Report

on the Case of

Gladys Mabel Richards deceased

For The Coroner

at the request of

Blake Lapthorne
Solicitors for Mrs Gillian MacKenzie
(daughter of the deceased)

by Professor R E Ferner
BSc MSc MB BS MD FRCP, FBritPharmacolS,
FBritToxicolS

Of

West Midlands Centre for Adverse Drug Reactions
City Hospital NHS Trust
Dudley Road
Birmingham B18 7QH

Dated 28th August 2012

Introduction

1. I am a Consultant Physician and Clinical Pharmacologist at City Hospital, Honorary Professor of Clinical Pharmacology at the University of Birmingham, and Director of the West Midlands Centre for Adverse Drug Reactions.

2. Since I qualified in 1978 and up to October 2010 I have seen many hundreds of general medical patients each year admitted to hospital as acute medical admissions. I have also been, and continue to be, responsible for outpatients with general medical conditions.

3. I teach and undertake research in clinical pharmacology, which is the study of drugs and medicines and their use in clinical practice.

4. I am an elected Fellow of the Royal College of Physicians, the British Pharmacological Society, and the British Toxicology Society; and a Registered Toxicologist.

5. My curriculum vitae is appended at Appendix 1.

6. I have been asked to consider the case of Gladys Mabel Richards with particular reference to the pain relief regimen provided to Mrs Richards; the cause of Mrs Richards's death; and the possible contribution of opiate pain relief to Mrs Richards's death.

7. I previously considered this as one of 86 cases investigated by the Hampshire Constabulary in or about 2003. At that time I was one of a small group of experts who considered each of the cases from the perspective of potential criminal charges. My understanding was, and remains, that for criminal charges to result in conviction it has to demonstrated beyond reasonable doubt that negligence caused death, and that the negligence could be categorised by a jury as 'gross'.

8. I see by reference to brief notes I made at that time that I did not consider it possible to demonstrate to the required standard that Mrs Richards's death was anything other than natural; or that there had been negligence. I believed, however, that prescribing had been suboptimal.

9. My understanding is that, for the purposes of the Coroner, it is necessary to consider the cause of death 'on the balance of probabilities.'

10. In order to assist me I have been provided with copies of the following documents, not all of which I will have seen in the past.

11. These documents are:

A. Record of interview with Gillian MacKenzie part 1

B. Record of interview with Gillian MacKenzie part 2

C. Statement of Gillian MacKenzie

D. Statement of Lesley Lack (Richards) 31st January 2000

E. Statement of Lesley Richards (previously Lack) 11th August 2004

F. Statement of Dr Richard Reid 7th June 2000

G. Statement of Dr Jane Barton undated

H. Record of interview with Phillip Beed
11.00 hours 24th July 2000

I. Record of interview with Phillip Beed
12.14 hours 24th July 2000

J. Record of interview with Phillip Beed
14.12 hours 24th July 2000

K. Record of interview with Phillip Beed
14.58 hours 24th July 2000

L. Record of interview with Phillip Beed
15.52 hours 24th July 2000

M. Record of interview with Margaret Couchman

10.26 hours 29th June 2000

N. Record of interview with Margaret Couchman

11.17 hours 29th June 2000

O. Record of interview with Christine Joyce

12.00 hours 15th June 2000

P. Record of interview with Christine Joyce

12.51 hours 15th June 2000

Q. Health records from Portsmouth Health Care

R. Medical records for Gladys Richards Institute of Naval Medicine Gosport

S. Health record for Gladys Mabel Richards (LH/1) page 1–714.

Medical History

12. The medical history as I understand it is briefly set out here.

Code A

14. The general practice records from 1941 onwards indicate that Mrs Richards was generally healthy.

Code A

16. In November 1987 she required treatment with the corticosteroid prednisolone for presumed polymyalgia rheumatic [an inflammatory disease of muscle]. [S.428].

17. By October 1988 she was noted to have a severe lack of short term memory [S.431], initially ascribed to 'benign forgetfulness'. A trial of

antidepressants achieved no improvement. [S.500]. A diagnosis of senile dementia was recorded on the 18th August 1994, when an abbreviated mental test score was 4 out of 10 [S.443]. By that time Mrs Richards was living in the Glen Heathers Rest Home. A reassessment in November 1996 showed a mental test score to be zero. [S.451].

