibiotic, cefaclor was commenced and the procyclidine was discontinued. He had been catheterised for urinary retention the week before (page 65 of 181). Microbiology tests of his sputum revealed a pseudomonas infection (page 112 of 181). A chest x-ray showed no evidence of focal lung disease (page 116 of 181). It was decided to reassess his mood once his medical problems had been addressed.

After about three weeks in hospital, on the 2nd January 1996 it was reported that he remained poorly, lethargic, his skin was breaking down and he was now nursed on a Pegasus bed. He was reported to be asking 'why don't you let me die?' (page 65 of 181). Blood test results on the 2nd January 1996 were mostly normal. There was a raised white blood cell count. $15.7x10^9$/L, due to an increase in neutrophils, $14.4x10^9$/L, in keeping with an infection (page 114 of 181). Liver enzymes were mildly abnormal with raised alkaline phosphastase of 110 IU/L, AST (aspartate aminotransferase) of 127 IU/L and a low albumin of 27g/L (upper limit of normal 95, 40 and lower limit of 37 respectively)(page 85 of 181). Rather than attribute his deterioration purely to his depression, Code A was referred to a geriatrician to see if any medical problems were contributing to his decline (page 65 of 181). A referral letter was written in the notes to Dr Lord, Consultant Geriatrician, on the 2nd January 1996 that noted Code A Code A mobility had deteriorated drastically during his admission and although his chest infection was now improving, he remained bed bound, expressing the wish to die. It also noted Code A complaints of intermittent abdominal pain (page 66 of 181).

When reviewed by Dr Banks on the 3rd January 1996, it was again noted that Code A was deteriorating, with a poor food intake and some breaks in his skin (page 66 of 181). In case undesirable effects of some of his medication were contributing to his decline, the diazepam was reduced to 2mg three times a day and the thioridazine and temazepam discontinued (pages 67 and 81 of 181).

He was seen by Dr Lord on the 4th January 1996. She listed Code A problems as 'chronic resistant depression – very withdrawn, completely dependent (Bartell 0), catheter by-passing, superficial ulceration of left buttock and hip, and hyoproteinaemic'. She suggested high protein drinks, bladder washouts twice a week, dressing to his skin ulcers and transfer to a long stay bed. Dr Lord felt his residential home place could be given up as he was unlikely to return (page 67 of 181). In the typed letter of the 8th January 1996, that summarised this review, Dr Lord stated that Mr Code A prognosis was poor and that he was unlikely to return to Hazeldene Rest Home (page 5 of 49).

Events at Gosport War Memorial Hospital, Dryad Ward, 5th January 1996 to 24th January 1996

On transfer to Dryad Ward on the 5th January 1996, the medical notes record Code A problems as consisting of 'immobility, depression, a broken sacrum with small superficial areas of the right buttock, a dry lesion on his left ankle and both heels suspect. Catheterised, transfers with hoist, may help to feed himself. Long standing depression on lithium and sertraline' (page 13 of 49). Code A medication was continued unchanged on transfer: sertraline 50mg twice a day, lithium carbohydrate

400mg at night, diazepam 2mg three times a day, thyroxine 50microgram once a day and daktacort cream (page 16 of 49). The nursing notes suggest that Code A settled into the ward well and went on to detail his pressure sores (page 25 of 49).

On the 8th January, a pain relief preparation 'arthortec' one tablet twice a day, containing a non-steroidal anti-inflammatory drug, diclofenac, was commenced and continued until the 10th January 1996 (page 16 of 49).

On the 9th January 1996 the medical notes entry reads 'painful right hand held in flexion, try *hot water* (this should be clarified as the handwriting is difficult to decifer). Also increasing anxiety and agitation,?sufficient diazepam, ?needs opiates' (page 13 of 49). The nursing notes record that he was very sweaty but was apyrexial (temperature not elevated) and that Code A stated that he had generalised pain (page 25 of 49).

On the 10th January 1996, oramorph (morphine solution, 10mg/5ml) 2.5ml (5mg) every four hours was prescribed but none given until the 11th January (page 17 of 49). Possibly also on the 10th January, diamorphine 40–80mg and hyoscine (hydrobromide) 200–400microgram SC (subcutaneous) in 24 hours were also prescribed (page 17 of 49). These were not used on the 10th or 11th January, and the drug chart appears to have been rewritten sometime on the 11th January (pages 18 and 19 of 49). The diamorphine was rewritten as 80–120mg along with hyoscine (hydrobromide) 200–400microgram and midazolam 40–80mg SC (subcutaneous) in 24 hours. The nursing notes for this day record 'Condition remains poor. Seen by Dr Tandy and Dr Barton. To commence on oramorph 4 hourly. This evening Code A seen and is aware of poor condition. To stay in long stay bed' (page 25 of 49).

