Cold Chain Management At Austin Health

Medicines Optimisation Service

Guidance package 2020

Austin HEALTH

About the Medicines Optimisation Service

The Medicines Optimisation Service (MOS) is a joint initiative of the Pharmacy Department and the Department of Clinical Pharmacology and Therapeutics, Austin Health, Melbourne. The service was established in May 2018 with the purpose of reviewing the use of medicines at Austin Health with an aspiration to optimise prescribing, dispensing and administration of medicines.

Acknowledgements

Anne McGrath (Medication Safety Committee)
Francine Tanner (Medication Safety Committee)
Stephen Cheung
Les Kirby
Austin Health Pharmacy department

Contact the Medicines Optimisation Service

Project Officers: Parnaz Aminian, Elizabeth Su
Project Lead: David Liew
Project Team: Christopher McMaster, Bonnia Liu
Director of Clinical Pharmacology and Therapeutics: Prof Albert Frauman
Director of Pharmacy: Kent Garrett
Contact: mos@austin.org.au
Telephone: (03) 9496 3225

Purpose

This document was developed by the Medicines Optimisation Service with the purpose to provide hospital pharmacy departments an operational framework to assess and improve the storage and management of their cold chain medicines. This framework was modelled using local experience at Austin Health and built with the intention of being generalisable to other hospitals.

Background

Cold chain is defined as the system of transporting and storing refrigerated medicines within the safe temperature range of +2°C to +8°C[1] . To guarantee the integrity of the medicine, cold chain needs to be maintained from point of manufacturing to point of administration. If at any point in the supply pathway, the medicine storage temperature deviates outside the recommended range of 2°C to +8°C, a cold chain breach has occurred. Repeated cold chain breaches can subject a medicine to a loss of potency and therapeutic failure, which can have dire consequences for the patient.
A departmental approach was taken to improve product accountability and enforce processes that mitigated the risk of a cold chain breach occurring.

1. National Vaccine Storage guidelines – Strive for 5, 3rd edition

Discovery

There is widespread knowledge surrounding the importance of maintaining cold chain, although there is no standardised process of monitoring the success of cold chain product movement around an institution. In theory, a gold standard approach in ensuring cold chain is maintained from the point of manufacture to the point of administration would involve individualised temperature monitoring (per medicine item). This approach, however, is cost intensive and difficult to justify - especially without any data alluding that there is a problem with the current process.
To be able to appropriately assess the need for intervention, our team implemented a series of discovery tools to elucidate the department's compliance in maintaining cold chain.

1. Observational audit of refrigerated medicines in clinical areas

Purpose of this audit was to ensure refrigerators did not contain excess medicines that could impact refrigerator air flow and product temperatures. Excess stock should be returned to pharmacy dispensaries for storage in refrigerators with centralized temperature monitoring.

Audit undertaken at Austin Health

Over two consecutive weeks, ward fridges in the Austin Tower were audited and excess medicines, defined as non-imprest medicines that were no longer required for inpatients were recorded and removed. 11 wards were audited with the following results:

- 107 units in ward fridges that could have been returned to pharmacy (Total cost: $3415.33)
- 3/107 units were expired (Wastage: $208)

As a result of this audit, an education session was presented to the clinical pharmacy team to raise awareness about issues identified in the audit and a recommendation was made for regular fridge clean outs to occur on a weekly to fortnightly basis. Follow up audits and periodic reminder emails were sent to help encourage uptake of the practice.

2. Development of cold chain breach management pathway and reporting system

Purpose of this tool was to provide pharmacy staff with a formalised way of dealing with cold chain breaches; reporting, responding and recording. Prior to the development of this tool, pharmacy staff were dealing with breach incidents in isolation and responding in various ways. There was no record of the cold chain breaches occurring in the department, making it difficult to assess for potential deficiencies in the cold chain product transport system.

Cold chain breach management pathway (See appendix 1)

A formalised process for pharmacy staff; providing a step by step guidance on how to deal with cold chain breaches. The pathway provided uniformity across the department in the way cold chain breaches are handled to promote product accountability and safety, and to assist in highlighting any deficiencies in transport processes.

Cold chain breach reporting system at Austin Health (See appendix 1)

A system that allows for a standardised method of reporting and recording cold chain breaches. This register was built into pre-existing Merlin dispensing software, rendering it accessible to every staff member at any campus. This system also enabled for real time reporting of cold chain breaches as the report would be emailed instantaneously to an action party to assist in product management (e.g. apply shortened expiries, stock rotation), maintaining product integrity and ensuring patient safety.