18. On the 4th February 1998 Gladys Richards was assessed at Glen Heathers by Dr V A Banks, Consultant in Old Age Psychiatry, who noted that 'this is a lady with severe dementia with, I think, end stage illness ...'

19. Dr Banks recommended treatment with haloperidol 500 micrograms three times daily as a regular prescription, and the possibility of adding trazodone 50 mg each morning. [S.472–73]. By March that year, Dr Banks found Mrs Richards to be 'more settled'. [S.470].

20. Records from 15th April 1996 to the 17th July 1998 show Mrs Richards to have fallen at least 20 times. [S.160–82].

21. On the 29th July 1998 Mrs Richards fell again and broke her right hip. [S.158. R39–44]. She was admitted to the Royal Naval Hospital Haslar and underwent surgery for hip replacement the following day. [R.53].

22. Mrs Richards was seen in hospital by Dr Reid, Consultant Geriatrician, who noted 'I have stopped her trazodone as her daughters feel that she is much more alert [?without] it. And added 'if she becomes noisy try either increased haloperidol or thioridazine'. [R.56].

23. In the early hours of the 8th August 1998 a House Officer was asked to see Mrs Richards because she was noisy and agitated. Although she fell asleep, he revisited her at 01.30 hours and prescribed 25 mg thioridazine.

24. Staff Nurse Code A wrote on the 10th August 1998 '...she is now fully weight bearing, walking with the aid of two nurses and a Zimmer frame ... Gladys needs total care with washing and dressing, eating and drinking, although her daughters are extremely devoted and like to come in and feed her at mealtimes... Gladys has a soft diet and enjoys a cup of tea ... Gladys is continent, when she becomes fidgety and agitated it means that she wants the toilet.' [R.59].

25. A brief note from the 11th August 1998 reads:

'transferred to [?] ward continuing care
'HPC (R) # NOfemur 30-7-98
'PMH hysterectomy 1955
'Cataract operations
'Deaf
'Alzheimer's
'O/E impression frail demented lady
'Not obviously in pain
'Please make comfortable
'Transfers with hoist
'Usually continent
'Needs help with ADL
'BARTEL 2
I' am happy for nursing staff to confirm death [initialled] JAB.'
[S.29].

26. I take HPC to mean history of presenting complaint

R to mean right
to mean fracture
NOfemur to mean neck of femur
PMH to mean past medical history
O/E to mean on examination
ADL to mean activities of daily living

JAB to be the initials of Jane Ann Barton.

27. The medication information on admission is recorded as:

Lactulose 10 ml twice daily by mouth

Haloperidol 1 mg twice daily by mouth....

[S.43].

28. A prescription written and signed by Dr Barton on the 11th August 1998 is for those two drugs. In addition as required medication includes:

Morphine sulphate oral solution (Oramorph) 10 mg in 5 ml 2.5 – 5 ml 4 hourly

Diamorphine 20-200 mg by subcutaneous infusion over 24 hours

Hyoscine 200-800 micrograms by subcutaneous infusion over 24 hours

Midazolam 20-80 mg by subcutaneous infusion over 24 hours.

[S.62].

29. The next entry appears to be made on the 12th August 1998, and is made on the regular prescription part of the drugs chart for:

Morphine sulphate oral solution

10 mg in 5mls [Oramorph] 2.5 mls 4 hourly by mouth

Oramorph 10 mg in 5mls orally nocte [at night].

30. Although these prescriptions are written on the regular prescription chart, they are endorsed in the margin PRN.

31. I take PRN to mean *pro re nata* - 'as required'. [S.64].

32. [I have been unable to find any related entry in the medical or nursing records to explain these prescriptions].

33. Two doses of morphine sulphate 10 mg appear to have been given on the 11th August 1998, one on the 12th August 1998 and one on the evening of the 13th August 1998. A further dose of 10 mg was given on the 14th August 1998. [S.62].

34. The next sequential entry appears to be related to a fall at 13.00 hours on the 13th August 1998, recording that no injury was apparent; followed by an entry at 19.30 hours 'pain right hip internally rotated Dr Brigg contacted advised X-ray at am and analgesia during the night. Inappropriate to transfer for X-ray thus daughter informed.' [Signed]. [S.45].