On the 11th January 1996 the diazepam was increased from 2mg to 5mg three times a day and the oramorph given as 5mg every 4 hours, with 10mg at night until the morning of the 15th January 1996 (page 19 of 49). On the 12th January 1996, the sertraline and lithium carbonate were discontinued.

On the 13th January 1996 the nursing notes record 'Catheter bypassing. Code A appears distress, suby g washout given. However, catheter continues to bypass heavily. Catheter removed, tip of same looks very mucky...' (page 25 of 49).

A medical notes entry on the 15th January 1996 summarises 'For TLC (tender loving care). Discussed with wife, agrees in view of the poor quality for TLC' (page 13 of 49). A syringe driver was commenced at 08.25am on the 15th January containing diamorphine 80mg, hyoscine hydrobromide, 400microgram and midazolam 60mg SC over 24 hours (pages 18,25,26 of 49). The nursing notes for that day detail 'Seen by Dr Barton. Syringe driver commenced....' and at 19.00pm 'Daughter informed of father's deterioration during the afternoon. Now unresponsive. Unable to take fluids and diet. Pulse strong and regular' (page 26 of 49).

On the 16th January 1996 haloperidol 5–10mg SC over 24 hours was prescribed (page 20 of 49) with Code A receiving haloperidol 5mg on the 16th January 1996 and 10mg on the 17th January 1996. The nursing notes entry reads 'Condition remains very poor. Some agitation was noticed when being attended to. Seen by Dr Barton. Haloperidol 5–10mg to be added to the driver' (page 26 of 49).

On the 17th January 1996, the dose of diamorphine was increased to 120mg and the midazolam to 80mg SC over 24 hours and both then

remained unchanged for the remainder of Code A life. The dose of hyoscine hydrobromide was increased twice on the 17th January to 600microgram then 1200micrograms SC over 24 hours; as was the dose of haloperidol, increasing to 10mg and then to 20mg SC over 24 hours (pages 6, 7 and 20 of 49). The dose of hyoscine hydrobromide then remained unchanged for the remainder of Code A life. There are several entries in the nursing notes on the 17th January: (09.00am) 'Seen by Dr Barton, medication increased 08.25am as patient remains tense and agitated. Chest very 'bubbly'. Suction required frequently this morning. Patient bed bathed, mouth care tolerated well. Skin marking easily despite hourly turning and use of Pegasus mattress and remains distressed on turning.' (14.30pm) 'Seen by Dr Barton, medication reviewed and altered. Syringe driver renewed at 15.35pm (two drivers).....Daughter informed of deterioration.' (20.30pm) 'Further deterioration in already poor condition. Appears more settled although still aware of when he is being attended to....' (page 27 of 49)..

On the 18th January 1996 the medical notes report 'further deterioration, SC (subcutaneous) analgesia continues, difficulty controlling symptoms, try nozinan' (levomepromazine) (page 15 of 49). This was commenced at a dose of 50mg SC over 24 hours (page 6 of 49). The nursing notes report 'poorly condition, continues to deteriorate.....' (page 27 of 49). Wife has visited for most of the day. Appears comfortable in between attention. Oral suction given with some effect' (page 28 of 49).

On the 19th January 1996 the nursing notes read 'A marked deterioration in an already poorly condition.....Breathing very intermittent, colour poor' (page 28 of 49). On the 20th January 1996 the medical notes entry reads

'Has been unsettled on haloperidol in syringe driver. Discontinue and change to higher dose nozinan, increase nozinan 50→100mg in 24 hours (verbal order)' (pages 6, 7 and 15 of 49). The nursing notes for the 20th January 1996 read Code A and both daughters have visited. Dr Brigg contacted regards to regime. Verbal order taken to double nozinan and omit haloperidol. Syringe driver recharged at 18.00hours. Appears comfortable at time of report...' (page 28 of 49).

