DRAFT REPORT

regarding

ARTHUR DENNIS BRIAN CUNNINGHAM (BJC/15)

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Reader in Palliative Medicine and Medical Oncology

AT THE REQUEST OF: Hampshire Constabulary

CONTENTS

1. SUMMARY OF CONCLUSIONS

Mr Cunningham was a frail 79 year old widower who lived in a nursing home. He had suffered from Parkinson's disease for many years and had an abnormal blood count possibly due to myelodysplastic syndrome. He had longstanding back pain due to an old war injury, that required maximal doses of weak (step 2) opioids. His behaviour could be difficult and this was the reason for a recent admission under the care of Dr Banks, consultant in old age psychiatry. During this admission, his abnormal behaviour and disturbed nights were considered to be due to a combination of depression and dementia. An antidepressant (mirtazapine), a mood stabiliser (carbamazepine), an antipsychotic (risperidone) and a sedative/hypnotic (triclofos) were commenced. These resulted in an improvement in Mr Cunningham's mood and sleep, which was maintained after his return to the nursing home.

Mr Cunningham was followed up at Dolphin Day Hospital on the 14th, 17th and 21st September 1998. Over this time, his sacral pressure sore worsened despite antibiotics and his general condition appeared to deteriorate; he was difficult to wake and was refusing to talk, drink or swallow medication and expressing a wish to die. On the 21st September and was admitted direct to Dryad Ward for treatment of the sore, a high protein diet and for 'oramorph (morphine solution) p.r.n. 'as required' if pain'. Dr Lord noted that Mr Cunningham's prognosis was poor but asked that the nursing home keep the bed open for the next three weeks at least.

During this admission, the medical care provided by Dr Barton fell short of a good standard of clinical care as defined by the General Medical Council that included the lack of clear note keeping, adequate assessment of the patient

and the prescription of a large dose range of diamorphine (up to 200mg) that was likely to be excessive to Mr Cunningham's needs. The lack of access to stat SC doses of diamorphine and midazolam, made some of the increases in the doses of diamorphine and midazolam he received in the syringe driver difficult to justify, especially when the increment was larger than generally seen. Further, other strategies of managing Mr Cunningham's pain on turning that may have been more successful were not pursued. In this regard, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mr Cunningham by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mr Cunningham by unnecessarily exposing him to the risk of receiving excessive doses of diamorphine. In the event, however, Mr Cunningham did not receive such high doses.

Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mr Cunningham a peaceful death, albeit with what appears to be a lack of sufficient knowledge regarding the use of diamorphine as detailed above. In my view, Mr Cunningham was dying in an expected way, the use of diamorphine, midazolam and hyoscine were justified given that both his chronic pain and behavioural disturbances required medication, and subsequently for retained secretions in his terminal phase. The starting doses used and the doses he subsequently received of diamorphine, midazolam and hyoscine were not unusual and had been arrived at in a step wise fashion. Although in my view, alternatives existed that would have better managed his pain on turning, other practitioners may well have followed a similar course to Dr Barton.

2. INSTRUCTIONS

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

3. ISSUES

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

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

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

4. BRIEF CURRICULUM VITAE

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

Trained in general medicine, including experience in health care of the elderly (acute medicine and rehabilitation) prior to specialising in Palliative Medicine, working in Specialist Palliative Care Units in Nottingham and Oxford. Appointed to present post as Senior Lecturer in 1995. Promoted to Reader in 2001. Carries out research in pain, breathlessness and exercise capacity. Regularly lectures on national and international courses. Palliative care

prescribing advisor to the British National Formulary (2002-). Expert reviewer for Prodigy national palliative care guidelines for general practitioners. Joint author of the Palliative Care Formulary that has sold over 30,000 copies, and the 3rd edition of Symptom Management in Advanced Cancer, with Dr Robert Twycross. Previously Chair of the Mid-Trent Cancer Services Network Palliative Care Group, Nottingham Cancer Centre Palliative Care Group, inaugural Secretary for the Science Committee of the Association for Palliative Medicine of Great Britain and Ireland and member of the National Institute for Clinical Excellence Lung Cancer Guidelines Development Group.

Operates the international Palliative Medicine mailbase mailing list and co-owns and edits www.palliativedrugs.com that publishes the Palliative Care Formulary on the internet. With over 17,000 members it is the largest Palliative Care resource of its kind. Provisional Member of the Expert Witness Institute.

5. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Arthur Dennis Brian Cunningham, including the entry in the Death Register.

[2] Full set of medical records of Arthur Dennis Brian Cunningham on CD-ROM.

[3] Operation Rochester Briefing Document Criminal Investigation Summary.

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

[5] Hampshire Constabulary Summary of Care of Arthur Cunningham.

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

[7] Portsmouth Health Care NHS Trust Policies:

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

ii) Prescription Writing Policy (July 2000).

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

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

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

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

[8] General Medical Council, Good Medical Practice (July 1998).

[9] British National Formulary (BNF). Section on Prescribing in Terminal Care (March 1998).

[10] British National Formulary (BNF). Section on Prescribing in the Elderly (March 1998).

6. CHRONOLOGY/CASE ABSTRACT

Events at Mulberry Ward, 21st July 1998 until the 28th August 1998

Mr Cunningham, a 79 year old widower who lived in Thalassa Nursing Home was admitted to Mulberry Ward, Gosport War Memorial Hospital (GWMH) under the care of Dr Banks, consultant in old age psychiatry, for

assessment of his physical and mental wellbeing (page 241 of 928). This was precipitated by the staff at the nursing home finding Mr Cunningham's behaviour difficult. It was considered that these behavioural problems related to the combination of depression and dementia (pages 67, 453 of 928). Mr Cunningham also had long-term problems relating to Parkinson's disease, constipation and was known to have an abnormal full blood count (low white cells and platelets; cells that help fight infection and the blood to clot respectively)(pages 67 and 68 of 928). The latter was discussed with Dr Cranfield, consultant haematologist, who considered it probably due to myelodysplastic syndrome (see technical issues) or possibly drug-related and it was noted that 'He [Mr Cunningham] is more susceptible to infection. Medical help should be sought early rather than later' (page 68 of 928). Repeated blood counts however, were stable and satisfactory, e.g. white cells 4.0 (neutrophils 2.8) x 10^9/L and platelets 113 x 10^9/L on the 26th August 1998 (page 191 of 928).

