OPERATION ROCHESTER

Re Elsie Devine

ADVICE

Introduction

1. On 21 November 1999, Elsie Devine, aged 88, died.

2. At the time of her death Mrs Devine was a patient at the Gosport War Memorial Hospital ('GWMH').

3. The cause of death was registered as renal failure (kidney failure), secondary to chronic glomerulonephritis (inflammation damaging part of the kidney).

4. During her time at GWMH, Mrs Devine was treated on a day to day basis by Dr Jane Barton, a Clinical Assistant in Elderly Medicine. Dr Barton is now aged 57 (date of birth Code A).

5. A thorough investigation into the events leading to and surrounding Mrs Devine's death has been carried out by the Hampshire Constabulary.

6. We have been asked to advise on the question of whether the evidence reveals the commission of any criminal offence by Dr Barton, and if so, whether there is a realistic prospect of conviction. The criminal offence to be considered is gross negligence manslaughter.

7. We should say at the outset that after careful consideration of all the materials provided to us we have reached the conclusion that the evidence does not reveal the commission of the offence of gross negligence manslaughter.

8. In reaching this conclusion we have, of course, had regard to the Code for Crown Prosecutors.

Background

9. Mrs Devine was born on Code A After the death of her husband in 1979, she lived with Code A in Fareham, Hampshire.

10. In the summer of 1999, Mrs Devine was diagnosed with chronic renal failure. A Consultant Nephrologist, Dr Judith Stevens, diagnosed an impaired kidney function which had most likely resulted from long-standing glomerulonephritis, and which had led to nephrotic syndrome (the leaking of protein from the kidneys).

11. From the summer of 1999, Mrs Devine's kidney function was in slow decline. The treatments available were aggressive treatments, and it was decided that the high risks which they involved outweighed any possible benefits to a woman of Mrs Devine's age and frailty. It was expected that her kidney function was likely to worsen.

12. Mrs Devine was also found to have an excessive production of immunoglobulin A. Investigations excluded the possibility that this was related to myeloma (a form of cancer characterised by an increased production of plasma cells in the bone marrow) or lymphoma.

13. On 9 October 1999, Mrs Devine saw her General Practitioner, Dr Smith, at the Health Centre in Fareham. She complained of pain whilst passing urine.

14. Dr Smith suspected a kidney infection, and referred Mrs Devine to the Queen Alexander Hospital in Portsmouth. In his referral letter, Dr Smith noted that Mrs Devine was, '*confused ++*', '*aggressive*' and '*wandering*'.

Queen Alexander Hospital

15. Mrs Devine was admitted to the Queen Alexander Hospital on 9 October under the care of Dr Duncan. She was noted to be frail, confused, pain free and hard of hearing.

16. An examination confirmed that:

    (1) Her cognitive function was impaired (she scored three out of ten on the short version of the mini-mental test); and

    (2) Her kidney function was impaired.

17. Mrs Devine received trimethoprim, an antibiotic, for a presumed urinary tract infection (although no infection was found in a subsequently obtained specimen of urine). On 12 October, she was still confused and aggressive, and an antipsychotic drug (haloperidol) was administered. She was referred to Dr Lusznat, a psychiatrist, for a psychogeriatric assessment. On 13 October, her antibiotic was changed to cefaclor in case she had an infection which was not responding to trimethoprim.

18. On 14 October, Mrs Devine was seen by Dr Taylor, a Clinical Assistant in Old Age Psychiatry, who worked under a Consultant, Dr Lusznat. She elicited a history of slow decline in Mrs Devine's functional abilities since January 1999. A mini-mental test registered a score of only nine out of thirty, which was indicative of severe dementia (a score of less than seventeen suggests definite cognitive impairment). Dr Taylor concluded that Mrs Devine was likely to have dementia and to have had an acute episode of confusion secondary to a urinary tract infection. (In a further report dated 18 October Dr Taylor incorrectly referred to Mrs Devine as having myeloma.)

19. Between 15 and 18 October, Mrs Devine's condition improved. She was more settled, less confused and was not aggressive. A final diagnosis was made of multi-infarct dementia (dementia caused by multiple small strokes which starve the brain of oxygen, resulting in damage and sudden loss in cognitive and functional ability).

20. Mrs Devine was assessed as fit for discharge. However, owing to her son-in-law's ill heath (he had been diagnosed as suffering from leukaemia), she was unable to return home and live with her daughter. A referral was made to the geriatricians, and she was assessed as suitable for rehabilitation at GWMH.

Gosport War Memorial Hospital

21. The GWMH is a 113 bed community hospital managed by the Fareham and Gosport Primary Care Trust. Between 1994 and 2002 it was part of the Portsmouth Health Care NHS Trust. The hospital is designed to provide continuing care for long stay elderly patients. It is operated on a day to day basis by nursing and support staff. Clinical expertise is provided by visiting General Practitioners, Clinical Assistants and Consultants. Elderly patients are usually admitted to GWMH by way of referral from local hospitals or general practitioners for palliative, rehabilitative or respite care.

22. On 21 October, Mrs Devine was transferred to GWMH. She was admitted to Dryad Ward after what appears to have been a very short time on Mulberry ward. The Consultant responsible for Dryad ward was Dr Ian Reid.

23. The doctor who saw Mrs Devine on a day to day basis was Dr Barton. Dr Barton was a General Practitioner at the Forton Medical Centre in Gosport. She worked at GWMH on a part time basis as a visiting Clinical Assistant.

24. The details of Mrs Devine's treatment were recorded in various sets of notes. These notes included the clinical notes, the nursing notes and the drug chart.

25. On the day of Mrs Devine's transfer, Dr Barton prescribed a morphine solution, to be taken as required. There is no entry in the notes as to why this was prescribed. In fact, it does not appear that any analgesic drug was administered to Mrs Devine until 18 November.

