

Bankstown – Lidcombe Hospital

Cold Chain Breach Incident

Final Report

13 February 2017

Prepared by Dr Stephen Conaty, Acting Director Population Health, SWSLHD and Ms Shane Bolsom, Acting Patient Safety Manager, SWSLHD on behalf of the Bankstown-Lidcombe Cold Chain Breach Investigation Team

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1. Purpose

On 2 February 2017, an Investigation Team was convened to investigate the cold chain breaches (CCB) at Bankstown - Lidcombe Hospital's Birthing Unit (3G) and the Postnatal ward (3E) and make recommendations to prevent future occurrence of these incidents. The Terms of Reference and Membership of the Investigation Team are included in **Appendix 1**. The purpose of the investigation as stated in the Terms of Reference were:

- a) To investigate the causes and extent of the CCB at the Birthing Unit and the Postnatal ward at Bankstown – Lidcombe Hospital.
- b) Make recommendations to Bankstown – Lidcombe Hospital and South Western Sydney Local Health District (SWSLHD) to prevent future occurrence of these incidents.

The scope of the investigation included the causes of the CCB, the systems that were in place to detect and rectify, compliance with policy and escalation and reporting of the event. The patient contact actions that followed the identification of compromised vaccine stock were outside the scope of the investigation and are not considered in this report other than to note the number of patients affected.

2. Conduct

This report has been prepared by Dr Stephen Conaty, Acting Director Population Health SWSLHD and Ms Shane Bolsom, Acting Patient Safety Manager SWSLHD on behalf of the Investigation Team to advise the Chief Executive and an internal steering group in relation to the cold chain breaches affecting two medication and vaccination fridges at Bankstown-Lidcombe Hospital.

The Investigation Team included two invited experts external to the SWSLHD from the National Centre for Immunisation Research and Surveillance and the NSW Ministry of Health

The Investigation Team met by telephone conference on Thursday 2 February 2017 to commence the process of evidence gathering and met at the Bankstown-Lidcombe Hospital site on Wednesday 8 February 2017 for assessment of the evidence and to inspect the fridges, records and ward environments. The report was written by Dr Stephen Conaty and Ms Shane Bolsom and endorsed by the Investigation Team.

No interviews with staff members were conducted. Information obtained from staff about the incidents was information relayed to the Bankstown - Lidcombe Hospital members of the Investigation Team in the course of their normal duties in reporting and investigating the incident (s).

As part of the investigation we asked the Head of Pharmacy (part of the Investigation Team) to conduct some experiments with the fridge model involved in these incidents and these findings are also incorporated into the report.

3. Background

Bankstown-Lidcombe Hospital (part of SWSLHD) is a principal referral group A1 hospital. It has a busy maternity unit. There are approximately 2,200 babies are born each year at the hospital. As part of usual maternity care, every baby at birth is offered hepatitis B vaccine. This is sometimes called the birth dose and is specifically to protect the baby from hepatitis B around the time of birth and in the first few months of life. Boostrix is a vaccine given to adults to boost their immunity against pertussis (whooping cough), diphtheria and tetanus. It is offered to pregnant women in the third trimester to protect infants through direct pertussis antibody transfer to the infant, or in the post-natal period if the woman missed the antenatal dose to protect the mother against pertussis and reduce the risk of infecting her infant.

Most vaccines used in Australia are temperature-sensitive substances that must be stored between +2°C and +8°C at all times to ensure they work effectively. There may be loss of potency if vaccines have been stored at temperatures outside this range. The cold chain describes a system to ensure all stages in manufacture, procurement, transport, storage and administration maintain a temperature within the 2 and 8 degree range.

A cold chain breach (CCB) is a term used to describe a temperature excursion outside this range that is significant or prolonged. When vaccines are repeatedly exposed to temperatures outside the recommended +2°C to +8°C range, the loss of potency is cumulative and cannot be reversed.

Bankstown – Lidcombe Hospital has 24 fridges that stock medication and 6 fridges that stock vaccines. In December 2014 / January 2015, Bankstown – Lidcombe Hospital purchased Thermoline Pharmaceutical / Vaccine Storage Refrigerators for storage of medications and vaccines. These were 145L capacity half size fridges with glass door and external temperature display (model number TEPR 145). The refrigerator displays HI/LO temperature and Door Ajar alarms. All alarms emit a visual and audible alarm (at the point of equipment) as well as activating a 'back to base' alarm system. The 'back to base' alarm notifies the Bankstown – Lidcombe Hospital switch board, staffed 24 hours a day, 7 days a week.

The refrigerator alarm limits are set by the manufacturer as High temperature 8°C Low temperature 2°C and Door Ajar to trigger at 5 minutes. The alarm is also triggered by any interruption to loss of power. Once the alarm is activated senior Nursing management is notified by switch board staff. The cause of the alarm is then investigated.

In March 2016, LogTag® temperature data loggers were introduced to assist the Pharmacy Department in determining the timeframe of a temperature excursion and if discarding of stock is required. Temperature data loggers are simple probe thermometers, which log and save temperature readings on inbuilt memory. A series of temperature readings can then be downloaded and analysed using a serial interface that connects to a PC computer. At Bankstown – Lidcombe Hospital the temperature data loggers are set to log the refrigerator temperature at 15 minutely intervals which enables 85 days of data to be stored. The data logging reports are not routinely downloaded and reviewed by ward/unit managers or pharmacy staff unless a problem is identified.

4. Summary of Events

Cold Chain Breach # 1 (CCB #1)

On 19 January 2017, the Bankstown – Lidcombe Hospital Pharmacy Department received notification that a back to base alarm from the Birthing Unit (BU) refrigerator had activated. The temperature data logger was downloaded to assist in determining the timeframe of a temperature excursion and if discarding of stock was required. The data was reviewed and it was identified that between 29 November 2016 and 19 January 2017 there were multiple excursions outside the recommended temperature of 2-8°C. During this timeframe the highest temperature outside the range was recorded as 11.6°C and the lowest was minus 0.8°C (see **Appendix 2**).