On the 21st January 1996, the medical notes entry reads 'Much more settled. Quiet breathing. Respiratory rate 6 per minute. Not distressed, continue' (page 15 of 49). Nursing entry for this day reads 'Very settled today' (page 28 of 49). On the 22nd January 1996 the nursing notes record 'poorly but very peaceful' (page 29 of 49). On the 23rd January 1996, the nursing notes record 'Poorly condition remains unchanged, has remained peaceful' (page 29 of 49). An untimed entry then reads 'Patients condition deteriorated suddenly at 01.40am and Code A died at 01.45am' (page 29 of 49). A verification of death entry was made in the medical notes (page 15 of 49).

On the death certificate, cause of death was given as 1a Bronchopneumonia.

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Syringe drivers, diamorphine, midazolam, haloperidol, levomepromazine (nozinan) and hyoscine hydrobromide

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24hours. Indications for its use include swallowing difficulties or a comatose patient. In the

United Kingdom, it is commonly used in patients with cancer in their terminal phase in order to continue to deliver analgesic medication. Other medication required for the control other symptoms, e.g. delirium, nausea and vomiting can also be added to the pump.

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

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated without being drowsy. Most practitioners caring for patients with cancer in

their terminal phase would generally aim to find a dose that improves the patients' symptoms rather than to render them unresponsive. In some patients however, symptoms will only be relieved with doses that make the patient unresponsive. A typical starting dose for an adult is 30mg a day. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (March 1995) recommends 20–100mg SC over 24hours. The Wessex protocol suggests a range with the lowest dose of 5mg a day. The regular dose would then be titrated every 24hours if the sedative effect is inadequate. This is generally in the region of a 33–50% increase in total dose, but would be guided by the severity of the patients symptoms and the need for additional 'as required' doses. These are generally equivalent to 1/6th of the regular dose, e.g. for midazolam 30mg in a syringe driver over 24hours, the 'as required' dose would be 5mg given as a stat SC injection. The duration of effect is generally no more than 4hours, and it may need to be given more frequently. As an active metabolite of midazolam is excreted by the kidneys, caution is required in patients with impaired kidney function.

Haloperidol is an antipsychotic. It is frequently used in syringe drivers for its antipsychotic and anxiolytic effects in patients with terminal delirium/agitation or as an anti-emetic. Compared to other antipsychotics, like levomepromazine, it is less sedative but can cause more problems with extrapyramidal effects and should be used with caution in patients with parkinsonism or Parkinson's disease. Extrapyramidal effects include parkinsonism, acute dystonia, acute akathesia and tardive dyskinesia. Parkinsonism consists of tremor, rigidity and slowing of movements; acute dystonia is spasm of muscles including those involving the eyes, head,

neck, trunk and limbs. They are usually abrupt in onset and associated with anxiety; acute akathesia is a form of restlessness of the muscles in which the person is compelled to move or change position and is associated with variable degrees of patient distress; tardive dyskinesia typically presents as involuntary chewing movements of the face and orofacial muscles.

A typical starting dose of haloperidol for an adult is 3–5mg a day with an upper dose range of 10–30mg orally or SC. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (March 1995) recommends 5–30mg SC over 24hours. The Wessex protocol suggests a range of 1.5–3mg up to three times a day orally. It is usual to prescribe additional doses for use 'as required' often in the dose range of 2.5–5mg SC. The dose is often prescribed so that it can be given hourly if required.

Levomepromazine is an antipsychotic. It is frequently used in syringe drivers for its antipsychotic and anxiolytic effects in patients with terminal delirium/agitation or as an anti-emetic. It is more sedative than haloperidol.

A typical starting dose of levomepromazine for an adult is 50mg SC over 24 hours, with an upper dose range of 300mg SC. A smaller dose, particularly in the elderly, can suffice or sedate without drowsiness. The BNF (March 1995) recommends 50–200mg SC over 24hours. The Wessex protocol suggests a range of 25–200mg SC over 24hours. It is usual to prescribe additional doses for use 'as required' often in the dose range of 6.25–25mg SC. The dose is often prescribed so that it can be given hourly if required.

Hyoscine hydrobromide is an antimuscarinic drug most commonly given to reduce excessive saliva or retained secretions ('death rattle'). It also has

anti-emetic, antispasmodic (smooth muscle colic) and sedative properties. Repeated administration can lead to cummulation and this can occasionally result paradoxically in an agitated delirium, highlighted in both in the BNF and the Wessex protocol (page 41). It is usually given in a dose of 600–2400micrograms SC over 24hours (BNF (March 1995)) or 400–600micrograms as a stat SC dose. The Wessex protocol gives a dose range of 400–1200micrograms over 24hours.

