

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)
Section 67 of the Coroners Act 2008

I, PARESA ANTONIADIS SPANOS, Coroner,

having investigated the death of ELLEN O'CONNOR without holding an inquest:

find that the identity of the deceased was ELLEN MARY O'CONNOR

born on 11 March 1918

and that death occurred on 13 May 2008

at Royal Melbourne Hospital, Grattan Street, Parkville, Victoria 3052

from:

- 1a. RENAL FAILURE
- 1b. GENTAMICIN THERAPY FOR URINARY TRACT INFECTION (SEPSIS)
2. RENAL ARTERY STENOSIS. CORONARY ARTERY DISEASE

Pursuant to Section 67(2) of the **Coroners Act 2008**, I make findings with respect to **the following circumstances:**

1. Mrs O'Connor was a 90-year-old lady with a past medical history that included ischaemic heart disease, rapid atrial fibrillation, chronic cardiac failure, hyponatraemia and hypertension. Her left kidney had been surgically removed in 2006.
2. On 23 April 2008, Mrs O'Connor suffered a mechanical fall and fractured her left olecranon (elbow) and left superior pubic ramus (pelvis). She was admitted to the Royal Melbourne Hospital (RMH) with planned surgery for internal fixation of the fracture scheduled and cancelled on four consecutive days. On the fourth day, 28 April 2008, surgery was cancelled as Mrs O'Connor was unwell with symptoms of a urinary tract infection (UTI). Her fracture was stabilised with a plaster slab and she was commenced on oral ciprofloxacin (an antibiotic) to treat the UTI.
3. Microbiology results returned on 4 May 2008 identified the source of the UTI as *Pseudomonas aeruginosa* bacteria which is sensitive to gentamicin, a potent antibiotic. As Mrs O'Connor's renal function was found to be normal at that time, a first dose of gentamicin¹ 240mg was administered

¹ Gentamicin (one of the aminoglycosides) is a potent and potentially nephrotoxic antibiotic prescribed for urinary tract infection.

intravenously at 9.20pm on 4 May 2008, based on an estimated weight of 45kgs. The following day urea and creatinine levels were still within the normal range.

4. Mrs O'Connor underwent surgery to stabilise her left elbow fracture on 6 May 2008. Following her return to the ward, medical records document decreased urinary output, elevated potassium and urea and creatinine at 23.6mmol/L and 290mmol/L respectively. Clinically, Mrs O'Connor was assessed to be dehydrated and her high potassium level was treated with resonium and calcium gluconate. Renal function continued to be monitored and continued to deteriorate despite cessation of contraindicated medications and increased oral intake of fluids. Investigations revealed that gentamicin was still just within the toxic range at 2mg/L on 8 May 2008, four days after the one and only dose given on 4 May 2008. The treating registrar assessed her to be in acute renal failure due to ischaemic acute tubular necrosis, and also considered the possibility of nephrotoxicity secondary to intravenous gentamicin. Her antihypertensive ramipril was ceased as a possible cause of renal impairment. Mrs O'Connor was encouraged to increase her oral fluid intake and her diuretic Lasix was ceased. On 9 May 2008, urea and creatinine levels were at 30mmol/L and 390mmol/L respectively. On 11 May 2008, creatinine peaked at 440mmol/L.

5. On 13 May 2008, urea and creatinine were still elevated but marginally improved at 24mmol/L and 360mmol/L respectively. Clinically, Mrs O'Connor was showing some improvement. She was responsive and talkative, less drowsy but complained of feeling tired. A nursing note at 9.00pm documented hypertension with a blood pressure of 190. At 9.20pm Mrs O'Connor was found deceased.

6. An autopsy was performed by Senior Forensic Pathologist Dr Michael Burke from the Victorian Institute of Forensic Medicine. Dr Burke summarised his anatomical findings as bronchopneumonia, coronary artery atherosclerosis, right renal artery stenosis, prior left nephrectomy, diverticulosis distal colon and cerebrovascular atherosclerosis. He formulated the cause of death as *renal failure secondary to gentamicin therapy for urinary tract infection (sepsis)* and noted *renal artery stenosis and coronary artery disease* as significant other conditions contributing to but not directly related to the cause or mechanism of death. Dr Burke reviewed the medical records and noted that Mrs O'Connor's renal function had been normal on admission, that she was given intravenous gentamicin for urinary tract infection and her renal function deteriorated rapidly thereafter. He commented that the renal failure may be related to gentamicin therapy with contribution from sepsis, dehydration and ischaemia/renal artery stenosis. Significantly, he noted a weight at autopsy of 35kgs, compared with the 45kg estimate used to calculate the dose of gentamicin at the RMH, as discussed below.

7. Statements were provided by consultant physician Dr Ian Jennens from RMH and Dr Peter Bradford, Executive Director, Clinical Governance and Medical Services, RMH. Dr Jennens reviewed Mrs O'Connor's medical records and provided a detailed outline of her clinical course. As at his review of Mrs O'Connor on the afternoon of 8 May 2008, Dr Jennens thought that her acute renal failure was due to a combination of factors including pre-renal causes with a documented period of hypotension, perhaps due to dehydration from fluid restriction together with diuretic therapy and GTN patch. He noted that Mrs O'Connor's death was sudden and unexpected at a time when her renal function and general condition had been improving, that he did not believe that she died from acute renal failure, that she was receiving clexane as DVT prophylaxis which may cause anticoagulation in renal failure and

that it was possible that she died from a haemorrhagic event to which renal failure may have contributed.