Mr Cunningham was also known to the geriatric services and Dr Lord, who had seen him several times over previous years. This mainly related to his Parkinson's disease (initially diagnosed in 1988) impairing his mobility, and the difficulties encountered with undesirable effects as the dose of his antiparkinsonian medication was increased; these included abnormal involuntary movements (dyskinesia), confusion (with hallucinations) and postural hypotension (low blood pressure on standing)(pages 345, 349, 351, 375, 377 of 928). Mr Cunningham had also injured his lumbar spine and both ankles in an aeroplane crash in 1945, requiring lumbar spine fusion and bone grafts. This led to numbness and weakness in the left leg and he was invalided out of the RAF. Backache, thought related to this

injury, had been reported as a considerable problem but that Solpadol (codeine 30mg and paracetamol 500mg), five to eight a day (i.e. 150–240mg codeine/day) was effective (pages 139 and 375 of 928). Other previous problems included a kidney stone (1992), a transurethral resection for an enlarged prostate (1992), diabetes mellitus (1994), initially tablet and subsequently diet controlled and high blood pressure (pages 7, 50, 65, 375, 445, 305, 379 of 928).

During his stay on Mulberry Ward, Mr Cunningham was commenced on an antidepressant, mirtazapine (page 71 of 928). It was noted that he would often call out for the first couple of hours in bed (page 72 of 928). The nurses commented that it took a long time to get him comfy at night having to make adjustments to his back rest and pillows etc. (page 72, 73 and 80 of 928) and he did complain of pain in the base of his spine (page 73 of 928). On the 4th August 1998, this led to his paracetamol being switched for co-proxamol 2 tablets four times a day, a similar strength analgesic to the Solpadol he had required before (page 80 of 928).

On the 17th August 1998 he had a very disturbed night with shouting and was subsequently commenced on an anti-epileptic drug carbamazepine 100mg at night (page 87 and 161 of 928), presumably as a mood stabiliser. The following night he was described as confused with paranoid and delusional ideas (page 87 of 928) and a sedative, triclofos 20ml (2g) at night was added. It was commented that this would be for a few nights, although this was continued long-term (page 88 and 161 of 928). Due to ongoing problems, on the 19th August 1998, an 'atypical' antipsychotic risperidone 0.5mg was added at 6pm (page 88 of 928). An antipsychotic is usually indicated in confused patients with paranoid and delusional ideas.

However, they risk worsening Parkinson's disease (see technical issues) and this may be why other approaches were tried first. An 'atypical' antipsychotic like risperidone would be less likely to worsen Mr Cunningham's Parkinson's disease compared to a 'typical' antipsychotic such as haloperidol. Mr Cunningham's mood and nights subsequently improved.

On admission to Mulberry ward, the skin over Mr Cunningham's pressure areas was intact (page 248 of 928). He was, however, at high risk of pressure sore development, scoring 19–20 on a Waterlow Score (>15 indicates high risk; >20 a very high risk of pressure sore development)(page 309 of 928). On or around the 23rd August 1998, a nursing care plan was started for a broken area on his sacrum that was treated with a thin DuoDERM dressing (page 293 of 928).

Mr Cunningham also had two urinary tract infections requiring antibiotics (pages 205 and 207 of 928) and developed renal impairment due to urinary retention, necessitating urinary catheterisation, following which his kidney function improved (urea 15.6mmol/L, creatinine 144micromol/L)(pages 173 and 175 of 928).

Mr Cunningham was reviewed by Dr Lord whilst on Mulberry Ward. Initially Dr Lord considered that his Parkinson's disease was stable and that his deteriorating mobility was more likely related to a weak pelvic girdle due to his old spinal injury (pages 74 and 105 of 928). Dr Lord suggested continuing the same dose of his antiparkinsonian medication (l-dopa) and to only add an extra controlled release formulation (Sinemet CR) at night if thought necessary. This was subsequently added by Dr Bank's team the same day (page 75 of 928). On a subsequent review on the 27th August

1998, Dr Lord considered that Mr Cunningham's Parkinson's disease had indeed deteriorated (pages 91, 92, 97 of 928) and offered to follow him up at Dolphin Day Hospital. Dr Lord also noted that Mr Cunningham was eating better and had gained weight from 65.5 to 69.7kg during his admission (pages 325, 327 and 329 of 928).

Mr Cunningham was discharged from Mulberry Ward on the 28th August 1998 on the following medication: Careldopa as Sinemet-110 (carbidopa 10mg/levodopa 100mg) one tablet four times a day; careldopa as Sinemet CR (carbidopa 50mg/levodopa 200mg) one tablet at night (*antiparkinsonian medication*); co-proxamol two tablets four times a day (*analgesic*); mirtazapine 30mg at night (*antidepressant*); risperidone 0.5mg at 6pm (*'atypical' antipsychotic*); triclofos 20ml (2g) at night (*hypnotic*); carbamazepine 100mg at night (*anti-epileptic; mood stabiliser*); amlodipine 5mg once a day (*for high blood pressure*); co-danthramer two capsules at night; magnesium hydroxide 10mg twice a day; senna two tablets at night (*laxatives*) (pages 162, 453 of 928).

Mr Cunningham's improved mood and nights appear to have been maintained on his return to Thalassa Nursing home; on the 11th September 1998, a community psychiatric nurse noted 'settled well back at the Nursing Home....no management or behavioural problems... Compliant, mood seems good' (pages 93 and 99 of 928).

Events at Dolphin Day Hospital, 14th September 1998 until 21st September 1998.

Mr Cunningham was reviewed by a doctor at Dolphin Day Hospital on the 14th September 1998. Due to increasing stiffness from his Parkinson's

disease, the careldopa (Sinemet-110) was increased to five times a day. Other plans were to liaise with the nursing home about his bowel habit, with a view to rationalising his laxative therapy, and his behaviour/sleep with a view to stopping his benzodiazepine p.r.n. ('as required'). It is unclear if Mr Cunningham was still taking a benzodiazepine p.r.n. He was not given a supply of diazepam on discharge from Mulberry Ward (pages 162, 163 of 928). The Dolphin Day Hospital nursing records note that Mr Cunningham reported that he was happy at Thalassa, that the nursing home staff said his bowels were satisfactory and that he slept well. The nursing staff at Dolphin Day Hospital were aware of his sacral sore and took a photograph (page 639 of 928); they clarified that he had a pressure relieving Spenco mattress and wheelchair cushion at the nursing home. The nursing home staff were asked to redress the sore later that week and it would be checked again at Mr Cunningham's next day hospital attendance (page 907 and 908 of 928).