The titration of the dose of analgesic, antipsychotic or sedative medication is guided by the patients symptom control needs. The number and total dose of 'as required' doses required over a 24hour period are calculated and this guides the increase necessary in the regular dose of the drugs in the syringe driver in a way that is proportional to the patients needs. The ideal outcome is the relief of the symptoms all of the time with no need for additional 'as required' doses. In practice, this can be difficult to achieve and the relief of the symptoms for the majority of the time along with the use of 1–2 'as required' doses over a 24hour period is generally seen as acceptable.

ii) The principle of double effect.

The principle of double effect states that:

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

This is a universal principle without which the practice of medicine would be impossible, given that every kind of treatment has an inherent risk. Many discussions on the principle of double effect have however, involved the use of morphine in the terminally ill. This gives a false impression that

the use of morphine in this circumstance is a high risk strategy. When correctly used (i.e. in a dose appropriate to a patient's need) morphine does not appear to shorten life or hasten the dying process in patients with cancer. Although a greater risk is acceptable in more extreme circumstances, it is obvious that effective measures which carry less risk to life will normally be used. Thus, in an extreme situation, although it may occasionally be necessary (and acceptable) to render a patient unconscious, it remains unacceptable (and unnecessary) to cause death deliberately. As a universal principle, it is also obvious that the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

8. OPINION

Events at Gosport War Memorial Hospital, Mulberry Ward 13th December 1995 to 5th January 1996

Code A was an 82 year old man who suffered from chronic depression. Deterioration in his mental and physical state led to his admission for assessment on Mulberry Ward under the care of Dr Banks. Examination revealed him to be depressed and withdrawn and a little agitated and irritable. He had signs of Parkinsonism which may have been due to undesirable effects of his medication. Despite a reduction in his medication his situation failed to improve. He developed a chest infection that required two different sorts of antibiotic to treat. Despite this, his physical deterioration and poor mental state continued. Rather than attribute his deterioration purely to depression, Code A was appropriately referred to a geriatrician, Dr Lord. It was documented that

his mobility had deteriorated drastically during his admission and that he had become bedbound, was complaining of intermittent abdominal pain and expressing the wish to die. His diazepam was reduced and thioridazine and temazepam discontinued, but still Code A failed to improve. Dr Lord's review indicated that Code A prognosis was poor and that he was unlikely to return to Hazeldene Rest Home. This implies that his transfer to Dryad Ward was for terminal care. There are no issues relating to the standard of care or treatment proferred to Code A during his admission to Mulberry Ward.

Events at Gosport War Memorial Hospital, Dryad Ward 5th January 1996 to 24th January 1996

Compared to the notes during Code A stay on Mulberry Ward, infrequent entries in the medical notes during his stay on Dryad Ward make it difficult to closely follow Code A progress over the last three weeks of his life. There are seven entries taking up just one and a half pages in length. In summary and in approximate chronological order, Code A Code A was prescribed Arthrotec, a non-steroidal anti-inflammatory drug. There was no record or assessment of pain in the medical notes, but the nursing notes recorded that he stated that he had generalised pain. He later complained of a painful right hand held in flexion for which ?*hot water* (to be clarified) was suggested. Increasing anxiety and agitation were also noted. Dr Barton queried whether he was receiving sufficient diazepam or required opiates. The possible cause of his painful right hand held in flexion is not documented in the medical notes.

The Arthrotec was discontinued after two days and he was commenced on morphine regularly. It is not clear from the notes what pain this was prescribed for, why the Arthrotec was stopped or why a 'weak' opioid like codeine was not felt appropriate. On the same day, a syringe driver was prescribed containing diamorphine 40–80mg and hyoscine (hydrobromide) 200–400microgram in 24hours to be used 'as required'. This was never given but when the drug chart was rewritten, apparently the next day, the dose range of diamorphine was increased to 80–120mg and midazolam 40–80mg added without reason.

His diazepam was increased on the 11th January 1996 and his sertraline and lithium carbonate discontinued on 12th January 1996 both without reason. On the 13th January 1996 the nursing notes record Code A to appear distressed. It is unclear if this was related to his urinary catheter bypassing or was more generalised.

