

STORAGE AND HANDLING

STORAGE OF FRIDGE MEDICATIONS AND
VACCINES

STORAGE OF FRIDGE MEDICATIONS AND VACCINES

PURPOSE

Women & Newborn Health Service (WNHS) is required to comply with all National and State Government, Department of Health and pharmaceutical policies and standards governing the safe storage of all medications. This includes the storage of selected pharmaceuticals in ward/unit refrigerators to ensure their safety and effectiveness. In addition, the storage of vaccines must be governed in accordance with Operational Directives and Vaccine Cold Chain Guidelines.

This guideline defines the minimum requirements at WNHS for storage of medications and vaccines which are deemed to require refrigeration according to legislation, licensing permit requirements and manufacturers' recommendations.

DEFINITIONS

Cold Chain: The system of transporting and storing refrigerated pharmaceuticals within the safe temperature range of +2 to +8°C from place of manufacture to the point of administration to the patient.

SCOPE

This guideline refers to all clinical and storage areas in WNHS storing medications which require refrigeration. In this guideline, medication(s) refers to **refrigerated** medication(s). That is, all medications required to be stored at temperatures between +2 to +8°C as per manufacturer's instructions.

RESPONSIBILITIES

Head of Pharmacy: As per Poisons Act 1964, Government of Western Australia, Department of Health, Permit Holder – HOD KEMH Pharmacy

'The registered nurse in charge of a ward or any other area where there is direct patient care is responsible for ensuring compliance with policies and procedures associated with the storage and accountability of scheduled medicines. The permit holder is responsible for the monitoring of that compliance.

The storage and accountability of scheduled medicines within the pharmacy and areas other than where direct patient care is provided is the responsibility of the permit holder.'

DETAILS

All persons handling refrigerated pharmaceutical are responsible for maintaining cold chain integrity.

Areas storing refrigerated pharmaceuticals must be aware and comply with Operational Directives.



Medications deemed suitable to be stored in a ward/unit/department medication fridge must be securely stored and managed in accordance with legislation, licensing permit requirements, manufacturers' recommendations and KEMH Policies.

SECURITY

All medication fridges must:

- Be kept in a secure area to prevent access by unauthorised persons. This should preferably be a locked area where other medications are stored. If space is unavailable in a locked area, a clean utility room may be used which is inaccessible to unauthorised persons.

APPROVED ITEMS FOR STORAGE IN MEDICATIONS FRIDGES

- Pharmaceuticals that are required to be stored to meet cold chain requirements as stated in the product information material of the pharmaceutical.
- Diagnostic or therapeutic devices requiring refrigeration according to manufacturer's specifications and there is no suitable alternative location.
- Manufactured items from pharmacy labelled for refrigeration.
- Pharmaceutical items as directed by the pharmacy department/staff.

ITEMS NOT TO BE STORED IN MEDICATIONS FRIDGES

- Storage of specimens for pathological analysis.
- Food or drink items.
- Where storage requirement of the pharmaceutical is not known – in these instances staff are to refer to their ward pharmacist for storage instructions.

MEDICATION FRIDGE REQUIREMENTS

- **Vaccine refrigerators are to be used exclusively for the storage of Vaccines.** Other medications are to be stored in a separate medication fridge.
- A sticker shall be placed on the refrigerator and near the power point and/or the front of the fridge stating " Medication / Vaccine Refrigerator, Do not turn off or disconnect".

All medication fridges must:

- Be temperature monitored and alarmed with approved devices;
- Be established in consultation with Pharmacy and Facilities Management; and
- Be connected to the essential power supply in preference of non-essential supply.

STORING VACCINES AND MEDICATIONS IN A REFRIGERATOR

- The refrigerator shall be placed out of direct sunlight and away from heat sources.
- The manufacturer's instructions for air circulation around the back and sides must be followed.
- The medications / vaccines shall be stored in their original packaging.
- The medications / vaccines shall not be placed against the refrigerator walls or air vents as this increases the risk of freezing. At least a 4cm gap between fridge walls and items must be maintained at all times.
- Freeze tolerant medications / vaccines (MMR, OPV, BCG) shall be placed on the shelves identified as being the coldest.