Mr Cunningham next attended Dolphin Day Hospital on the 17th September 1998. It was noted that his sacral pressure sore appeared infected and he was commenced on an antibiotic, metronidazole 200mg three times a day (page 317, 459 of 928). The nursing notes entry for this visit report that the occupational therapist (OT) was to order a wheelchair and a Roho cushion. They noted that the pressure sore was exuding++ but not redressed due to reduced compliance from Mr Cunningham, although no specific details are given. It was noted that he would not wake after a rest on bed and was refusing to talk, drink or swallow medication but expressed a wish to die. It was noted he was seen by Dr Lord, and that the

plan was to possibly admit him when next reviewed (pages 908, 909 of 928).

On the 21st September 1998, Mr Cunningham was reviewed at Dolphin Day Hospital by Dr Lord who noted that he was very frail. Tablets were found in his mouth some hours after they had been given. There was an offensive smelling large necrotic sacral ulcer with a thick black scar and grazes over his buttocks (photographed, page 64 of 928). In addition there was a small black scar and redness over the left lateral malleolus (ankle). Dr Lord listed Mr Cunningham's problems as 'sacral sore (she specified 'in nursing home' possibly meaning that this is where it developed. My understanding is that it started during his admission to Mulberry ward, but considerably worsened at the nursing home), Parkinson's disease (she considered this no worse), old back injury, depression and element of dementia, diabetes mellitus – diet (controlled) and catheter for urinary retention' (page 642 of 928). Dr Lord admitted Mr Cunningham direct to Dryad Ward that day, stopped the amlodipine (his blood pressure was normal/low for someone his age), the co-danthramer laxative (this can irritate the skin around the perineum/sacrum), the metronidazole and asked for Mr Cunningham be nursed on his side and to apply Aserbine to the sacral ulcer; this is a desloughing agent, that helps to ablate local infection. She also noted that Mr Cunningham should receive a high protein diet and 'oramorph (morphine solution) p.r.n. 'as required' if pain' (page 643 of 928). Dr Lord asked that the nursing home keep the bed open for the next three weeks at least and noted that Mr Cunningham was agreeable with the admission. Dr Lord also noted that Mr Cunningham's prognosis was poor (page 457, 642, 643, 909 of 928).

Events at Dryad Ward, Gosport War Memorial Hospital, 21st September 1998 until 26th September 1998.

21st September 1998

An entry in the medical notes reads 'Transfer to Dryad Ward. Make comfortable. Give adequate analgesia. I am happy for nursing staff to confirm death' (page 645 of 928). The drug chart used in the day hospital was continued as an inpatient. This revealed that Mr Cunningham had prescriptions for regular co-proxamol, mirtazapine, risperidone, Sinemet-110, Sinemet CR, senna, carbamazepine, magnesium hydroxide and triclofos. Prescriptions for his amlodipine, co-danthramer and metronidazole had been crossed out (pages 753, 755 of 928). On the p.r.n. 'as required' section Oramorph 2.5–10mg up to every four hours and Actrapid insulin 5–10 units according to a sliding scale were prescribed (page 752 of 928). On another section, the where the word 'regular' prescription has been crossed out and replaced with p.r.n. and circled, Mr Cunningham was also prescribed diamorphine 20–200mg, hysocine (hydrobromide) 200–800microgram and midazolam 20–80mg all subcutaneously (SC) over 24h (page 756 of 928). Finally, he was prescribed metrotop, a topical antibiotic gel (page 756 of 928). Mr Cunningham received 5mg oramorph at 14.50pm and 10mg at 20.15pm (page 753 of 928). A syringe driver containing diamorphine 20mg and midazolam 20mg was commenced at 23.10pm (page 756 of 928).

At 18.00h Mr Cunningham took co-proxamol (but none thereafter), Sinemet-110 and magnesium hydroxide. Following his admission, it does

not appear as though Mr Cunningham received any mirtazapine, risperidone, Sinemet CR, carbamazepine or triclofos (753 and 755 of 928). The 'Exception to prescribed orders' section of the drug chart gives 'sedated' as the reason that Mr Cunningham did not receive his co-proxamol, Sinemet CR and senna at 22.00h (page 754 of 928).

The nursing summary notes read 'Admitted from DDH with history of Parkinson's, dementia and diabetes diet controlled diabetic. Catheterised on previous admission for retention of urine. Large necrotic sore on sacrum. Seen by Dr Barton. Dropped left foot. Back pain from old spinal injury. 14.50h Oramorph 5mg given prior to wound dressing. A later entry notes 'Remained agitated until approximately 20.30h. Syringe driver commenced as requested. Diamorphine 20mg, midazolam 20mg at 23.00h. Peaceful following (page 867 of 928).

The nursing care plan entry relating to the ulcers notes 'Dressing applied to buttock at 18.30h. Aserbine cream to black necrotic area and zinc and caster oil to surrounding skin: very agitated at 17.30pm, Oramorph 10mg/5ml at 20.20pm. Pulled off dressing to sacrum (page 880 of 928).

Nursing care plan entry relating to settling for the night notes 'Driver commenced at 23.10pm containing diamorphine 20mg and midazolam 20mg. Slept soundly following. BS (blood sugar) at 23.20pm 3.4mmol/L. 2 glasses of milk taken when awake. Much calmer this am. Sacral sore oozing but left exposed as requested' (page 876 of 928).

22nd September 1998

The drug chart reveals that Mr Cunningham took doses of Sinemet-110 at 06.00, 09.00, 12.00 and 18.00h, magnesium hydroxide at 09.00h and

senna at 22.00h (page 753 and 755 of 928). The 'Exception to prescribed orders' section of the drug chart gives 'not in stock' as the reason that Mr Cunningham did not receive his Sinemet CR and carbamazepine and 'on syringe driver' as the reason he did not receive the triclofos at 22.00h (page 754 of 928).