35. At 13.00 hours on the 13th August a dose of haloperidol 2 mg per ml, 0.5 ml [1 mg] was administered against a prescription written that day 'if noisy'. [S.66].

36. A note from the 14th August 1998 reads:

> 'Sedation/pain relief has been a problem.
> 'Screaming not controlled by haloperidol by 1 gm/tds [sic] but very sensitive to Oramorph.
> 'Fell out of chair last night.
> '(R) hip shortened and internally rotated
> 'Daughter aware and not happy
> 'Please X-ray
> 'Is this lady well enough for another surgical procedure?
> [Initialled JAB].' [S.29].

37. An X-ray shows a dislocation of the hip replacement. [S.77].

38. On the afternoon of the 14th August Mrs Richards was readmitted to the Royal Naval Hospital Haslar.

39. P Beed, Charge Nurse on Daedalus Ward, noted in a letter to 'Haslar A & E' that there had been no change in treatment since transfer except for the addition of Oramorph as required. [S.61]. A letter from Dr Barton to Lieutenant Commander Spalding thanked him for readmitting Mrs Richards for the dislocation of her replaced hip. [S.63].

40. Mr Beed states that Mrs Richards was given 10 mg of morphine sulphate at 11.50 hours; Dr Barton states that she was given 15 mg [7.5 mls] at midday.

41. The blood test recorded in the Haslar notes include a creatinine concentration of 98 micromoles per litre, a urea concentration of 5 mmol/L, and haemoglobin of 148 g/L. [Normal results showing no evidence of kidney failure, dehydration, or anaemia.] [R.45].

42. The dislocation was reduced under intravenous midazolam and at 14.00 hours on the 14th August 1998. [S.67].

43. The reduction was carried out on the Accident Department trolley under anaesthesia. [S.73].

44. A note from 22.15 hours that day suggests that she had remained unresponsive for some time. [S.67].

45. A note from the 15th August 1998 states '...she is now fully alert and has begun taking oral fluids. She remains disorientated. She has been given co-codamol and has been maintained on 2 litres O_2 by nasal specs...' [S.198].

46. By the 17th August 1998 the registrar judged that Mrs Richards was fit for discharge. [R.68].

47. When readmitted to [?Daedalus] Ward at Gosport War Memorial Hospital Mrs Richards was noted to appear 'peaceful'. [S.30].

48. The note also includes the instruction 'only give Oramorph if in severe pain'.

49. When readmitted from Haslar, Mrs Richards was placed in an uncomfortable position with her leg bent. [C.12, M12].

50. A nursing note timed at 13.05 reads 'in pain and distress— agreed with daughter to give her mother Oramorph 2.5 mg in 5 ml [sic]. Daughter reports surgeon to say her mother must not be left in pain if dislocation again ... Dr Barton contacted and ordered an X-ray.' [S.46].

51. The X-ray did not show a dislocation.

52. A note on the 18th August 1998 reads:

> 'Still in great pain
> 'Nursing a problem
> 'I suggested sc diamorphine/haloperidol/midazolam
> 'I will see daughter today
> 'Please make comfortable [initialled] JAB.' [S.30].

53. I take sc to mean subcutaneous.

54. A nursing note reads 'Reviewed by Dr Barton. For pain control via syringe driver...' [S.46].

55. The regular prescription part of the drugs chart for the 18th August 1998 has prescriptions for

> diamorphine 40–200 mg in 24 hours and
> haloperidol 5–20 mg in 24 hours.

56. The recorded administrations are for three doses of morphine sulphate oral solution 5 mg in 2.5 ml on the 17th and one dose of 10 mg in 5 ml; with two further 10 mg doses of morphine sulphate oral solution at [?]00.30 and 04.30 hours on the 18th August. [S.62, S64].

57. From 11.45 hours on the 18th August 1998 40 mg diamorphine was given every 24 hours with 5 mg of haloperidol, 400 micrograms of hyoscine and 20 mg of midazolam every 24 hours. [S.62, S64].

