PROFESSOR BLACK

BLACK

Version 2 of complete report 4th January 2005 – Elsie Devine

SUMMARY OF CONCLUSIONS

Mrs Elsie Devine was an 89-year-old lady admitted to the Queen Alexandra Hospital following a crisis at home on the 21st 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.

The expert opinion is:

> 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.
>
> The major problem in deciding whether this lady's care was sub- optimal is the lack of documentation. Good medical practice (GMC, 2001) states that "good clinical care must included an adequate assessment of the patient's condition, based on the history and symptoms and, if necessary, an appropriate examination"... "in providing care you must, keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed". The major gaps in the written notes, as documented in my report, represent poor clinical practice to the standards set by the General Medical Council. However, by itself it does not prove that the care actually received by Mrs Devine was sub-optimal, negligent or criminally culpable.
>
> In my view the drug management at Gosport was sub-optimal. There was no apparent justification for the Diamorphine to be written up prn on admission to Gosport. The logic for the prescription of Fentanyl is not explained, there was a three hour overlap between the prescription for the subcutaneous Diamorphine and Midazolam and the removal of the Fentanyl patch, the starting doses of both Midazolam and Diamorphine were higher than conventional guidance. The effect of higher than standard dosage of Diamorphine and Midazolam may have shortened her life by a short period of time. This would have been no more than hours to days. However, she was already terminally ill and appeared to receive good palliation of her symptoms. While her care was sub-optimal I cannot prove it negligent or criminally culpable.

Professor Black

Version 2 of complete report 4th January 2005 – Elsie Devine

SUMMARY OF CONCLUSIONS

Mrs Elsie Devine was an 89-year-old lady admitted to the Queen Alexandra Hospital following a crisis at home on the 21st 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.

The expert opinion is:

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.

The major problem in deciding whether this lady's care was sub- optimal is the lack of documentation. Good medical practice (GMC, 2001) states that "good clinical care must included an adequate assessment of the patient's condition, based on the history and symptoms and, if necessary, an appropriate examination"... "in providing care you must, keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed". The major gaps in the written notes, as documented in my report, represent poor clinical practice to the standards set by the General Medical Council. However, by itself it does not prove that the care actually received by Mrs Devine was sub-optimal, negligent or criminally culpable.

In my view the drug management at Gosport was sub-optimal. There was no apparent justification for the Diamorphine to be written up prn on admission to Gosport. The logic for the prescription of Fentanyl is not explained, there was a three hour overlap between the prescription for the subcutaneous Diamorphine and Midazolam and the removal of the Fentanyl patch, the starting doses of both Midazolam and Diamorphine were higher than conventional guidance. The effect of higher than standard dosage of Diamorphine and Midazolam may have shortened her life by a short period of time. This would have been no more than hours to days. However, she was already terminally ill and appeared to receive good palliation of her symptoms. While her care was sub-optimal I cannot prove it negligent or criminally culpable.

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.

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

3. CURRICULUM VITAE

Name David Andrew Black

Address Code A

Telephone Code A **E-mail:** Code A

DOB Code A

Place Windsor, England.

Marital status Married with 2 children.

GMC Full registration. No: 2632917

Defence Union Medical Defence Union. No: 152170C

EDUCATION

Leighton Park School, Reading, Berks.	1969-1973
St John's College, Cambridge University.	1974-1977
St Thomas' Hospital, London SE1	1977-1980

DEGREES AND QUALIFICATIONS

BA, Cambridge University	1977

(Upper Second in Medical Sciences)	
MB BChir, Cambridge University	1980
MA, Cambridge University	1981
MRCP (UK)	1983
Accreditation in General (internal) Medicine	
and Geriatric Medicine	1989
FRCP	1994
MBA (Distinction) University of Hull.	1997
Certificate in Teaching	2001
NHS/INSEAD Clinical strategists program	2003

SPECIALIST SOCIETIES

British Geriatrics Society

British Society of Gastroenterology

British Association of Medical Managers

PRESENT POST

Dean Director of Postgraduate Medical and Dental Education	
Kent, Surrey and Sussex Deanery.	2004-present
Consultant Physician (Geriatric Medicine)	1987-present
Queen Marys Hospital, Sidcup, Kent.	
Associate member General Medical Council	2002-present

PREVIOUS POSTS

Associate Dean.	
London Deanery.	2004
Medical Director (part time)	1997-2003
Queen Mary's Hospital	
Operations Manager (part time)	1996-1997
Queen Marys Hospital, Sidcup, Kent	
Senior Registrar in General and Geriatric Medicine	