The nursing summary notes read 'Mr Farthing has telephoned. Explained that a syringe driver containing diamorphine and midazolam was commenced yesterday evening for pain relief and to allay his anxiety following an episode when Arthur tried to wipe sputum on a nurse saying he had HIV and was going to give to her. He also tried to remove his catheter and emptied the bag and removed his sacral dressing throwing it across the room. Finally, took off his covers and exposed himself (page 867 of 928). Syringe driver changed to 20.20h contains diamorphine 20mg and midazolam 20mg, appears less agitated this evening (page 868 of 928).

Nursing care plan relating to the ulcer notes '23.00h. Dressing came off. Reapplied as above' (page 880 of 928). Further entries on the 24th, 25th and 26th of September all report renewal of the dressing with no comments that it was of any discomfort or distress to Mr Cunningham (page 880 of 928).

Nursing care plan entry relating to settling for the night notes 'Driver running as per chart. Very settled night. Blood sugar 5mmol/L at 06.00h (page 876 of 928).

23rd September 1998

The drug chart reveals that Mr Cunningham took Sinemet-110 at 06.00h (page 753 of 928). The 'Exception to prescribed orders' section of the drug chart gives 'unable to take' as the reason that Mr Cunningham did not subsequently receive his co-proxamol, risperidone, Sinemet-110, carbamazepine and triclofos (page 754 of 928). A syringe driver containing diamorphine 20mg, hyoscine 400micrograms and midazolam 20mg SC over 24h was commenced at 09.25h. This was discarded at 20.00h to be replaced by one containing diamorphine 20mg, hyoscine 400microgram and midazolam 60mg (page 756 of 928).

The nursing summary notes read 'Seen by Dr Barton. Has become chesty overnight to have hyoscine added to driver. Stepson contacted and informed of deterioration. Mr Farthing asked if this was due to the commencement of syringe driver and informed that Mr Cunningham was on a small dosage which he needed. To phone him if any further deterioration' (page 868 of 928) An entry timed 13.00h reads 'Mr and Mrs Farthing seen by me - Sister Jean Hamblin and Staff Nurse Freda Shaw. Very angry that driver had been commenced. It was explained yet again that the contents of his syringe driver were to control his pain. It was also explained that the consultant would need to give her permission to discontinue the driver and we would need an alternative method of giving pain relief. Has also been seen by Pastor Mary for 1½h this afternoon. He is now fully aware that Brian is dying and needs to made comfortable. Driver renewed at 20.20h with diamorphine 20mg, midazolam 60mg and hyoscine 400microgram. Family have visited. (page 868 of 928).

Nursing care plan entry relating to settling for the night notes 'Became a little agitated at 23.00h, syringe driver boosted with effect. Seems in some

discomfort when moved, driver boosted prior to position change. On back at time of report. Sounds chesty this morning. Catheter draining urine very concentrated (page 876 of 928).

24th September 1998

Entry in the medical notes reads 'Remains unwell. Son has visited again today and is aware of how unwell he is. SC analgesia is controlling pain just. I am happy for nursing staff to confirm death.' This note is written out of sync, most likely in error, on the page preceding the first inpatient entry (pages 643, 645 of 928).

At 10.55h a syringe driver containing diamorphine 40mg, hyoscine 800microgram and midazolam 80mg was commenced (page 756 of 928).

The nursing summary notes read 'Report from night staff that Brian was in pain when being attended to. Also in pain with day staff especially his knees. Syringe driver renewed at 10.55 with diamorphine 40mg, midazolam 80mg and hyoscine 800micrograms. Dressing renewed this afternoon – see care plan. Son – Mr Farthing seen by Dr Barton this afternoon and is fully aware of Brian's condition. In the event of death, Brian is for cremation' (page 869 of 928). A later entry timed 21.00h notes 'Mr Cunningham's grandson telephoned, informed of grandfathers condition. Nursed on alternate sides during night, is aware of being moved. Sounds "chesty" this morning. Catheter draining (page 869 of 928).

Nursing care plan entry relating to settling for the night notes 'All care given, nursed from side to side. Peaceful nights sleep. Syringe driver running as prescribed. On back at time of report. Starting to sound chesty this morning (page 876 of 928).

25th September 1998

An entry in the medical notes reads 'Remains very poorly. On syringe driver. For TLC (tender loving care)' (page 645 of 928).

A new drug chart was written with prescriptions for diamorphine 40–200mg, hyoscine 800microgram–2g and midazolam 20–200mg all SC over 24h (page 837 of 928). Mr Cunningham received a syringe driver containing diamorphine 60mg, hyoscine 1200micrograms and midazolam 80mg (page 837 of 928).

The nursing summary notes read 'All care given this a.m. Driver recharged at 10.15h, diamorphine 60mg, midazolam 80mg and hyoscine 1200microgram.....Son present at time of report, carer also visited' (page 869 of 928).

Nursing care plan entry relating to settling for the night notes 'peaceful night, position changed still does not like being moved' (page 876 of 928).

26th September 1998

An entry was made in the medical notes by nurses Turnbull and Tubbritt to confirm Mr Cunningham's death at 23.15h (page page 645 of 928).

A syringe driver containing diamorphine 80mg, hyoscine 1200microgram and midazolam 100mg was commenced at 11.50h (page 837 of 928).

The nursing summary notes read 'Condition appears to be deteriorating slowly. All care given. Sacral sore redressed, mouth care given. Driver recharged and 11.50h, diamorphine 80mg, hyoscine 1200micrograms, midazolam 100mg. No phone calls from family this a.m. Mrs Sellwood phoned to enquire on condition (page 869 of 928). A later entry timed

'night' reads 'Brian's condition continued to deteriorate' and noted that he died at 23.15h (page 869 and 872 of 928).

Nursing care plan entry relating to settling for the night notes 'Condition continued to deteriorate. Relatives informed. Arthur died peacefully at 23.15h' (page 876 of 928).

28th September 1998

An entry in the medical notes by Dr Brook reads 'Death certificate (D/W (discussed with) Dr Lord). I. Bronchopneumonia, II. Parkinson's disease, sacral ulcer (page 645 of 928). I note that the copy of the entry in what I have assumed to be the death register, records cause of death as Ia. Bronchopneumonia only (supplied by Hampshire Constabulary).

7. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

i) Myelodysplastic syndrome

This is a disorder of the stem cells in the bone marrow that reduces the effective production of various types of blood cells. It is characterised by a progressive fall in one or more of the red, white or platelet cell counts causing, for example, anaemia, reduced immunity to infections or an increased risk of bleeding; 30–40% of patients die of infection ± bleeding. In 20–40% of patients it transforms into a leukaemia.