The refrigerated stock (see **Appendix 3**) was isolated and the excursions were escalated to the Acting Director of Nursing and Midwifery Services and Acting Operational Nurse Manager. A decision was made to decommission the BU fridge and utilise the stock from the adjacent Postnatal ward whilst testing of the fridge was conducted. To ensure essential stock was readily available, additional stock was placed in the Afterhours Pharmacy, in the event the Postnatal ward stock was depleted.

On 20 January 2017, the temperature excursions were escalated to the Bankstown – Lidcombe Hospital Acting General Manager, who advised the SWSLHD Public Health Unit (PHU), the SWSLHD Acting Chief Executive, Acting Director of Operations and Acting Director of Clinical Governance. The effects of the temperature breaches on the vaccines and medications stored in the fridge was not clear at the time and the data was referred to the NSW Ministry of Health to confirm if further actions following the CCB needed to be taken. The previously isolated medications and vaccinations from the BU fridge were discarded in accordance with local policy Bankstown – Lidcombe Hospital Policy Directive: Safe Use of Medication and Refrigerators BNK_PD2014_013 (rescinded) and SWSLHD Policy Directive: Safe Use of Medication and Vaccine Refrigerators SWSLHD_PD2015_017

On Saturday 21 January 2017 and Sunday 22 January 2017, the Birthing Unit fridge was tested with two temperature data loggers (the current logger and a new logger) placed in the empty fridge. During the testing period the temperatures recorded by the two loggers and the fridge monitor were consistent.

Whilst awaiting confirmation of actions to take following the CCB the Bankstown – Lidcombe Hospital commenced identifying mothers and babies who may have been affected during the period. There were 264 babies (including one set of twins) born to mothers who were screened as Hepatitis B negative in the antenatal period. Of these, 8 mothers elected not to vaccinate their babies at the time of birth. Therefore 256 babies were administered the vaccine during this period. There were 9 babies born to mothers known to be Hepatitis B positive who also received the Hepatitis B vaccine in this period.

Cold Chain Breach # 2 (CCB #2)

On 22 January 2017 15:55 hours, the Postnatal ward fridge back to base alarm was triggered with a high temperature alarm. The Pharmacy Department were notified and the temperature data logger within the refrigerator was downloaded and the stock was isolated until the data from the logger was reviewed. The data was reviewed and it was identified that between 18:00 hours on 20 January 2017 and the time that the alarm was triggered there

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were multiple excursions outside the recommended temperature of 2-8° C. During this timeframe the lowest temperature outside the recommended range was minus 0.4°C (see **Appendix 4**).

The refrigerated stock was isolated and new limited stock was placed in the adjacent wards vaccination / medication fridge.

The data was also referred to the NSW Ministry of Health to confirm if this CCB required further action. Whilst awaiting confirmation Bankstown – Lidcombe Hospital determined six (6) babies, born to mothers screened Hepatitis negative in the antenatal period, received their Hepatitis B vaccination (Hep B Vax II) and three (3) mothers received a Boostrix vaccine during this period.

Cold Chain Breach # 3 (CCB #3)

Following the above breaches, a review was conducted of records of all data which had been previously downloaded from medication fridge temperature data loggers since March 2016 (date of purchase). This review identified that on 26 July 2016, Pharmacy had been notified of a problem with the Postnatal fridge temperature data logger (on the daily temperature record for that day it was recorded that the logger was flashing red and the NUM was notified). The data logger flashes if there is a temperature excursion outside 2-8°C for two consecutive recordings. The downloaded data identified multiple low temperature excursions of sub-zero temperatures since 24 May 2016, with the lowest temperature recorded at minus 1.9 degrees (see **Appendix 5**). The refrigerated stock was isolated and discarded on 26 July 2016.

There was difficulty in establishing some facts due to staff recollection as the CCB #3 event occurred 6 months prior to the Investigation Team being convened. It was not recalled whether the low temperature excursion were brought to the attention of senior Pharmacy staff.

91 mothers received Boostrix and 91 babies received hepatitis B vaccine (including 6 babies to hepatitis B positive mothers).

5. Immediate cause of the low temperature event (s) – factors contributing

The Investigating Team reviewed a range of evidence to assist in the identification of the immediate cause of the low temperature. The Investigation Team determined quantity and loading of stock, placement of the temperature data loggers within the fridge and fridge design may have contributed to the immediate cause of the low temperature events.

Design

The Thermoline Pharmaceutical / Vaccine Storage Refrigerator utilises fan force to circulate air internally through the fridge. Constant air flow is required throughout the cabinet to maintain the desired temperature. Correct loading of the shelves must be considered for efficient refrigeration performance.

To enable optimal performance of the circulation of refrigerated air the instruction manual states a minimum of 100 millimetre space should be maintained at the rear and sides of the

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fridge all times. To prevent items placed on the shelves from encroaching back and front walls of the refrigerator each shelf has a front and rear barrier; however, the sides of the shelves do not provide a similar barrier. The Investigation Team identified that when items are stacked on top each other and items sit above the shelf barrier encroachment of the space and subsequent interruption of internal airflow could occur.

The fridge temperature sensor is located at the rear of the fridge, under the bottom shelf and is protected within a tube that has a single opening to allow airflow on the left hand side. The sensor does not have a barrier, similar to the shelving, and a review of the Thermoline Refrigerator Instruction Manual identified that there are no instructions provided for the user on the placement of stock adjacent to the sensor to ensure adequate airflow and accurate internal temperature readings.

Quantity and Loading of Stock.

