Investigation report

The quality of healthcare services provided to a patient by Friendly Society Private Hospital

Version

Office of the HEALTH OMBUDSMAN

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Investigation report—The quality of healthcare services provided to a patient by Friendly Society Private Hospital

Published by the Office of the Health Ombudsman, October 2016

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1. Introduction

This report outlines the investigation I conducted into the adequacy of systems in place at Friendly Society Private Hospital to ensure the appropriate:

- administration of medication to patients
- procedures for responding to adverse drug reactions
- procedures for incident reporting.

The investigation commenced as a result of a complaint I received about the treatment provided to a patient by nursing and medical practitioners in October 2013 and July 2014. The complaint prompted a systemic investigation into the concerns raised about the circumstances in which the patient could be administered medication on two separate occasions when she had a known allergy to the medication, and the procedures in place to respond to, report on, and address the incident.

2. Health service provider

The Friendly Society Private Hospital is a private, not-for-profit, 143-bed surgical and medical facility located at 33 Crofton Street, Bundaberg West. The hospital employs a team of more than 400 medical, nursing, support and allied health professionals servicing the Bundaberg and Wide Bay–Burnett communities.

3. Background

3.1 Incident one

On 29 September 2013, a female patient was admitted to Friendly Society Private Hospital with lower back pain. At the patient's initial *admission nursing assessment*, the assessing nurse recorded no allergies against the patient's admission records.

While being treated as an inpatient for back pain, the patient developed severe abdominal pain. The patient's treating medical practitioner ordered urinalysis on 1 October 2013. The results of the urinalysis were suggestive of a urinary tract infection and the treating medical officer prescribed the patient trimethoprim 300 milligrams daily on 1 October 2013.

At 1900 on 1 October 2013, a registered nurse reviewed the patient's *patient assessment form*, noted that no allergies were recorded and marked the allergy section in the patient's medication chart as 'nil known'. The registered nurse then administered the first dose of trimethoprim to the patient.

A second registered nurse administered a second dose of trimethoprim to the patient on 2 October 2013. When later questioned by hospital staff who reviewed the incident on behalf of the hospital, the registered nurse advised that she did not remember whether she asked the patient about known allergies and believes she checked the incorrect allergy documentation on the medication chart prior to administering the trimethoprim.

On 3 October 2013, a registered nurse identified the patient was suffering from an allergic reaction and reported the reaction to the treating medical officer who ceased trimethoprim immediately.

The allergic reaction manifested as a grade 2 anaphylactic reaction with associated pain and resulted in the extension of the patient's admission and family disruption. The patient received ongoing treatment for her back pain and allergic reaction and was discharged from the hospital on 16 October 2013 having fully recovered from the allergic reaction.

3.2 Incident two

The patient was re-admitted to the Friendly Society Private Hospital on 11 July 2014 with a non-related injury to her admission of September 2103. Assessment at Bundaberg Hospital identified the patient was also suffering bladder distention and an indwelling urinary catheter was inserted prior to her transfer to Friendly Society Private Hospital.

Upon admission to Friendly Society Private Hospital on 11 July 2014, the patient's allergy to trimethoprim was recorded on both her admission and medication charts. Urinalysis of the patient conducted on 13 July 2014 identified traces of protein and blood, suggestive of a urinary tract infection. On 16 July 2014, the patient's treating medical practitioner prescribed oral trimethoprim 300 milligrams daily, despite the medication chart being marked with an adverse drug reaction alert warning label and trimethoprim being recorded on page one of the medication chart as being an allergen.

As per the patient's medication chart, trimethoprim was administered to the patient by nursing staff at approximately 2000 on 17 July 2014 and again at 2000 on 18 July 2014.

On 19 July 2014, a registered nurse identified an allergic reaction presenting as blistering visible on the patient's back and shoulders and notified the treating medical practitioner. The medical practitioner immediately ceased the trimethoprim. The patient's allergy manifested as a grade 2 anaphylactic reaction and caused significant painful blistering to large areas of the patient's body.

The patient initially underwent steroidal treatment for the allergic reaction and between 20 July 2014 and 3 August 2014 received daily wound care for the blistering.

On 19 July, the patient's daughter raised concerns with the hospital coordinator regarding the standard of care delivered to the patient.

The hospital coordinator subsequently met with the patient's daughter on 20 July 2014 and apologised for the medication error on behalf of the hospital and the treating medical officer.

The nurse unit manager and director of clinical services also met with the patient and members of the patient's family during her admission and apologised for the issues and explained the hospital would investigate the incidents.

The patient was discharged from the hospital on 4 August 2014.