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

A syringe driver is a small portable battery-driven pump used to deliver medication subcutaneously (SC) via a syringe, over 24h. Indications for its

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

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

Midazolam is a benzodiazepine, a diazepam like drug. It is commonly used in syringe drivers as a sedative in patients with terminal agitation. Sedation can be defined as the production of a restful state of mind. Drugs that sedate will have a calming effect, relieving anxiety and tension. Although drowsiness is a common effect of sedative drugs, a patient can be sedated

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

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

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

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

Hyoscine hydrobromide is an antimuscarinic drug most commonly given to reduce excessive saliva or retained secretions ('death rattle'). It also has anti-emetic, antispasmodic (smooth muscle colic) and sedative properties. Repeated administration can lead to cummulation and this can occasionally result paradoxically in an agitated delirium, highlighted in both in the BNF and the Wessex protocol (page 41). It is usually given in a dose of 600–2400microgram SC over 24h (BNF (March 1995)) or 400–600microgram as a stat SC dose. The Wessex protocol gives a dose range of 400–1200microgram over 24h.

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

use of 1–2 'as required' doses over a 24h period is generally seen as acceptable.

iii) Boosting syringe drivers

Given that it was in widespread use, I am assuming that Dryad Ward had access to the Graseby MS26 syringe driver that has a boost button, but this should be clarified. The use of the boost button is generally not recommended as, for example:

1) The dose delivered by the boost is generally insufficient

Generally, the contents of a syringe being delivered by a Graseby MS26 syringe driver would be made up to a certain length, e.g. 50mm to be infused over 24h, i.e. just over 2mm/h. One actuation of the boost button moves the plunger on the syringe driver 0.23mm. In relation to the recommended rescue dose for breakthrough pain, this is likely to be inadequate. For example, a reasonable breakthrough dose is generally 1/6th of the 24h dose and this would equate to about 8mm. Nevertheless, boosting also presents a problem on how the amount and frequency of the boosting is prescribed and how it is recorded by the nursing staff.

2) There is no lockout period

Although each booster dose is small, there is nothing to stop the boost button being repeatedly depressed and released. Hence, the potential exists for the contents of the syringe driver to be administered much more quickly than the intended 24h.

3) The overall duration of the infusion is reduced

This may cause problems in some settings, e.g. the community.

4) There are usually several drugs in the syringe driver

It may only be indicated to boost the dose of one of the drugs in the syringe driver, but all of the contents are unavoidably boosted.

Hence, rather than boosting a syringe driver, usual practice is to ensure that patients have access to stat p.r.n. medication, that they may require to control their symptoms, in appropriate doses to be given subcutaneously, e.g. an analgesic, sedative and antipsychotic.

iv) The principle of double effect

The principle of double effect states that:

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

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

double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care.

8. OPINION

Events at Mulberry Ward 21st July 1998 until 28th August 1998

Mr Cunningham was a 79 year old man who suffered from depression and dementia. He also had Parkinson's disease and probable myelodysplasia, which left him more susceptible to infection. He had chronic back pain caused by an injury to his lumbar spine. This meant that it could take a long time to get him comfortable at night, requiring several adjustments to his backrest and pillows. The pain was helped by regular co-proxamol and previously codeine, about 240mg/day, but not by paracetamol alone.

Mr Cunningham was considered to be depressed and was commenced on an antidepressant. His behaviour was erratic and he had a number of disturbed nights. He was subsequently commenced on carbamazepine and triclofos without apparent success. Carbamazepine is an anti-epileptic drug. I am not familiar with its use for a disturbed night per se in the depressed and demented elderly, but I am aware that it can be given as a mood stabilising drug, usually in the setting of a manic-depressive disorder. Triclofos is a chloral hydrate derivative. I am not familiar with the use of triclofos as a hypnotic in the confused, depressed and demented elderly. The addition of the atypical antipsychotic risperidone did however, appear to coincide with an improvement with Mr Cunningham's nights and subsequently during the admission his mood improved. He was at high risk of developing a pressure sore and the skin over his sacrum broke

down during the admission. He developed two urinary tract infections and required catheterisation for urinary retention. By the time of his discharge he was eating better and had gained weight. His mood, behaviour and nights had improved and this was maintained on his return to Thalassa Nursing Home. There are no issues relating to the standard of care or treatment proferred to Mr Cunningham during his admission to Mulberry Ward.

Events at Dolphin Day Hospital, Gosport War Memorial Hospital, 14th September 1998 until 21st September 1998

Mr Cunningham appeared happy at Thalassa and the staff reported that his behaviour was manageable and he slept well. The sacral pressure sore had progressed despite pressure relieving aids at the nursing home. The day hospital staff appropriately examined, photographed, swabbed and redressed the sacral area and arranged follow up. Over the subsequent two visits the sacral pressure sore worsened despite an antibiotic. On the 17th September 1998, Mr Cunningham's physical and mental state appeared to be deteriorating; he was difficult to wake after resting on a bed, refused to talk, drink or swallow medication and expressed a wish to die. When Dr Lord saw Mr Cunningham on the 21st September 1998, tablets were found in his mouth some hours after they had been given. Dr Lord noted that Mr Cunningham was very frail and that his prognosis was poor. Prognostication can be difficult, but increasing immobility and difficulty with swallowing/taking oral medication are recognised poor prognostic factors. However, it does not appear as though Dr Lord necessarily anticipated that Mr Cunningham was imminently dying

as she admitted him for more intensive therapy to his ulcer, as opposed to terminal care; she recommended a high protein diet, indicating that he might live long enough to benefit from this, and asked the nursing home to keep his bed open for the next three weeks at least. Dr Lord also asked that Mr Cunningham receive Oramorph p.r.n. for pain, underlining p.r.n. It should be clarified if this represents an intentional emphasis, and if so, the significance of this. There are no issues relating to the standard of care or treatment proferred to Mr Cunningham during his attendance at Dolphin Day Hospital.