The Investigation Team identified that for each CCB the fridges were overstocked with vaccines, medications and other stock not required to be refrigerated (e. g. IV fluid giving set). An image taken of the Birthing Unit (3G) fridge (CCB #1), prior to the removal and isolation of stock, showed that the refrigerated stock was stacked on all shelves above the shelf barrier and the fridge temperature sensor was surrounded by the stock on the fridge base and the shelf above.

An independent company accredited in the commissioning, installation, maintenance of medical refrigeration was engaged to test/inspect the two fridges in Maternity and Birthing units to determine what may have been the cause of the temperature issues. On 23 January 2017, a report was provided which determined that the refrigerators were in working order. The report noted that the amount and loading of refrigerated stock and concluded that the airflow to the temperature sensor had likely been blocked and was in a warm pocket causing continuous refrigeration and lowering of the fridge temperature. The report also noted that the fridge was pushed up against the wall, which may cause the compressor to overheat due to a lack of air flow. Though overheating of the compressor can cause it to seize it was not considered to have contributed to the low temperature events.

The Thermoline Refrigerator Instruction Manual instructs correct loading of the shelves to be considered for efficient refrigerator performance. This includes allowing air space around the product and distributing the load evenly over all the shelves rather than stacking everything on one shelf. The manual does not provide instruction on maximum stock levels / overstocking or efficiency of refrigeration if overstocking occurs.

Experiment #1

The Investigation Team attempted to recreate the fridge environment of CCB #1 utilising a fridge located in the Pharmacy Department, based on the image of the fridge content of CCB #1 and the isolated stock from CCB # 2. Six (6) Temperature Data loggers were placed in various positions within the fridge. Data downloaded from the loggers identified the average temperature recorded by the loggers varied between 3.3 °C to 5.9 °C whilst the minimum temperature recorded varied between –minus 0.1 °C and 4.4 °C. The logger placed at the rear of the fridge, closest to the refrigerated airflow logged the lowest average (3.3 °C) and minimum temperature (-0.1 °C) whilst the logger at the placed on the base of the fridge recorded the highest average (5.9 °C) and minimum temperature (4.4 °C). In contrast the fridge sensor which was surrounded by the refrigerated stock recorded temperatures

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between 5.4 °C and 7.8 °C (these were the minimum and maximum temperatures on the display unit). (See **Appendix 6**)

Placement of the Temperature Data Loggers within the Fridge

An independent company engaged to test/inspect on the two fridges noted in the report that the Temperature Data logger in the BU was placed on an upper shelf of the fridge. This meant the reading logger was reading the temperature of the air coming off the refrigeration coil which is the coldest place in the fridge.

Experiment #2

To understand whether placement of a logger in the cold airstream alone could lead to near zero temperature recordings the Investigation Team placed six (6) temperature data loggers in various positions within an empty fridge located in the Pharmacy Department. Data was downloaded from the loggers identified the average temperature recording for the loggers variation was between 5.3°C to 7.1°C whilst the minimum temperature recorded varied between 3.3°C and 6.6°C. Similar to Experiment #1 the logger placed at the rear of the fridge, closest to the refrigerated airflow logged the lowest average (5.3°C) and minimum temperature (3.3°C) whilst the logger at the placed on the base of the fridge recorded the highest average (7.1°C) and minimum temperature (6.6°C). Unlike Experiment #1 no low temperature events occurred and the fridge sensor temperature was recorded between 4.6 and 5.6 °C. (See **Appendix 7**)

6. Detection of / Failure to Detect the Low Temperature Events

Temperature Monitoring

Recording of refrigerator temperatures are to be manually logged by staff and recorded on a Refrigerator Temperature Chart. There were four monitoring charts utilised at Bankstown – Lidcombe Hospital between May 2016 and January 2017. These included the Temperature Charts located in the Bankstown – Lidcombe Hospitals Policy Directive (BNK_PD2014_180) Monitoring of all Refrigerators used for Storage of Medicines on Wards and Departments (rescinded) and the SWSLHD Policy Directive (SWSLHD_PD2015_017) Safe Use of Medications and Vaccine Refrigerators, the NSW Health Vaccination Temperature Chart and a newly developed Bankstown- Lidcombe Refrigerator Temperature Monitoring chart which was officially published with the newest Bankstown –Lidcombe Hospitals Policy Directive published in January 2017

- The Bankstown – Lidcombe Hospital chart located in the rescinded policy, did not allow for twice daily recording of fridges containing vaccines and instructed staff to recheck temperature in one hour if a temperature excursion was identified. Data loggers were not required to be monitored on this chart.
- The SWSLHD enables twice daily monitoring, utilises colours to indicate dangerous temperatures, provides advice on actions required if a temperature excursion occurs and enables documentation of actions taken. The chart escalation process dangerous temperature excursion is to the Nurse Unit Manager (NUM) or Afterhours Nurse Manager (AHNM) The Data loggers checks are not required to be monitored on this chart.

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- The NSW Health Refrigerator Monitoring Chart enables twice daily monitoring, utilises colours to indicate temperature excursions for escalation, provides advice on actions required if a temperature excursion occurs and enables documentation of actions taken. The chart escalation process for temperature excursion is to the local Public Health Unit (PHU). The Data loggers are not required to be monitored on this chart.
- The newly developed Bankstown- Lidcombe Refrigerator Temperature Monitoring chart enables twice daily monitoring, provides advice on actions required if Temperature excursions occur, enables documentation of actions taken and records monitoring of data loggers.

Daily temperature records for all fridges were available for review and demonstrated records with multiple missed days and sometimes recordings of single current fridge temperatures rather than the minimum and maximum temperatures reached.

In CCB #3, the monitoring chart was changed on 16 July 2016 from the rescinded Bankstown- Lidcombe chart to the newly developed Bankstown- Lidcombe Refrigerator Temperature Monitoring chart. This chart enabled staff to identify two occasions where the Temperature data logger indicated a temperature excursion with a red light displayed and documentation of actions taken. The first excursion was found on the 21 July 2016 and the Nurse Unit Manager was notified and the second excursion occurred on 26 July 2016, the Nurse Unit Manager was notified and on this occasion escalation to the Pharmacy Department occurred.