26. On 25 October, Mrs Devine was seen by Dr Reid. He noted that she was mobile unaided, washed with supervision, dressed herself and was continent. The notes stated that she was mildly confused and also referred to '*chronic renal failure*'.

27. On 1 November, Mrs Devine was again seen by Dr Reid. She was found to be physically independent, but '*quite confused and disorientated*'.

28. On 11 November, as recorded on the drug chart but not in the clinical notes, thioridazine, an antipsychotic drug, was prescribed on an as required basis. Mrs Devine

received one to two doses of 10mg each day until 17 November. She was also prescribed trimethoprim for a presumed urinary tract infection.

29. On 15 November, Dr Reid noted that Mrs Devine was very aggressive and restless, and that the administration of thioridazine had been needed. Her urine sample had revealed no infection, although her white cell count had risen.

30. Owing to her growing confusion, Mrs Devine was referred back to Dr Lusznat on 16 November. An entry in the medical notes stated that her renal function was deteriorating.

31. On 18 November, Mrs Devine was seen on the ward by Dr Taylor, who had previously seen her at the Queen Alexander Hospital. Dr Taylor noted that her condition had deteriorated and that she had become more aggressive and restless. Mrs Devine was refusing medication, although she did not seem to be depressed. Dr Taylor recommended that she be put on a waiting list for Mulberry ward (a psychiatric ward). She noted that Mrs Devine's physical condition was stable. However, the results of a blood test, which had been taken on 16 November, showed that her creatinine (a compound formed in protein metabolism and involved in the supply of energy for muscular contraction) had risen from 187 to 360. The significance of this increase is that it demonstrates that Mrs Devine's renal function was deteriorating.

32. On the same day, Dr Barton prescribed the application of a fentanyl patch (25microgram per hour). The patch was applied at 9.30 a.m. (Fentanyl is a strong opiate based analgesic drug similar to morphine.) This was recorded on the drug chart, but no entry was made in the clinical or nursing notes explaining why the treatment was commenced.

33. On 19 November, Dr Barton noted that Mrs Devine's condition showed a '*marked deterioration overnight*', and that there had been a further deterioration in her general condition that day. Mrs Devine was aggressive and confused (to the point where it took two nurses physically to restrain her). Dr Barton noted that the fentanyl patch had been commenced the previous day. The note went on:

'*Needs SC* [subcutaneous] *analgesia with midazolam. Son seen and aware of condition and diagnosis. Please make comfortable. I am happy for nursing staff to certify death.*'

34. The nursing notes for the same day stated: '*marked deterioration over past 24 hours. Extremely aggressive this am refusing all help from staff.*'

35. The nursing notes and the drug chart indicate that on 19 November Mrs Devine was treated in the following way:

    (1) Chlorpromazine 50mg was administered intramuscularly at 8.30 a.m. (Chlorpromazine is an antipsychotic drug);

    (2) A syringe driver containing diamorphine 40mg and midazolam 40mg was commenced at 9.25 a.m. (Diamorphine is an opiate based analgesic drug. Midazolam is a sedative. A syringe driver is a pump used to deliver medication via a syringe over twenty-four hours, commonly used in the treatment of patients in their terminal phase);

    (3) The fentanyl patch was removed at 12.30 p.m.

36. The drug chart records that all of the above treatments had been prescribed by Dr Barton.

37. The next entry in the clinical notes recorded Mrs Devine's death. Death was pronounced at 8.30 p.m. on 21 November. It was noted that Mrs Devine had died peacefully.

38. The entries in the summary nursing notes made after the treatment of 19 November had commenced suggest that Mrs Devine was peaceful until she died.

39. The drug chart showed that the doses of diamorphine and midazolam remained unchanged, and that no additional medication was administered.

40. The death certificate registered the cause of death as renal failure, secondary to chronic glomerulonephritis.

The Independent Review Panel Report

41. Following Mrs Devine's death, Code A made a complaint to the Portsmouth Healthcare NHS Trust. The complaint related to the adequacy of the hospital's communication with Mrs Devine's family whilst she was being treated at GWMH, and the appropriateness of the clinical response to her medical condition.

42. The complaint was dealt with by the Trust's Independent Review Panel. A hearing was held on 22 May 2001, and the Panel produced a report dated 10 August 2001.

43. Dr Barton gave oral evidence to the Panel. Her evidence, as recorded in the Panel's report, may be summarised as follows:

    (1) On 18 November, Mrs Devine's renal function was deteriorating, her protein was low and she was not eating well. A subcutaneous fluid infusion was not appropriate as Mrs Devine would have been able to pull it out. Therefore a fentanyl patch was started instead;

    (2) It had been difficult to tell from Mrs Devine's agitated and restless state whether or not she was in pain, and there were limited options for making her comfortable;

    (3) Dr Barton had had previous success with a fentanyl patch, and felt that this was the best treatment for Mrs Devine. Although she may not have been strictly in physical pain, she was obviously in mental pain. That needed relieving, just as physical pain needed relieving;

    (4) On 19 November, Dr Barton explained to the family that Mrs Devine had deteriorated and had had to be sedated;

    (5) It had not been possible to discuss the use of opiates (i.e. fentanyl and diamorphine) with the family before they were given as it had been clinically necessary to give them immediately;

    (6) A syringe driver was prescribed because Dr Barton wanted to avoid frequent intramuscular injections which could have hurt and upset Mrs Devine. The driver administered drugs at a slow, steady rate with low disturbance to the patient;

    (7) Dr Barton would normally have started a patient at between 10 and 20mg of diamorphine and midazolam, depending on the patient's size and whether or not the patient had opiates in their system. The dose given to Mrs Devine was 40mg as she had shown resistance to the fentanyl patch;

(8) At the time the syringe driver was set up, Dr Barton believed that Mrs Devine was dying.

