

	DOCUMENT NAME	DOCUMENT NUMBER
	COLD CHAIN MANAGEMENT AT THE FRIDGE SITE	MED-CCM/003

VERSION	1	
COMPILED BY		DATE 07/2025
AUTHORIZED BY		
NEXT REVISION DATE		07/2027

1. PURPOSE & SCOPE

To ensure that all **thermolabile medicines** are stored, monitored, and handled in a manner that preserves their integrity and always complies with cold chain standards (2°C to 8°C)

Applies to all health care personnel who manage, store, monitor, or handle refrigerated medicines at the practice

2. RESPONSIBILITIES

<u>Job description of person responsible</u>	<u>Duties</u>
Cold Chain Officer	Daily monitoring, recordkeeping, and fridge maintenance
Practice Manager	Oversight, equipment procurement, and staff training
All Staff	Follow procedures for handling and storage of cold chain medicines

3. LEGAL & REGULATORY REFERENCES

Medicines and Related Substances Act, 1965

Good Pharmacy Practice (GPP) Guidelines

WHO Guidelines on the International Packaging and Shipping of Vaccines

National Department of Health Cold Chain Management Guidelines

4. COLD CHAIN MANAGEMENT PROCEDURE

4.1 Refrigerator Setup

- Use only **dedicated medical refrigerators**; domestic fridges are not permitted.
- Place a **minimum–maximum thermometer** or **digital temperature logger** in the center of the fridge.
- Store medicines **in original packaging**, never against fridge walls or in fridge door compartments.
- Maintain an **uninterrupted power supply**; connect to a generator where possible.

4.2 Temperature Monitoring

- Record fridge temperature **twice daily** (morning and afternoon) on the **temperature log sheet**.
- Acceptable range: **2°C to 8°C**
- If temperature is outside this range:
 - Mark the log.
 - Quarantine affected stock (label clearly).
 - Notify the Practice Manager immediately.
 - Investigate and rectify the cause.

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4.3 Storage Protocol

- Do **not store** any food or drink in the medicine fridge.
- Keep a **minimum stock** to avoid overloading the fridge.
- Arrange items to allow proper airflow (avoid stacking tightly).

4.4 Power Failure Contingency Plan

- Keep **ice packs** and a **cool box** onsite for temporary storage.
- If power outage occurs:
 - Record the time and duration.
 - Transfer medicines to backup cold storage (if >30 mins downtime).
 - Monitor fridge recovery once power returns.

4.5 Maintenance

- Check the fridge **monthly** for cleanliness and frost buildup.
- Schedule **annual calibration** of thermometers/loggers.
- Fridge must be clearly labelled: **“Medicine Storage – Do Not Unplug”**.

5. TRAINING

All staff must receive **annual training** on cold chain procedures.

Documented attendance records must be kept.

6. INTERNAL SUPPORTING DOCUMENTATION

Document	Number	Retention period	Location
Cold Chain Temperature Log (daily)			
Maintenance Log			
Power Outage Incident Log			
Fridge Cleaning Record			
Calibration Certificate (annually)			

7. NON-COMPLIANCE RISKS

Loss of medicine potency

Clinical harm to patients

Regulatory non-compliance and audit failure

8. ATTACHMENT

Receipt Acknowledgement for this SOP

