Bankstown-Lidcombe Hospital

Medical Gases Incident:

Interim Report

Prepared by the Chief Health Officer

2 August 2016

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1. Purpose

This Report has been prepared by the Chief Health Officer to update the NSW Minister for Health in relation to critical incidents that occurred at Bankstown-Lidcombe Hospital in June and July 2016: dispensing incorrect gas to two neonates through a neonatal resuscitaire in Theatre 8. The Report outlines the key events, the actions taken and the investigations underway.

2. Introduction

Bankstown-Lidcombe Hospital (part of South Western Sydney Local Health District [SWSLHD]) is a principal referral group A1 hospital with tertiary affiliations to the University of NSW, University of Sydney and University of Western Sydney. It provides a wide range of general medical and surgical services and some sub-specialty services to communities in Bankstown-Canterbury Local Government Area (LGA). Clinical services in the Hospital are mainly at role delineation level 5.

It provides clinical services in: emergency medicine; cardiology; surgical sub-specialties including general, ENT, colorectal, peripheral neurosurgery, ophthalmology, orthopaedics, plastics, upper gastrointestinal pancreatic and biliary, vascular, breast and urology; medical sub-specialties including general medicine, endocrinology, gastroenterology, infectious diseases, neurology, neurophysiology, renal medicine, respiratory and rheumatology; cancer therapy including medical & surgical oncology, chemotherapy and haematology; intensive care unit/high dependency unit; maternity, gynaecology, special care nursery and paediatrics; mental health; drug health; rehabilitation and aged care; and imaging.

In relation to maternity services, Bankstown-Lidcombe Hospital has 10 neonatal cribs in the Special Care Nursery and six Birthing Unit suites, which are supported by eight operating theatres.

On average 2,220 babies are born each year at Bankstown-Lidcombe Hospital.

3. Background / Summary of Events

In January 2014 a baby was delivered in the Birthing Unit at Bankstown-Lidcombe Hospital who required resuscitation. During the resuscitation the oxygen cylinder emptied and staff transferred the baby to the Special Care Nursery across the corridor to ensure ongoing oxygen supply for the resuscitation.

Following a Root Cause Analysis (RCA) investigation into the circumstances surrounding the care provided, the Hospital installed piped oxygen outlets in the Birthing Unit that provided a constant oxygen supply for the resuscitaires in the Birthing Unit.

The decision was subsequently made to install piped oxygen to the neonatal resuscitaires in the Operating Theatres. Bankstown-Lidcombe Hospital engaged BOC Limited to install, test and commission piped oxygen for the resuscitaires in Operating Theatres 1-8. This work was undertaken on 14 July and completed on the morning of 15 July 2015. While Theatre 8 continued to be in use, there was no cause for the newly installed gas outlet to be used until late June 2016.

Tests were undertaken on the oxygen outlet for the neonatal resuscitaire by BOC Limited on the 14-15 July 2015 following the installation of the new pipes. The key requirements for the commissioning process are outlined in the Australian Standard (AS 2896-2011) *Medical gas systems – Installation and testing of non-flammable medical gas pipeline systems*.

Extract from AS 2896-2011
5.7 Certification of systems
5.7.1 Operational test
Prior to the commissioning of a medical gas system, testing by a designated person shall be performed to determine that the concentration of the medical gas is correct and that there is no contamination. A member of the health care facility experienced in the administration of medical gases to patients and such other persons as are required by the administration of the health care facility, shall be present and witness the tests. Where non-respirable medical gases, e.g. nitrous oxide and carbon dioxide are piped, tests shall be performed by the anaesthetist-in-charge or a delegated anaesthetist.

Issues around testing, commissioning and compliance with the Australian Standard will be subject to review by the independently chaired investigation (RCA) team which also has independent engineering, paediatric and anaesthetic experts. These issues are also likely to form part of the coronial investigation.

In late June 2016, Baby 1 was born and required resuscitation. The baby survived, with an unexpected poor outcome. An investigation through the RCA process was commenced to understand the reasons for the unexpected poor outcome.