44. Dr Lord also gave evidence to the Panel. She stated that the years 1998 and 1999 were a time of considerable change for Dryad ward. It had gone from being a ward which provided continuing care for patients until they died, to providing respite care for patients until they were discharged. This meant that the culture of the ward changed from one which was quite stable, to one with a high turnover of patients with complicated medical problems. She said that an average continuing care ward received fifty patients a year whereas in 1998/1999, Dryad ward received 255 patients. She went on to say that as the ward was so busy, staff found it particularly difficult to deal with patients such as Mrs Devine who had physical and psychiatric problems.

45. The Panel found that there had been inadequate communication between the hospital and Mrs Devine's family. In respect of the clinical care which the hospital had provided, the Panel reached the following conclusion:

'The dosage of drugs given to Mrs Devine was appropriate for an elderly patient in her condition. Although 40mg of diamorphine and 40mg of midazolam are quite high doses, it was necessary to give this amount because of Mrs Devine's extreme agitation and lack of response to previous medication.

The clinical response to Mrs Devine's care was appropriate...'

The Police Investigation

46. Hampshire police first investigated the deaths of elderly patients at GWMH in 1998. This followed the death of Gladys Richards. Mrs Richards died at GWMH on 21 April 1998. Her daughters made a complaint to the police regarding the treatment she had received. The police investigated the matter twice, and submitted files to the Crown Prosecution Service ('CPS'). In August 2001, the CPS advised that there was insufficient evidence to provide a realistic prospect of conviction in respect of any individual involved in the care of Mrs Richards.

47. Local media coverage of the case prompted relatives of other patients who had died at GWMH to complain to the police. These complaints were investigated, but no files were submitted to the CPS.

48. On 22 October 2001, the Commission for Health Improvement launched an investigation into the management, provision and quality of health care in GWMH. The Commission's report was published in May 2002, and set out a number of factors which contributed to a failure to ensure good quality patient care.

49. Following publication of this report, the Chief Medical Officer, Sir Liam Donaldson, commissioned Professor Richard Baker to conduct a statistical analysis of mortality rates at GWMH.

50. On 16 September 2002, Anita Tubbritt, a nurse at GWMH, handed over to the hospital a bundle of documents which minuted the concerns nursing staff had had in 1991 and 1992 regarding, amongst other matters, increased mortality rates in elderly patients and the prescription of diamorphine by Dr Barton. The documents were made available to the police.

51. As a result of this disclosure, Hampshire police decided to conduct a further inquiry.

52. A total of ninety cases were reviewed by the police. These included the death of Mrs Devine. A team of medical experts led by Professor Robert Forrest was appointed to conduct the review. The team was not asked draft a report on each case, but to categorise the care provided as optimal, sub-optimal or negligent. Approximately sixty cases were categorised as sub-optimal, and were referred to the General Medical Council. A further fourteen cases were categorised as negligent.

53. The cases categorised as negligent are now the subject of an on-going review by Dr Andrew Wilcock, an expert in palliative medicine and medical oncology, and Dr Robert Black, an expert in geriatric medicine. Mrs Devine's case is the first to have been reviewed.

54. In the present case, Dr Wilcock has prepared a report, dated 10 December 2004 (and signed on 16 December), and a further undated report commenting on Dr Barton's police interview. Dr Black has prepared a report, dated 4 January 2004. In addition, Dr Dudley, an expert in renal medicine, has prepared a reported dated 2 March 2005.

Dr Barton

55. As part of the police investigation into the fourteen cases which had been reviewed and categorised as negligent, Dr Barton was interviewed under caution in relation to the death of Mrs Devine. Dr Barton attended for the interview voluntarily on 4 November 2004. She was represented by a solicitor, Ian Barker.

56. Dr Barton read two lengthy prepared statements, and then declined to answer any questions which were put to her by the interviewing officers. The first prepared statement may be summarised as follows:

    (1) Dr Barton is a Registered Medical Practitioner. She qualified in 1972 at Oxford University. She joined her current General Practitioners' practice in 1980;

    (2) In addition to her practice, in 1988 she took up the post of the sole Clinical Assistant in Elderly Medicine at GWMH. She resigned in 2000;

    (3) Her position at GWMH was a training post and a part time appointment;

    (4) Initially the appointment was for four sessions each week, one of which was allocated to her partners to provide out of hours cover. This was later increased so that by 1998, the Trust had allocated her five sessions per week, of which one and a half were given to her partners for the out of hours aspect of the post. She was therefore expected to carry out her duties in three and a half sessions per week. That was in addition to her General Practitioner duties;

    (5) By 1998, Dr Barton was working on Daedalus and Dryad wards. A Consultant was responsible for each ward. However, they had considerable responsibilities elsewhere, and their actual time at the hospital was significantly limited;

    (6) Dr Barton would arrive at the hospital each morning at 7.30 a.m. She would visit both wards, reviewing patients and liasing with staff, before commencing her General Practitioner duties at 9 a.m. She would return to the hospital virtually every lunchtime, when new patients were admitted. Quite often, she would return to the hospital after her surgery hours at about 7 p.m. Nursing staff

would also telephone her at the surgery and at home to discuss developments and problems with particular patients;

(7) Dr Barton provided the only day to day medical input on the wards;

(8) Her work involved looking after a large number of elderly patients approaching the end of their lives, and requiring continuing care. The vast majority had undergone treatment in the acute sector and were transferred to GWMH for rehabilitation, continuing care or palliative care;

(9) Dr Barton and the nursing staff tried to offer a level of freedom from pain, physical discomfort, unpleasant symptoms and medical distress, which is difficult to offer in an acute setting and is more allied to palliative care;