On the 15th January 1996 a syringe driver was commenced containing diamorphine 80mg, hyoscine hydrobromide 400micrograms and midazolam 60mg. The indication for this is not clear. Once the syringe driver was commenced he became unresponsive and his family informed.

On the 16th January 1996 the nursing notes stated that he was agitated when being attended to. Haloperidol 5mg was prescribed and administered, although there was no entry in the medical notes. On the 17th January 1996 the dose of diamorphine was increased to 120mg, the haloperidol to 10mg (subsequently 20mg), the midazolam to 80mg and the hyoscine hydrobromide to 600microgram (subsequently 1200microgram). No reason is given in the medical notes, although the

nursing notes report Code A to be tense and agitated and have a very 'bubbly' chest.

The medical notes entry on the 18th January 1996 report symptoms were difficult to control but does not specify which symptoms. Levomepromazine was then commenced at a dose of 50mg SC over 24hours. On the 20th January 1996 an entry in the medical notes report Mr Pittock to be unsettled and the dose of levomepromazine was increased from 50 to 100mg and the haloperidol was then discontinued. Thereafter Code A appeared to be settled until his death in the early hours of the 24th January 1996. Given the nature of Code A decline and problems with respiratory tract secretions, bronchopneumonia appears to be the most likely cause of his death, as stated on the death certificate.

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

The overall care given to Code A whilst on Mulberry Ward, Gosport War Memorial Hospital was not substandard.

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

- good clinical care must include an adequate assessment of the patient's condition, based on the history and clinical signs including, where necessary, an appropriate examination

- in providing care you must keep clear, accurate, and contemporaneous patients records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed
- in providing care you must prescribe only the treatment, drugs, or appliances that serve patients' needs
- in providing care you must be willing to consult colleagues.

Specifically:

i) The notes relating to Code A transfer to Dryad Ward are inadequate. On transfer from one service to another, a patient is usually reclerked highlighting in particular the relevant history, examination findings and any planned investigations to be carried out.

ii) Pain is the most likely reason for prescribing the non-steroidal anti-inflammatory drug (Arthrotec). However, pain was not documented in the notes, nor was any pain assessed.

iii) Code A painful right hand held in flexion does not appear to have been appropriately assessed. From its description it may have been tetany causing carpopedal spasm and the common causes of this should have been considered, e.g. a low serum calcium or magnesium deficiency. Less likely is a dystonia but given that some of his medications could cause extrapyramidal effects (see technical background) this possibility should also have been considered. As hypocalcaemia is reported to cause mood disturbance such as anxiety and agitation, it would have been particularly relevant to consider.

iv) It should be clarified why Dr Barton felt Code A needed opioids. From the medical notes, it appears to relate to his increasing anxiety and agitation. This

is not an appropriate indication for the use of opioids. If opioids were being suggested for his painful hand, this would also be inappropriate. The medical notes state no other pain. The nursing notes do state he had generalised pain, but the lack of a full pain assessment makes it difficult to know what pain this represented; for example, was it related to muscle and/or joint stiffness from immobility, his pressure sores or abdomen?

v) It is not clear from the medical notes the indication for which the morphine was commenced. If it was for pain then this should have been documented and assessed. It was a reasonable starting dose for someone of his age and morphine is used in palliative care for generalised pain related to muscle or joint stiffness due to immobility or painful pressure sores.

vi) It is not clear what the indications were for prescribing the syringe driver on the 10th January 1996 and for the medications it contained. It is not usually necessary to utilise the SC route unless a patient is unwilling or unable or to take medications orally (e.g. difficulty swallowing, nausea and vomiting). From the drug chart Code A did not appear to have these problems (page 18 of 49). No instructions were given on the drug chart on when the syringe driver should be commenced, how this would be decided and by whom. The dose of diamorphine was initially written as a dose range of 40–80mg, only to be subsequently rewritten the next day as 80–120mg without explanation of why a higher dose range was necessary. Based on Code A existing opioid dose, all of the doses of diamorphine are likely to be excessive for his needs. Given his total dose of oramorph (morphine solution) of 30mg in 24hours, an appropriate dose of diamorphine using a 1:2 or the more usual 1:3 dose conversion ratio, would have been 10–15mg in 24hours. There is no justification given for

this in the medical notes. Similarly, the indications for including the hyoscine hydrobromide and midazolam should have been documented. The dose range of midazolam of 40–80mg would generally be seen as excessive for someone of Code A age. However, taking into account he was a long term user of benzodiazepines, a higher than usual starting dose would likely be necessary.