Events at Dryad Ward Gosport War Memorial Hospital 21st September until 26th September 1998

Compared to the notes during Mr Cunningham's stay on Mulberry Ward and attendance at the Dolphin Day Hospital, infrequent entries in the medical notes during his stay on Dryad Ward make it difficult to closely follow Mr Cunningham's progress over the last six days of his life. There are three short entries prior to the confirmation of death, taking up half a page in length. In summary and in approximate chronological order, there is no formal clerking on Mr Cunningham's admission to Dryad ward. Instead, there is a short entry that gives the impression that Mr Cunningham was for terminal care which is at some variance to Dr Lord's assessment. The Oramorph was prescribed p.r.n. as requested by Dr Lord. In addition, diamorphine 20–200mg, hysocine (hydrobromide) 200–800microgram and midazolam 20–80mg subcutaneously (SC) over 24h were prescribed p.r.n. On the 21st September, Mr Cunningham received Oramorph 5mg at 14.50h prior to a wound dressing, which is a reasonable

approach to try and minimise discomfort and an appropriate dose given his existing analgesic use. He was then reported to be very agitated at 17.30h. Nevertheless, he took his regular co-proxamol at 18.00h and a wound dressing applied at 18.30h. At 20.20h he was given Oramorph 10mg. The reason for this is unclear and it should be clarified if the Oramorph was given for pain or anxiety. Oramorph is not indicated for anxiety per se, particularly in the confused elderly, and risks aggravating the confusion. It should be clarified why a 10mg dose was considered necessary rather than repeating the 5mg dose. Given that he was 'sedated' at 22.00h, it is possible that the 10mg dose was excessive for Mr Cunningham.

An entry in the nursing notes on the 22nd September, in response to enquiry by the family, retrospectively reports that the syringe driver was commenced on the 21st September for pain relief and anxiety following an episode the evening before (time not specified) when Mr Cunningham exhibited abnormal and possibly delusional behaviour. Given that Mr Cunningham was prone to such behaviour, it would have been particularly appropriate in my view to ensure that he continued to receive his usual carbamazepine, risperidone, mirtazapine and triclofos as recommended by the old age psychiatry team. It should be clarified why this was not done on the day of his admission. He may have been having difficulty with taking/co-operating with taking oral medication, although he managed some of his medication that day. It should also be clarified who decided to commence the syringe driver containing diamorphine 20mg and midazolam 20mg at 23.10h. Diamorphine is not indicated for anxiety per se, particularly in the confused elderly, and risks aggravating the

confusion. If it was for pain, 20mg is in keeping with the starting dose range (10–20mg/24h) that many would use for a patient with inadequately relieved pain despite the maximal use of co-proxamol/codeine. A number of practitioners probably would use midazolam in this setting, although as it impairs memory, it can sometimes aggravate rather than improve confusion and the use of an antipsychotic is preferable in my view. His Parkinson's would limit the use of the most commonly used antipsychotic, haloperidol, although a small dose of levomepromazine could have been a reasonable alternative in my view (see technical issues). A midazolam dose of 20mg is in keeping with the usual starting dose range (5–30mg/24h).

Nevertheless, most practitioners in my experience, would initially prescribe small stat PO/SC doses of an analgesic, sedative anxiolytic and antipsychotic to be used p.r.n. (e.g. diamorphine 2.5mg, midazolam 2.5mg, levomepromazine 6.25mg respectively would be reasonable given Mr Cunningham's age and frailty). Firstly, this is because the needs of patients vary greatly and makes judging their requirements difficult; sometimes multiple increasing doses are needed; sometimes, a small one-off dose is adequate as the 'crisis' is temporary. For example, whilst there are a number of possible causes for Mr Cunningham's agitation, one may have been that he was a patient with dementia reacting to the initial move to unfamiliar surroundings and unfamiliar staff. In these circumstances, non-drug approaches, maintaining his usual medication and, if necessary, intermittent sedation could be seen as more appropriate initial responses rather than commencing a syringe driver straight away. Hence, the patients' p.r.n. requirements guide the need for regular analgesia/sedation

and the appropriate dose. Secondly, the continuing use of additional p.r.n. doses informs the need to increase the regular analgesia/sedation and guides an appropriate dose increment. It should be clarified why this approach was not considered appropriate for Mr Cunningham.

Mr Cunningham's behaviour did appear to settle on the syringe driver and on the 22nd September there were no reports of pain during the night or when his dressing was reapplied to the sacral ulcer. It is unclear how sedated he was, but he was able to take his Sinemet-110 orally regularly on the 22nd September, but again, no carbamazepine, risperidone, mirtazapine or triclofos were given.

From the 23rd September Mr Cunningham's condition deteriorated; he was unable to take his oral medication and had become chesty. This was most likely the start of a bronchopneumonia. Given his overall condition, biological prospects and his expression of the wish to die, it was reasonable in my view not to pursue aggressive therapy. Hyoscine hydrobromide 400microgram was added to the syringe driver to try and reduce secretions. This was appropriate and the dose within the usual starting dose range (400–600microgram/24h). However, it should be borne in mind that hyoscine can worsen an agitated delirium (see technical issues). Mr Cunningham's son appeared angry that the syringe driver had been commenced and the reasons for this should be further explored. It was explained to him that the consultant would need to give her permission to discontinue the driver. He saw the pastor and subsequently appeared accepting of the situation. It should be clarified if Dr Barton or Dr Lord were made aware of this consultation and Dr Lord specifically asked to comment. As Mr Cunningham was no longer able to take his usual

analgesic and sedative medication, a syringe driver would be clearly indicated at this point. The syringe driver was renewed at 20.00h with an increased dose of midazolam (increased from 20mg to 60mg). It should be clarified who decided to increase the dose and why. There were no comments relating to agitation in the notes prior to its renewal and it is unclear why 60mg was chosen as opposed to an increase to 30mg or 40mg for example. Later, at 23.00h the nursing notes document that the syringe driver was boosted when Mr Cunningham became agitated and also prior to changing his position. It should be clarified what usual practice, guidelines or policy existed on Dryad Ward with regard to boosting syringe drivers. This practice is not generally recommended (see technical issues).