(10) By 1998, Dr Barton's workload had become excessive. There had been a marked increase in the dependency of the patients and an increase in their numbers. There was limited Consultant input, and only a marginal increase in the nursing staff. Dr Barton raised this matter with the Trust management in 1998. She thought about resigning, but felt obliged to remain and care for her patients. In reality, she was doing her best in the most trying circumstances;

(11) On a day to day basis Dr Barton was left with the choice of attending to her patients and making notes as best she could on the one hand, and making more detailed notes at the expense of neglecting patients on the other. The detail in her notes suffered as a consequence. (Dr Wilcock has commented that he does not regard this as an adequate excuse for failing to keep proper notes);

57. Dr Barton's second prepared statement may be summarised as follows:

(1) On the day of Mrs Devine's admission to GWMH, Dr Barton recorded a previous diagnosis of dementia, myeloma and hypothyroidism. She was also aware of chronic renal failure;

(2) The plan was to get to know Mrs Devine and access her rehabilitation potential with the probability of a transfer to a rest home in due course;

(3) On the day of Mrs Devine's admission, Dr Barton prescribed oramorph on an as required basis. She was concerned that a low dose of pain relieving medication should be available in case Mrs Devine experienced distress or discomfort when a doctor was not present;

(4) Dr Barton would have seen Mrs Devine every morning when reviewing patients;

(5) The entry in the note on 18 November (made by Dr Taylor) stated that Mrs Devine's condition was stable, in fact there had been a significant deterioration of her renal function. The results of a blood test, taken on 16 November and available on 18 November, showed that her creatinine had increased to 360;

(6) After discussions with the team caring for Mrs Devine, who were concerned about her discomfort and the fact that she was refusing to take medication, Dr Barton decided to commence a fentanyl patch. This was an attempt to calm the patient, make her more comfortable and enable nursing care. A subcutaneous infusion was not appropriate as Mrs Devine was likely to have removed it;

(7) On the morning of 19 November, Dr Barton found Mrs Devine in an extremely agitated state, hanging onto the bars in the main corridor. She was very anxious and distressed and would not allow anyone to approach to administer her usual medication. In due course the team was able to administer chlorpromazine 50mg intramuscularly. This made Mrs Devine quite drowsy, and the decision was made to discontinue the fentanyl patch (which would have taken twenty-two hours to reach steady drug levels), and opt instead for subcutaneous analgesia;

(8) As Mrs Devine had already received opiates in the form of the fentanyl patch and had been resistant to it, Dr Barton prescribed diamorphine 40mg via a syringe driver together with midazolam 40mg. The sole intention was to relieve Mrs Devine's significant distress, anxiety and agitation which was clearly upsetting her;

(9) At this point, it was clear that Mrs Devine's renal function had declined markedly, superimposed on her dementia, and that she was now dying;

(10) Following death, Dr Barton prepared a death certificate recording renal failure as the cause of death. When the registrar felt that that was not sufficiently specific, she later added chronic glomerulonephritis.

The Report of Dr Wilcock

58. Dr Wilcock is a Reader in Palliative Medicine and Medical Oncology at the University of Nottingham and an Honorary Consultant Physician of the Nottingham City Hospital NHS Trust.

59. He has reviewed the care given to Mrs Devine at the Queen Alexander Hospital and GWMH, and has produced a report dated 10 December 2004 (signed on 16 December 2004). He describes Mrs Devine as a frail 88 year old lady with significant medical problems.

60. Dr Wilcock came to the conclusion that the care provided to Mrs Devine at the Queen Alexander Hospital was not suboptimal, and that the diagnosis of multi-infarct dementia was consistent with her symptoms.

61. Dr Wilcock has raised a number of concerns relating to the treatment Mrs Devine received at GWMH:

'*The medical care provided by Dr Barton to Mrs Devine following her transfer to Gosport War Memorial Hospital, Dryad Continuing Care Ward 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, July 1988, 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 and, if necessary, an appropriate examination*
- *in providing care you must keep clear, accurate and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to the patients and any drugs or other treatment prescribed*

- *in providing care you must prescribe only the treatment, drugs or appliances that serve the patient's needs.'*

62. In relation to the care provided by Dr Barton, the concerns of Dr Wilcock may be summarised as follows:

    (1) The infrequent entries in the clinical notes make it difficult to follow closely Mrs Devine's progress over the last month of her life;

    (2) The cause of Mrs Devine's admission to GWMH, that is, acute confusion as a consequence of multi-infract dementia, possibly aggravated by an infection which was not responding to trimethorprim, was not recorded in the notes. This was an important omission, as knowledge of these matters could influence the management of any future deterioration. It would have allowed a doctor to consider the possibility that a sudden deterioration might represent a temporary, rather than an irreversible, decline;

    (3) The medical notes mistakenly referred to Mrs Devine as having myeloma (this had previously been noted in error by Dr Taylor at the Queen Alexander Hospital, but the information contained in clinic letters from the haematologist Dr Cranfield made the situation clear). The belief that a patient had such a condition might influence a doctor when assessing whether any deterioration was temporary or irreversible;

    (4) The reason for prescribing the fentanyl patch on 18 November is not recorded in the notes. In the absence of pain being noted as a problem, it is difficult to justify the prescription. If analgesic drugs were appropriate, normally simple analgesics would be administered first, progressing to weak opioids, and then to strong opioids (it is sometimes necessary to deviate from this general approach when a patient is in severe pain). A fentanyl patch, however, would not have been appropriate, as even the lowest strength patch was likely to deliver too high a dose of strong opioid for an elderly, frail and opioid naïve patient. The dose of 25microgram per hour can deliver the equivalent of up to 135mg of morphine a day. This exceeds the typical recommended starting dose in adults of 60mg a day, or 30mg in the case of frail, elderly patients, and would have exceeded any need for strong opioids Mrs Devine may have had;