vii) The dose of diazepam was increased on the 11th January 1996 with no mention of this in the medical notes.

viii) The sertraline and lithium carbonate were discontinued on the 12th January 1996 with no mention of this in the medical notes. It was unclear if this was on the advice of the psychogeriatricians or not; my understanding is that sertraline should not be discontinued abruptly as this is associated with a withdrawal syndrome that can include anxiety, agitation and delirium. A gradual withdrawal of lithium is also advised (BNF).

ix) A syringe driver was ultimately commenced on the 15th January 1996. It is not documented why it had become necessary to give these medications via a syringe driver. Code A appeared to have been taking his oral medications and the medical entry noted that he 'will eat and drink'. There was no mention in the medical or nursing notes of pain, retained secretions, agitation or anxiety that day. If he was more drowsy and unable to take his medication it would have been reasonable, particularly if he required morphine for pain relief. However, taking into account Code A dose of morphine, the starting dose of diamorphine (80mg) was likely to be excessive for his needs as detailed above. The reasons for including the hyoscine hydrobromide (400microgram) and midazolam (60mg) over 24hours were not documented. The dose of midazolam of 60mg over 24hours is an above average starting

dose for somebody of Code A age (see technical issues). He had however, been on long term benzodiazepines and in these patients a larger than usual starting dose may be necessary.

x) On the 16th January 1996 the nursing notes reported some agitation when Code A Code A was being attended to. Haloperidol 5mg SC over 24hours was added to the syringe driver. Haloperidol is a reasonable part of the approach to treating delirium or terminal agitation in someone of Code A age. It should be given with caution, given Code A parkinsonism, as it can cause extrapyramidal effects (see technical issues). However, it is not clear from the notes that his agitation had been assessed and hence the possible underlying causes of the agitation considered. Drugs (or their withdrawal) are one of the common causes of agitation or terminal restlessness. Of particular relevance to Code A these would include the use of opioids, particularly in inappropriate and excessive doses, hyoscine hydrobromide and benzodiazepines (Wessex Protocol, pages 30, 34). It is possible that a reduction in the dose of diamorphine may have helped Mr Pittock's agitation.

xi) On the 17th January 1996 the dose of diamorphine was increased to 120mg and the midazolam to 80mg SC over 24hours with no reason given in the notes. The nursing notes suggest that Code A remained tense and agitated. There is no documentation that a medical assessment was undertaken to determine whether his being 'tense' related to muscle and joint stiffness, possible extrapyramidal effects from the haloperidol or that other causes of agitation had been considered. Again, rather than increase the diamorphine, a reduction may have been more appropriate. Similarly, the discontinuation or reduction in the dose of haloperidol, or substitution for

an antipsychotic with a lower risk of causing extrapyramidal effects, e.g. levomepromazine, may have been appropriate.

The nursing notes suggest that Code A was 'bubbly' due to retained secretions and this appears to be the reason for the hyoscine hydrobromide dose being increased twice in one day from 400 to 600microgram then to 1200microgram SC over 24hours.

xii) The medical notes entry on the 18th January 1996 suggested that Code A Code A symptoms were difficult to control but did not document which symptoms. Levomepromazine 50mg SC over 24hours was commenced. This is an appropriate drug to use for terminal agitation when haloperidol is insufficient. The dose is in keeping with that recommended by the BNF and the Wessex Protocol. However, it would have been usual to substitute it for the haloperidol rather than use it concurrently.

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

In relation to the above:

Issue i (lack of clear documentation that an adequate assessment has taken place)

A medical assessment usually consists of information obtained from the patient or others (the history) and the findings of a physical examination that is documented in a structured fashion. Although the history can be restricted to the most salient points, it is unusual to omit relevant sections, e.g. past medical history, drug history, etc.) and given Code A medical problems, in

my view, a general examination should have been undertaken and documented.

Reclerking of a patient when a different medical team takes over responsibility of care, helps to ensure that they are aware of the patient's current problems, relevant medical history and physical condition. If new problems subsequently develop, and abnormal physical findings are found on examination, it can be helpful for the doctor when considering the differential diagnosis and management to know if the findings are really new or old. A clear assessment and documentation of subsequent medical care are particularly useful for on-call doctors who may have to see a patient whom they have never met for a problem serious enough to require immediate attention.

