

Version 3 of complete report – June 02 2008 – Elsie Devine

SUMMARY OF CONCLUSIONS

Elsie DEVINE

DOB: Code A

DOD: 21/11/1999

Mrs Elsie Devine was an 88-year-old lady admitted to the Queen Alexandra Hospital following a crisis at home on the 9th October 1999. She has symptoms of confusion and aggression on a background of known chronic renal failure, IgA Paraproteinaemia, Hypothyroidism and a dementing illness. There was little improvement in the Queen Alexandra Hospital and she was transferred to the Gosport War Memorial Hospital on 21st October for continuing care.

In the Gosport War Memorial Hospital she deteriorates over the first two weeks in November and by 19th November is terminally ill. She receives palliation including subcutaneous Diamorphine and Midazolam and dies 21st November 1999.

However there were significant failings in the medical care provided to Mrs Devine as well as deficiencies in the use of the drug chart at Gosport War Memorial Hospital.

1. INSTRUCTIONS

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

2. ISSUES

- 2.1. Was the standard of care afforded to this patient in the days leading up to her death in keeping with the acceptable standard of the day.
- 2.2. If the care is found to be suboptimal what treatment should normally have been proffered in this case.

3. CHRONOLOGY/CASE ABSTRACT. (The numbers in brackets refer to the page of evidence)

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- 3.1 In March 1998 (120) Mrs Devine was seen in a geriatric outpatient department with cellulitis, mild hypothyroidism, mild CCF, haemoglobin of 13 (317) and a creatinine of 90 (337).
- 3.2 In December 1998 she was seen in an orthopaedic clinic (102) and was found to be clinically fit for a knee replacement.
- 3.3 In March 1999 her haemoglobin was 12.8 (311) and her creatinine in February was 143 (325).
- 3.4 In April she was seen by a consultant geriatrician where she was found to be "moderately frail" although also noted to be "bright mentally" (84). Her weight was 58.8 kgs (144), her haemoglobin 11.5 (307) and a creatinine 151 (84).
- 3.5 She was referred to a renal physician and was also seen by a haematologist between June 1999 and September 1999. In June 1999 (60) her creatinine was 160, her haemoglobin 11.2 (297), her weight was 55.4 kgs (151). In July 1991 (50) the haematologist found 6% plasma cells and an albumen of 22 (52), immune paresis (70) and suggested a watch and wait approach. In September 1999 her renal physician noted that she had chronic renal failure with small kidneys and nephrotic syndrome with marked oedema. It was thought likely that this was on a background of progressive glomerulonephritis (60) and she had an incidental IgA paraproteinaemia. Her Creatinine was 192 and her haemoglobin 10.5 (295).
- 3.6 On 9th October, she was admitted to the Queen Alexandra Hospital following a social crisis at home as Mrs Devine lived with her daughter and son-in-law. Mrs Devine's son-in-law had cancer and her daughter could no longer cope. There was a story of confusion and aggression, which was suggested, had become worse prior to her admission. The clinical diagnosis was of a possible urinary tract infection, with an underlying dementing illness. However, Mrs Devine was never documented to be pyrexial (256) and the mid-stream urine sample had no growth (367). There is no full blood count available in the notes for the 9th October. The admission clerking, which would be expected to be available, either before page 31 or around pages 157 and 158 also appears to be missing from the notes.
- 3.7 On the 12th October (31) she is noted to be distressed and agitated and undergoes a CT scan of her head, which shows involuntional changes only (24). She receives a single dose of Haloperidol (160) (267). On the 13th October her haemoglobin is 10.8 with a white cell count of 14.5 (293).
- 3.8 On the 15th October she is noted to be wandering (166) on the same day she is assessed by Dr Taylor, Clinical Assistant for the Mental Health Team