(5) Although Mrs Devine's condition showed a marked deterioration on 19 November, the notes do not indicate whether or not sufficient consideration had been given to the possible reversible causes of the deterioration. (For example, exposure to the strong opioid delivered by the fentanyl patch, or the worsening of Mrs Devine's renal function, possibly caused by dehydration.) The common causes of confusion which are reasonably simple to reverse should almost always be excluded or pursued as a minimum. This would involve a measured approach, which did not render Mrs Devine unresponsive;

(6) Dr Barton's use of chlorpromazine on 19 November appears justified on the grounds of Mrs Devine's agitation and confusion, but the dose prescribed could be seen as excessive for her needs. The dose of 50mg was double that recommended for an elderly, frail patient, and it is likely to have caused prolonged drowsiness. A dose of 12.5mg or at most 25mg would have been preferable. Mrs Devine's mental condition may have improved as the peak effect of the chlorpromazine wore off. However, Dr Barton did not allow any opportunity for the long term effect of the dose to be assessed. Within an hour of the administration of the chlorpromazine, the syringe driver was commenced;

(7) Dr Barton's use of midazolam on 19 November appears justified on the grounds of Mrs Devine's agitation and confusion, but the dose administered could be seen as excessive for her needs. A daily dose of 20 to 80mg was prescribed, although no instructions were given as to how the dose could be altered within that range. In fact, the dosage was commenced at 40mg, which was likely to lead to drowsiness. It would have been more appropriate to give small doses (2.5 to 5mg) by intermittent subcutaneous injection as required. The use of midazolam in a syringe driver with the purpose of keeping Mrs Devine sedated to the point of being unresponsive could only be justified if it was considered without reasonable doubt that she was experiencing confusion as a terminal event and was actively dying. In these circumstances, most, but not all, practitioners would in any case use a dose which would improve symptoms without rendering the patient unresponsive (for example, 10mg);

(8) Diamorphine is an analgesic drug, but there is no indication in the notes explaining why it was prescribed on 19 November. In the absence of pain, shortness of breath or a cough, there was no justification for the use of diamorphine in a syringe driver. If Mrs Devine was in a degree of pain which

warranted the administration of strong opioids, the dose of 40mg was in any event excessive. It would have been more appropriate to administer smaller doses (such as 2.5mg) by intermittent subcutaneous injection. If, for whatever reason, it was felt preferable to give Mrs Devine diamorphine via a syringe driver, a starting dose of 5 to 10mg would have been more appropriate. The dose of 40mg was likely to cause drowsiness and increase the risk of delirium. It would have caused Mrs Devine's renal function to have declined further.

63. Dr Wilcock then considered the effect of the care provided by Dr Barton, and the degree to which the care she provided was suboptimal. His observations may be summarised as follows:

(1) If Mrs Devine had naturally entered the terminal phase of her life, Dr Barton could be seen, at best, as a doctor who had been attempting to allow her patient to die peacefully, albeit with what appears to have been an inappropriate and excessive use of medication owing to a lack of sufficient knowledge;

(2) Mrs Devine's death was not typical of a patient dying from chronic renal failure. That condition is generally more gradual in onset, with progressively worsening renal failure and increasing weakness and drowsiness. A rapid worsening of Mrs Devine's mental state would be more suggestive of an underlying aggravating factor, such as an infection, a stroke or a drug;

(3) Although it is possible that Mrs Devine was dying 'naturally', it is also possible that her mental state had deteriorated in a temporary or reversible way and that she was not in her terminal phase;

(4) In situations where diamorphine or midazolam are inappropriate or excessive for the patient's 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;

(5) Given the doubt that Mrs Devine had definitely entered her terminal phase, Dr Wilcock came to the following conclusion:

'[A]*t worst, Dr Barton could be seen as a doctor who breached the duty of care she owed to Mrs Devine by failing to provide treatment with a reasonable*

amount of skill and care. This was to a degree that disregarded the safety of Mrs Devine by unnecessarily exposing her to inappropriate and excessive doses of medications such as the fentanyl...patch that could have resulted in a worsening of her agitation and confusion. Dr Barton's response to this was to further expose Mrs Devine to inappropriate and/or excessive doses of midazolam and diamorphine that could have contributed more than minimally, negligibly or trivially to her death. As a result Dr Barton leaves herself open to the accusation of gross negligence manslaughter.'

64. Dr Wilcock has also prepared a draft overview, dated 4 September 2006, in relation to Operation Rochester as a whole. In this overview, Dr Wilcock states that it is '*difficult to judge*' whether Mrs Devine had entered a 'natural' irreversible terminal decline (prior to the relevant acts or omissions on the part of Dr Barton), as there was '*significant morbidity present*'. Dr Wilcock has added the following note of caution to his opinion:

'*Note: prognosis is difficult to accurately judge and it is best to consider the above an indication, in my opinion, of which end of a spectrum a patient would lie rather than a more definite classification.*'

The Report of Dr Black

65. Dr Black, a Consultant in Geriatric Medicine, has prepared a report dated 4 January 2004. Dr Black's conclusions may be summarised as follows:

    (1) By 19 November, Mrs Devine was terminally ill and it was reasonable for a clinician to come to that conclusion [para.6.15];

    (2) It is possible, or perhaps even probable, that without any treatment, Mrs Devine would have died on 21 November [para.6.23];

    (3) It is possible that the medication prescribed by Dr Barton did shorten Mrs Devine's life by a short period, but it also had the effect of relieving Mrs Devine's distress for the last 58 hours of her life [para.6.24];

    (4) The care provided to Mrs Devine was sub-optimal, but it could not be proved negligent or criminal [para.7.3].