Issue ii (lack of adequate assessment and documentation of Code A *pain and use of Arthrotec).*

There should have been an adequate assessment of the patients' condition. If Code A complained of pain, this should have been noted and attempts made to assess as a minimum the site, severity, aggravating/relieving factors and likely cause of the pain. This is undertaken in order to identify the most likely underlying cause of the pain. Different pain relieving approaches can be helpful for some pains and not others. Knowledge of the cause of the pain thus provides a rational basis to how the pain is managed. Without a documented pain assessment I am unable to comment on the appropriateness of the use of Arthrotec.

The prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issue iii (lack of adequate assessment and documentation of Code A *painful right hand)*

There should have been an adequate assessment of the patients' condition. If a patient is experiencing what sounds like tetany (painful muscle spasms), the possible causes of this should be considered and appropriate investigations carried out. As a minimum, in my view, blood levels of calcium should have been measured, as if low, simple replacement of calcium could have improved a distressing symptom. It would be a reasonable course of action to be taken by all but the junior of doctors.

Issue iv (possible inappropriate use of opioids for Code A *anxiety and agitation)*

It should be clarified for what reason Dr Barton was considering the use of opioids. Opioids are not indicated for the relief of anxiety and agitation per se. The prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issue v (lack of adequate documentation regarding the use of oral morphine/lack of adequate assessment and documentation of Code A *pain)*

There should be clear documentation in the medical notes of why and when the morphine was commenced. If it were for pain, attempts should have been made to assess as a minimum the site, severity, aggravating/relieving factors and likely cause of the pain.

Issue vi (lack of adequate documentation regarding the prescription of the syringe driver 'as required' on 10th January/ prescription of treatment that may exceed the patients' needs)

There should have been clear documentation in the medical notes as to why a syringe driver was prescribed 'as required'. It is unusual to prescribe a syringe driver 'as required' especially containing drugs with a range of possible doses. This is because of the inherent risks that would arise from a lack of clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing a drug as a range, particularly a wide range, is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. It is not usual in my experience for such decisions to be left for nurses to make alone.

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

The daily dose of diamorphine 40mg–80mg, rewritten one day later as 80–120mg is not justified at all in the notes. It is likely to be excessive for Code A **Code A** needs. An appropriate dose of diamorphine would have been 10–15mg in 24hours. Doses of opioids excessive to a patient's needs are associated with an increased risk of drowsiness, delirium, nausea and vomiting and respiratory depression.

The reasons for the inclusion of midazolam and hyoscine hydrobromide in the syringe driver should also have been documented. Decisions made and the prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issues vii and viii (lack of adequate documentation regarding the change in medication)

There should be clear documentation in the medical notes of why the diazepam was increased and the sertraline and lithium carbonate were discontinued. Decisions made and the prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issue ix (lack of adequate documentation regarding the prescription of the syringe driver on 15th January/prescription of treatment that may exceed the patients' needs)

There should be clear documentation in the medical notes of why the syringe driver was commenced containing those drugs. In particular, why a dose of diamorphine, that exceeded his current opioid requirements was justified. An appropriate dose of diamorphine would have been 10–15mg in 24hours. Doses of opioids excessive to a patient's needs are associated with an increased risk of drowsiness, delirium, nausea and vomiting and respiratory depression. Decisions made and the prescribing of drugs should be documented in the notes in keeping with the GMC guidelines.

Issue x (lack of adequate assessment and documentation of Code A *agitation)*

There should have been an adequate assessment of Code A agitation. This would have included considering, as a minimum, if any of the common causes of agitation were possibly contributing to his agitation (e.g. as listed in the Wessex protocol pages 30, 34). The assessment should have been documented in the medical notes. Such an approach should have allowed consideration if drugs (or their withdrawal) were a possible contributory factor to Code A agitation. In particular, whether the dose of opioid was appropriate and not excessive to his needs.

Issue xi (lack of adequate documentation regarding the change in dose of drugs in the syringe driver on the 17th January 1996)

There should be clear documentation in the medical notes as to why the dose of diamorphine was increased to 120mg, the midazolam to 80mg SC over 24hours and the hyoscine hydrobromide dose increased twice from 400 to 600 microgram then to 1200microgram SC over 24hours.