On 13 July 2016, Baby 2 was born in the same operating theatre. Baby 2 required resuscitation and died. This birth was referred for a mandatory patient RCA. The unexpected death of Baby 2 was notified to the Coroner on 13 July 2016, with the senior paediatrician advising Baby 2's family that this was required under the law. Later that day, in response to the referral, police from Bankstown Police Station attended the Hospital to conduct their inquiries.

Another paediatrician involved in the clinical review of the cases requested testing of the gas outlets in Theatre 8 on July 14 2016 to understand whether this could have in any way contributed to the unexpected outcome. A work order for this testing was put in place. BOC Limited has publicly stated they received the work order on 20 July 2016. The gas outlet was not required to be used from July 14 2016. It was tested by BOC on 21 July and Theatre 8 was closed from this date.

The Coroner was advised of additional information relating to the gas outlet on 22 July 2016. There has been continued communication with the coronial investigators since that time.

<u>Testing Medical Outlets</u>

On 21 July 2016 a BOC Limited technician attended to test the medical gas outlets for neonatal resuscitaires in all Operating Theatres 1 to 8 in Bankstown-Lidcombe Hospital. The testing was undertaken in the presence of a member of the Hospital engineering department.

The BOC Limited technician conducted a gas purity check for the neonatal resuscitaire in Operating Theatre 8 and verbally advised the Hospital representative that the presence of oxygen was not detected.

The BOC Limited technician repeated this test in the remaining Operating Theatres (1 to 7), which confirmed the presence of oxygen at an appropriate level from each neonatal resuscitaire oxygen outlet.

The Hospital representative immediately escalated the test results to the Midwifery Unit Manager, Birthing Unit, who in turn immediately notified the Hospital's Director of Nursing & Midwifery Services and the Acting General Manager.

The Acting General Manager informed SWSLHD Acting Director Operations, who then informed the Director Clinical Governance and the Chief Executive of SWSLHD on the morning of 21 July 2016.

Actions Following Initial Testing Results

On 21 July, Theatre 8 was immediately closed. Further confirmatory tests were undertaken by HOSLAB Pty Limited on the same day and they provided a report confirming that no oxygen was detected and that the outlet was emitting nitrous oxide.

The initial report from BOC Limited was verbal and a written report was not provided on 21 July. On 22 July General Counsel for NSW Health wrote to BOC Limited (email received by BOC 22 July) seeking the written report as well as advice whether BOC Limited was aware of similar issues. A response by close of business 22 July was sought.

On Monday 25 July BOC Limited responded indicating that oxygen concentration emitted from the outlet in question (Theatre 8 resuscitaire) was 0.6 per cent. This would be considered negligible. BOC Limited confirmed that it was conducting an investigation and needed to undertake further tests at the site. BOC Limited subsequently conducted site visits on 27 and 28 July 2016.

Following notification of the test results, SWSLHD initiated a review of all neonate cases that required resuscitation in Operating Theatre 8 since the commissioning was undertaken in accordance with the NSW Health Lookback Policy Directive.

Interrogation of Surginet (a theatre booking system), cross checked against the birth register and medical records, indicated 36 patients gave birth in this Operating Theatre. A full review of the clinical records was completed on the morning of Friday 22 July

2016. This showed the neonatal resuscitaire in Theatre 8 was used on two neonates (Baby 1 and Baby 2).

Gas outlets in Operating Theatres and Birthing Units were ordered to be tested in all Hospitals across SWSLHD, commencing on 21 July and completed on 26 July.

NSW Health has written to BOC Limited advising it will not be further engaging the firm to undertake installation, commissioning and testing work in NSW Health facilities until the causes of the error are understood. It is also reviewing the firm's contractual obligations in relation to the Bankstown-Lidcombe Hospital installation.

The Hospital Engineer involved in the commissioning has been stood down pending the outcome of the investigation.

4. SWSLHD Further Response

4.1 Families

Open Disclosure

Open disclosure is a process for ensuring that open, honest, empathic and timely discussions occur between patients and/or their support person(s) and health service staff following a patient safety incident. The process undertaken complied with the NSW Health Open Disclosure Policy.