Back to Base Alarm

As described previously the back-to-base alarms require the refrigerator alarm to be triggered at 5 minutes at temperatures above 8 °C and below 6 °C. A review of the Bankstown – Lidcombe Hospital switch board records was conducted which indicated that the back-to-base alarm had not been triggered during the CCBs.

Data logging

As outlined in the background section of this report in March 2016 LogTag® temperature data loggers were purchased to assist the Pharmacy Department in determining the timeframe of a temperature excursion and if discarding of stock is required. Temperature data loggers are simple probe thermometers, which log and save temperature readings on inbuilt memory. A series of temperature readings can then be downloaded and analysed using a serial interface that connects to a PC computer. At Bankstown – Lidcombe Hospital the Temperature data loggers are set to log the refrigerator temperature at 15 minutely intervals which enables 85 days of data to be stored. The loggers have a number of parameters that can be altered. The loggers record a temperature at a point in time rather than an average temperature for a period. The recording interval can be altered to record temperature more frequently but the memory is limited to a number of data points. More frequent temperature recording reduces the period of time that a logger can record for. The logger flashes red if two consecutive temperatures are outside the set range.

7. System policies and procedures

The following relevant policy directives and guidelines were in force at the time of the cold chain breaches.

- Australian Government National Vaccine Storage Guidelines – Strive for 5 (2013) 2nd Edition
[http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/D7EDA378F0B97134CA257D4D0081E4BB/\\$File/strive-for-5-guidelines.pdf](http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/D7EDA378F0B97134CA257D4D0081E4BB/$File/strive-for-5-guidelines.pdf)
- NSW Health Policy Directive: Hepatitis B Vaccination Policy
PD2005_222 http://www0.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_222.pdf
- NSW Health Policy Directive: Medication Handling in NSW Public Health Facilities
PD2013_043
http://www0.health.nsw.gov.au/policies/pd/2013/pdf/PD2013_043.pdf
- South Western Sydney Local Health District (SWSLHD) Policy Directive: Safe Use of Medication and Vaccine Refrigerators
SWSLHD_PD2015_017 http://intranet.sswahs.nsw.gov.au/sswpolicies/pdf/swslhd/swslhd_pd2015_017.pdf
- Bankstown – Lidcombe Hospital Policy Directive: Safe Use of Medication and Refrigerators BNK_PD2017_013
(rescinded) http://intranet.sswahs.nsw.gov.au/SSWPolicies/pdf/Bankstown/BNK_PD2017_013.pdf

To support cold chain management in the NSW Health system, Health Protection NSW has developed the following tools:

- Vaccine cold chain management power point presentations available on the NSW Health website at www.health.nsw.gov.au/immunisation :
- A dedicated cold chain webpage is available at www.health.nsw.gov.au/immunisationproviders
- Vaccine Management & Storage Self-Audit Tool (available on the Quality Audit Reporting System -QARS)
- Vaccine Refrigerator Temperature Chart (available to order from the Stream Direct Catalogue)

On review of the policy directives, guidelines and educational tools available staff are advised to escalate a CCB to NUM or AHNM, isolate and make a list of compromised medications and vaccines and if required, dispose of stock in consultation with the Pharmacy Department. In CCB #3, this process was followed, however no further investigation was conducted into the number of patients who received potentially compromised vaccines.

In CCB #1 and CCB #2, it was recognised by a senior Pharmacist that the stability of vaccines exposed to a sub zero temperatures was unknown. Additional steps were incorporated in the actions taken by Bankstown-Lidcombe Hospital conformation of the CCB, escalation to the Public Health to investigate the efficacy of the exposed vaccines.

Stock Management

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The Bankstown – Lidcombe Hospitals Pharmacy Department provides each department with an imprest list (qualities of stock to be held on the ward). The departments / wards are required to review their imprest daily and order additional stock if the stock levels are depleted. Once ordered the Pharmacy Department dispense the stock and staff in the clinical area unpack / load the medications / vaccines into the locked medication room or refrigerator. This ordering process occurs for both refrigerated and non-refrigerated medications / vaccines.

In all three CCB events the level of medications / vaccinations requiring refrigeration exceeded the imprest list provided by the Pharmacy. Additionally, imprest stock traditionally refrigerated that did not require refrigeration (such as suppositories) were also stored in the fridges. This resulted in overstocking.

The SWSLHD Policy Directive: Safe Use of Medication and Vaccine Refrigerators SWSLHD_PD2015_017 does provide an example of an audit tool which requires auditing for inappropriate contents within the fridge including pharmaceutical products not requiring refrigeration however the policy does not provide guidance on the frequency the audit is required to be completed.

8. Findings

Causes of the low temperature fridge event

Finding 1: The cause of the periods of low temperature cycling of the fridge were almost certainly due to stock crowding the inbuilt temperature sensor at the right hand base of the fridge.