3. Mapping the movement of cold chain medicines around the institution

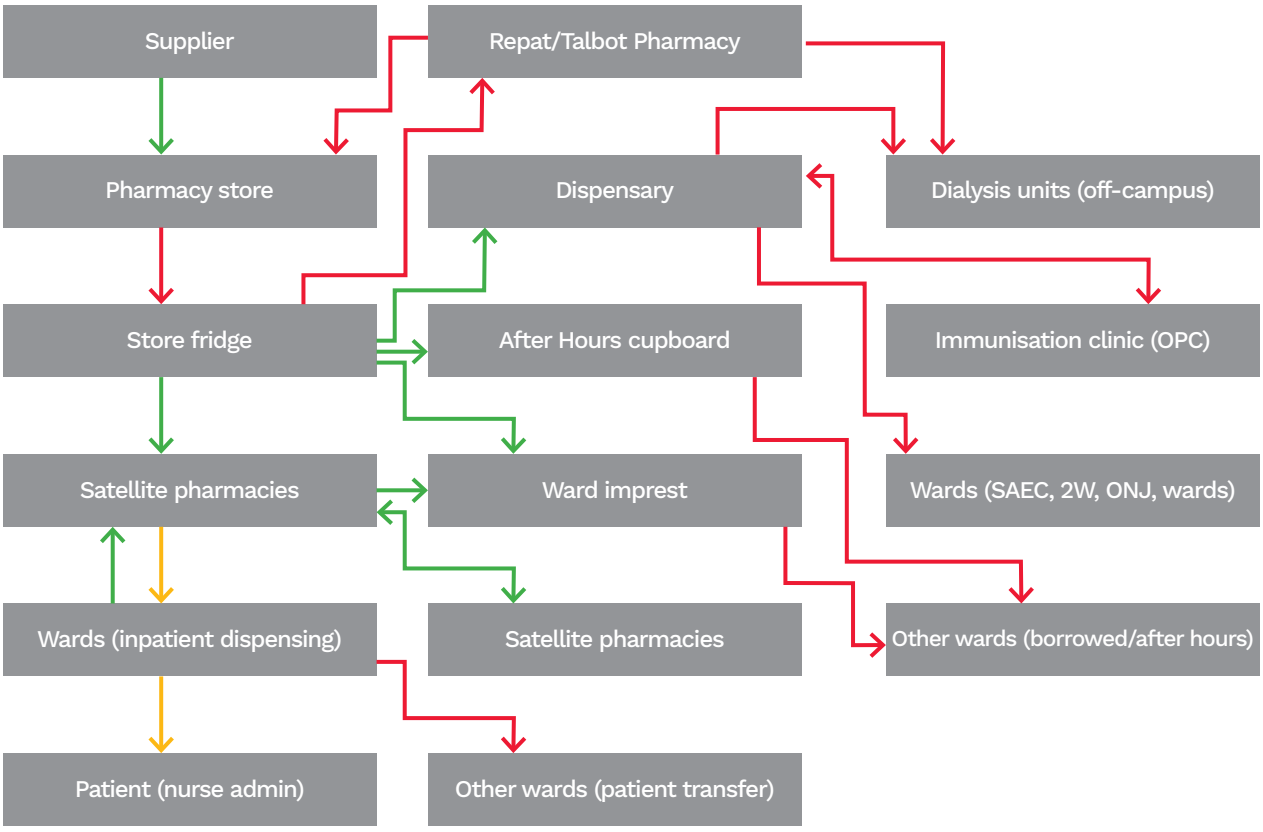
Purpose of this exercise was to elucidate the journey of refrigerated medicines throughout the hospital and enable evaluation of their transport in between sites.

Mapping the movement of cold chain medicines at Austin Health:

The movement of refrigerated medicines around the hospital was mapped, using a simple schematic. The journey of the product, highlighted by the arrows, was stratified into risk of breach; high, medium or low.