The two families were contacted on Friday 22 July (Baby 2 parents at 11:39 hours, Baby 1 at 12:44 hours) by a senior paediatrician who indicated he wished to inform them of additional information from the investigation. They were invited to have a meeting at a time of their choosing to enable their desired support person(s) to be present.

Present at these meetings were a paediatrician, senior Local Health District personnel, senior Hospital personnel and a senior social worker. The dates of these meetings were as follows:

- Baby 1: 22 July 2016 at 18:00 hours
- Baby 2: 23 July 2016 at 15:00 hours

The families were also provided with a 24 hour/seven day contact number for a Hospital representative.

Ongoing Contact

Both families were contacted on Monday 25 July 2016 by a senior clinician and senior social worker to offer additional support and to offer the opportunity to clarify issues raised in the open disclosure process.

Discussions with the families included information regarding counselling services available and the establishment of a plan to continue communication and support.

The family of Baby 1 continues to receive ongoing care and support from NSW Health. A care co-ordinator was appointed to assist the family.

The family of Baby 2 has been offered regular communication with a senior paediatrician and senior social worker. Information regarding Arabic-speaking counselling services has been provided.

Bankstown-Lidcombe Hospital has indicated its willingness to pay the costs of any additional external counselling services to support the family.

4.2 Staff Communication

A meeting was conducted on Friday 22 July 2016 with key representatives from Birthing Unit, Operating Theatres and management to advise of the information available.

Once families were advised on Friday 22 July 2016 and Saturday 23 July 2016, staff directly involved in the two incidents were advised via phone on the evening of Saturday 23 July 2016, to attend a staff briefing session on Monday 25 July 2016. The Employee Assistance Program (EAP) has continued to support staff, particularly staff of the Birthing Unit, Operating Theatres, ICU, Special Care Nursery and the Antenatal Outpatient Clinic.

Senior nursing staff across the Hospital attended a general briefing session and were advised of support services. Additionally, senior Hospital staff have been in touch with staff daily to ensure suitable support is made available and confirming welfare status of staff. Human Resources is undertaking ongoing daily briefings with EAP to confirm support services are focused on the appropriate departments and individual staff.

4.3 Independently Chaired (Root Cause Analysis (RCA)) Investigation

A decision to commence an RCA in relation to Baby 1 was made on 23 June 2016. Baby 2's death was referred to a mandatory RCA on 13 July 2016. However, due to the critical information in relation to the error with the gas outlet being discovered, a new RCA covering the cases of Babies 1 and 2 was initiated on Monday 25 July. The first meeting of the investigation team was on Friday 29 July.

Whilst the key focus of the RCA will be installation and commissioning of the gas outlet, the investigation will consider issues such as the management of the pregnancy of the mothers, and clinical management of the newborns.

The original pipes in operating theatres were installed as part of the build of Bankstown-Lidcombe Hospital's Operating Theatres in the late 1990s. The installation of the original pipelines will be reviewed as part of the RCA investigation.

As provided for by NSW Health policy, both families will be provided with the outcomes of the RCA pertaining to their particular case. The Coroner will be provided with a copy of the RCA report.

The RCA team will be led by Professor Michael Nicholl, Clinical Director, Division of Women's, Children's and Family Health, Northern Sydney Local Health District. Membership of the RCA team includes:

- Senior Anaesthetist (external to LHD and supported by the Royal Australian and New Zealand College of Anaesthetists)
- Neonatologist (external to LHD)
- Senior Paediatrician & Clinical Director (SWSLHD)
- Nurse Manager Operating Theatres (SWSLHD)
- Clinical Midwifery Consultant (SWSLHD)
- Patient Safety Manager (SWSLHD)
- Patient Safety Manager (Clinical Excellence Commission)
- Director, Clinical Governance(SWSLHD)
- Manager, Capital Works (SWSLHD)
- Engineer (external to LHD)
- Engineer (independent to NSW Health)

5. NSW Health system response

Appendix D outlines the concurrent investigations underway.

On 21 July, the NSW Ministry of Health was notified of the incident and convened a teleconference to establish the key facts and support state-wide and local response to the incident.