The Report of Dr Dudley

66. Dr Dudley, a Consultant in Renal Medicine, has prepared a report dated 20 March 2005. Dr Dudley's conclusions may be summarised as follows:

    (1) Beyond all reasonable doubt, Mrs Devine was dying from a combination of amyloidosis, progressive renal failure and dementia [para.8.1];

    (2) Although it may have been possible to have stabilised Mrs Devine's condition for a few days, a further deterioration culminating in death was inevitable [para.8.2].

The Statement of Dr Reid

67. During the course of the police investigation, Dr Reid, the consultant responsible for Dryad Ward, made a number of witness statements.

68. In relation to the administration of the fentanyl patch, Dr Reid made the following observations:

    '*I have been asked why an "analgesic" (painkiller) of the strength of Fentanyl has been prescribed and administered to a patient who according to their medical record have* [sic] *not made any complaint of pain. This is best explained as follows...It is often the case that an elderly patient who is very confused and/or distressed may not be able to communicate that they are in pain and may also not display any symptoms or signs of pain other than their confusion, restlessness and aggression...In my opinion the continued distress, restlessness and aggression being displayed by Mrs Devine could be an indication of pain that she was suffering and was unable to communicate.*'

69. In Dr Reid's opinion, there were three options on 18 November: to increase the dosage of sedative, to cease sedative and administer an analgesic or to administer a combination of sedative and analgesic. He states that continued sedation would probably have involved the administration of several daily injections, which would have caused Mrs Devine further distress:

'The primary concern in these circumstances would be the comfort of the patient and in particular to relieve any distress and pain they were suffering.'

70. The other matters dealt with in Dr Reid's statements may be summarised as follows:

(1) Rather than commencing the fentanyl patch, it may have been more appropriate to have administered individual subcutaneous injections of small doses of diamorphine over twenty-four hours to assess its effect on Mrs Devine. However, this would have involved multiple injections that may have caused further distress and may not have led to a relief of her symptoms;

(2) The administration of chlorpromazine 50mg was at the upper limit of the dosage range for an initial injection;

(3) It would have been more prudent to have started the administration of diamorphine at a dosage of 20 to 30mg. A dose of 40mg may have led to over sedation, but, on the other hand, 20 to 30mg might not have relieved Mrs Devine's distress;

(4) It is of some concern that midazolam was administered at a time when the chlorpromazine may not have reached its maximum effect, although it should be borne in mind that the midazolam was being administered as a slow infusion over a twenty-four hour period. This could have led to some over sedation during the first few hours. 20mg would have been a more appropriate starting dose;

(5) The use of a syringe driver to administer the diamorphine and midazolam was appropriate in the circumstances.

The Legal Framework

71. The ingredients of the offence of gross negligence manslaughter are set out in R. v. Adomako [1995] 1 A.C. 171. The Crown must establish:

(1) That there was a duty of care owed by the accused to the deceased;

(2) That there was a breach of that duty by the accused;

(3) That the breach resulted in death (causation);

(4) That the breach is to be characterised as gross negligence and therefore a crime.

72. In determining whether there has been a breach of the duty the ordinary civil law of negligence applies. The test is objective. It is the failure of the accused to reach the standard of the reasonable man placed in the position of the accused.

73. An accused is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of professional opinion skilled in the particular activity in question, even though there is a body of competent professional opinion which might adopt a different technique. (The '*Bolam* test', after *Bolam* v. *Friern Hospital Management Committee* [1957] 1 W.L.R. 582 at 587.)

74. The breach of duty may arise by reason of an act or an omission.

75. If there has been a breach it is essential to show that the breach was a cause of the death. It is to be noted that the breach need not be the sole cause of death or even the main cause of death. It is sufficient for it to be an operating cause, that is, something which is not *de minimis*.

76. In *Adomako*, Lord Mackay of Clashfern L.C., describing the test for gross negligence, stated:

'*...the ordinary principles of the law of negligence apply to ascertain whether or not the defendant has been in breach of a duty of care towards the victim who has died. If such a breach of duty is established the next question is whether the breach of duty caused the death of the victim. If so, the jury must go on to consider whether that breach of duty should be categorised as gross negligence and therefore as a crime. This will depend on the seriousness of the breach of duty committed by the defendant in all the circumstances in which the defendant was placed when it occurred. The jury will have to consider whether the extent to which the defendant's conduct departed from the proper standard of care incumbent upon him, involving as it must have done a risk of death to the patient, was such that it should be judged criminal.*'

77. The test was affirmed by the Court of Appeal in R. v. Amit Misra, R. v. Rajeer Srivastova [2004] E.W.C.A. Crim. 2375:

> '*In our judgment the law is clear. The ingredients of the offence have been clearly defined in Adomako...The hypothetical citizen, seeking to know his position, would be advised that, assuming he owed a duty of care to the deceased which he had negligently broken, and that death resulted, he would be liable to conviction for manslaughter, if, on the available evidence, the jury was satisfied that his negligence was gross. A doctor would be told that grossly negligent treatment of a patient which exposed him or her to the risk of death, and caused it, would constitute manslaughter.*'

78. In *Adomako*, Lord Mackay went on to say:

> '*The essence of the matter which is supremely a jury question is whether, having regard to the risk of death involved, the conduct of the defendant was so bad in all the circumstances as to amount in their judgment to a criminal act or omission.*'

79. The conviction for gross negligence manslaughter was confirmed in the case of *Adomako*. The evidence revealed that the appellant had failed for eleven minutes or so to identify the cause of the patient's respiratory difficulty as a dislodged endothroceal tube. Other means of restoring the supply of oxygen were frantically tried but the simple and obvious procedure of re-attaching the tube was not performed, something that, according to expert evidence, would have been done by a competent anaesthetist within thirty seconds of observing the patient's difficulty. The expert evidence called on behalf on the prosecution was to the effect that the standard of care was 'abysmal' and 'a gross dereliction of care'.