- Low risk (green): defined as a journey, involving the use of an esky packed by a trained staff member or a journey requiring less than 15 minutes of transport between locations and handled by one person. 15 minutes was assigned as the maximum time to encompass vaccine safety guidelines. (Strive for 5)[1]
- Medium risk (yellow): defined as a journey requiring less than 15 minutes of transport and involves handling by multiple persons
- High risk (red): defined as a journey that involves handling by multiple persons or journey exceeding 15 minutes of transport or person involved in transport is not pharmacy trained

As a result of this audit, an education session was presented to the clinical pharmacy team to raise awareness about issues identified in the audit and a recommendation was made for regular fridge clean outs to occur on a weekly to fortnightly basis. Follow up audits and periodic reminder emails were sent to help encourage uptake of the practice.



1. National Vaccine Storage guidelines – Strive for 5, 3rd edition

Development of interventions

Information gathered in the discovery phase was used to highlight deficiencies in the current system, assist in developing and prioritizing intervention and further exploratory studies.

- Results from the observational audit led to a series of recommendations and improvements to the pharmacy dispensing process and ward recycling process.
- Real time reporting of cold chain breaches via the cold chain breach reporting system allowed for timely investigation of the nature of breaches with the persons involved.
- The process of mapping the movement of cold chain medicines around the institution and stratifying for risk assisted in prioritizing intervention implementation. Medium and high risk journeys were deemed as needing intervention.

Proposed interventions:

Medium and high risk of breach journeys were listed and where appropriate, assigned with a pragmatic intervention that could be achieved using available resources. Some journeys required further exploratory work to be undertaken to better elucidate the risk and guide intervention.

Medium risk of cold chain breach	Proposed intervention or exploratory study
Satellite pharmacies to wards (inpatient dispensing)	Reducing inpatient dispensing of refrigerated medicine to a maximum of 3 days' supply Improved labelling of refrigerated products
Ward fridges to patient administration	Education to nursing staff about the importance of maintaining cold chain until administration

High risk of cold chain breach	Proposed intervention or exploratory study
Dispensary to wards (Monday- Sunday)	Implementation of courier cooler process
Dispensary transfer of vaccines to outpatient clinics	Implementation of temperature-monitored vaccine coolers
Dispensary transfer of erythropoietin agonists to satellite dialysis units	Exploratory study required: Temperature monitoring of eskies using Data loggers Implementation of 'Refrigerated item transport record' label and online form for receipting deliveries
After Hours cupboard (AHC) to wards	Implementation of product labelling with 'REFRIGERATE' label upon stocking of AHC fridge by pharmacy store staff Implementation of 'Refrigerated item transport record' label for completion by nursing staff upon product transfer
Intercampus transfer of refrigerated items	Education of staff in dispensaries to notify receipting site prior to sending refrigerated stock
Ward imprest fridges to other wards (outside of pharmacy hours)	Implementation of 'Refrigerated item transport record' label for completion by nursing staff upon product transfer
Inpatient medicines being transported between wards upon patient transfer	Implementation of 'Refrigerated item transport record' label for completion by nursing staff upon product transfer
Refrigerated stock from pharmacy store to pharmacy store fridge (PH01) - delivery from suppliers	Implementation of a receipting system that ensure esky deliveries are unpacked into fridge within 30 minutes of arrival

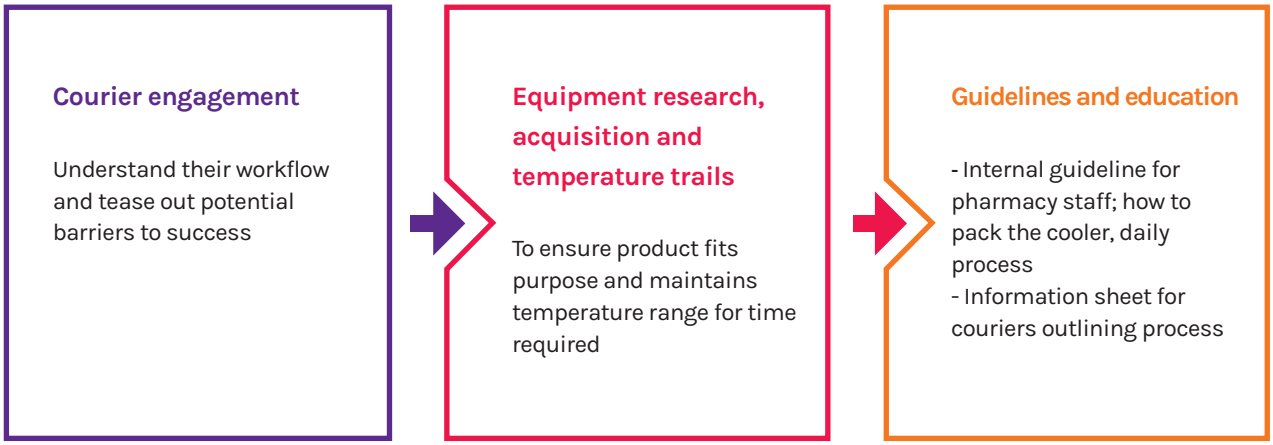
Implementation

To assist with the efficiency of the implementation process, interventions were grouped under:

