



**Office of the  
Health Complaints Commissioner  
2007**

**700-0412033 Case summary of an ‘own motion’ investigation into the death of a patient in a private palliative care unit and whether this could be attributed to a medication error.**

***Section 23 (1)(c) “a health provider acted unreasonably in the manner of providing a health service” and s.23 (1)(d) “a health provider failed to exercise due skill”.***  
**Report issued December 2006.**

On 18 January 2005, the Commissioner gave notice to an organisation of an ‘own motion’ investigation pursuant to Section 40 (1)(d) of the *Health Complaints Act 1995*. The matters under investigation related to the circumstances surrounding the death of a patient, in December 2004 while an inpatient at a private hospice/palliative care unit and whether the patient’s death could be attributed to a medication error.

The Hospice offers specialist care to persons in need of supportive terminal care. Three of the palliative care beds in the hospice are funded by the Department of Health and Human Services (DHHS). Central to the investigation was whether the palliative care service provided was in accord with accepted palliative care therapeutic practice. A consultant was appointed to conduct a clinical review and report on various aspects of the investigation. The Nursing Board of Tasmania (NBT) and Medical Council of Tasmania (MCT) were advised of the investigation and provided with a copy of the report of the investigation and the relevant medical records.

The matter under investigation involved a 38-year-old female, who had been diagnosed with broncho-alveolar carcinoma in mid 2004. Despite treatment her condition worsened, and her worsening pain reportedly was not controlled by her analgesia. She was admitted on four occasions to a public hospital and in November 2004 and became a client of PCS. She had expressed a desire to remain at home cared by a General Practitioner but in December 2004 was transferred to the hospice for pain relief and symptom control. She died some 4 hours and 15 minutes after an unusually large dose of Clonazepam.

At the hospice an initial dose of 1 ml (2500mcgs) Clonazepam was administered by a nurse sublingually at 0015 hours. The GP’s order is written ‘clonazepam drops 0.5 – 1 ml orally tds’ and the question under investigation was whether the dose was unusually large and caused or contributed to the timing of the patient’s death. There was a further question as to whether the GP advised the nurse to administer 1 ml rather than start with the lower range and titrate upwards. At 0120 hours, the ketamine infusion was started, as the patient was documented as being unable to

settle, moaning and moving around in the bed. At 0500 hours the patient was checked again, there were no respirations, there was no pulse, the patient was cold to touch. The patient's death was not reported at the time to the Coroner although s. 19 of the *Coroners Act 1995* required such action.<sup>1</sup>

The consultant advised that one millilitre (ml) of Rivotril drops contains 2.5 mg of clonazepam<sup>ii</sup> and that the normal starting dose range in palliative care practice, for 'as required' ('prn') prescription, for the indication of terminal restlessness or agitation, is 0.25-0.5 mg delivered by the oral or sublingual route.<sup>iii</sup> Further that "*it is normal practice in palliative care to start at the lower end of a prescribed range and titrate upwards, unless there are pressing reasons to the contrary.*"

In his opinion 2.5 mg of clonazepam is a very large dose, which, (a) may have contributed to the timing of death and (b) would have been questioned by a nurse with palliative care experience and the dose *is substantially higher than usual clinical practice and accepted palliative care therapeutic practice in Australia and internationally*. While he regards this as a *quality of care* issue he is more hesitant about making a specific death causation claim stating that the cause of death "*is inherently more likely to be multifactorial and hard to determine*".

The sole nurse on duty at the hospice was a nurse with virtually no palliative care experience and no specialist palliative care nursing qualifications. Her only induction to the hospice was two orientation shifts and she had not undergone any professional development during her employment with the organization. In 2004 she was not required to undertake annual drug competency testing and the drug Clonazepam was not a drug she had administered often.

One factor relevant to the death causation issue is whether it was anticipated that the patient would die during the night. There is conflicting evidence as to whether the patient's death was imminent and a paucity of documentation and a lack of objective clinical evidence indicating whether or not the patient's death was imminent. The question was relevant to the issue of whether a medication error caused the patient's death or the timing of her death.