58. By 20.00 hours on the 18th August 1998, a note reads: 'Patient remained peaceful and sleeping.' [S.47].

59. There is no indication that she was in pain or awake after that entry.

60. Mrs Richards passed no urine after the 19th August 1998. [D.14].

61. A clinical note from the 21st August 1998 read 'much more peaceful needs hyoscine for rattly chest.' [S.30].

62. At 21.20 hours that day Mrs Richards died. [S.48].

Comments

Morphine and diamorphine.

63. Morphine is an opiate drug. Opiates are drugs derived from the opium poppy. The principle opiates are morphine, diamorphine (heroin) and codeine (methyl morphine). Opiates are used to treat pain. Some also have value as cough suppressants or antidiarrhoeal agents.

64. The *British National Formulary (BNF)* is an authoritative source of prescribing information provided to prescribers in the United Kingdom twice each year by the Department of Health.

65. It describes the indications, contraindications, cautions, and dosage to be used for almost all medicines commonly prescribed in the United Kingdom. 'Indications' are the reasons for prescribing; 'contraindications' are the conditions that prevent prescribing; and 'cautions' are the circumstances in which the prescriber should take special care.

66. The *BNF* states that analgesics such as morphine and diamorphine are usually used to relieve moderate to severe pain particularly of visceral origin. It also notes that repeated administration may cause dependence and tolerance, but this is no deterrent to control of pain in terminal disease.

67. While there is no upper limit to the dose of opiate to be used in terminal care, there is always a judgement to be made between the relief of pain on the one hand and the adverse effects of opiates on the other hand.

68. These adverse effects include nausea, constipation, depression of the rate and depth of respiration, and depression of consciousness.

69. The *BNF* recommends that a reduced dose of opiate is used in elderly or debilitated patients.

70. It also notes that in the control of pain in terminal illness, the listed cautions should not necessarily deter the use of opiates.

71. Diamorphine is more potent than morphine – that is, a smaller dose of diamorphine is required to have the same effect as a given dose of morphine. The *BNF* suggests as an approximate guide that 10 mg or oral morphine is equivalent to 3 mg of intramuscular diamorphine.

Palliative care

72. The British National Formulary defines palliative care as 'the act of total care of patients whose decease is not responsive to curative treatment.'

73. In practice, this means relieving the distress of patients who are dying. That in turn means that a decision has to be made before instituting palliative care that a patient is indeed dying.

74. Even in palliative care, it is not necessary or desirable to give medicines by injection if they can be given by mouth.

75. It is common practice in palliative care to provide anti-emetics (anti-sickness medicine), anxiolytics (anti-anxiety medicine), and laxatives in addition to analgesics (pain killers).

76. In patients who are dying and who are unable to swallow, it is common to give drugs by subcutaneous injection. It is usual practice in the palliative care of such patients to give diamorphine and an antiemetic such as methotrimeprazine or haloperidol that also had sedative properties Agitation is commonly treated with midazolam.

77. If patients who are dying also have rattly secretions in the chest, then this may be eased by the administration of hyoscine.

Prescribing

78. The purpose of written prescriptions is for doctors to provide clear, unambiguous, and precise instructions for the dispensing and administration of medicines.

79. This task is considerably eased by hospital drug charts, which have separate sections for medicines to be given once only, medicines to be

given as required, and medicines to be given regularly. The drug charts used at Gosport War Memorial Hospital followed this pattern.

Consideration of the case of Gladys Richards

80. Mrs Richards, when she returned from the Royal Naval Hospital Haslar on the 17th August 1998, was said to be 'peaceful'.

81. This assessment seems at odds with the fact that she was malpositioned in bed; and that by 13.05 hours she was recorded to be 'in pain and distress.'

82. It was in my view reasonable to give her a dose of morphine sulphate orally at that stage. In fact she was given a total of 45 mg of morphine sulphate orally from 13.10 hours on the 17th to 04.30 hours on the 18th August 1998. This is a substantial dose, but would have been reasonable if it was necessary to alleviate pain.

83. There is no record as to what was thought to be the cause of the pain at the time, even though it required a substantial dose of morphine. Subsequent statements suggest that it was a haematoma [that is, a palpable bruise]. If that is so, it would be expected to resolve in a few days to a few weeks.

84. There is an additional difficulty in patients who are not able to express clearly their thoughts and feelings—especially patients with dementia. That is that manifestations of distress from pain and from psychological upset cannot easily be disentangled.