- Freeze sensitive medications / vaccines (DTPa containing vaccines; Hib, pneumococcal, Influenza, Hepatitis, Polio and some varicella vaccines) shall be placed on the shelves where the temperature is more stable.

MONITORING AND RECORDING OF MEDICATION FRIDGE TEMPERATURES

- Each vaccine / medication fridge is to have a method of monitoring for cold chain integrity. A fridge must be fitted with

Continuous Live Monitoring (Soft Logic ®)

- A dedicated line of live recording with breach parameters.
- Monitoring of the fridges occurs via a central process by Pharmacy
- This is the preferred method of temperature recording in the hospital

EVALUATION AND MONITORING

The Nurse/Midwife Manager or Head of Department is the person responsible for ensuring compliance with storage and accountability of temperature sensitive medications and vaccines within the medication fridges.

The Poisons Permit holder (Chief Pharmacist) will be responsible for the monitoring of that compliance. The Poisons Permit holder will also be responsible for the storage and accountability of medicines in non-patient areas.

Compliance monitoring includes

- Baseline audit of all medication fridges in WNHS to determine current status of fridge types
- Reviewing the proportion of clinical areas complaint with this guideline and relevant operational directives
- Reviewing the alarm settings, performance testing and associated response processes to activated alarms
- Reviewing the number of reports to the site Facilities Management per annum (in relation to cold chain breaches)
- Number of incidents of stock loss due to cold chain breaches per annum
- Annual cold chain audit

COLD CHAIN BREACH

Exposure of refrigerated pharmaceuticals to temperatures outside the recommended range of +2°C to +8°C (excludes fluctuations up to +12°C, lasting no longer than 15 minutes), when stock taking, restocking or cleaning.

Note-1: It is acceptable for temperature-sensitive medicines to have brief excursions beyond this temperature (up to +12°C for 15 minutes) in the course of restocking or cleaning the fridge.

Note 2: Repeated temperature excursions outside of the temperature range may have a cumulative effect on medication and vaccine efficacy.

Do not discard any medication / vaccine until advice is sought from pharmacy



In Hours

During the hours of 0700 – 1530, Monday to Friday excluding public holidays

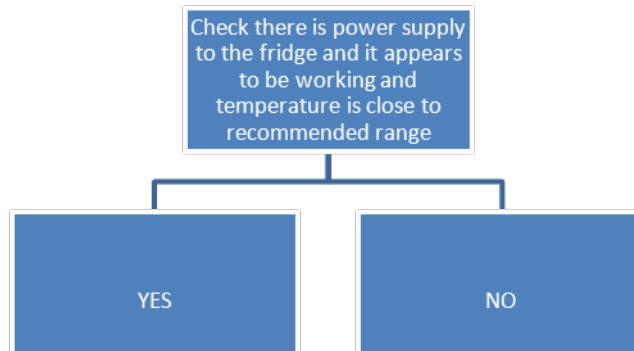
Out of hours

All other times not In Hours

In Hours – Cold Chain Breach

NOTIFICATION & QUARANTINE

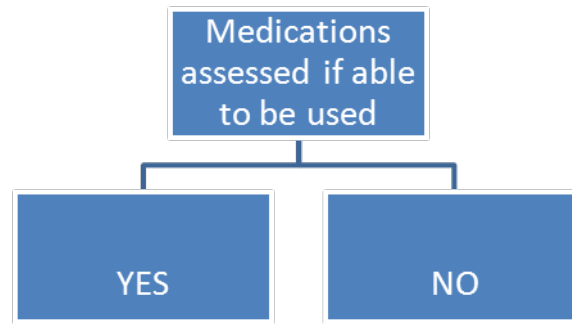
- A page will be received by the Ward Clinical Manager
- A page will also be received by the Hospital Cover manager, but not be actioned
- The Ward Manager is to



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|--|---|
| <ul style="list-style-type: none">• Place a sign on the fridge
“Quarantine – Cold Chain Breach”• Notify staff to seek alternative stock• Contact Pharmacy to assess the cold chain breach• Place stock in a container or bag labelled | <p>“Quarantine – Cold Chain Breach”</p> <ul style="list-style-type: none">• Move stock to an alternative fridge in the hospital• Alert staff not to use quarantined stock and where to find alternative stock.• Contact Pharmacy• Contact Physical resources• |
|--|---|