Guy's Hospital London and St Helen's Hospital Hastings.	1985-1987
Registrar in General Medicine and Gastroenterology St Thomas' Hospital, London.	1984-1985
Registrar in General Medicine Medway Hospital, Gillingham, Kent	1983-1984
SHO rotation in General Medicine Kent & Canterbury Hospital, Canterbury	1982-1983
SHO in General Medicine Kent & Sussex Hospital, Tunbridge Wells	1981-1982
House Physician, St Thomas' Hospital	1981
House Surgeon, St Mary's Portsmouth	1980

PUBLICATIONS

Acute Extrapyramidal Reaction to Nomifensine
DA Black, IM O'Brien
Br Med J, 1984; 289; 1272

Transit Time in Ulcerative Proctitis
DA Black, CC Ainley, A Senapati, RPH Thompson
Scand J Gasto, 1987; 22; 872-876.

Lingual Myoclonus and Dislocated Jaw
DA Black, S Das
Br Med J, 1986; 292; 1429

Endoscopic Sclerotherapy for Bleeding Oesophageal Varices in the Elderly
DA Black, RPH Thompson
J Clin and Exper Gerontol, 1987; 9: 131-138

Mental State and Presentation of Myocardial Infarction in the Elderly
DA Black
Age and Ageing, 1987; 16; 125-127

Hyperbilirubinaemia in the Elderly
DA Black, I Sturgess

J Clin and Expt Geront, 1987, 9, 271-284

Malabsorption: Common Causes and their Practical Diagnosis

DA Black

Geriatrics 1988, 43, 65-67

Pseudotumour Cerebri in a patient with Castleman's Disease

DA Black, I Forgacs, DR Davies, RPH Thompson

Postgrad Med J, 1988; 64; 217-219

Non-Surgical Intervention; A First Choice in obstructive Jaundice

DA Black

Geriatric Medicine, 1988; 18(4); 15-16

Endoscopy: Investigation of choice for many Elderly GI Problems

DA Black

Geriatric Medicine, 1988; 18(9); 14-16

Hepatic Stores of Retinol and Retinyl Esters in Elderly People

DA Black, E Heduan and WD Mitchell

Age and Ageing, 1988; 17; 337-342

Elderly People with low B12 Levels do need Treatment

DA Black

Geriatric Medicine 1989, 19(1); 21-22

NSAIDS and Ulcer disease in Old Age

DA Black

Geriatric Medicine (special supplement) April 1989; 4-5, 8-11

The Independent Living Fund

DA Black

Br Med J (editorial) 1989, 298; 1540

Ischaemic Hepatitis

DA Black

Geriatric Medicine, 1989, 19(9); 92

Laparoscopic cholecystectomy: not without pitfalls in the elderly

DA Black

Geriatric Medicine 1991 21(10); 21

The successful medical management of gastric outflow obstruction associated with the use of non-steroidal anti-inflammatory drugs in the elderly
RJ Geraghty, DA Black and SA Bruce
Postgrad Med J 1991; 67; 1004-1007
Bronchodilator response to nebulized salbutamol in elderly patients with stable chronic airflow limitation
RJ Geraghty, C Foster, DA Black & S Roe
Respiratory Medicine 1993 23(5); 46-57
The reality of community care: a geriatricians viewpoint
DA Black
In: Care of elderly people. South East Institute of Public Health 1993; 81-89
Accidents: a geriatrician's viewpoint
DA Black
In: Care of elderly people. South Thames Institute of Public Health. 1994; 53-58.
Community Care Outcomes
DA Black
Br J of Clin Pract 1995 49(1); 19-21
Choice and Opportunity
DA Black
Geriatric Medicine 1996 26(12) 7.
Emergency Day Hospital Assessments
DA Black
Clinical Rehabilitation. 1997; 11(4); 344-347
Geriatric Day Hospital. A future?
DA Black
Opinion in General and Geriatric Medicine. 1997, 1.1, 4-6.
The Health Advisory Service
DA Black
JAGS 1997; 45; 624-625.
The Rhetoric and Reality of Current Management Training for NHS Clinical Directors