The medical notes entry on the 24th September reports that the analgesia was 'just' controlling Mr Cunningham's pain. It is not clear from the medical notes exactly what pain this relates to, although the night staff had reported he appeared to be in some discomfort on turning and the day staff reported that he was in pain when attended to, especially his knees. No additional details are given that would help in considering appropriate management, e.g. was it short-lived or prolonged etc. Mr Cunningham had Parkinson's disease and was immobile and highly likely to experience muscle and joint stiffness that could lead to pain on turning/moving his knees. Pain on turning, often settles quickly once in the new position. If not, it is usually managed by keeping the number of turns to a minimum, and by giving supplementary stat SC doses of diamorphine ± midazolam prior to turning. Increasing the regular opioid is not always satisfactory, as the dose of opioid required to eliminate all pain on movement can be excessive for the

patient whom for the majority of the time is resting and pain free. A dose of opioid that is excessive to a patients' need is associated with undesirable effects such as nausea, vomiting, sedation, confusion and respiratory depression. Mr Cunningham's diamorphine was increased from 20mg to 40mg. At 100%, this is a greater increment than usual (33-50% of the preceding dose) and it should be clarified why this was felt necessary. Increments of this magnitude may be appropriate, but are usually indicated/justified by the amount of additional p.r.n. doses of diamorphine a patient may be requiring. Mr Cunningham's midazolam was increased from 60mg to 80mg and the hyoscine from 400microgram to 800microgram. Similar to the reasons stated above, providing supplementary stat doses of midazolam prior to turning is often more effective than increasing the regular sedative.

On the 25th September 1998 the dose of the diamorphine in the syringe driver was increased to from 40mg to 60mg (i.e. a 50% increase) and the hyoscine from 800microgram to 1200microgram. There is no entry in the medical notes explaining this but the nursing notes suggest it was for pain on turning. Again, in my experience, when a patient is in pain on turning but at all other times pain free, settled and relaxed, it is more effective and more appropriate to provide additional analgesia and/or sedative prior to turning rather than increase the overall dose.

On the 25th the diamorphine was further increased from 60mg to 80mg (a 25% increment) and the midazolam from 80mg to 100mg. There is no reason documented for this increase and this should be clarified. Mr Cunningham died at 23.15h. Mr Cunningham's death was not unexpected, he was frail, immobile and susceptible to infection. Bronchopneumonia is

the most likely cause of death. I am uncertain why Parkinson's disease and sacral ulcer that appear to have been put on the death certificate were not on the copy of the entry of what I assume to be the death register and this should be clarified.

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

The overall care given to Mr Cunningham whilst on Mulberry Ward or attending Dolphin Day Hospital, Gosport War Memorial Hospital was not substandard.

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

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

Specifically:

i) The notes relating to Mr Cunningham's transfer to Dryad Ward are inadequate. On admission, even when a patient is already known to the service, they are usually clerked highlighting in particular the relevant history, examination findings, planned investigations and care plan.

ii) It is unclear why the syringe driver was prescribed p.r.n. on the 21st September 1998. No instructions were given on the drug chart on when the syringe driver should be commenced, what drugs it should contain, in what dose, how this would be decided and by whom. The dose of diamorphine was initially written as a wide dose range of 20–200mg with no justification given for this in the medical notes. Based on Mr Cunningham's existing opioid dose, whilst a starting dose of 20mg was reasonable, the higher doses are likely to be excessive for his needs. In patients with cancer, it is unusual if opioid requirements have to be increased by more than 3-fold in the terminal phase (check Lancet paper – may need to adjust), i.e. in Mr Cunningham's case, an increase from 20mg to 60mg would not be that unexpected. The need for a 10-fold increase however, i.e. 20mg to 200mg, is rarely necessary and likely to be excessive for his needs. Similarly, the indications for the prescription of the hyoscine hydrobromide and midazolam should have been documented in the medical notes.

iii) It is unclear why Mr Cunningham received the 10mg dose of morphine.

iv) It is unclear why the syringe driver was commenced on the 21st September 1998. The nursing notes retrospectively suggest that the syringe driver was commenced to allay Mr Cunningham's anxiety and pain. It is not clear who decided to start it, the drugs and the doses to use. It should be clarified why, if he was able to take oral medication, his usual medication had not

been offered to him, or if he was unable to take oral medication, why stat SC doses of a sedative or analgesic were not considered appropriate.

v) Justification for continued increase in diamorphine, midazolam and hyoscine. Mr Cunningham's diamorphine was increased four-fold and his midazolam five-fold over a six day period. This appeared from the nursing notes to be due to Mr Cunningham being 'aware of being moved/does not like being moved'. The reason for the final increase is not clear. Mr Cunningham appeared comfortable in between times 'peaceful nights sleep/'peaceful night'. In this setting increasing the regular analgesic/sedative is not always effective in my experience and other strategies could have been considered, e.g. minimising turning, stat SC doses of diamorphine and/or midazolam prior to turning. Dr Barton could have sought advice, particularly when several dose increments had not been effective in preventing Mr Cunningham's apparent distress on turning. Other practitioners may well have followed a similar course of action however.

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

In relation to the above:

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

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

etc. For example, a read through Mr Cunningham's notes from his time on Mulberry ward, would help a doctor to appreciate the importance of ensuring the continuation of his mirtazapine, carbamazepine, triclofos and risperidone medication. Or, in circumstances where this may not be possible, providing the use of oral or, if unable to use the oral route, subcutaneous stat doses of a sedative and/or antipsychotic to be used as required.

Clerking of a patient also provides a baseline for future comparison. If new problems subsequently develop, and abnormal physical findings are found on examination, it can be helpful for the doctor when considering the differential diagnosis and management to know if the findings are really new or old. A clear assessment and documentation of subsequent medical care are particularly useful for on-call doctors who may have to see a patient, whom they have never met, for a problem serious enough to require immediate attention.

Issue ii (lack of clear, accurate, and contemporaneous patients records which report drugs prescribed; prescribing only the treatment, drugs, or appliances that serve patients' needs)

There should have been clear documentation in the medical notes as to why a syringe driver containing possibly diamorphine, midazolam and hyoscine was prescribed 'as required'. It is unusual to prescribe a syringe driver 'as required' especially containing drugs with a range of possible doses. This is because of the inherent risks that would arise from a lack of clear prescribing instructions on why, when and by how much the dose can be altered within this range and by whom. For these reasons, prescribing a

drug as a range, particularly a wide range, is generally discouraged. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. It is not usual in my experience for such decisions to be left for nurses to make alone.

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

The wide dose range of diamorphine 20mg–200mg, is not justified at all in the notes. Doses at the upper of this range are likely to be excessive for Mr Cunningham's needs. Doses of opioids excessive to a patient's needs are associated with an increased risk of drowsiness, delirium, nausea and vomiting and respiratory depression.