ASSESSMENT & ACTION

- Pharmacy will determine the extent of the cold chain breach and if the medication is able to be used
- Pharmacy will monitor the fridge to ensure it is maintaining a temperature within an acceptable range, if not will notify physical resources and organise a replacement fridge
- Pharmacy will make a record in the Cold Chain Breach register
- Pharmacy will notify the Ward Clinical Manager to take appropriate action



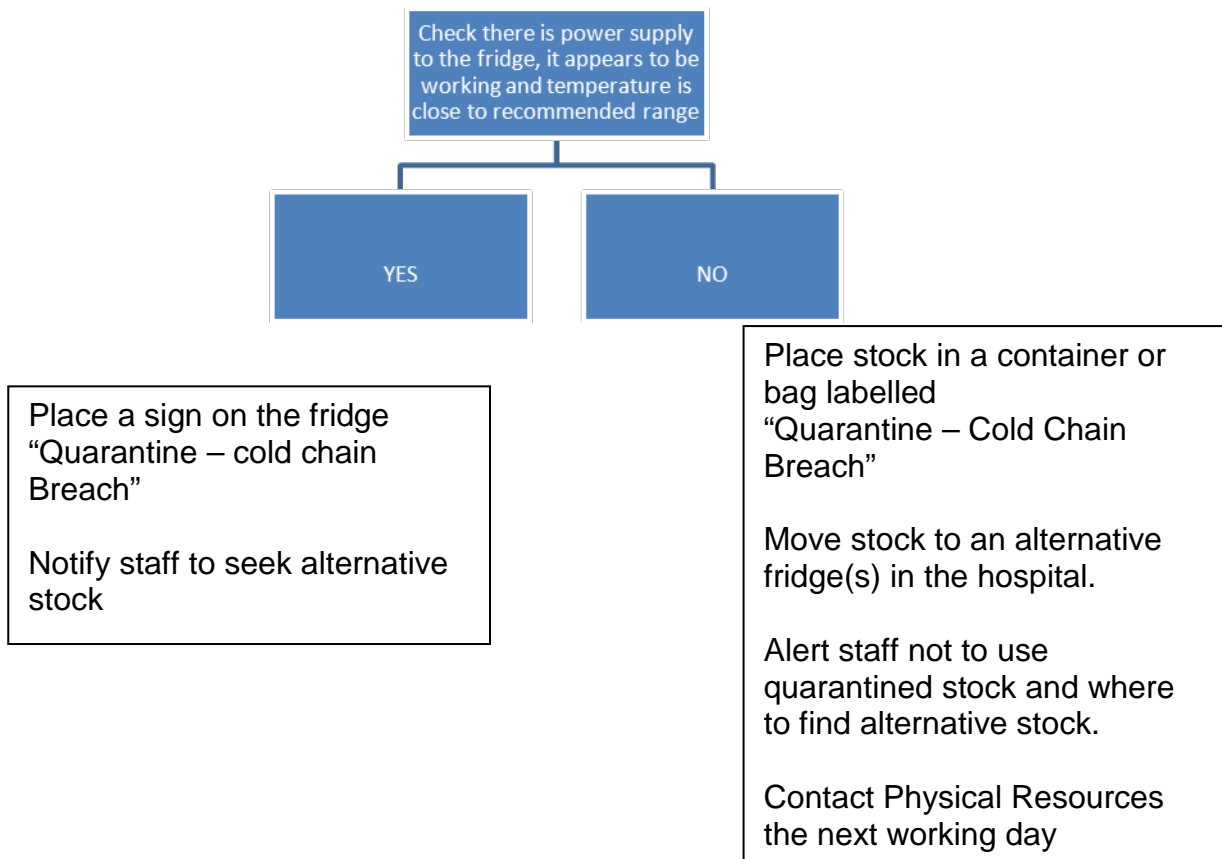
- Medications returned to fridge
- Staff advised that medication can be used

- Unfit medications are returned to Pharmacy for destruction
- Replacement stock organised
- Staff advised