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- who noted the history of confusion and disorientation and a 10 months history of mental deterioration (28). She was confused and disorientated but no longer aggressive. She was now mostly co-operative and friendly but tended to get lost, he also noted she was deaf. Her Mini Mental Test Score was 9/30, indicating moderate to severe dementia and he suggested that she would need ongoing institutional care. On the 18th October her creatinine was 201 (171).
- 3.9 On 20th October, there is a letter of an assessment from a locum consultant geriatrician (20). Who notes that she can stand, may have had a urinary tract infection on top of her chronic renal failure and that she was quite alert.
 - 3.10 She is then transferred to the Gosport War Memorial Hospital with a discharge summary (24) that states she has chronic renal failure, paraproteinaemia, multiple infarct disease and an Abbreviated Mental Test Score of 3/10.
 - 3.11 On 21st October she is transferred to the Gosport War Memorial Hospital and is for "continuing care" (154). Her Barthel dependency is noted to be 8 with a Mini Mental Score of 9/30. Dr Barton incorrectly writes that she has 'Myeloma' (154) in the notes.
 - 3.12 On 25th October she is mobile unaided, washes with supervision, remains confused.
 - 3.13 On the 1st November she is quite confused (155) and is wandering. On the 9th November investigations show haemoglobin of 9.9, white cell count of 12.6 (289) and a creatinine of 200 (349). An M.S.U reported on 11th November (363) shows no growth.
 - 3.14 15th November she is noted to be very aggressive, very restless (155) and "is on treatment for a urinary tract infection". However, it is noted that the MSU from 11th November showed no growth. The medical note for the 15th is unsigned, I presume to be Dr Reid.
 - 3.15 18th November (156) she is seen by the mental health team who note that in their view that "this lady has deteriorated and become more restless and aggressive, is refusing medication and not eating" but also noted "her physical condition is stable". She is put on the waiting list for Mulberry Ward. Creatinine on 16th November is 360 and a potassium 5.6 (349).
 - 3.16 19th November there has been marked deterioration over night. The notes state "confused, aggressive, Creatinine 360, Fentanyl patch commences yesterday, today further deterioration in general condition needs subcut analgesia with Midazolam. Son seen and aware of condition and diagnosis, hence make comfortable. I am happy for nursing staff to confirm death"

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- (156). The nursing notes (222) confirm marked deterioration over last 24 hours. "Chlorpromazine given IM. 9.25. Subcut syringe commenced Diamorphine 40 mgs and Midazolam 40 mgs, Fentanyl patch removed. Son seen by Dr Barton at 13.00 and situation explained to him. He will contact his sister regarding and inform her of Elsie's poor condition. 20.00 daughter visited and seen by Dr Barton. Nocte: peaceful night syringe driver recharged at 07.25."
- 3.17 20th November the nursing notes (223) state, "condition remains poor, family have visited and are aware of poorly condition. Seen by Pastor Mary. Nocte: peaceful night extremities remain oedematous, skin mottling, syringe driver changed at 07.15. Dose of Diamorphine 40 mgs. Midazolam 40."
- 3.18 21st November. Nursing notes (223), "condition continues to deteriorate slowly. Asked to see at 20.30 hours patient died peacefully"
- 3.19 Barthel scores are recorded on 21st October 8; 31st October 16, 17th November 10; 14th November 10; 21st November 1 (202) Her weight on 21st October was 52.5 kgs (200).

Drug Chart analysis: 1 dose of Haloperidol was given in the Queen Elizabeth hospital on the 13th October (269). Drug chart at Gosport showed a single dose of Chlorpromazine given at 08.30 on 19th November (277) confirming the nurses' cardex.

The patient had received regular doses of Thioridazine (often given for confused behaviour) from the 11th November up unto 17th November (277). A small dose of prn 2.5 – 5 mgs Oramorphine had been written up on admission to Gosport but had never been prescribed. Hyoscine had also been written up and not prescribed.

Trimethoprim (for a presumed urinary tract infection) is prescribed on 11th November (277 & 276) and continued until 15th November. A 25-microgram patch per hour of Fentanyl is written up on the 18th November and a single patch is prescribed at 9.15 on 18th November (276). The evidence from the nursing cardex is that the Fentanyl patch is removed on the morning of the 19th (223) at 12.30 (275) 3 hours after the time the subcutaneous infusion was started.

A new drug chart is written up on 19th November for Diamorphine 40 – 80 mgs subcut in 24 hours and Midazolam 20 – 80 mgs subcut in 24 hours. The drug card (279) confirms that 40 mgs is put into the syringe driver at 09.25 19th, 7.35 on 20th and 7.15 on 21st and 40 mgs of Midazolam at each of those times. All other drugs had been stopped.