4. The investigation

4.1 Office of the Health Ombudsman assessment

On 9 August 2014, the patient's daughter submitted a complaint to my office in relation to the treatment her mother had received at the hospital during her admissions in September–October 2013 and July 2014. The matter was subsequently accepted for assessment and a notice was issued to the hospital's chief executive officer under the *Health Ombudsman Act 2013*[1] requiring additional information and documentation about the treatment provided to the patient at the hospital.

The assessment of the matter identified six healthcare providers (nursing and medical practitioners) employed at the facility who were involved in the care and treatment of the patient when she suffered allergic reactions on both admission episodes.

During the assessment process, my office obtained the following documentation and information relevant to the complaint:

- all medical and clinical records relevant to the patient's admission to the hospital between 29 September 2013 and 16 October 2013
- all medical and clinical records relevant to the patient's admission to the hospital between 11 July 2014 and 4 August 2014
- a written submission from the acting director of nursing compliance, dated 24 September 2014, responding to the complaint on behalf of the hospital.

At the conclusion of the assessment process, my delegate decided to refer the individual registered health practitioners to the Australian Health Practitioner Regulation Agency (AHPRA) as it was considered their conduct may amount to unprofessional conduct.

4.2 Australian Health Practitioner Regulation Agency assessment

AHPRA undertook a review of the treatment each registered health practitioner provided to the patient and advised the office of the following outcomes at the conclusion of their assessment:

- The Medical Board of Australia concluded that the medical practitioner's practice in treating the patient was unsatisfactory and accepted undertakings.
- The Nursing and Midwifery Board of Australia decided that:
  - two of the nurses involved with the patient's care should be cautioned because their practice of the profession was unsatisfactory
  - no further action should be taken in relation to two other nurses because their conduct was adequately being dealt with by the hospital

[1] Section 48

– no further action should be taken against one nurse because the complaint against this nurse was misconceived.

Following the conclusion of the assessment, and the referral of the registered practitioners to AHPRA, the complaint in relation to the hospital as a facility was referred to the Investigations division in my office.

4.3 Office of the Health Ombudsman investigation

My office commenced an investigation of the hospital on 15 October 2014. An investigation plan identified the scope of the investigation as follows:

1. Whether the hospital's responses to the adverse drug reactions were timely and appropriate.
2. Whether the hospital had appropriate protocols and procedures relating to administration of medication.
3. Whether the hospital had appropriate protocols and procedures relating to adverse drug reactions.
4. Whether the hospital had appropriate protocols and procedures relating to incident reporting.

On 22 December 2014, my office requested further information from the hospital via a notice served under the *Health Ombudsman Act 2013*.[2]

On 22 January 2015, the hospital responded to the request for further information, providing the following documentation:

- administration of medication policy
- adverse drug reactions—prevention and reporting policy
- clinical documentation policy
- clinical handover policy
- incident reporting policy
- risk management policy
- root cause analysis report relating to the patient
- new graduate clinical orientation program
- staff attendance records for policy update training.

Following a review of the documentation provided, additional information was requested from the hospital on 29 April 2015.

[2] Section 228

On 15 May 2015, the hospital providing the following additional documentation:

- minutes from the Medical Advisory Committee (dated 13 October 2014)
- annual mandatory medication safety training package
- allergic reaction case-study and presentation notes (training)
- employee attendance record for patient allergic reaction case-study training
- online pharmacology training report (staff responses to allergy question)
- medication safety presentation package
- progress report on the hospital staff completion rates for medication safety training package.

4.3.1 Clinical advice

A request for clinical advice was drafted seeking specific advice in response to the following questions:

1. What do you consider are the main factors that led to the incidents occurring?
2. Do you consider the responses of the hospital to these incidents were timely and appropriate?
3. Do you consider the hospital has appropriate protocols in place relating to the administration of medication?
4. Do you consider the hospital has appropriate protocols in place relating to adverse drug reactions?
5. Do you consider the hospital has appropriate protocols in place relating to incident reporting?
6. Do you have any further comments you wish to provide in relation to this matter?

On 11 December 2015, clinical advice was sought from a registered nurse, who was provided all relevant records and documentation.

On 18 December 2015, the clinical advice was provided and is summarised below.

1. **What do you consider are the main factors that led to the incidents occurring?**

Human error and decision making are the main factors in these incidents, including:

- failure of the treating medical officer to review the relevant medical history specifically related to previous and documented adverse drug reactions
- failure of the nursing staff to comply with organisational policies and procedures related to medication administration and professional standards
- failure of the nursing staff to immediately notify the treating medical officer when they had identified that the patient was ordered and had received several doses of a medication previously known to have caused her an adverse drug reaction.

Regarding the failures of the nursing staff:

- The hospital's *Induction to clinical area* document addresses the learning needs of all staff who commence in the facility regarding the specific areas at issue.