The effect of this crowding is to impede cold air reaching the sensor and creating a small pocket of relatively warm air. This signalled to the fridge compressor to turn on and drive cold air into the fridge which lowered the temperature in the remainder of the fridge to low and sometimes near zero temperatures. There are several pieces of evidence which support this finding as follow:

- There was photographic evidence of the fridge on 3G (Birthing Unit) being crowded with stock on the Sunday 22 January when the alarm sounded and the Pharmacist was called in. In the photograph the right lower area of the fridge is blocked to the immediate left and above (see **Appendix 2**).
- Anecdotal reports support that this relative stock crowding is typical of the fridges on both the birthing unit and Postnatal ward
- The experiment conducted with the same model of fridge by the Pharmacy Department at Bankstown was able to reproduce similar cold temperatures in the fridge by blocking the lower right area of the fridge with stock around the sensor to left and above (see **Appendix 6**)
- The fridge maintenance contractors agree that this is a likely explanation

Finding 2: A misplaced logger is a less likely explanation for the cold temperature recordings

The main alternative explanation for the cold temperature recordings is that the data logger was misplaced for a period of time in the cold airstream of the fridge. The cold air from the

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compressor falls from the top back of the fridge compartment and direct exposure of a data logger temperature probe to the cold airstream may record a cold temperature that is not representative of the main body of the fridge. The evidence that does not support this is as follows:

- The data loggers in both fridges were reported by staff to have been clipped on to the wire rack shelving in a central area of the fridge. This is a measure introduced by pharmacy to ensure correct placement of loggers.
- An experiment conducted in the Pharmacy Department with the same model of fridge (empty) run overnight with 5 data loggers placed at various positions including in the cold airstream shows that temperatures recorded by even misplaced loggers in the cold airstream do not reach the near zero temperatures in these cold chain incidents.

However, it should be noted that there was some variation in the recorded temperature inside the fridge depending on the placement of the logger and a misplaced logger could have contributed partly to the very low temperatures recorded during these cold chain breach events.

Systems to detect and rectify the cold chain breaches

Finding 3: Daily temperature min/max monitoring and the back to base alarm did not and could not detect this cold chain breach event.

Two of the cold chain breaches detailed in this report were prolonged and were not detected at the time they occurred and not for a period of weeks afterwards. In CCB#1 and CCB#2 a back to base alarm to switch was the trigger alerting to a problem. The alarm was triggered in each of these incidents by the sensor reading above 8 degrees for 5 minutes. The actual low temperature CCB events were only an incidentally discovered when the data logger temperature recordings were downloaded. For each of these cold chain breaches we have good supporting evidence that the fridge sensor was not detecting these low temperature events and consequently the min / max recordings did not register these cold temperatures and the back to base alarm was not triggered. The evidence supporting this finding is as follows:

- A log of the back to base alarm is kept at the switchboard and no alarms in the Birthing Unit and Postnatal ward were triggered over the periods when these low temperature events occurred
- Minimum / maximum daily temperature recordings in the Birthing Unit period in early December 2016 were well recorded and consistently recorded minimum temperatures that were well within the 2-8 range rather than low minimums. This was precisely during a period when the data logger recorded consistently low minimums
- During the fridge experiment #1 conducted by the Pharmacy department in which they tried to block the sensor with stock the internal minimum recorded in the fridge display for this period was 5.4 degrees.

Finding 4: (Twice) daily recording of fridge temperatures (minimums and maximums) were irregularly and often incorrectly completed.

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Daily temperature records for all fridges were available and demonstrated records with missed days and sometimes recordings of single temperatures rather than minimums and maximums.

Finding 5: The back to base alarm system functioned appropriately

The failure of the back to base alarm to sound associated with the low temperatures was because it was attached to the fridge sensor and display that was recording and displaying temperatures within the normal range.

Finding 6: There was no set schedule for downloading the data logger information and this contributed to a relatively long period of time before the discovery of CCB#1 and CCB#3.

The data logging system was sensibly being used as a diagnostic tool to assess whether fridge alarms indicated important or prolonged excursions above or below 2 – 8 degrees. However, without a regular schedule of downloading this affected the ability to detect these unusual cold chain breaches in a timely manner.

Immediate action and escalation of the detection of the probable cold chain breaches

Finding 7: For CCB#1 and CCB#2 appropriate action and escalation occurred when the event was detected by pharmacy. This escalation was through the Operational Nurse Manager and then to the General Manager and to the Public Health Unit for advice.

Finding 8: CCB#3 was not appropriately escalated beyond pharmacy.

CCB#3 was only uncovered during review prompted by CCB#1 and CCB#2 of the previously printed records for the data loggers for all vaccine fridges. This event was brought to the attention of pharmacy on 26 July 2016 and immediate corrective actions was taken to quarantine and discard stock.

However, despite the data logger record being downloaded there does not appear to have been the understanding in the pharmacy staff that the data logger record indicated an event that may have compromised vaccine stock and that escalation was required.

Finding 9: There is some evidence that the importance of a red flashing alert on the data logger is not understood or the necessity to escalate not appreciated.

During CCB#3 there were two annotations on the daily temperature recording charts that the data logger was flashing red and a note that the NUM had been notified. This occurred on 21 July 2016 and 26 July 2016. There was no escalation to pharmacy for the first event. It was presumed that the Nurse Unit Manager (NUM) notified the Pharmacy department that the indicator light on the Temperature Data Logger was red on 26 July and that was the mechanism that brought this to the attention of pharmacy.

Policies in place, adherence to policy and adequacy of policy

Finding 10: The form for daily temperature monitoring used in the wards was the form from the 2014 Bankstown policy which only required daily temperature recording of fridges rather than twice daily which is the accepted standard for vaccine fridges (and current LHD policy).

Finding 11: Neither the Bankstown policy or the SWSLHD policy stipulated a frequency for downloading temperature data logger information.

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In the SWSLHD policy the logger is assumed to be a mechanism to retrospectively review fridge performance and this is the way data loggers were being used in Bankstown.

Finding 12: Neither the Bankstown Policy, SWSLHD policy nor the Ministry form have any clear place or prompt to record other observations such as a flashing or alerting data logger.

This is a strictly local facility matter given that there are a range of data loggers that have a variety of displays and a variety of ways they alert out of temperature excursions.

Finding 13: The Bankstown policy and current SWSLHD policy do not mention escalation of suspected cold chain breaches to the Public Health Unit for expert advice.

9. Recommendations

Recommendation 1: The findings of this report should be brought to the attention of the fridge manufacturer (Thermoline).