Drug	Date prescribed	Prescribed as	Prescriber	Given
Oramorphine	21/10	10 mgs in 5 mls	Barton	---

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		2.5 – 5 mls PRN		
Fentanyl	18/11	25 µg Skin – 3 days Regular	Barton	18/11 0915
POSSIBLE NEW DRUG CHART				
Diamorphine	19/11	40 - 80 mgs S/C in 24 hours Regular	Barton	19/11 0925 40 mgs 20/11 0735 40 mgs 21/11 0715 40 mgs
Midazolam	19/11	80 – 120 mgs S/C in 24 hours PRN	Barton	19/11 0925 40 mgs 20/11 0735 40 mgs 21/11 0715 40 mgs

4. TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

- 4.1 This section will consider whether there were any actions so serious that they might amount to gross negligence or any unlawful acts, or deliberate unlawful killing in the care of Elsie Devine. Also whether there were any actions or omissions by the medical team, nursing staff or attendant GP's that contributed to the demise of Mrs Devine, in particular, whether beyond reasonable doubt, the actions or omissions more than minimally, negligibly or trivially contributed to death.
- 4.2 In particular I will discuss:
- whether it was appropriate to decide on 19th November that Mrs Devine was terminally ill and if so whether symptomatic treatment was appropriate and
 - whether the treatment that was provided was then appropriate.
- 4.3 Mrs Devine had progressive mental and physical deterioration starting in January 1999. Before that she had had relatively minor medical problems, a normal haemoglobin and creatinine and was put on a waiting list for a knee replacement at the end of 1998. Orthopaedic surgeons do not generally list people for knee replacements if they look or are significantly frail. Such patients tend to make poor functional recoveries.
- 4.4 Mrs Devine's physical deterioration can be marked by her slowly falling haemoglobin from 13 in 1998 (317) to 9.9 (289) in November 1999. Her albumin also falls and is documented at 22 in July 1999 (52) then extremely low at 18 (349) on admission to Gosport. At the same time her creatinine rises over the course of the year from 90 in 1998 to 160 in June 1999 and around 200 on admission to the Queen Alexandra Hospital in October 1999. The physicians, including the renal physician and the haematologist that she saw, all conclude this was a progressive problem with no easily treatable or remedial cause. The small kidneys shown on ultrasound usually suggest irreversible kidney pathology. I would agree with that assessment.
- 4.5 The history taken by the mental health team from her daughter, also describe mental deterioration and increasing confusion over the course of

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- the year. Such confusion is often missed in hospital appointments, although the comment that she did not bring her drugs or know what drugs she was taking in September 1999 (40) is a marker of probable mental impairment. The notes fail to come to any definitive diagnosis as to whether this is Alzheimer's disease or vascular dementia. This is difficult and cannot be criticised. It is probably more likely to be vascular dementia on its basis of its moderately rapid progression, and that she had another systematic illness going on identified by the renal physician as probable glomerulonephritis.
- 4.6 When admitted to the Queen Alexandra Hospital with significant behavioural problems the original working assumption was that this was an acute event, caused by a probable underlying infection. However, no infection was ever demonstrated on the investigations ordered, and no pyrexia was identified, although the admission notes are missing. It is likely that her behaviour had gradually been deteriorating, the crisis then occurred with the social crisis in her family. Admitting patients acutely to hospital will often exacerbate confusion in an already underlying dementing illness.
- 4.7 The natural history of most dementia's is of some fluctuation on a downward course, both in terms of symptoms and progression of the underlying disease. When seen by the mental health team on 15th October (28), though her behaviour was not seriously disturbed at that time, they documented a mini-mental state examination of 9/30 indicating moderate to severe underlying dementia. The mental decline had been rapidly progressive over the same year, as had her physical decline. Although she received Haloperidol at Queen Alexandra, and Thioridazine at Gosport I think it is unlikely that any therapeutic intervention significantly altered the progression of either her mental or her physical deterioration.
- 4.8 On admission to Gosport Dr Barton writes in the notes that the patient has Myeloma (a malignant disease) rather than the Paraproteinaemia (a pre-malignant condition) that has actually been diagnosed. She may have mistakenly believed that she had a progressive cancer as well as her dementia and renal failure. This (not uncommon mistake by non-specialists) might have influenced the management of care, by making Dr Barton think the patient had an untreated malignant condition.

There is no physical examination of the patient on admission, or if there was, it is not recorded in the notes.