- It would have been reasonable to expect that the relevant staff member who identified the drug allergy issue should have immediately informed the treating medical officer or, if unavailable, the hospital coordinator. The hospital implemented an educational program to ensure that staff awareness of the escalation process is embedded into clinical practice.

2. **Do you consider the responses of the hospital to these incidents were timely and appropriate?**

The responses of the accountable officers of the hospital appear to be timely and appropriate, specifically:

- The nurse who was the first recipient of concerns raised by the patient's daughter escalated the matter to the hospital coordinator.
- A meeting with the patient's daughter is documented and outlines the concerns raised, explanations and agreed actions.
- The following business day, the nurse unit manager held further discussions with the patient's daughter regarding her concerns.
- From information contained in the clinical notes, it appears that the patient's daughter was informed of the process to raise her concerns regarding her mother's care while in the hospital.

These actions demonstrate timely and appropriate action and reflect that the hospital meets relevant National Safety and Quality Health Service (NSQHS) standards—specifically compliance with standard 1 (Governance), sub-standards 1.14, 1.15 and 1.16.

3. **Do you consider the hospital has appropriate protocols in place relating to the administration of medication?**

The hospital's *Administration of medication CS 12.02* policy document meets the required standards of:

- NSQHS medication safety standards (standard 4)
- Nursing and Midwifery Board of Australia national competency standards
- Heath (Drugs and Poisons) Regulation 1996.

The progress reports provided by the hospital on organisational progress of improvement strategies demonstrates a culture of ongoing monitoring, audits and evaluation at an individual and organisational level.

4. **Do you consider the hospital has appropriate protocols in place relating to adverse drug reactions?**

The hospital's *Adverse drug reactions—prevention and reporting CS 12.03* policy document outlines the responsibilities of all staff members.

The educational records provided by the hospital regarding training undertaken after these events demonstrate that the organisation has taken this matter seriously.

5. **Do you consider the hospital has appropriate protocols in place relating to incident reporting?**

The hospital's *Incident reporting HS 03.13* policy document meets the requirements of the NSQHS governance and quality improvement standards.

The requirement for staff to be aware and have knowledge of their responsibilities in complying with the policy and standards is covered in the hospital's *Induction to clinical area* document. The timeframe for all new staff to complete this induction is eight weeks. The hospital would be in a position to audit compliance of the completion of this induction for all new staff.

6. **Do you have any further comments you wish to provide in relation to this matter?**

It is unclear if the hospital has in place a consistent methodology to assess a patient's cognitive status that informs clinical management. For example, the available clinical documentation relating to both of the patient's admissions shows an absence of assessment and reassessment of her cognitive status, despite there being a change in her status between admissions and possibly during each admission.

The clinical documentation does not record whether the patient had capacity. The notes suggest that she did not have capacity but no substitute decision maker was identified in the records. Clearer communication with the substitute decision maker and/or family regarding the patient's medical history, relevant to planned treatment, could have potentially prevented the drug error.

In the absence of an existing framework, there may be benefit for the hospital to consider how it can better address the care needs of patients with cognitive impairment through the application of NSQHS standard 1. An appropriate starting point for such systems improvement may be via implementing the principles of the Australian Commission on Safety and Quality in Health Care, specifically *Actions for health service managers*, *Actions for clinicians* and *Actions for consumer*.

4.3.2 Analysis

The evidence supports the view that the main factors leading to the patient suffering allergic reactions while an inpatient at the hospital in October 2013 and July 2014 were human error and poor decision making by medical and nursing staff involved with her care, rather than any systemic procedural, policy or educational failures attributable to the hospital as a facility.

The clinical advisor specifically identified:

- a failure of the first treating medical officer to review medical history and previous documented adverse drug reactions
- a failure of nursing staff to comply with organisational policy and procedure related to medication administration
- a failure of nursing staff to notify the first treating medical officer in a timely manner after identifying that the patient was administered a medication previously known to have caused an allergic reaction.

This advice is corroborated by the outcomes of the AHPRA assessment of the identified health practitioners:

- The Nursing and Midwifery Board of Australia cautioned two of the nurses involved with the patient's care because their practice of the profession was unsatisfactory and not in accordance within the organisational policies of the hospital and relevant professional standards.
- The Medical Board of Australia decided to take action, via an undertaking from the medical practitioner, because his practice of the profession was below the standard reasonably expected of a practitioner with his level of training and experience.

It is highlighted that AHPRA, after assessing the performance of the individual health practitioners, has not identified any issues with the hospital's policy or procedure.

Investigation issue one—the hospital's response to the adverse drug reaction

The information gathered throughout the investigation supports the view that the hospital responded to the patient's allergic reactions in a timely and appropriate manner.