Recommendation 2: All Thermoline fridges at Bankstown-Lidcombe Hospital should have the bottom shelf adjacent to the sensor labelled appropriately so that stock is not placed in such a way as to block or isolate the sensor.

Recommendation 3: Nursing and midwifery staff should be educated about appropriate fridge stocking and appropriate and consistent placement of data loggers.

Recommendation 4: Twice daily minimum and maximum temperature monitoring of vaccine fridges should be reinforced through education and appropriate forms provided.

Recommendation 5: A clear process of escalation of possible cold chain breaches needs to be articulated in SWSLHD policy or Facility policy / procedures and this should include the roles of wards, Pharmacy, Executive and the Public Health Unit.

Recommendation 6: A review of the range of medication / vaccine fridges in other SWSLHD facilities should be conducted so that the same consistent advice and labelling about stock placement is available for other facilities that use fridges with similar sensor placement.

10. Appendices

1. Terms of Reference
2. Temperature data logger record for CCB #1
3. Fridge picture and stock isolated list CCB #1
4. Temperature data logger record for CCB #2
5. Temperature data logger record for CCB #3
6. Experiment #1
7. Experiment #2

Appendix 1 – Terms of Reference



Terms of Reference

Working group to investigate and report on causes of the cold chain breach Bankstown-Lidcombe Hospital Birthing unit and Perinatal ward

1. PURPOSE

- a. To investigate the causes and extent of the cold chain breaches at the Birthing unit and the Perinatal ward at Bankstown Hospital.
- b. Make recommendations to Bankstown Hospital and South Western Sydney Local Health District to prevent future occurrence of these incidents.

2. SCOPE

Within scope

- a. The causes of the cold chain breach / fridge low temperature event
- b. Systems in place and actions that may or may not have been taken to detect and rectify the low temperature fridge event
- c. Compliance with relevant policy
- d. Escalation and reporting of the event

Not within scope

- e. Determining if, vaccines were compromised as a result of a cold-chain breach and whether follow-up actions should occur.
- f. Whether the agreed follow-up actions were appropriate following the establishment of the fact that a previous event had occurred.
- g. The implementation of follow-up actions including contacting mothers, offering revaccination and similar.

3. MEMBERSHIP

- Stephen Conaty, Acting Director Population Health (Chair)
- Shane Bolsom, Acting Patient Safety Manager, SWSLHD (Secretariat)
- Lucy Nair, Head of Department, Pharmacy, Bankstown-Lidcombe Hospital
- Innocent Mtabari, Operational Nurse Manager, Bankstown-Lidcombe Hospital
- Madhumati Chatterji, Acting Director, Public Health Unit, SWSLHD
- Kylie McNulty, Clinical Nurse Specialist, Immunisation, Public Health Unit, SWSLHD
- Ms Sonya Nicholl, Senior Policy Analyst, Immunisation Unit, Health Protection NSW
- Karen Orr, Clinical Nurse Consultant, National Centre for Immunisation Research and Surveillance
- Gregory Allen, Engineering Bankstown-Lidcombe Hospital

4. MEETING FREQUENCY

Two or three meetings with a two week time frame

5. REPORTING RELATIONSHIPS

The working group reports to the SWSLHD BLH Cold Chain Steering Group

6. RECORDS MANAGEMENT

Agenda, minutes and report will be placed in SWF17/172

7. FINDINGS

A draft report of findings will be prepared by the working group for consideration

Version	Author	Date
1.0	Stephen Conaty	01/02/17
Final	Stephen Conaty plus Steering group	02/02/17

Appendix 2 - Temperature data logger record for CCB #1

LogTag

Recorder has been downloaded 18/01/2017 5:02:56 PM (UTC +10:00, daylight time)

Alarm Status Recorder Info

Low ✗ Fail	Serial #: 1000568020	Model: TRIX-8	Battery: OK	Trip #: 1
High ✓ OK	User ID: Birthing Unit			

Recorder Configuration

Start type: Push button start	Temperature alarms
Start delay: 15 Minutes	Lower: 2.0 °C after 2 Consecutive
Interval: 15 Minutes	Upper: 8.0 °C after 2 Consecutive
Alert indicator: Enabled lower & upper	
OK indicator: Enabled	

Recorded Data

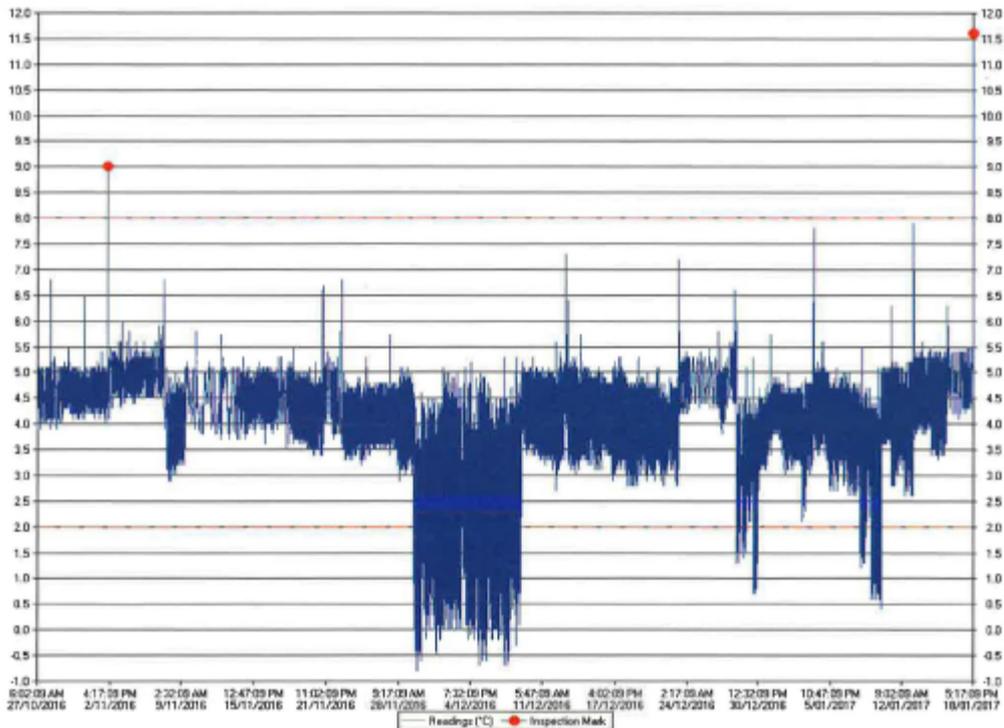
First reading: 27/10/2016 6:02:09 AM	Temperature statistics
Last reading: 18/01/2017 5:17:09 PM	Lowest: -0.8 °C
Elapsed Time: 83 Days, 11 Hours, 15 Minutes	@ 30/11/2016 1:02:09 AM
Total readings: 8014	Highest: 11.6 °C
First evaluated: 27/10/2016 6:02:09 AM	@ 18/01/2017 5:17:09 PM
Last evaluated: 18/01/2017 5:17:09 PM	Average reading: 4.1 °C
Evaluated Time: 83 Days, 11 Hours, 15 Minutes	Standard Deviation (S): 1.1 °C
Evaluated Readings: 8014	Mean Kinetic 4.14 °C