DA Black
MBA dissertation. 1997. University of Hull.
Community Institutional Medical Care- for the frail elderly.
DA Black & CE Bowman
Br Med J. (Editorial). 1997, 315; 441-442.
Remains of the day.
DA Black
Health Services Journal. 1998. 19 Feb. p32.
Nutritional problems in old age
DA Black
Opinion in General and Elderly Medicine. 1998. 2(1): 12-13.
Constipation in the elderly :causes and treatments.
DA Black
Prescriber. 1998; 9(19); 105-108.
Intermediate not Indeterminate Care
CE Bowman & DA Black
Hospital Medicine. 1998; 58; 877-9
Improving geriatric services
DA Black
JRColl Physicians Lond 1999; 33: 113. (also p152)
General internal medicine and speciality medicine- time to rethink the relationship.
JM Rhodes, B Harrison, D Black et al.
JR Coll Physicians Lond 1999, 33: 341-347.
Iron deficiency in old age
DA Black & CM Fraser.
British Journal of General Practice. 1999; 49; 729-730
A systems approach to elderly care
DA Black, C Bowman, M Severs.
Br J Health Care Management, 2000, 6(2), 49-52
The Modern Geriatric Day Hospital

PCO001183-0009

DA Black.
Hospital Medicine. 2000.61(8);539-543
Complaints, Doctors and Older People
DA Black
Age and Ageing. 2000; 29(5):389-391.
NSF Overview
DA Black
Geriatric Medicine 2001; 31(4):11-17 & 31(5)
Anaemia
D Sulch, DA Black
Geriatric Medicine 2001; 31(6): 46-49
Professional Review Mechanism. Chapter in: Clinical Governance Day to Day.
DA Black.
British Association of Medical Managers 2002; 41-56.
Induction for newly appointed consultants
DA Black
Clinician in Management. 2002; 11(1); 9-13
Average length of stay, delayed discharge and hospital congestion.
DA Black and M Pearson
BMJ 2002;325:610-611
An audit of outcomes in day hospital based crisis interventions.
David A Black
Age Ageing 2003; 32; 360-361
Quality Improvement in the UK
DA Black
Chapter 119 In: Brocklehurst's Textbook of Geriatric Medicine. 6th Edition Ed: Tallis and Fillit. 2003.
The new NHS framework for handling performance concerns.
David A Black
Hospital Medicine 2004; 65 (2): 112-115
Not because they are old- revisited

DA Black
Age and Ageing. 2004;33; 430-432

BOOK

British Geriatrics Society compendium of policy statements and statements of good practice. Edited by DA Black & A Main. First Edition. 1995.

RECENT SIGNIFICANT PRESENTATIONS

Secondary care as part of the whole system. Laing & Buisson conference on intermediate care. April 2001
The impact of the NSF on everyday Clinical Care. Conference on Clinical governance in elderly care . RCP May 2001
The Geriatricians view of the NSF. BGS Autumn Meeting 2001
The Organisation of Stroke Care. Physicians and managers working together to develop services. Professional training and clinical governance in geriatric medicine. All at Argentinean Gerontological Society 50th Anniversary meeting. Nov 2001
The future of Geriatric Medicine in the UK. Workshop: American Geriatrics Society May 2002
Liberating Front Line Leaders. Workshop: BAMM Annual Meeting June 2002
Revalidation - the State of Play. A Survival Guide for Physicians. Mainz July 2002
Medical Aspects of Intermediate Care. London Conference on building intermediate care services for the future. Sept 2002
Developing Consultant Careers. Workshop: BAMM Medical Directors Meeting. Nov 2002
Lang and Buisson. Update on Intermediate Care Dec 2002
Intermediate Care Update: London National Elderly Care Conference. June 2003.
Appraisal- an update. GMC symposium on revalidation. Brighton. June 2003.
Innovations in emergency care for older people. HSJ Conference. London July 2003.
Emergency Care & Older People: separate elderly teams? RCP London March 2004
Professional Performance & New Consultants. London Deanery Conference April 2004

Mentoring as part of induction for new consultants. Mentoring in Medicine Conference. Nottingham. April 2004

The Future of Chronic Care- Where, How and Who? CEO & MD conference. RCP London. June 2004

Mentoring as part of consultant induction. Surviving to Thriving. New Consultant Conference, London June 2004

360 Degree Appraisal. Chairman National Conference. Nottingham June 2004

Maintaining Professional Performance. BAMM Annual Summer School. June 2004

Chronic Disease management. BGS Council Study Day. Basingstoke. July 2004

MMC post FP2. BGS Study Day. Basingstoke. July 2004

Designing care for older peoples. Emergency services conference. London July 2004.