On the morning of 22 July, all Local Health Districts and Specialty Health Networks were instructed to provide advice in relation to the following:

1. What is the process to verify that the gases coming from medical gas outlets on the wall are correct at commissioning and if there are any changes to the gas supply?
2. Are clinicians involved in this process and how?
3. How frequently are gas outlets checked?

At 2 pm on 22 July the Clinical Excellence Commission (CEC) held a teleconference with Local Health Districts and Specialty Health Networks to confirm the nature of the request, timelines for response, and address any issues requiring clarification. Appendix B identifies the responses to these questions. Later on 22 July an assurance from Local Health Districts and Specialty Health Networks that the identified processes were adhered to was sought.

Issues associated with incorrect piping of gases (such as nitrous oxide being emitted instead of oxygen) would have clinically significant impacts. The risk assessment identified this to be a very low risk of occurrence but potentially having catastrophic consequences. This particular error can occur where nitrous oxide and oxygen are both piped such as in Operating Theatres and requires there to be an error in the installation and the subsequent testing process. The CEC reviewed the Incident Management System to search for any incidents of this nature and found none.

On Monday 25 July 2016, Local Health Districts and Specialty Health Networks were instructed to undertake testing (i.e. analysis of gas type) of any recently commissioned units or where pipe work has been undertaken (e.g. operating theatres, critical care, emergency departments and maternity) in the last 24 months particularly focusing on areas where the gas outlets may not have been used or used infrequently. This advice was requested to be provided within 24 hours.

Late on Monday 25 July the scope was extended to all new works or refurbishments within the last five years and this was followed up with additional correspondence on Tuesday 26 July. Appendix C provides a status report in relation to this work.

On 29 July, in order to provide further assurance, the Minister directed testing of all gas outlets in NSW Health facilities be undertaken. The Secretary wrote to all Chief Executives of Local Health Districts and Specialty Health Networks to:

1. Test, using a gas analyser, each medical gas outlet installed within any facility (new build or upgrade) within the last five years to confirm the gas type and concentration. The testing is to include air and oxygen medical gas outlets whether collocated with other gases or not.

   Advice confirming that the testing has occurred and the outcome of that testing is to be provided to the Chief Health Officer by close of business Monday 1 August 2016.

2. Test, using a gas analyser, all other medical gas outlets in NSW Health facilities to confirm the gas type and concentration. The testing is to include air and oxygen medical gas outlets whether collocated with other gases or not.

   Advice confirming the testing has occurred and the outcome of that testing is to be provided to the Chief Health Officer by close of business Monday 15 August 2016.

Health Infrastructure confirmed that for capital works managed by Health Infrastructure a three-step process for commissioning is undertaken. Step 1, the subcontractor to the principal contractor confirms the installation is compliant with the design. Step 2, the principal contractor will confirm to NSW Health representatives that the system is ready to be tested and Step 3, the certification process occurs in accordance with AS 2896-2011.

NSW Health has initiated the formation of a working group, to be led by the CEC, to review if additional state-wide policy is required to further support use of the Australian Standard 2896-2011: *Medical Gas Systems – Installation and Testing of Non-flammable Medical Gas Pipeline Systems.*