Low Alarm

Triggered: @ 29/11/2016 8:32:09 PM
Time below: 5 Days, 3 Hours, 45 Minutes
Occurrences: 68
°C - Minutes below: 8184.00

High Alarm

Triggered: (none)
Time above: 22 Minutes, 30 Seconds
Occurrences: 0
°C - Minutes above: 69.00



Events Info

2/11/2016 11:02:09 AM	Inspection
18/01/2017 5:17:09 PM	Inspection

Appendix 3 - Fridge picture and stock isolated list CCB #1

Photograph of fridge on 3G (Birthing Unit) when inspected by the pharmacist on Thursday 19 January 2017 after back to base alarm. Note that the sensor located at the bottom right of the fridge cannot be seen – obscured by stock.



Birthing Unit Fridge Stock Quantity

HB vaccine paed	73
Prostin (dinoprostin) 2mg	2
Clindamycin 600microg/4mL	6
Metaraminol 10mg/mL	4
Syntometrine500microg/5iu	44
Prostin (dinoprostone)F2 5mg/1mL	3
Novorapid flexipen	1
Ergometrine 500microg/1mL	14
Actrapid penfill 100iu/mL	4
Clindamycin 300mg/2mL	4
Celestone Chronodose 5.7mg/mL	30
Oxytocin 10IU/mL	159
Oxytocin 5IU/mL	210

Appendix 4 – Temperature data logger record for CCB #2

LogTag

Recorder has been downloaded 22/01/2017 4:06:45 PM (UTC +10:00, daylight time)

Alarm Status Recorder Info

Low	✗	Fail	Serial # : 1000567907	Model : TRIX-8	Battery : OK	Trip # : 5
High	✓	OK	User ID : Maternity			

Recorder Configuration

Start type : Push button start	Temperature alarms
Start delay : 15 Minutes	Lower : 2.0 °C after 2 Consecutive
Interval : 15 Minutes	Upper : 8.0 °C after 2 Consecutive
Alert indicator : Enabled lower & upper	
OK indicator : Enabled	

Recorded Data

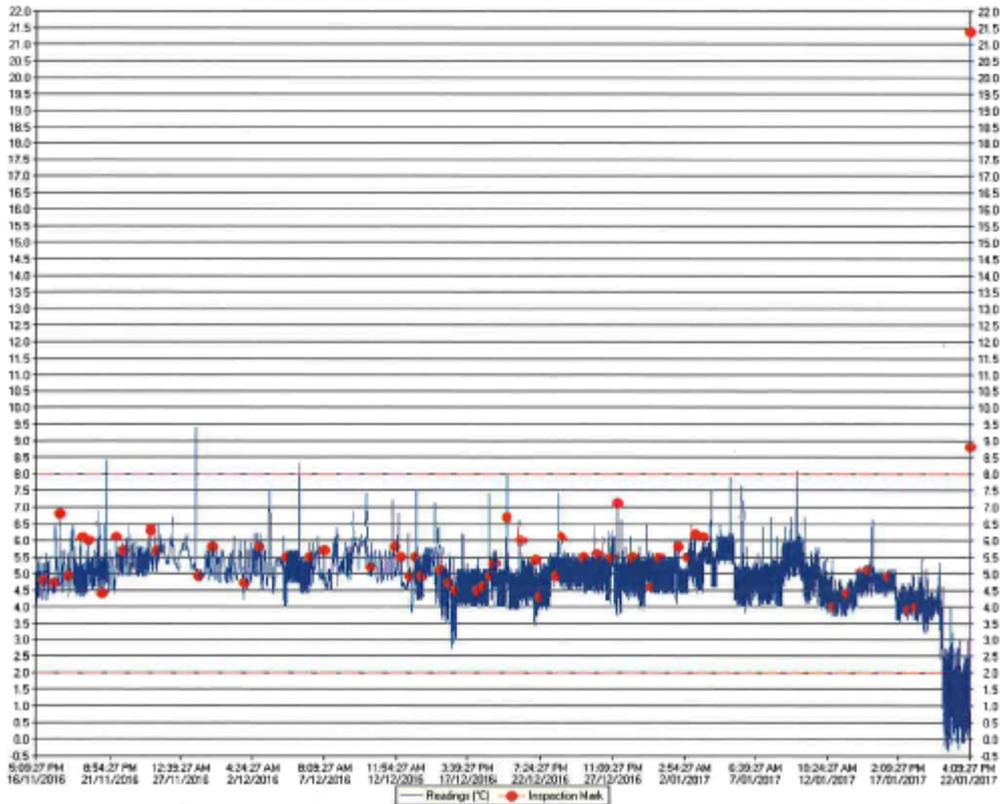
First reading : 16/11/2016 5:09:27 PM	Temperature statistics
Last reading : 22/01/2017 4:09:27 PM	Lowest : -0.4 °C
Elapsed Time : 66 Days, 23 Hours	@ 21/01/2017 5:09:27 AM
Total readings : 6429	Highest : 21.4 °C
First evaluated : 16/11/2016 5:09:27 PM	@ 22/01/2017 4:09:27 PM
Last evaluated : 22/01/2017 4:09:27 PM	Average reading : 4.9 °C
Evaluated Time : 66 Days, 23 Hours	Standard Deviation (S) : 0.9 °C
Evaluated Readings : 6429	Mean Kinetic Temperature 4.93 °C