The Modern Geriatric Day Hospital. Multidisciplinary Day. South East Kent hospitals. Sept 2004

Geriatricians and Acute General Medicine. BGS Autumn Meeting . Harrogate Oct 2004

4. DOCUMENTATION

This Report is based on the following documents:

[1] Full paper set of medical records of Elsie Devine.

[2] Full set of medical records of Elsie Devine 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 Elsie Devine.

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

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

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

5.1. In March 1998 (120) she was seen in a geriatric outpatient department with cellulitis, mild hypothyroidism, mild CCF, haemoglobin of 13 (317) and a creatinine of 90 (337).

5.2. In December 1998 she was seen in an orthopaedic clinic (102) and was found to be clinically fit for a knee replacement.

5.3. In March 1999 her haemoglobin was 12.8 (311) and her creatinine in February was 143 (325).

5.4. 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).

5.5. 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 glumerulonenephritis (60) and she had an incidental IgA paraproteinaemia. Her Creatinine was 192 and her haemoglobin 10.5 (295).

5.6. 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.

5.7. On the 12th October (31) she is noted to be distressed and agitated and undergoes a CT scan of her head, which shows involutional 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).

5.8. 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 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).

5.9. 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.

5.10. 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.

5.11. On 21st October she is received to the Gosport War Memorial Hospital and is transferred for "continuing care" (154). Her Barthel dependency is noted to be 8 and her Mini Mental Score is 9/30. Dr Barton incorrectly writes that she has 'Myeloma' (154) in the notes.

5.12. On 25th October she is mobile unaided, washes with supervision, remains confused.

5.13. 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.

5.14. 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.

5.15. 18th November (156) she has rapidly deteriorated, become more restless and aggressive and is refusing medication. She is seen by the mental

health team who note that in their view that there was no new physical problem ongoing and put her on the waiting list for Mulberry Ward. Creatinine on 16th November is 360 and a potassium 5.6 (349).

5.16. 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" (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."

5.17. 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."

5.18. 21st November. Nursing notes (223), "condition continues to deteriorate slowly. Asked to see at 20.30 hours patient died peacefully"

5.19. 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 Diamorphine 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.

6 TECHNICAL BACKGROUND / EXAMINATION OF THE FACTS IN ISSUE

6.1. 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.

6.2. In particular I will discuss:
a) whether it was appropriate to decide on 19th November that Mrs Devine was terminally ill and if so whether symptomatic treatment was appropriate
and
b) whether the treatment that was provided was then appropriate.

6.3. 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.

6.4. 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.

6.5. The history taken by the mental health team from her daughter, also describe mental deterioration and increasing confusion over the course of 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 rapid progression, and that she had another systematic illness going on identified by the renal physician as probable glomerulonenephritis.

6.6. 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.

6.7. 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.

6.8. 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 in non-specialists) might have influenced the management of care.

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, 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.

6.9. 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.

6.10. On admission under the routine drugs that were prescribed, it is noted that both Hyoscine and a small dose of Diamorphine were written up prn. It is often common practice in hospitals where there are non-resident staff or great shortage of medical staff to try and write up all possible drugs that might need to be prescribed as prn drugs, so that if a crisis occurs a needed drug can be prescribed by a nurse without a doctor having to immediately attend. In my experience it is unusual though for a patient who has no known causes of severe pain, nor had an underlying cardiac condition to write up Diamorphine prn and indeed, Hyoscine is normally written up for treating upper airway secretions in dying patients.

A possible interpretation is that actually many of the patients transferred to this ward for "continuing care" or "slow-stream rehabilitation" were actually patients who it was expected were unlikely to leave hospital. A group of patients who are not immediately dying but who are either too ill to be put through the trauma of applying and moving to a nursing home, only to die shortly after, or is not clear what their outcome will be, certainly exists in all hospitals. It may be that as it was not unusual for patients to actually become (appropriately and expectedly) terminally ill, it had become normal practice to write up drugs that might be needed. In my view this is poor clinical practice, even if it might appear pragmatic practice.

6.11. 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.

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 major change in condition. Yet the lack of medical notes makes a proper assessment of the situation difficult and is poor clinical practice.

6.12. 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 200 can extremely rapidly decompensate and become seriously ill. On 19th November there is further marked deterioration overnight.