Appendix A – Timeline of events

Date	Event
Late June 2016	Attempted resuscitation of Baby 1 using wall-outlet labelled "oxygen" in Operating Theatre 8. First time outlet has been used since installation. Baby transferred to high-level facility for care.
23 June 2016	Decision for a Root Cause Analysis investigation into the circumstances around Baby 1's birth and care.
13 July 2016	Attempted resuscitation of Baby 2 using wall-outlet labelled oxygen in Operating Theatre 8. Resuscitation attempt unsuccessful. Death reported to the Coroner, family informed by senior paediatrician of the referral. NSW Police attended Bankstown-Lidcombe Hospital after the referral to the Coroner.
14 July 2016	Paediatrician requests check of gas outlet used for neonatal resuscitations; engineering work order issued as paediatrician was interested in exploring any possible contribution to the unexpected poor outcome. The gas outlet in Theatre 8 neonatal resuscitaire was not required to be used in the period until Theatre 8 was closed.
21 July 2016	Gas outlet in Operating Theatre 8 neonatal resuscitaire tested by both BOC limited and HOSLAB and found to be emitting nitrous oxide instead of oxygen. Theatre 8 was closed. Testing of all gas outlets in operating theatres and birthing units across South West Sydney Local Health District commenced (concluded 26 July 2016). Ministry of Health and Clinical Excellence Commission notified. Process for Open Disclosure commenced.
22 July 2016	Contact made with the families to notify them of the facts surrounding the two births through an open disclosure process. Open disclosure occurred with family of Baby 1 at 6pm. Family of Baby 1 requested privacy. An appointment was made with Family of Baby 2 for the following day. General Counsel NSW Health writes to BOC Limited seeking urgent advice. Chief Executive SWSLHD writes to the State Coroner informing him of information relating to gas outlets not known when the initial report is made.
23 July 2016	Family of Baby 2 open disclosure meeting held at 3pm.
25 July 2016	BOC Limited writes to NSW Health advising that it is conducting an investigation. Visit to site by NSW Police (on behalf of the State Coroner).
26 July 2016	Media conference conducted by Minister for Health and Health Secretary. Follow up site visit by Police.
27 July 2016	Site inspection by BOC and LHD experts. Follow up visit by Police and their expert engineer.
28 July 2016	Further site visit by BOC, LHD and Police.
29 July 2016	First meeting of independently chaired Root Cause Analysis investigation team.

Appendix B – Response to questions regarding gas outlet commissioning processes (excluding SWS LHD)

LHD	Verification Process	Frequency of check (pressure/flow)
St Vincent's	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
SCHN	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Central Coast	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Far West	Has been verified by two independent gas technicians and a LHD technician with specific medical gas training. Process in place to ensure future verification complies with AS2896-2011, through the inclusion of a clinician.	Outlets checked six monthly, i.e. more frequently than required by AS2896-2011
Hunter New England	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Illawarra Shoalhaven	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Mid North Coast	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Murrumbidgee	Verified according to the AS2896-2011.	Outlets checked six monthly, i.e. more frequently than required by AS2896-2011
Nepean Blue Mountains	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Northern NSW	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Northern Sydney	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
SES	Verified according to the AS2896-2011.	Outlets checked at least annually (some as often as monthly), exceeding the requirements of AS2896-2011
Southern NSW	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Sydney	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Western NSW	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Western Sydney	Verified according to the AS2896-2011.	Outlets checked as per AS2896-2011
Justice & Forensic MH	No outlets in use in facilities in recent times. New outlet in the process of commissioning will be verified according to the AS2896-2011.	New outlet (still being installed) will be checked as per AS2896-2011

Appendix C – Checking of newly-commissioned gas outlets for gas type (within past 5 years) - updated 1700hrs 5 August

Updates are noted in red.

LHD	Sites where re-testing complete	Sites remaining to be re-tested	Expected completion date/Status
SCHN	Sydney Children's Hospital, Randwick The Children's Hospital at Westmead	Nil	Complete No issues identified
Southern NSW	South East Regional Hospital (Bega) Yass Hospital Moruya Hospital Goulburn Hospital Batemans Bay	Nil	Complete No issues identified
CCLHD	Gosford Hospital Wyong Hospital Woy Woy Hospital Long Jetty Hospital	Nil	Complete No issues identified
SLHD	Canterbury Hospital Royal Prince Alfred Hospital Concord Hospital	Nil	Complete No issues identified
NBMLHD	Blue Mountains Day Procedure Centre Nepean Hospital	Nil	Complete No issues identified
WSLHD	Auburn Hospital Westmead Hospital Blacktown Hospital Mt Druitt Hospital	Nil	Complete No issues identified
ISLHD	Shoalhaven Hospital Shellharbour Hospital Wollongong Hospital Bulli Hospital	Nil	Complete No issues identified
HNE	John Hunter Hospital Tamworth Hospital Narrabri Hospital Scott Memorial Hospital - Scone Glen Innes Hospital Manilla Hospital Singleton Hospital Armidale Hospital Cessnock Hospital Inverell Hospital Muswellbrook Hospital Gunnedah Hospital	Nil	Complete No issues identified
FWLHD	Broken Hill Health Service	Nil	Complete No issues identified
MNC	Bellingen River District Hospital Wauchope District Hospital Coffs Harbour Health Campus Port Macquarie Base Hospital Kempsey District Hospital Macksville District Hospital	Nil	Complete No issues identified
SWS	Liverpool Hospital Campbelltown Hospital Fairfield Hospital Bowral Hospital	Nil	Complete No issues identified