80. Thus for the purposes of liability the test is objective. The *Adomako* test does however require the jury to decide that the conduct of the accused was so bad that it ought to be stigmatised as a crime '*in all the circumstances in which the defendant was placed when the breach of duty occurred*'. This enables account to be taken of all the circumstances and their likely effect on the actions of a reasonable man.

81. Unlike states of mind such as recklessness and intention, negligence does not presuppose any particular state of mind on the part of the accused. It is a standard that reflects fault on his part. The main feature distinguishing negligence from intention and recklessness

(as it is commonly understood) is that there is no requirement that the accused should foresee the risk that the actus reus might occur. Negligence involves an objective assessment of an objectively recognisable risk. Evidence as to the accused's state of mind is not a pre-requisite of a conviction (see *Attorney General's Reference (No. 2 of 1999)* [2000] 2 Cr.App.R. 207, CA).

82. In *R. v. Prentice* [1994] Q.B. 302 the Court of Appeal, without purporting to give an exhaustive definition, considered that proof of any of the following states of mind may properly lead a jury to make a finding of gross negligence:

    (1) Indifference to an obvious risk of death;

    (2) Actual foresight of the risk of death coupled with an intention nevertheless to run it;

    (3) An appreciation of the risk of death coupled with an intention to avoid it but also coupled with such a high degree of negligence in the attempted avoidance as the jury consider justifies conviction;

    (4) Inattention or failure to advert to a serious risk of death which goes beyond mere inadvertence in respect of an obvious and important matter which the defendant's duty demanded he should address.

83. The effect of the above authorities may be summarised as follows:

    (1) The starting point of any consideration of gross negligence manslaughter is the decision of the House of Lords in *Adomako*;

    (2) The essence of the matter which is supremely a jury question is whether, having regard to the risk of death involved, the conduct of the accused was so bad in all the circumstances as to amount in their judgment to a criminal act or omission;

    (3) Although there may be cases where the defendant's state of mind is relevant to the jury's consideration when assessing the grossness and criminality of his conduct, evidence of state of mind is not a pre-requisite to a conviction for manslaughter by gross negligence;

(4) A defendant who is reckless, in the ordinary sense of the word, may well be more readily found to be grossly negligent to a criminal degree;

(5) Failure to advert to a serious risk going beyond mere inadvertence in respect of an obvious and important matter which the accused's duty demanded he should address is one possible route to liability;

(6) The accused can only be guilty of gross negligence manslaughter if the jury is satisfied that his conduct fell sufficiently short of what a reasonable man would have done placed as the defendant was, and that the conduct should be condemned as a crime.

84. It seems to be clear that the situation in which the accused found himself must be taken into account when determining liability and this will include a consideration of such matters as the experience of the accused and the difficulties under which he was acting when he did the act or made the omission of which complaint is made.

85. Support for the proposition that the situation in which the accused found himself may be taken into account when deciding whether the negligence should be judged criminal and, for that matter, whether there is a realistic prospect of conviction, is to be found in *Prentice*. The accused were doctors. They administered two injections to a patient, without checking the labels on the box or the labels on the syringes before doing so. The injections had fatal results. The accused were tried in the Crown Court and convicted after the judge had given the jury a direction on recklessness (whether the risk would have been obvious to a reasonable man). Their convictions were quashed by the Court of Appeal and Lord Taylor CJ stated:

'In effect, therefore, once the jury found that "the defendant gave no thought to the possibility of there being any such risk" on the judge's directions they had no option but to convict. ...if the jury had been given the gross negligence test, they could properly have taken into account "excuses" or mitigating circumstances in deciding whether the high degree of gross negligence had been established. The question for the jury should have been whether, in the case of each doctor, they were sure that the failure to ascertain the correct mode of administering the drug and to ensure that only that mode was adopted was grossly negligent to the point of criminality having regard to all the excuses and mitigating circumstances of the case.'

86. Lord Taylor went on to identify the excuses and mitigating circumstances of the case, which included the individual doctors' experience and subjective belief.

Analysis

Overview

87. Mrs Devine was a frail, elderly women. She suffered from chronic renal failure, caused by a long-standing kidney condition. It was expected that her renal function would continue to deteriorate.

88. In October 1999, prior to her admission to GWMH, she experienced acute confusion, and was diagnosed with multi-farct dementia. It was also possible that she had a kidney infection, or some other type of infection, which aggravated her mental health, although none was detected in her urine samples.

89. On 1 November, Mrs Devine appeared confused and disorientated. By 11 November, it was felt necessary to prescribe an antipsychotic drug. Mrs Devine remained confused, to the point where it became necessary to refer her back to a psychiatrist. On 18 November, a recommendation was made that she be put on a waiting list for a psychiatric ward. By this time, her renal function had deteriorated further.

90. On 18 November, Dr Barton prescribed an analgesic drug in the form of a fentanyl patch. The following day, Mrs Devine's condition appeared to have deteriorated further, and Dr Barton took the view that she was dying. Dr Barton prescribed a further antipsychotic drug, and the administration via a syringe driver of an analgesic drug with a sedative.

91. On 21 November, Mrs Devine died.

Summary of the Experts' Opinions

92. Dr Wilcock has observed that the deficiencies in the clinical notes kept by Dr Barton make it difficult to follow closely Mrs Devine's progress whilst at GWMH.

93. His overall opinion in relation to the care provided by Dr Barton may be summarised as follows:

    (1) She failed to give adequate consideration to the possible reversible causes of Mrs Devine's condition; and

    (2) She prescribed excessive doses of fentanyl, chlorpromazine, midazolam and diamorphine on 18 and 19 November.

94. Dr Wilcock concludes that Dr Barton's conduct could be regarded as grossly negligent. This conclusion is based on the opinion that there was reasonable doubt that Mrs Devine had entered the terminal phase of her life. In those circumstances, Dr Barton ought to have given proper consideration to the possible reversible causes of Mrs Devine's condition, in particular, whether she had deteriorated as a consequence of commencing the fentanyl patch. Her failure to do so may have been grossly negligent.