The consultant considered that the patient's oncological history placed her in a category of the '*high risk*' for poor cancer pain control and that specialist palliative medicine inpatient management would normally be regarded as essential. He questioned whether this patient would have been more properly managed in a designated or dedicated palliative care bed at a public hospital, in close proximity to oncology services. On the basis of his review, the conclusion is that this patient probably required acute hospital care for radiotherapy to improve pain control and that a request for urgent re-assessment and consideration of emergency radiotherapy would have been beneficial. This patient fell into a '*high risk*' category for poor cancer pain control, and the conclusion was that private hospice beds are not suitable for the care of patients with complex specialist palliative medicine needs.

Other systemic issues arose during the course of the investigation. These included the organisation's credentialing system for granting medical practitioners the right to admit patients, the palliative care qualifications, training and experience of nursing staff and ancillary matters. These matters to varying degrees impacted on the quality

and safety of the palliative care service at the hospice and whether the service met the standards as defined in the *Standards for Providing Palliative Care for all Australians?*<sup>iv</sup>

The death, the certification of the death by the GP who ordered the Clonazepam, the failure to conduct an adequate clinical audit and the failure to report the matter to the Coroner raised questions as to whether the organisation had a reporting system in place which would have met the objectives of the National Strategy, Tasmanian Palliative Care Plan and the Australian Safety and Quality Council (the Council) standards.

An objective of the National Palliative Care Strategy is to develop an accountability and reporting framework in both the public and private sector and across all service delivery settings (including inpatient palliative care units, acute hospital, home and community),<sup>v</sup> to develop performance indicators and monitor performance against service benchmarks. The Council defines 'sentinel events' as "*events in which death or serious harm to a patient has occurred*". "*Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs*" is on the agreed national list of sentinel events.<sup>vi</sup>

Having regard to these standards, the conclusion is that the incident should have been the subject of a comprehensive clinical audit and evaluation informed by a palliative care specialist. Further the organisation should have reported the matter to the Coroner. The organisation in this instance did not follow its own credentialing procedures for granting the GP admitting rights, did not ascertain her level of experience in the field of palliative care and did not, within a reasonable time, ratify the temporary privileges granted in August 2004.

The sole nurse on duty at the hospice at the relevant time lacked palliative care qualifications, training and experience and the organization routinely did not employ nurses with palliative care experience on the night or weekend shifts at the hospice.

The organization in response to this incident appointed a number of well credentialed specialist staff, established a Clinical Audit Committee, reviewed their Medical Staff Association Rules and By-Laws, Policies and Regulations and revised a number of their policies and procedures. The organization appointed a Palliative Care Specialist Nurse Manager, whose qualifications include a Master of Palliative Care from Flinders University and appointed a Consultant Physician with extensive experience in pain management and palliative care, as Medical Director. A Medical Advisory Committee has been established for the hospice. The actions taken by the organisation since this incident should enhance the safety and quality of the palliative care service provided to patients at the hospice.

The granting of Admission Rights and Privileges to the GP was incomplete. The GP had previously been granted temporary admitting rights in relation to another patient, but at the relevant time the MAC was in abeyance and the documentation required in support of her admission was incomplete.

The findings of the investigation were that the practice of employing nurses without palliative care experience on a casual basis to work the night and weekend shifts at

POHH was not an appropriate practice and should cease forthwith. A recommendation was made to that effect. The only alternative was that if nurses with palliative care qualifications were not available then the organization should select registered nurses prepared to work these shift and provide the relative palliative care training or provide resources to train the nurses to attain competency in palliative care.

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i See section 3 defining 'reportable death' and clause (v), (vi) and s.19 on the obligation to report a death.

ii Roche, Australian Medicines Handbook 2005, p593

iii See p 187, Therapeutic Guidelines, Palliative Care, 2001.

iv Fourth edition Palliative Care Australia May 2005

v "National Palliative Care Strategy" ISBN 0 642 447330 Objective 2.3 and strategy 2.3.4 & 2.3.5.

vi Safety and Quality Council Sentinel Events Fact Sheet