85. It is unclear from the records why it was believed that Mrs Richards was dying on the 18th August 1998. There is no specific record of any change in her condition other than that she was 'still in great pain.'

86. Set against this, Mrs Richards was clearly very frail. She needed help with all her activities of daily living. She was thought to be near the end of her life when seen by Dr Banks in February 1998; and she had undergone major surgery and minor surgery in the three weeks before she died.

87. Even if it had been decided that Mrs Richards was not a candidate for any active intervention, but should be made comfortable, there was no reason to switch from oral to subcutaneous treatment while she was still able to swallow. [See, for example, P.27].

88. Having made the decision to start a subcutaneous infusion of diamorphine, there appears to have been no intention of reassessing its effects. There was no provision for the administration of fluids other than by mouth. This was not in itself wrong if a decision had been made to administer palliative care at the end of life.

89. With regard to the dose of diamorphine chosen, this replaced a dose of 45 mg of oral morphine sulphate given over approximately 16 hours: equivalent to approximately 70 mg of morphine sulphate in 24 hours. Oral morphine 10 mg is equivalent to intramuscular diamorphine 3 mg. That means that oral morphine 70 mg is equivalent to intramuscular diamorphine 21 mg, and approximately the same amount subcutaneously. The administration of 40 mg diamorphine therefore represented an effective doubling of the dose of opiates.

90. In terminal care it is right and proper to ensure that patients are pain-free and free from distress; but that end might well have been achieved with a substantially lower dose of diamorphine. This was particularly so given the concurrent administration of both midazolam and haloperidol.

91. In the absence of clinical records explaining the decision to switch from standard care with oral morphine to palliative care with subcutaneous diamorphine, it is not possible to be certain that Mrs Richards was able to take medicines by mouth at a time when she was in great pain.

92. If she was not, and there was no obvious treatment that would alleviate her pain, then one cannot say that her treatment was criminally negligent.

93. However, it was noted by her daughter that Mrs Richards stopped passing urine two days before she died; and that she was receiving no fluids. There was no other apparent reason for her to be unable to take fluids by mouth, and she had indeed been doing so prior to the 18th August 1998. It is therefore very likely that the administration of subcutaneous diamorphine, and the concurrent administration of midazolam and haloperidol, rendered Mrs Richards too drowsy to take oral fluids, increased the risk of her developing renal failure, and hastened her demise.

Opinion

94. Mrs Gladys Richards was a frail elderly woman who had undergone hip surgery and shortly afterwards had a closed reduction of a dislocation of the replaced hip.

95. Interventions such as hip replacement and reduction under anaesthesia put a strain on older people, and occasionally can have fatal consequences.

96. Interventions such as hip replacement and reduction under anaesthesia can cause pain.

97. It is right to make patients comfortable and pain-free.

98. Mrs Richards may have required oral morphine for pain relief.

99. If she had been unable to swallow, then it would have been reasonable to give subcutaneous diamorphine.

100. There is no evidence that I have seen to show why she was given subcutaneous diamorphine.

101. There is no evidence that I have seen to explain why the effective dose of opiate was substantially increased when the prescription of oral morphine was changed to a prescription for subcutaneous diamorphine.

102. Morphine and diamorphine in sufficiently large doses cause a reduction in consciousness and in the rate and depth of breathing, and can cause death.

103. Midazolam and methotrimeprazine are commonly given in terminal care to reduce agitation and nausea.

104. Both midazolam and methotrimeprazine are sedative drugs.

105. Mrs Richards was apparently sedated after the commencement of subcutaneous infusion of diamorphine, midazolam, and methotrimeprazine on 18th August 1998.

106. Mrs Richards was not given fluids while in her sedated state.

107. Mrs Richards stopped passing urine while in her sedated state.

108. It is very likely that the administration of subcutaneous diamorphine, and the concurrent administration of midazolam and haloperidol, rendered Mrs Richards too drowsy to take oral fluids,

increased the risk of her developing renal failure, and hastened her demise.

Declaration

109. I understand that my duty is to help the court on matters within my expertise, and that this duty overrides any obligation to those by whom I am instructed or by whom I am paid. I confirm that, in writing this report, I have complied with that duty.

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

Signed .Code A...

Professor R E Ferner