- Staff involvement categories; e.g. pharmacists and technicians, store staff and external to pharmacy. By grouping in this manner, it promoted efficient implementation as all interventions pertaining to pharmacists and technicians were educated simultaneously as a package
- Single phase roll out and multiphase roll out; e.g. setting up a cooler to be used by the couriers required engagement from an external department, equipment acquisition and guideline preparation; thus requiring a more extensive rollout plan

Example: Grouping of interventions

Example: Courier cooler implementation – multiphase roll out. See appendix 2 for more information.



Review and maintenance

1. Real time investigation of cold chain breaches

The nature of each cold chain breach, reported through the cold chain register, was investigated and explored in real time to highlight any deficiencies to system processes. Staff involved with the breach were questioned and where applicable, education of processes were undertaken. Real time investigation provided prompt closure to the incident, timely feedback to staff, an opportunity to prevent future incidents and efficient use of staff time as there was no prolonged or drawn out follow up activities.

Example: Breach entered through cold chain register, investigated by Medicines Optimisation Service and a change in process actioned to prevent future incidents.

Product	Breach	Outcome	Action
Insulin protaphane innolet (5 units)	Delivered from store around 4pm to satellite pharmacy. Left in esky by the entrance, not unpacked into fridge Found at 9am.	New expiry given to product. Cold chain breach documentation sticker filled out and placed on product.	CHANGE IN PROCESS AND STAFF EDUCATION: Store staff to deliver refrigerated stock directly to technician. If no one is available, to remove stock from esky and place in fridge directly.

2. Data review from cold chain breach register

Review of the data captured from the cold chain breach register over an 18 month period showed that there were:

- total of 28 breaches recorded on register
- an additional 19 breaches were reported to Medicines Information for advice and not entered through register
- 11 of the total breaches (11/47) were reported via register as well as to Medicines Information

This data highlighted that there was a level of double handling of information between the teams and upon further exploration and discussion, it was evident that the process could be more efficient. To enhance usability and promote efficiency, the following changes were made to the cold chain breach management process:

- revised wording of flowchart to remove ambiguity and improve clarity (see Appendix 3)
- all enquiries to Medicines Information about refrigerated medicine stability post temperature excursions to be made via the cold chain breach register (data fields were added to accommodate this change)
- the addition of a 'Frequently asked question (FAQ) – cold chain breach' electronic document for pharmacy staff. This was created in collaboration with Medicines Information to help empower pharmacists to manage cold chain breaches and education on how to interpret the product information

InvCode	Inv Description	Unit_Qty	Meds_Info_Adv	Batch & Expiry	Breach_Details	Outcome
LINE1	LINEZOLID 600mg/300mL INF EA(1)	3	Y	xxx645, 00/00/2020	bags found in fridge	awaiting MI advice

Example: Automatic email sent to Medicines Information and Medicines Optimisation Service post entry on cold chain breach register. Medicines Information log enquiry and report back to enquirer for advice; Medicines Optimisation Service investigate nature of breach and implement solutions (where applicable)

Cold chain breach management - frequently asked questions

This document provide advice on brand specific products stability and is correct at time of writing. if you have any questions or concerns about specific products, please contact Medicines Information via druginfo@austin.org.au or via ext5668.

All cold chain breaches must be entered in the cold chain breach register on Merlin ([cold). See Teams/DV-Pharmacy/MOS Pharmacy/Files for more information.