Low Alarm

Triggered : @ 20/01/2017 6:09:27 PM
Time below : 1 Day, 5 Hours, 30 Minutes
Occurrences : 32
°C - Minutes below : 2146.50

High Alarm

Triggered : (none)
Time above : 1 Hour, 22 Minutes, 30 Seconds
Occurrences : 0
°C - Minutes above : 246.00



Appendix 5 – Temperature data logger record for CCB #3

LogTag

Recorder has been downloaded 26/07/2016 10:55:14 AM (UTC +10:00, daylight time)

Alarm Status Recorder Info

Low	X	Fail	Serial # : 1000567907	Model : TRIX-8	Battery : OK	Trip # : 2
High	X	Fail	User ID : Maternity			

Recorder Configuration

Start type : Push button start	Temperature alarms
Start delay : 15 Minutes	Lower : 2.0 °C after 2 Consecutive
Interval : 15 Minutes	Upper : 8.0 °C after 2 Consecutive
Alert indicator : Enabled lower & upper	
OK indicator : Enabled	

Recorded Data

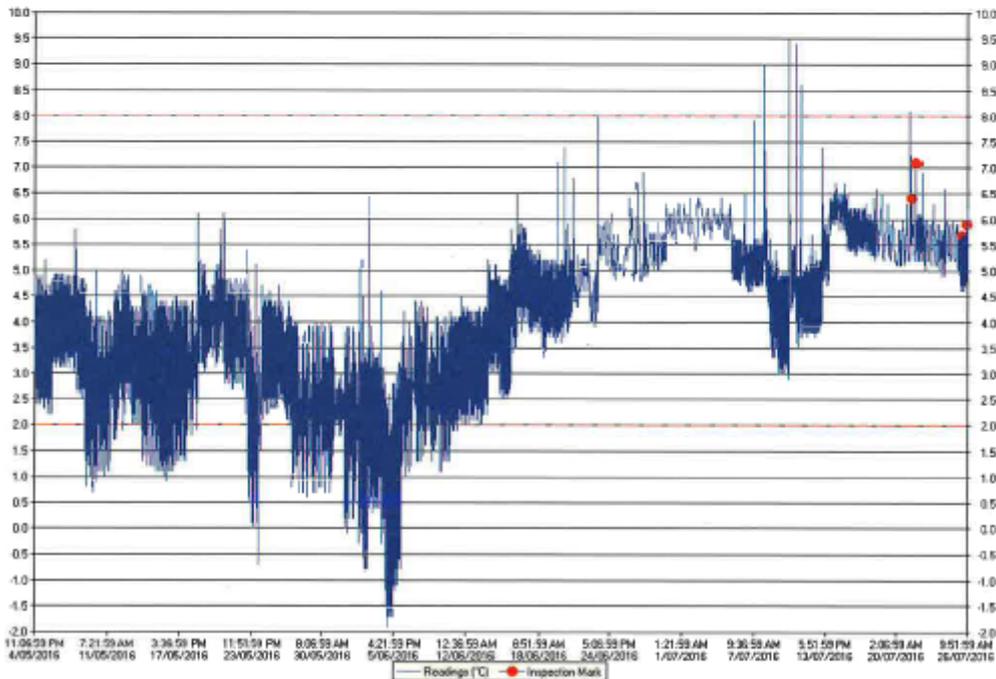
First reading : 4/05/2016 11:06:59 PM	Temperature statistics
Last reading : 26/07/2016 9:51:59 AM	Lowest : -1.9 °C
Elapsed Time : 82 Days, 10 Hours, 45 Minutes	@ 5/06/2016 2:06:59 AM
Total readings : 7916	Highest : 9.5 °C
First evaluated : 4/05/2016 11:06:59 PM	@ 10/07/2016 11:21:59 AM
Last evaluated : 26/07/2016 9:51:59 AM	Average reading : 4.1 °C
Evaluated Time : 82 Days, 10 Hours, 45 Minutes	Standard Deviation (S) : 1.5 °C
Evaluated Readings : 7916	Mean Kinetic 4.23 °C

Low Alarm

Triggered : @ 23/05/2016 10:36:59 PM
Time below : 7 Days, 23 Hours
Occurrences : 53
°C - Minutes below : 9754.50

High Alarm

Triggered : @ 11/07/2016 1:36:59 PM
Time above : 1 Hour, 30 Minutes
Occurrences : 1
°C - Minutes above : 73.50



Events Info

21/07/2016 11:36:59 AM	Inspection
21/07/2016 8:21:59 PM	Inspection
25/07/2016 9:21:59 PM	Inspection
26/07/2016 8:21:59 AM	Inspection

Appendix 6 - Experiment 1

Photograph of fridge with placement of loggers and stock. Note that the sensor located at the bottom right of the fridge cannot be seen – obscured by stock



Appendix 7 - Experiment 2

Photograph of fridge with placement of loggers. Note that the sensor located at the bottom right of the fridge.