95. On the other hand, if Mrs Devine was in fact in her terminal phase, Dr Wilcock concludes that Dr Barton may been seen as a doctor who was allowing her patient to die peacefully, albeit by prescribing excessive dosages of analgesic, antipsychotic and sedative drugs.

96. In his overview of 4 September 2006, Dr Wilcock has stated that it is difficult to judge whether Mrs Devine entered the terminal phase naturally, as significant co-morbidity was present.

97. Dr Black's view is that by 19 November Mrs Devine was terminally ill, and that even without treatment, it is probable that she would have died on 21 November. Dr Dudley agrees that death was inevitable.

Discussion

98. In assessing whether the evidence in this case reveals the commission by Dr Barton of the offence of gross negligence manslaughter, we have had regard to the following two matters:

(1) In the circumstances as they were on 19 November, could a reasonable clinician have concluded, as did Dr Barton, that Mrs Devine had naturally entered her terminal phase? and

(2) Had Mrs Devine in fact naturally entered her terminal phase by 19 November?

99. As to what a reasonable clinician could have concluded, the following matters are relevant:

(1) Mrs Devine was a frail, elderly lady;

(2) She had been diagnosed with chronic renal failure;

(3) It had been decided that, owing to the risks involved, the causes of her condition would not be treated;

(4) In the summer of 1999, her renal function was deteriorating;

(5) It was expected that her renal function would continue to deteriorate;

(6) On 16 November, her renal function deteriorated further;

(7) From 11 November, Mrs Devine's mental condition was declining, and by 19 November, it was noted that she had shown a marked deterioration;

(8) In Dr Wilcock's opinion, Mrs Devine's death was not typical of a patient dying from chronic renal failure. A rapid worsening of her mental state would be more suggestive of an underlying aggravating factor, such as an infection, a stroke or a drug;

(9) Dr Wilcock accepts, however, that Mrs Devine may have naturally entered her terminal phase;

(10) From the time of Mrs Devine's admission to the Queen Alexander Hospital to the time of her death, it had been suspected that she might have an infection. However, no infection was detected in her urine samples;

(11) The notes do not suggest that consideration was given to the possibility that the fentanyl patch had led to the worsening of Mrs Devine's mental condition between 18 and 19 November;

(12) Dr Reid makes some criticisms of Dr Barton, but endorses her general approach;

(13) Dr Black states that Mrs Devine had naturally entered the terminal phase, and that it is probable she would have died without treatment;

(14) Dr Dudley also states that it is beyond doubt that Mrs Devine was dying from renal failure.

100. Having considered the matters above, in our opinion it could not to be proved to the criminal standard that Dr Barton was negligent in coming to the conclusion that Mrs Devine had naturally entered her terminal phase.

101. As to whether Mrs Devine had in fact naturally entered her terminal phase, the following matters are relevant:

(1) Dr Barton believed that by 19 November, Mrs Devine had naturally entered her terminal phase;

(2) In Dr Wilcock's opinion, Mrs Devine's death was not typical of a patient dying from chronic renal failure. A rapid worsening of her mental state would be more suggestive of an underlying aggravating factor, such as an infection, a stroke or a drug;

(3) However, Dr Wilcock accepts that there was a possibility that Mrs Devine had naturally entered her terminal phase;

(4) Dr Black and Dr Dudley state that Mrs Devine was dying naturally.

102. Having considered the matters above, our opinion is that it cannot be proved to the criminal standard that Mrs Devine had not naturally entered her terminal phase. Dr Wilcock accepts that if Mrs Devine had naturally entered the terminal phase of her life,

Dr Barton can be seen as a doctor who (while failing to keep clear and accurate records), acting in good faith, attempted to allow Mrs Devine a peaceful death.

103. When considering the question of criminal responsibility, it is important to keep in mind the essential criticism of Dr Barton. The essential criticism is that she failed to conduct an adequate or proper investigation into whether Mrs Devine had in fact entered the terminal phase. If this criticism has force, and Mrs Devine had not entered the terminal phase, it would follow that Dr Barton's subsequent action (that is, the prescription of chlorpromazine, diamorphine and midazolam) was inappropriate; the action was taken in ignorance of the true position, in circumstances where that state of ignorance had been induced by negligence. In that case, Dr Barton's negligence would have been a substantial cause of Mrs Devine's death.

104. However, the essential criticism is difficult to sustain because it is accepted, as a reasonable possibility by Dr Wilcock, and as a certainty by Dr Black and Dr Dudley, that Mrs Devine had in fact entered the terminal phase. If this was the case, Dr Barton's subsequent action may not have been inappropriate. To put this another way, if Mrs Devine had entered the terminal phase, Dr Barton's failure to carry out an adequate and proper examination becomes a matter of historical irrelevance for the purpose of the offence of gross negligence manslaughter, because she would have been treating the patient in an appropriate manner (that is, prescribing drugs for the purpose of providing palliative care, albeit in excessive doses).

105. This analysis is of crucial significance when considering the question of whether or not the gross negligence alleged caused the death of Mrs Devine. The gross negligence was the failure to carry out an adequate or proper examination of whether Mrs Devine was in the terminal phase. The cause of death may have been attributable simply to the terminal phase of chronic renal failure. In those circumstances, it follows that causation could not be established beyond reasonable doubt.

Conclusions

106. In the light of what has been set out above, in our opinion the evidence does not reveal the commission of the offence of gross negligence manslaughter. In particular:

(1) Dr Barton's conclusion that Mrs Devine was dying of chronic renal failure cannot properly be characterised as negligent, let alone grossly negligent; and

(2) Causation could not be established as a matter of law.

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