Medicine	Manufacturer's recommendation around temperature excursion	Suggested action
Clindamycin 600mg/4ml injection	Dalacin: Stable at room temperature [i]	Dalacin: Return product to fridge and manufacturer expiry maintained.
	Clindamycin Mylan: Store at room temperature, do not refrigerate for more than 24 hours[ii]	Clindamycin Mylan: if refrigerated for>24 hours, discard product

Example: Extract of 'Cold chain breach management- frequently asked questions' document

3. Staff education

Cold chain breaches are not a regular occurrence and as some staff have never had to deal with the repercussions of a breach, it can be challenging to engage staff in the education process. To combat this, regular education and reminders are required to ensure that staff know how to undertake the new process or remember where to seek information when faced with a breach. To assist with this:

- Visual reminders on all refrigerators in the satellite dispensaries (coloured flowchart with cold chain breach documentation stickers)
- Follow up emails to staff who have enquired about a breach to Medicines Information but have not entered it through the cold chain breach register (note: with the improved cold chain register (Appendix 3), this will address this discrepancy)
- Visits to clinical areas, review of ward fridges and discussions with ward pharmacists and technicians responsible for fridge clean outs
- Provision of feedback to pharmacy staff on revised processes due to a cold chain breach

Summary of process

Appendix

1. Cold chain breach response pathway and cold chain breach register

Entry of incident into the 'cold chain breach register' (on dispensing software) sends an automated email notification to response team.

1 Isolate product

2 Investigate likely time window of cold chain breach

3 If>15 minutes for vaccines or >30 minutes for other medicines, consult product information for advice. If unsure, contact Medicines Information. If within those time windows at room temperature, can be returned to refrigerator for reuse.

4 If Shortened expiry, notify department(via email) to see whether stock can be used preferentially

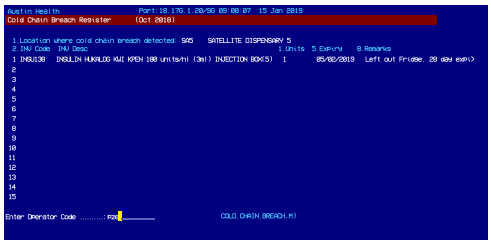
5 Document cold chain breach in 'Cold chain breach register' on Merlin dispensing software

see example →

Cold chain Breach register - Merlin

For all refrigerated products that have been stored outside the recommended range of +2°C to +8°C

1. Zoom cold([cold)
2. Fill out prompts provided:
- Location where breach detected (e.g. ward, satellite)
- Product and number of units exposed
- Expiry: if new expiry given to product based on product information and/or discussion with Medicines Information. If Medicines Information not available to give advice, proceed with documentation in Merlin and add comment in remarks. If expiry unchanged, enter in expiry from product label.
- Remarks: document nature of cold chain breach; where product was found and outcome



6 Complete cold chain breach documentation sticker and put on product (available in all satellites, dispensaries and store)

see sticker →

COLD CHAIN BREACH RECORD
Estimated time out of the fridge: .....
Today's date: .....
Adjusted expiry date: .....
Information source: .....

2. Implemention of cooler for courier transport

Phase 1: courier engagement

A meeting with the head of courier services was had to discuss the feasibility of a cooler use for courier transport to the wards. The following were discussed:

- Courier schedule (weekdays and weekends)
- Features on cooler product that would complement process (e.g. straps to tie the cooler to the trolley, size)
- Number of couriers that would require education on this process
- Any foreseeable challenges.

Phase 2: product research and acquisition

1. Exploratory conversations were had with various persons in pharmacy (e.g. Manufacturing, Dispensary) to deduce the type, number and size of refrigerated products that were sent to the wards via the courier.

2. Various companies were contacted and information about their cooler products were obtained. A product that fit most of the criteria was found. Our criteria was:

- Light and compact for ease of use by courier
- Straps for connection to courier trolley (to prevent it from being misplaced)
- Simple and quick to prepare for the dispensary staff (as would be a new daily process)
- Had sufficient room to fit most products (e.g. dispensing of refrigerated items is limited to 3 days thus most dispensings would fit in the space. Liposomal amphotericin in 250mL bags and Total Parenteral Nutrition (TPN) made by manufacturing pharmacists were excluded due to their favourable stability data)
- Medical grade (preferable)

3. Cooler product purchased was medical grade with data suggesting that temperatures between 2-8 degrees Celsius could be maintained for 36 hours. An in-house temperature trial of the cooler was conducted to:

- Verify the advertised temperature range
- Assess the necessary time of gel pack conditioning required to ensure that cooler temperatures didn't drop below 2 degrees Celsius

4. The following labelling was administered to the following items:

- Gel packs: PHARMACY – FOR COURIER USE ONLY, IF FOUND PLEASE RETURN TO .....
- Cooler: REFRIGERATED MEDICINES MUST BE PUT INTO FRIDGE UPON DELIVERY. THIS COOLER IS FOR THE TRANSPORT OF PHARMACY FRIDGE ITEMS (NOT INCLUDING TPN OR MANUFACTURED BAGS.) FROZEN GEL PACKS TO BE REPLACED IN PHARMACY ON 9:30AM COURIER ROUND

5. To assist with workflow, the cooler remains on the courier trolley at all times and there are four gel packs in circulation at any one time (two with courier in cooler and two in pharmacy freezer).