The clinical advisor specifically stated that the responses of the relevant accountable hospital staff members to the allergic reactions were timely and appropriate and reflected that the hospital meets the relevant NSQHS standards, specifically:

Standard 1—Governance and quality improvement systems:

- *1.4 Implementing training in the assigned safety and quality roles and responsibilities.*
- *1.5 Establishing an organisation-wide risk management system that incorporates identification, assessment, rating, and controls and monitoring for patient safety and quality.*
- *1.6 Establishing an organisation wide quality management system that monitors and reports on the safety and quality of patient care and informs changes in practice.*

Investigation issue two—the hospital's protocols for medication administration

The information gathered throughout the investigation supports the view that the hospital has appropriate protocols and procedures relating to the administration of medication.

The clinical advisor stated that the hospital's *Administration of medication* policy meets the required standards of the NSQHS medication safety standards (standard 4), the Nursing and Midwifery Board of Australia national competency standards and the Heath (Drugs and Poisons) Regulations 1996.

Investigation issue three—the hospital's protocols for adverse drug reactions

The information gathered throughout the investigation supports the view that the hospital has appropriate protocols and procedures relating to response and management of adverse drug reactions.

The clinical advisor stated that the hospital's *Adverse drug reactions—prevention and reporting* policy outlines the appropriate responsibilities of all staff members.

Investigation issue four—the hospital's protocols for incident reporting

The information and evidence gathered throughout the investigation supports the view that the hospital has appropriate protocols and procedures relating to incident reporting.

The clinical advisor stated that the hospital's *Incident reporting* policy clearly meets the requirements of the NSQHS governance and quality improvement standards and that awareness and knowledge of individual staff members' responsibilities in meeting this standard is covered in the hospital's *Induction to clinical area* document.

Additional comments

While the clinical advisor was satisfied with the hospital's policies and procedures as they related to this incident, they identified some additional areas for improvement. Specifically, they noted:

- the clinical records make it unclear whether
  - the hospital has a consistent methodology to assess and reassess a patient's cognitive status to inform clinical management
  - the hospital has a consistent methodology for staff to record the involvement, visitation and/or telephone enquiries made by any family member
  - the patient had capacity and if not, who the substitute decision maker was regarding decisions about her care
  - in administering medications to manage the adverse drug reaction, there was a clinical assessment undertaken to determine what (if any) impact those medications may have had on the patient's cognitive status
- the hospital may benefit from
  - considering whether it can better address the care needs of patients with cognitive impairment through the application of NSQHS standard 1 (Governance) and the relevant Australian Commission on Safety and Quality in Health Care principles
  - a self-assessment of the hospital against NSQHS standard 4 (Medication Safety) to support sustained service improvement
  - having a consistent documented process of family and/or carer involvement throughout the clinical process—this could be measured against NSQHS standard 1 (Governance), standard 4 (Medication Safety) and standard 6 (Clinical Handover).

5. The hospital's response to the draft report

On 2 June 2016, my office provided a copy of the draft investigation report to the hospital's chief executive officer inviting the hospital to provide any comments in response to the report as required under the *Health Ombudsman Act 2013*.[3]

On 5 July 2016, the hospital's chief executive officer confirmed that the hospital was satisfied with the investigation report and had no comments.

6. Conclusion

The information obtained and considered during this investigation supports the conclusion that human error and poor decision making were the main factors leading to the administration of trimethoprim to a patient who had a known allergy to the medication.

There is no evidence of systemic issues at the hospital, including procedural or policy failures, that could have or did contribute to the incidents. This conclusion is affirmed by the clinical advisor who said:

- The responses of the relevant accountable hospital staff members to the allergic reactions were timely and appropriate and reflected that the hospital meets the relevant NSQHS standards.
- The hospital's *Administration of medication* policy meets the required standards of the NSQHS medication safety standards, the Nursing and Midwifery Board of Australia national competency standards and the Heath (Drugs and Poisons) Regulations 1996.
- The hospital's *Adverse drug reactions—prevention and reporting* policy outlines the appropriate responsibilities of all staff members.
- The hospital's *Incident reporting* policy clearly meets the requirements of the NSQHS governance and quality improvement standards and that awareness and knowledge of individual staff members' responsibilities in meeting this standard is covered in the hospital's *Induction to clinical area* document.

Overall, I am of the view that no further action should be taken under the *Health Ombudsman Act 2013*[4] as the identified issues have been appropriately resolved or finalised through the outcome of the complaints against the individual registered health practitioners involved with the patient's care.

The hospital has been advised of my decision to close the matter.

Leon Atkinson-MacEwen
Health Ombudsman

12 October 2016

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[3] Section 86
[4] Section 44(1)(a)(iv) of the Act.