When transferred to the Gosport Hospital on 21st October, probably to await nursing home placement, she had a number of markers suggesting a very high risk of in-hospital death. She had been in hospital over two weeks, the longer you are in hospital the more likely you are to die in hospital. She had a possibility of delirium on top of a rapidly progressive dementing illness, again a marker of high in-hospital mortality and finally,

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she had an extremely low albumin of 18, probably one of the strongest markers of a poor outcome. Serum albumin is an indirect marker of nutritional status, in particular a marker of protein metabolism. A low albumin and poor nutritional status makes a patient highly susceptible to infection, pressure sores and an inability to cope with the physiological stresses.

- 4.9 On 25th October she appears to be stable in the ward environment at Gosport, however, by the 1st November there has been a deterioration and she is noted to have become quite confused and is wandering again.
- 4.10 On admission under the routine drugs that were prescribed, it is noted that both Hyoscine and a dose of Diamorphine were written up prn. No explanation of this management decision is made in the notes, nor has any pain been recorded in the notes.
- 4.11 There are no medical notes between the 1st November and the 15th November at which time she is noted to be very aggressive and very restless, there must have been clinical deterioration over that period of time. Blood tests are sent on 9th November (289) and an MSU has also been sent and reported on 11th November (363) although this is normal. It is unlikely that these tests would have been done if there had not been a significant change in her condition. Indeed, it appears that she was put on antibiotics for a presumed (subsequently proved mistakenly) urinary tract infection. Either the tests and antibiotics prescription were undertaken without seeing the patient, or the patient was seen and no record was made in the notes. Both would be poor medical practice.

The drug chart analysis also demonstrates she was now receiving regular Thioridazine, an anti-psychotic medication which is often prescribed for significantly disturbed behaviour in older patients. The change in behaviour noted, the new medication started, the antibiotics prescribed (277,276) and the blood and urine tests carried out (289,363) all suggest a significant change in condition. Yet the lack of medical notes makes a proper assessment of the situation difficult and is poor clinical practice.

- 4.12 The simple investigations and pragmatic management does not work though. By 18th November she has deteriorated further, is very restless and confused and is now refusing medication. Further blood tests have been carried out on 16th November that now show that creatinine has almost doubled to 360 and her potassium is 5.6. She is now in established acute on chronic renal failure. A patient who is already frail and running with a creatinine of over 200 can extremely rapidly decompensate and become seriously ill. On 19th November there is further marked deterioration overnight.

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- 4.13 There is no doubt this lady is now very seriously ill. The question that would have to be answered between the 15th and 19th, was this a further acute event that could be easily reversed. The straightforward investigations had been performed and the decision would presumably be to have to return the lady to the District General Hospital for further investigation and management, possibly even on a high dependency unit. The other possible decision to be made was that this was a progression of a number of incurable problems and actually she was terminally ill. In these circumstances the decision would then be to decide what form of symptomatic or palliative care was most appropriate.

Mrs Devine was seen by Dr Reid on 15th and Dr Barton may have seen her on the on 18th, the day Fentanyl was started. This should be clarified as no clinical note is made on the 18th. This is poor practice.

- 4.14 It may have been in the mind of the doctor who (possibly) saw her on 18th that she probably was terminally ill. Evidence for this is that she started her on a Fentanyl patch on top of the regular Thioridazine, which she was already receiving. However, the logic of starting the Fentanyl patch is not explained in the notes, and the psychiatric doctor who saw her the same day thought her physical condition "was stable". Further Fentanyl is a slow release opioid analgesic, which the BNF states it is not suitable for acute pain or when rapid changes in analgesia are required. The reason is that although Fentanyl 25 is the equivalent of 90 mgs of Morphine a day it will take several days to get to a steady state drug level. However, the normal starting dose of Morphine for pain is 30 – 60 mgs a day thus the lack of explanation for the choice of Fentanyl, or the dose chosen, in a patient without documented pain is poor clinical practice.
- 4.15 It is my opinion, certainly by the 19th November, this lady was terminally ill and it was a reasonable decision to come to this conclusion. However, it is possible that her more rapid deterioration was due to the use of Fentanyl on top of her other medical problems. Equally not all clinicians would come to exactly the same conclusion and some might have referred her back to the DGH when a creatinine of 360 was noted on 16th November. However, on balance I believe that many clinicians would come to the same conclusion after a month in hospital.
- 4.16 Having made the decision that the lady was terminally ill, the next decision was whether or not to offer palliative care. Mrs Devine was reported as extremely restless and aggressive and in some distress. In my view it would now be appropriate to provide high quality palliative care.