Phase 3: guidelines and education

Courier staff, dispensary staff and weekend pharmacists were educated on the new process through the delivery of guidelines, face-to-face tutorials, communiques and email correspondence. An example of one of the guidelines used is displayed below:

Courier transport process for refrigerated medicines from main dispensary to wards – internal guideline:

First thing in the morning:

- Satellite technician or pharmacist to take two frozen "Medactiv gel packs" out of freezer for conditioning or slight melting (so that medicines don't freeze in contact with gel packs).

On 9:30am morning courier round:

- Satellite technician or pharmacist to place conditioned "Medactiv gel packs" on each side of "iCool MediCube" in courier trolley.
  The "iCool MediCube" has been calibrated to remain between 2-8°C for 36 hours.
- Satellite technician or pharmacist to put two "Medactiv gel packs" in ONJ dispensary freezer in preparation for the next day.
- Courier to place dispensed refrigerated medicines from dispensary fridge into "iCool MediCube" for transport. Refrigerated medicines must be dispensed in clear bags labelled with ward for delivery.
- Courier to place a laminated "Refrigerated item" card into the corresponding ward slot of courier trolley.
- On delivery to ward, refrigerated items must be handed directly to a ward staff member to be placed into the ward fridge.

iCool Medicube cooler with conditioned gel packs ready for use by courier

If a refrigerated medicine is left outside of 2-8°C for >30min (>15min for vaccines), alert a pharmacist to instigate cold chain breach processes.

Note:
Cold storage during courier transport of pharmacy manufactured items such as TPN and liposomal amphotericin is not required as these items have sufficient stability for several hours at room temperature.

3. Revised cold chain breach management pathway

Austin Health Pharmacy Department: Cold Chain Breach management flowchart

1 Quarantine product and store in fridge, separate from dispensing stock in a clearly labelled bag whilst investigating stability.

2 Investigate likely time window of cold chain breach. If<15 minutes for vaccines or <30 minutes, no further action required and stock can be returned to dispensing stock. If outside that time frame, continue with Step 3.

3 Document cold chain breach in 'cold chain breach register' on Merlin using Zoom cold ([cold)

see example

4 If shortened expiry, notify department (via email or Teams using General Pharmacy page) to see whether stock can be used preferentially

5 Complete cold chain breach documentation sticker and put on product (Available in all satellites, dispensaries and store. Contact Liz or Parnaz via Teams to order more supplies)

see sticker

COLD CHAIN BREACH RECORD
Estimated time out of the fridge: .....
Today's date: .....
Adjusted expiry date: .....
Information source: .....

Cold chain Breach register - Merlin

For all refrigerated products that have been stored outside the recommended range of +2°C to +8°C

1. Zoom cold([cold)
2. Fill out prompts provided:
- Location where breach detected (e.g. ward, satellite)
- Product and number of units exposed
- Need advice from Meds info? (Y/N):
    1. See 'Cold chain breach - FAQ' (located Teams/ DV-Pharmacy/MOS Pharmacy/Files) for advice on common products
    2. Check product information in MIMS
    3. If unable to find an answer, seek advice from Medicines information (Enter Y) - this Merlin entry will be automatically emailed to Medicines information team and they will contact you with a response. There is no need to call or email them to place the enquiry.

- Batch no. and expiry: If multiple batch no. and expiries, separate by a comma (e.g. XXX 29/3/20, YYY 30/5/20)
- Breach details (reason, duration, temperature)
- Outcome: If awaiting Meds info advice, "awaiting MI" or record your own findings e.g. 'stable 28 days at room temp, new expiry given'

For further information contact:

Medicines Optimisation Service

A joint initiative of the Pharmacy Department and the Department of Clinical Pharmacology and Therapeutics, Austin Health, Melbourne

Phone

(03) 9496 3225

Email

mos@austin.org.au

austin.org.au