8. Dr Bradford advised that the gentamicin dose had been ordered by Dr Cheryl Choong, a second year resident in Plastic Surgery who was covering the orthopaedics unit after hours. Both the orthopaedics registrar and consultant were available by telephone to provide advice, assistance and supervision to Dr Choong if required. Dr Choong advised that she thinks she would have been aware of that urine cultures grew *Pseudomonas aeruginosa* and that it was sensitive to gentamicin and that she would have been aware of Mrs O'Connor's age, weight and past medical history at the time. Dr Bradford provided a copy of the Gentamicin Starting Dose Calculator which would have been available to clinicians at the time, via the hospital's intranet. The calculator has been available since 2003, and since 2005, use of the calculator has been part of the Intern Orientation program. The calculator provided a clear guide for determining the correct dose according to the patient's weight, age and renal function (by reference to creatinine clearance rate).

9. It was conceded that the 240mg dose administered to Mrs O'Connor was excessive. According to the guidelines/calculator, the recommended dose was 2-3mg per kilogram in a person aged 60 or over with a creatinine clearance of less than 50mls/minute. Mrs O'Connor's creatinine clearance rate was marginally over at 51mls/minute on 4 May 2008. If she weighed 45kgs at the time as was estimated by Dr Choong, an appropriate dose would be between 80-120mg. However, it is not clear that the weight estimate was accurate. At autopsy on 20 May 2008, one week after her death, Mrs O'Connor weighed only 35kgs. At this weight an appropriate dose range would be between 70-105mg.

10. I find that Mrs O'Connor died from renal failure secondary to gentamicin therapy administered for urinary tract infection, with indirect contribution from renal artery stenosis and coronary artery disease.

COMMENTS:

Pursuant to Section 67(3) of the **Coroners Act 2008**, I make the following comment(s) connected with the death:

1. Given the circumstances of Mrs O'Connor's death, I asked the Health and Medical Investigation Team (HMIT)² to assess the resources available to assist clinicians in arriving at the appropriate dose of gentamicin. HMIT reviewed the medical records, conducted information searches and, in order to understand current standard hospital based prescribing practice, conducted telephone interviews of a sample of rural and metropolitan public hospital pharmacists and a pharmacist from the state-wide medicine information line located at the

² The role of the Health and Medical Investigation Team (HMIT) is to assist the Coroner's investigation into the nature and extent of deaths, which occurred during the provision of healthcare and identify potential system factors in healthcare related deaths. HMIT personnel comprise of practising Physicians and Clinical Research Nurses who draw on their medical, nursing and research experiences, skills and knowledge, to independently evaluate clinical evidence for the investigation of reportable healthcare deaths and to assist in identifying remediable factors that may assist in prevention and risk management in health services settings.

Alfred Hospital. In addition, the HMIT also conducted telephone interviews of an infectious diseases medical consultant and a clinical pharmacologist.

2. The HMIT identified a degree of variability between the resources available to clinicians in hospital from hard copies of commonly used "Therapeutic Guidelines: Antibiotics"³ and MIMs, through access to the same guides online through the Department of Health's Clinicians' Health Channel, to hospital specific information in the form of published clinical practice guidelines (which could vary from hospital to hospital) and intranet located dose calculators. In terms of the latter, HMIT noted that it is not clear how the computer programs are validated and there is no international standard for programming.

3. This case highlights the importance of clinicians taking time to check the correct dose of gentamicin and the need for accurate, standard and readily accessible information about gentamicin, to ensure effective prescribing and patient safety.

RECOMMENDATIONS:

Pursuant to Section 72(2) of the **Coroners Act 2008**, I make the following recommendation(s) connected with the death:

1. That, via the Victorian Department of Health Quality, Safety and Patient Experience Hospital and Health Service Performance Unit, Hospital Administrators direct clinicians/prescribers to the "Therapeutic Guideline: Antibiotic" resources in their individual hospitals and alert them to changes in the "Therapeutic Guideline: Antibiotic" 2010/edition 14 relevant to the prescription of gentamicin for empirical and/or directed therapy.

2. Given the identified variability in resources available to assist clinicians/prescribers in calculating the appropriate dose of gentamicin, patient safety would be enhanced if, via the Victorian Department of Health Quality, Safety and Patient Experience Hospital and Health Service Performance Unit, Hospital Administrators defined a clear consultation pathway for prescribers to access senior medical staff with a specialist interest in infectious diseases to assist with gentamicin decision-making.

Pursuant to rule 64(3) of the Coroners Court Rules 2009, I order that the following be published on the internet:

This finding in its entirety.

I direct that a copy of this finding be provided to the following:

³ The HMIT noted that subsequent to Ms O'Connor's death, the "Therapeutic Guidelines: Antibiotics" 2010/edition 14 draws a distinction between empirical and directed therapy with gentamicin. For empirical therapy, the recommended maximum period is 48 hours, thereafter a targeted antibiotic, sensitive to the culture must be selected. Initial dose calculation is determined according to age and body weight, with subsequent doses determined by reference to creatinine clearance/renal function.

The family of Mrs O'Connor

Dr Peter Bradford, Executive Director, Clinical Governance and Medical Services,
Melbourne Health

Ms Alison McMillan, Director, Quality, Safety and Patient Experience Hospital and Health
Service Performance, Department of Health Victoria

Mrs Maggie Game, Executive Officer, Australasian Society for Infectious Diseases (ASID)
Adult Drug Information Line, Alfred Hospital

Signature:



A handwritten signature in black ink, appearing to read "P. Spanos", is written over a horizontal line.

PARESA ANTONIADIS SPANOS
CORONER

Date: 22 February 2012