The reasons for the inclusion of midazolam and hyoscine hydrobromide in the syringe driver should also have been documented.

Issue iii (prescribing only the treatment, drugs, or appliances that serve patients' needs)

It is unclear why Mr Cunningham was given the 10mg dose of Oramorph. He had only received 5mg of Oramorph previously and this was to cover a dressing change. It would be usual to repeat the same dose of opioid (i.e.

5mg), unless it was ineffective in providing analgesia. Opioids are not indicated for the relief of anxiety and agitation per se. In a confused, elderly patient, opioids may worsen the confusion, particularly at doses associated with sedation. It is possible that the 10mg dose may have contributed to Mr Cunningham being too 'sedated' to take his 22.00h medication.

Issue vi (lack of clear, accurate, and contemporaneous patients records which report drugs prescribed; prescribing only the treatment, drugs, or appliances that serve patients' needs)

It is not clear who decided to start the syringe driver on the 21st September 1998, the drugs it contained and the doses to use. It should be clarified why, if Mr Cunningham was able to take oral medication, his usual medication had not been given, or, if unable to take oral medication, why stat SC doses of a sedative or analgesic were not considered appropriate. Doctors, based upon an assessment of the clinical condition and needs of the patient usually decide on and prescribe any change in medication. It is not usual in my experience for such decisions to be left for nurses to make alone.

Morphine is used in palliative care for generalised pain related to muscle or joint stiffness due to immobility or painful pressure sores and the starting dose of diamorphine used were within the starting dose range considered reasonable given Mr Cunningham's prior analgesic use and age.

Issue v (lack of clear, accurate, and contemporaneous patients records which report drugs prescribed; prescribing only the treatment, drugs, or appliances that serve patients' needs; willing to consult colleagues)

If symptoms are 'difficult to control', this should prompt an adequate (re)assessment to carefully (re)consider the possible contributing factors to ensure that all reasonable steps had been taken. If symptoms were not improving despite several increases in analgesic and sedative medication it would be seen as good practice for a doctor to seek additional information or advice from one of the consultants, another colleague or a member of the palliative care team. There is no documentation in the notes that suggests that Dr Barton did this.

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

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

In my view, given Mr Cunningham's circumstances, the use of diamorphine, midazolam and hyoscine was reasonable. The main issues of contention are firstly, the large dose range of diamorphine prescribed for the 'as required' syringe driver (200mg), as this was likely to exceed the dose likely to be appropriate for Mr Cunningham. It is unclear how Dr Barton

determined or justified this dose. A dose of diamorphine excessive to Mr Cunningham's needs would be associated with an increased risk of drowsiness, confusion, agitation, nausea and vomiting and respiratory depression. Mr Cunningham's administered dose of diamorphine did not however, reach these high levels.

Secondly, the lack of p.r.n. stat SC doses of diamorphine and midazolam meant that the there was a lack of guidance to aid appropriate dose titration or justification for the continued increases in the doses of diamorphine and midazolam. Mostly these were increases within the 33–50% range that would be considered typical. Sometimes increases were greater than this (i.e. diamorphine 20mg to 40mg, 100%) or without documented reason/justification, e.g. the diamorphine 60mg to 80mg and the midazolam 20mg to 60mg and subsequently 80 to 100mg. It was not clear who determined these increases, Dr Barton or one of the nursing staff, and this should be clarified. However, my understanding is that Dr Barton, as the prescriber, retains overall responsibility for the administration of these drugs. Finally, other strategies exist that could have been employed to manage Mr Cunningham's pain on turning, that in my view could have been more successful than continuing to increase the regular doses, and in this regard it is possible that the doses of diamorphine and midazolam Mr Cunningham received risked being excessive for the majority of the time he was still and comfortable. Even so, at the doses Mr Cunningham did receive, they were not excessive to the point of leaving him unresponsive, as he reacted to being moved.

In patients with cancer, the use of diamorphine and other sedative medications (e.g. midazolam, haloperidol, levomepromazine) when

appropriate for the patients needs, do not appear to hasten the dying process. This has not been examined in patients dying from other illnesses to my knowledge, but one would have no reason to suppose it would be any different. The key issue is whether the use and the dose of diamorphine and other sedatives are *appropriate* to the patients needs. Although the principle of double effect could be invoked here (see technical issues), it remains that a doctor has a duty to apply effective measures that carry the least risk to life. Further, the principle of double effect does not allow a doctor to relinquish their duty to provide care with a reasonable amount of skill and care. This, in my view, would include the use of a dose of strong opioid that was *appropriate* and not excessive for a patient's needs.

There appears little doubt that Mr Cunningham was 'naturally' coming to the end of his life. His death was in keeping with a progressive irreversible physical decline, documented over at least 10 days by different clinical teams, accompanied in his terminal phase by a bronchopneumonia. Dr Barton could be seen as a doctor who, whilst failing to keep clear, accurate, and contemporaneous patient records had been attempting to allow Mr Cunningham a peaceful death, albeit with what appears to be an apparent lack of sufficient knowledge, illustrated, for example, by the reliance on large dose range of diamorphine by syringe driver rather than a fixed dose along with the provision of smaller 'as required' doses that would allow Mr Cunningham's needs to guide the dose titration. Dr Barton could also be seen as a doctor who breached the duty of care she owed to Mr Cunningham by failing to provide treatment with a reasonable amount of skill and care. This was to a degree that disregarded the safety of Mr Cunningham by unnecessarily exposing him to potentially receiving

excessive doses of diamorphine. In the event, however, such large doses were not administered, and in my opinion, the use of diamorphine, midazolam and hyoscine in these doses could be seen as appropriate given Mr Cunningham's circumstances.

9. LITERATURE/REFERENCES

British National Formulary 35 (March 1998).

Prescribing in Terminal Care, pages 12–15.

British National Formulary 47 (March 2004).

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

Palliative Care Handbook, Guidelines on Clinical Management, Third Edition 'Wessex Protocol' Salisbury Palliative Care Services May 1995.

10. EXPERTS' DECLARATION

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

10. I have attached to this report a statement setting out the substance of all facts and instructions given to me which are material to the opinions expressed in this report or upon which those opinions are based.

11. STATEMENT OF TRUTH

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

Signature: _____ Date: _____