Issue xii (lack of adequate assessment and documentation of Code A *symptoms, willingness to consult colleagues)*

If symptoms are 'difficult to control', this should prompt an adequate (re)assessment to carefully (re)consider the possible contributing factors to ensure that all reasonable steps had been taken to attend to any underlying causes as appropriate.

If, despite the initial management plan, symptoms are 'difficult to control', it would also be seen as good practice for a doctor to seek additional

information or advice. There is no documentation in the notes that suggests that Dr Barton did this, for example, seeking additional information or advice from the Wessex protocol, one of the consultants, another colleague or a member of the palliative care team.

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

Dr Barton had a duty to provide good palliative and terminal care and an integral part of this is the relief of pain and other symptoms to ensure the comfort of the patient. In doing so, as in every form of medical care provision, she would be expected to demonstrate a good standard of practice and care. In this regard, Dr Barton fell short of a good standard of clinical care as defined by the GMC (Good Medical Practice, General Medical Council, October 1995 pages 2–3) with particular reference to a lack of clear note keeping, adequate assessment of the patient, providing treatment that was excessive to the patients' needs and willingness to consult colleagues.

Most significantly, the dose range of diamorphine prescribed for the 'as required' syringe driver, and the dose finally administered (80mg), far exceeded that generally considered to be an appropriate starting dose (10–15mg) given Code A existing opioid usage. It is unclear how Dr Barton determined or justified this dose. A dose of diamorphine excessive to Code A needs would be associated with an increased risk of drowsiness, confusion, agitation, nausea and vomiting and respiratory depression.

Code A was described as tense and agitated several times following the syringe driver being commenced. This may have been due to a number of reasons, e.g. his depression, the developing pneumonia or a terminal

agitation. In this regard the use of midazolam, haloperidol and levomepromazine could be seen as justified. However, an assessment of the possible causes of his agitation should have been carried out, particularly if seen as difficult to manage. This would have included considering if drugs, such as the diamorphine, were a possible contributing factor to his agitation. At the very least, it should have prompted a review of the appropriateness of Code A dose of diamorphine.

In patients with cancer, the use of diamorphine and other sedative medications (e.g. midazolam, haloperidol, levomepromazine) when appropriate for the patients needs, do not appear to hasten the dying process. This has not been examined in patients dying from other illnesses to my knowledge, but one would have no reason to suppose it would be any different. The key issue is whether the use and the dose of diamorphine and other sedatives are *appropriate* to the patients needs. In situations where they are inappropriate or excessive to the patients needs, it would be difficult to exclude with any certainty that they did not contribute more than minimally, negligibly or trivially to the death of the patient. Although the principle of double effect could be invoked here (see technical issues), it remains that a doctor has a duty to apply effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose of strong opioid that was *appropriate* and not excessive for a patient's needs.

There appears little doubt that Code A was 'naturally' coming to the end of his life. His death was in keeping with a progressive irreversible physical

decline, documented over several weeks by different medical teams, accompanied in his terminal phase by a pneumonia. At best, Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Code A a peaceful death, albeit with what appears to be an excessive use of diamorphine. This may have been due to an apparent lack of sufficient knowledge, illustrated, for example, by the prescription and use of doses of diamorphine by syringe driver that were inappropriately large for Code A circumstances and did not reflect his current opioid requirements; the reliance on large dose ranges of diamorphine by syringe driver rather than a fixed dose along with the provision of smaller 'as required' doses that would allow Code A Code A needs to guide the dose titration; and a lack of consideration that the opioids may have been aggravating his agitation. It is my opinion however, that given the lack of documentation to the contrary, Dr Barton could also be seen as a doctor who breached the duty of care she owed to Code A by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Code A by unnecessarily exposing him to excessive doses of diamorphine that could have resulted in a worsening of his agitation. Dr Barton's response to this was to further increase Code A dose of diamorphine. Despite the fact that Code A was dying 'naturally', it is difficult to exclude completely the possibility that a dose of diamorphine that was excessive to his needs may have contributed more than minimally, negligibly or trivially to his death. As a result Dr Barton leaves herself open to the accusation of gross negligence.

9. LITERATURE/REFERENCES

British National Formulary 29 (March 1995).

Prescribing in Terminal Care, pages 12–15.

British National Formulary 47 (March 2004).

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

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition

'Wessex Protocol' Salisbury Palliative Care Services May 1995.

10. EXPERTS' DECLARATION

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

11. STATEMENT OF TRUTH

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

Signature: Code A Date: 25th April 2005