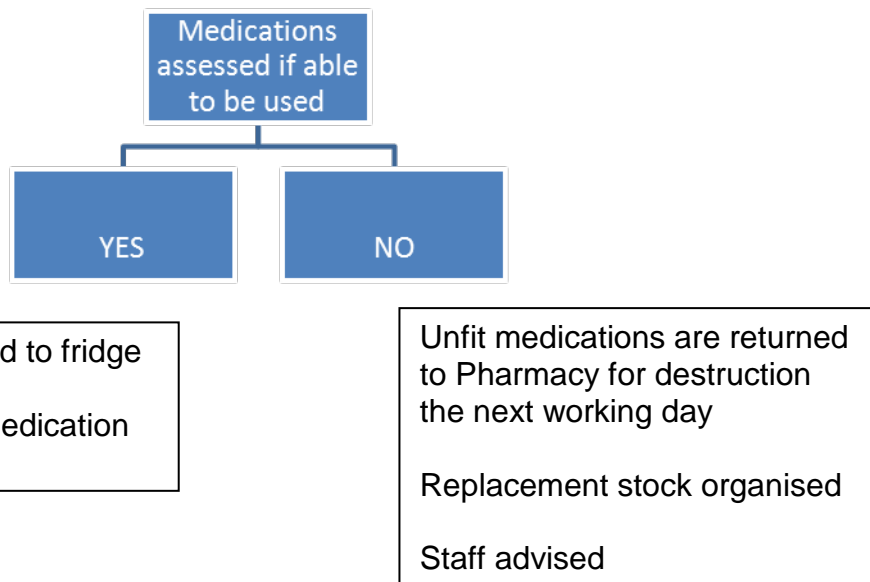
OUT OF HOURS – COLD CHAIN BREACH

- A page will be received by the Hospital Clinical Manager
- A page will also be received by the Ward Clinical Manager, but not be actioned.
- An assessment is made if urgent action is required, or followed up the next working day for a fridge in an unstaffed area. The Hospital clinical manager is to ensure that the cold chain breach is communicated to both the Ward Clinical Manager and Pharmacy the next working day
- If immediate action is required, the Hospital manager is to



ASSESSMENT & ACTION

- Ward Pharmacist/On-call Pharmacist will determine the extent of the cold chain breach and if the medication is able to be used
- Ward Pharmacist /On-call Pharmacist will monitor the fridge to ensure it is maintaining a temperature within an acceptable range, if not will notify physical resources and organise a replacement fridge
- Pharmacy will make a record in the Cold Chain Breach register
- Pharmacy will notify the Hospital Clinical Manager to take appropriate action



MEDICATION FRIDGE CLEANING AND MAINTENANCE

WARD AREAS

- Pharmacy will coordinate the fridge cleaning of all medication and vaccine fridges at KEMH

PHARMACY

- Cleaning of pharmacy medication fridges is to be organised by the Chief Pharmacist

FREQUENCY OF CLEANING

- All medication and vaccine fridges are to be cleaned at a minimum of three monthly in addition to when required
- Documentation of all regular cleaning is to be recorded on the cleaning log attached to each fridge

SERVICING OF MEDICATION FRIDGES

Facilities Management will be responsible for ensuring the maintenance servicing schedule for all vaccine and medication fridges in the hospital.

PROCESS AUDITING

The Pharmacy department is to conduct a yearly audit of each area in conjunction with the Engineering (Refrigeration Supervisor) to assess for compliance with this policy.

Audit results to be forwarded to the Medication Safety Review Group (MSRG) for review and action.

Physical resources is to validate and provide routine testing on all equipment required in the monitoring of medication and vaccine fridges.



REFERENCES / STANDARDS

Department of Health and Ageing.2013. **National Vaccine Storage Guidelines.**

National Standards – 4 Medication Safety

Legislation – Nil

Related Policies - [0355/11 Vaccine Cold Chain Guidelines](#)

[KEMH Guidelines Pharmacy and Medication](#)

[Safe Use of Medication Refrigerators Policy \(2014\)](#)

Other related documents – [National Vaccine Storage Guidelines \(Strive for 5\)](#)

RESPONSIBILITY

Policy Sponsor	Chief Pharmacist
Initial Endorsement	September 2009
Last Reviewed	October 2014
Last Amended	May 2015
Review date	October 2017

**Do not keep printed versions of guidelines as currency of information cannot be guaranteed.
Access the current version from the WNHS website.**

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