LHD	Sites where re-testing complete	Sites remaining to be re-tested	Expected completion date/Status
	Bankstown-Lidcombe Hospital (Camden – N/A no works in the last 5 years)		
NNSW	Byron Hospital Murwillumbah Hospital Health One Pottsville Tweed Hospital Ballina Hospital Casino Hospital Lismore Base Hospital Maclean District Hospital Yamba Community Health Grafton Base Hospital	Nil	Complete No issues identified
NSLHD	Manly Hospital Mona Vale Hospital Ryde Hospital Hornsby Ku-ring-gai Hospital Royal North Shore Hospital	Nil	Complete No issues identified
SESLHD	Prince of Wales Hospital Sydney & Sydney Eye Hospital The Sutherland Hospital Royal Women's Hospital St George Hospital	Nil	Complete No issues identified
WNSW	Dubbo Base Hospital Forbes District Hospital Parkes District Hospital Gulgong Health Service Peak Hill Health Service Eugowra Health Service Bathurst Health Service Walgett Health Service Cowra District Hospital Orange Health Service	Nil	Complete No issues identified
Sydney LHD	Canterbury Hospital Concord Hospital Royal Prince Alfred Hospital Chris O'Brien Lifehouse Sydney Dental Hospital	Nil	Complete No issues identified
Murrumbidgee LHD	Tumut Hospital Gundagai District Hospital Corowa District Hospital Young Hospital Deniliquin Hospital Hillston District Hospital Lockhart District Hospital Griffith Hospital Coolamon Hospital Temora Hospital Wagga Wagga Rural Referral Hospital	Nil	Complete No issues identified
St Vincent's Health Network	St Vincent's Hospital	Nil	Complete No issues identified
JH&FMH Network	N/A - nil newly commissioned work	N/A	N/A
ASNSW	N/A - no piped gas	N/A	N/A

Appendix D – Concurrent Investigations

1. Coronial Investigations

On 13 July 2016 the Coroner was notified of the death of Baby 2 and in response Police attended Bankstown-Lidcombe Hospital on that day.

On 25 July 2016, the State Coroner's Court informed SWSLHD that Deputy State Coroner Dillon had assumed jurisdiction over the death. Police from Bankstown Police Station are now investigating on behalf of the Coroner.

It is unknown at this stage whether the matter will proceed to an inquest. This will be determined by the Coroner.

SWSLHD has undertaken to provide the State Coroner with a copy of the Root Cause Analysis Report once it is available.

2. Root Cause Analysis - an investigation of the root causes of adverse incidents

As per *PD2014_004 Incident Management Policy*, Root Cause Analysis teams are expected to report within 70 calendar days from when the incident was notified in the incident management system.

A decision to commence an RCA in relation to Baby 1 was made on 23 June 2016. A mandatory RCA in relation to Baby 2 was initiated on 13 July 2016. A combined RCA covering Baby 1 and 2 was instituted on 25 July and had its first meeting on 29 July 2016.

3. Other inquiries

An independent engineer is being engaged by NSW Health to undertake a full review of the installation and commissioning of the gas outlets in Operating Theatres 1-8, including the original pipe installation in the 1990s. The Report will be provided to the RCA team and the Chief Executive of the LHD.

By letter dated 25 July 2016, BOC Limited advised that it was conducting an investigation and needed to undertake further tests at the site. BOC subsequently conducted site visits on 27 and 28 July 2016.

BOC also advised that it was not aware of any similar issues which may impact on other sites.

On 29 July 2016, NSW Health was advised Safework NSW has requested an inspection of the site.