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- 4.17 She is then written up for Diamorphine and Midazolam by subcutaneous infusion and the Fentanyl patch prescribed the previous day is removed. There was a three-hour overlap in the prescription of these drugs but this is unlikely to have had a major clinical effect. There is also a discussion regarding her status with a member of her family. There appears to be no dissent as to the appropriateness of her proposed care with either the nurses or the family.
- 4.18 Two drugs are used, Diamorphine and Midazolam intravenous infusion pump. The main reason for using both was terminal restlessness. There is no doubt that Midazolam is widely used subcutaneously in doses from 5 – 80 mgs per 24 hours. The dose of Midazolam used was 40 mgs per 24 hours, which is within current guidance although many believe that elderly patients may need a lower dose of 5 – 20 mgs per 24 hours (Palliative Care. Chapter 23 in Brocklehurst's Text Book of Geriatric Medicine 6th Edition 2003).
- 4.19 The addition of Diamorphine is more contentious. Although there was serious restlessness and agitation in this lady, no pain was definitively documented and Diamorphine is particularly used for pain in terminal care. Diamorphine is compatible with Midazolam and can be mixed in the same syringe driver. However, despite the lack of pain Diamorphine is widely used, and believed to be a useful drug, in supporting patients in the terminal phase of restlessness. One study of patients on a long stay ward (Wilson J.A et al Palliative Medicine 1987; 149 – 153) found that 56% of terminally ill patients on a long-stay ward received opiate analgesia. The dose of Diamorphine actually prescribed was 40 mgs. The normal starting dose for pain, of morphine, is 30 – 60 mgs and Diamorphine subcutaneously is usually given at a maximum ratio of 1:2 (i.e. 15 – 30 mgs). Mrs Devine was prescribed on an unusually high starting dose of Diamorphine although probably equivalent to the dose of Fentanyl already started. There is no explanation of this decision in the notes.
- 4.20 24 hours later Mrs Devine is reported to be comfortable and without distress, she finally dies approximately 58 hours after starting the mixture of Diamorphine and Midazolam, and as far as can be deciphered from the notes, without distress.
- 4.21 The prediction how long a terminally ill patient will live is virtually impossible and even palliative care experts show enormous variation (Higginson I.J. and Costantini M. Accuracy of Prognosis Estimates by 4 Palliative Care teams: A Prospective Cohort Study. BMC Palliative Care 2002 1:1.) I believe that it is certainly possible; that without any treatment, considering her creatinine of 360 on 16th November, she would have been dead on the 21st November.

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- 4.22 There is no explanation in the notes for the apparently high doses of drugs used to relieve her symptoms considering her age of 88 years and her previous lack of use of analgesia. It is possible that the medication did shorten her life by a short period of time but she was also out of distress for the last 58 hours.

5. OPINION

- 5.1 Mrs Elsie Devine presents an example of the most complex and challenging problems in geriatric medicine. This included progressive medical and physical problems causing major clinical and behavioural management problems to all the care staff she comes into contact with.

- 5.2 However there were significant failing in the medical care provided to Mrs Devine, in particular:

- The failure to undertake a physical examination of the patient on admission to the Gosport War Memorial Hospital, or if it was undertaken the failure to record in the notes.
- The prescription of PRN Oramorphine in admission to the Gosport War Memorial Hospital in a patient with no recorded pain or condition likely to need Oramorphine.
- The failure to see the patient between the 1st – 15th November yet to order blood tests and antibiotics, or if she was seen, to make a record in the notes.
- The failure to make any medical notes or explanation on the 18th November as to why Fentanyl was started and why the dose chosen was used.
- The failure to provide any explanation for the use of Diamorphine and the choice of an apparently high starting dose in the syringe driver.

- 5.3 There was also deficiencies in the use of the drug chart at the Gosport War Memorial Hospital, in particular:

- The 'Regular' prescription of Fentanyl is never crossed off the drug chart although replaced by the syringe driver.
- Prescribing a range of doses of both Diamorphine and Midazolam on the regular side of the drug chart.
- The failure to write dosages of controlled drugs in words and figures as well as total dosages given.

6. EXPERTS' DECLARATION

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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.

10. 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: _____