

Health Law Seminar

Improving patient outcomes

Clinical governance update

8 September 2016

Presented by:

Zara Officer

Special Counsel

(02) 9390 8427

zara.officer@holmanwebb.com.au

HOLMANWEBB
LAWYERS

Recent Reports

- ❑ Australian Commission of Safety and Quality in Healthcare – Review of serious failures in reported test results for Prostate-Specific Antigen (PSA) testing of patients by SA Pathology – July 2016
- ❑ NSW Health – Bankstown-Lidcombe Hospital medical gases incident: final report prepared by the Chief Health Officer 26 August 2016
- ❑ Common themes and lessons learnt

Reported Test Results for PSA Testing by SA Pathology

- ❑ **March 2015** – SA Pathology started reporting PSA levels in patients at low levels
- ❑ **7 November 2015** – assay lots used by SA Pathology inaccurate in the range of 0.03 to 0.08 ug/L, with positive bias of 0.03 ug/L
- ❑ Usual number of undetectable PSA results decreased by 90%
- ❑ Number of patients showing detectable PSA following previously undetectable PSA increased from 49% to 89%

Reported Test Results for PSA Testing by SA Pathology

- ❑ Complaint from urologist end of **January 2016**
- ❑ Further telephone complaints made by clinicians and patients through February and March 2016
- ❑ **18 March 2016** SA Pathology writes to all urologists explaining the problem
- ❑ **March 2016** notice on SA Pathology website
- ❑ **4 April 2016** media exposure, then
- ❑ **April 2016** “look back” process commenced

Reported Test Results for PSA Testing by SA Pathology

Recommendations

- ❑ A formal apology to the patients
- ❑ New management structure, including clinical expertise to monitor and inform production of results
- ❑ Quality control procedures to meet national standards and regularly audited
- ❑ National accreditation for SA Pathology
- ❑ Implement enhanced risk management system, clinical staff to be trained in open disclosure

Bankstown-Lidcombe Hospital

Medical Gas Incidents

- ❑ Incorrect gas administered to two neonates through neonatal resuscitaire in operating theatre 8
- ❑ Baby 1 born late **June 2016** – survived but unexpected poor outcome
- ❑ Baby 2 born **13 July 2016**, R.I.P
- ❑ **14 July 2016** paediatrician requested testing of gas outlets in theatre 8
- ❑ **21 July 2016** gas outlets tested – nitrous oxide emitted from O₂ outlet in theatre 8 neonatal resuscitaire

Bankstown-Lidcombe Hospital Medical Gas Incidents

Background

- ❑ **2014** baby resuscitated, oxygen cylinder emptied
- ❑ Hospital installed piped oxygen to birthing unit
- ❑ Later decision made to install piped O₂ to neonatal resuscitaire in OT's
- ❑ **2 June 2015** approval to proceed
- ❑ **14 and 15 July 2015** installation performed, completed
16 July 2015

Bankstown-Lidcombe Hospital Medical Gas Incidents - Response

- ❑ **13 July 2016** Coroner's referral and police investigation
- ❑ **21 July 2016** after gas outlet testing, theatre 8 closed.
Rectification completed **18 August 2016**
- ❑ **22 July 2016** review of clinical notes of all births in theatre 8 completed
- ❑ **25 July 2016** commencement of testing all gas outlets across NSW Health facilities in NSW – completed **15 August 2016**
- ❑ **July 2016** RCA report into both incidents commissioned
- ❑ Independent expert report commissioned
- ❑ **26 August 2016** final report of CHO

Bankstown-Lidcombe Hospital Medical Gas Incidents



Bankstown-Lidcombe Hospital Medical Gas Incidents - Recommendations

- ❑ MOH review senior management role in clinical and corporate governance in commissioning clinical infrastructure at the hospital
- ❑ MOH promulgate a requirement for contractors to have a separation of the installer and the tester (this not currently required in Australian Standard)
- ❑ MOH write to Australian Standards to require separation of installer and tester, and clarify when anaesthetist should attend testing
- ❑ New clinical process for unexpected hypoxia - checking and changing gas supply and circuits

Common Themes and Lessons Learned

- ❑ Mechanisms to escalate issues to senior management, staff trained on severity indicators
- ❑ Disharmony in culture can contribute to problems
- ❑ Involvement of multidisciplinary teams
- ❑ Monitor that activities performed are widely accepted as competent professional practice
- ❑ Avoid delay in dealing with an issue once raised to senior management

Common Themes and Lessons Learned

- ❑ Policies for adverse event reporting, investigation, RCA, look back and open disclosure
- ❑ Management accountability
- ❑ Use of technology to identify issues

Common Themes and Lessons Learned

Guideposts:

- ❑ Urgent investigation and response, use appropriately qualified external experts
- ❑ Notification to relevant external bodies without delay – e.g. TGA, ARPRA
- ❑ Notification to management and Board
- ❑ Implementation of policies and procedures to reduce the risk, and update as necessary
- ❑ Multidisciplinary team approach
- ❑ Media policy
- ❑ Open disclosure as relevant, including public apology as appropriate



If you would like any further information regarding this presentation, please contact:

ZARA OFFICER |
SPECIAL COUNSEL

P: (02) 9390 8427

E: zara.officer@holmanwebb.com.au