6.13. There is no doubt this lady is now very seriously ill. The question that would have to be answered by the doctors (she was seen by both Dr Reid and Dr Barton) on 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. This is poor practice. Dr Barton is a Clinical Assistant and I am not currently aware of the status of Dr Reid. It is not clear from the notes whether any further advice was obtained from the consultant legally responsible for the care of this patient or whether Drs Barton and Reid were highly experience and knowledgeable clinicians working with a considerable degree of clinical freedom based on a long-standing relationship with their clinical consultant.

6.14. It was presumably in the mind of the doctor who (probably) 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. This is an opioid analgesic usually reserved for severe pain, but it is possible that it was prescribed for severe restlessness in a terminally ill patient (see paragraph 2.20). The lack of explanation is poor clinical practice.

6.15. 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. 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.

6.16. 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 inappropriate not to provide high quality palliative care.

6.17. 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.

6.18. A pharmacist's opinion should be obtained on the actual way the drug was prescribed. I am not certain the prescription of Diamorphine follows national guidance in writing dosages in words and figures as well as the total dosages. It is also written in a way that leaves some discretion to the dosage to be used to the nursing staff.

6.19. 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 slightly lower dose of 5 – 20 mgs per 24 hours (Palliative Care. Chapter 23 in Brocklehurst's Text Book of Geriatric Medicine 6th Edition 2003).

6.20. 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 ratio of 1:2 (i.e. 15 – 30 mgs). It could therefore be argued that Mrs Devine was prescribed up to twice the usual starting dose of Diamorphine. There is no exact science to judging the dose of Diamorphine to give, although it is normal clinical practice to start low and increase the doses rapidly to obtain symptom control.

6.21. In my view the death certificate would appropriately say:
1a: Acute on-chronic renal failure
1b: Chronic Glomerulonephritis

2a: IgA Paraproteinaemia
2b: Dementia

At the time of writing I have not seen the death certificate.

6.22. 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.

6.23. 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; it may even have been probable that without any treatment, considering her creatinine of 360 on 16th November, she would have been dead on the 21st November.

6.24. It is also apparent that the doses of drugs used to relieve her symptoms were high considering her age of 89 years and her previous lack of use of either of medications. 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.

6.25. I am therefore not able to say that the use of Fentanyl, Diamorphine and Midazolam were prescribed with the intention of deliberately shortening her life or indeed, nor that they had the definite effect of shortening her

life in more than a minor fashion.

7. OPINION

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

7.3 The major problem in deciding whether this lady's care was sub-optimal is the lack of documentation. Good medical practice (GMC, 2001) states that "good clinical care must included an adequate assessment of the patient's condition, based on the history and symptoms and, if necessary, an appropriate examination"... "in providing care you must, keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatments prescribed". The major gaps in the written notes, as documented in my report, represent poor clinical practice to the standards set by the General Medical Council. However, by itself it does not prove that the care actually received by Mrs Devine was sub-optimal, negligent or criminally culpable.

7.3 In my view the drug management at Gosport was sub-optimal. There was no apparent justification for the Diamorphine to be written up prn on admission to Gosport. The logic for the prescription of Fentanyl is not explained, there was a three hour overlap between the prescription for the subcutaneous Diamorphine and Midazolam and the removal of the Fentanyl patch, the starting doses of both Midazolam and Diamorphine were higher than conventional guidance. The effect of higher than standard dosage of Diamorphine and Midazolam may have shortened her life by a short period of time. This would have been no more than hours to days. However, she was already terminally ill and appeared to receive good palliation of her symptoms. While her care was sub-optimal, I can not prove it negligent or criminally culpable.

8 LITERATURE/REFERENCES

1. Good Medical Practice, General Medical Council 2002
2. Withholding withdrawing life, prolonging treatments: Good Practice and decision making. General Medical Council 2002.

3. Palliative Care, Welsh J, Fallon M, Keeley PW. Brocklehurst Text Book of Geriatric Medicine, 6th Edition, 2003, Chapter 23 pages 257-270.
4. The treatment of Terminally Ill Geriatric Patients, Wilson JA, Lawson, PM, Smith RG. Palliative Medicine 1987; 1:149-153.
5. Accuracy of Prognosis, Estimates by 4 Palliative Care Teams: A Prospective Cohort Study. Higginson IJ, Costantini M. BMC Palliative Care 2002:1:129

9. 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.

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.

Version 2 of complete report 4th January 2005 – Elsie Devine

Signature:______________________________________ Date: ________________