

Policy Applies to:

Employees of Suite 22, Infection Prevention Nurse, authorised vaccinators and Specialists of Suite 22.

Related Standards

- EQUIP 1.5.2 Infection Control
- Ngā Paerewa Health and Disability Services Standard NZS 8134:2021
- National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017.

Cultural Considerations

Māori and Pasifika leadership groups were invited to review this policy. Outcome: no cultural considerations were identified in this review.

Rationale:

This policy describes requirements supporting cold chain management at Mercy Hospital Dunedin.

Objectives:

- To ensure the correct storage and temperature management of vaccines and cold chain equipment.
- To maintain the integrity of the product which requires cold chain management.
- To maintain certification of Cold Chain Compliance or Accreditation.

Implementation:

Cold Chain Accreditation

Mercy Hospital must achieve Cold Chain Compliance (CCC) to be able to provide occupational immunisation programmes, such as the influenza programme.

The documentation from our CCC visit is in the Cold Chain Influenza Vaccinator folder stored in the vaccine fridge room, located in Suite 22 and templates are held electronically at the following location:

F:\Clinical\Infection Prevention Nurse\Influenza\Cold chain docs

Influenza Vaccine requirements

Influenza Vaccine stock is pre-ordered and timed to arrive when it is nationally released.

Influenza vaccination is available to Mercy Hospital staff in the first instance. Where resources and supplies are available vaccinations can be extended to credentialed specialists, Marinoto Clinic staff, and some on-site external service providers who are over 18 years of age.

Ordering and stockkeeping of vaccines

Suite 22 Clinic staff (and the Infection Prevention Nurse while the Influenza vaccine is stocked) undertake a stock count monthly on the last Monday of the month and order vaccines as appropriate.

All vaccines are logged in the vaccine register including arrival date and time name, batch number, expiry date and total number in stock by the staff member who receives the order and unpacks the order into the cold chain fridge.

The vaccine register can be accessed in the Cold Chain Influenza Vaccinator folder on the 2nd floor, in Suite 22 and templates are saved electronically at the following location:

F:\Clinical\Infection Prevention Nurse\Influenza\Cold chain docs

The vaccine register is saved for 10 years.

Minimum and maximum levels of Influenza vaccine

Minimum influenza vaccine stock during Flu season is 10 doses.

Maximum influenza vaccine stock 180 doses.

Receiving and storing vaccines

All vaccinating staff must complete a cold chain orientation and know what to do when a vaccine order arrives from the distributor or hospital pharmacy.

- Vaccines are checked to ensure they have arrived within the indicated timeframe on the packaging.
- Vaccines are unpacked from the insulated delivery box and plastic as quickly as is practical on arrival.
- Vaccines are left in their original packaging, as this acts as insulation and protects vaccines sensitive to light.
- Vaccine stock is rotated so that those with earlier expiry dates are used first.
- Vaccines are placed in the refrigerator a minimum of 2.5 cm from the sides/ roof/ back/ bottom of the refrigerator to allow for air circulation.
- Vaccine boxes can be stacked as long as circulation rules are applied (point above).

National cold chain audit logger

The applicable staff know they need to check each vaccine delivery for any national cold chain audit loggers and that they will need to follow the instructions supplied.

Cold chain equipment – operation and maintenance

Mercy Hospital uses a pharmaceutical refrigerator to store vaccines.

Vaccinators are aware of the following requirements of the pharmaceutical refrigerator:

- is not used to store non-medical materials (e.g., food or lab specimens).
- is positioned in a well-ventilated room.
- is away from direct sunlight or a heat source.
- is at least 4 to 10 centimetres away from surrounding surfaces to allow air to circulate the condenser.

- has nothing placed on the top of it, except the daily minimum/maximum recording charts.
- has an independent power point, that is either hard-wired into the wall and/or has a large bright notice advising to not unplug.
- Has a surge protector if required by the refrigerator manufacturer.

Te Whatu Ora immunisation coordinator will be contacted for consultation when purchasing new equipment or if there are any questions regarding cold chain equipment.

Refrigerator temperature monitoring

Vaccine cold storage requires 2 independent methods of daily temperature logging.

The refrigerator's built-in temperature monitor records the minimum and maximum cold chain refrigerator temperatures daily. The minimum and maximum temperatures are reset after they have been recorded. The minimum and maximum temperatures are recorded at the same time each working day (first thing in the morning is recommended to pick up any cold chain breaches that may have occurred overnight).

The current temperature records are kept in the Suite 22 Treatment room and archived in the Influenza Cold Chain Folder with the Infection Prevention and Control Nurse.

An electronic template of the Cold Chain temperature monitoring book is available in the file F:\Clinical\Infection Prevention Nurse\Influenza\Cold chain docs

Fridge daily readings are on the 2nd Floor Vaccine Fridge temperature recording form and stored on top of the fridge.

Central Electronic Temperature monitoring of the Mercy vaccine fridge is used to record every 5 minutes remotely by cloud-based software and results are stored electronically. A weekly report is received via email by the Infection Prevention Nurse, on Monday and reviewed alongside the daily minimum/maximum temperature for that week. Any unusual variations are discussed promptly with the Te Whatu Ora Southern immunisation/cold chain coordinator. The central monitoring records can be reviewed at any time via <https://www.saclient.com> in response to temperatures outside the +2°C to +8°C temperature range. See Appendix Five.

Saved central monitoring reports are saved electronically on Mondays at F:\Clinical\Drug Fridges Temperature Monitoring\Suite 22

The immunisation/cold chain coordinator will be contacted if the temperature goes below 2°C, is between 8°C and 12°C for more than 30 minutes or is more than 12°C.

The following staff have access to the central monitoring system on a regular basis.

Name	Designation
Sarah Hydes	IPC Nurse
Rebecca Fraser	Suite 22 Practice Nurse
Jay Cooper	Suite 22 Administration
Grant Brown	IT Systems Analyst
On-call executive	On-call executive cell phone holder
<p><i>No built-in fridge temperatures are recorded over a shutdown period. Central Electronic Monitoring is continuous. Out-of-hours electronic alerts for cold chain excursions are texted to the executive on-call cell phone and emailed to the Infection Prevention Nurse and the IT Systems Analyst.</i></p> <p><i>No cold chain medications are to be stored during the shutdown period to limit the risk of vaccine excursion and vaccine waste.</i></p>	

Anyone can access the central monitoring system and check the data (Appendix Five).

Vaccine Use

One vaccine pack is taken from the cold chain refrigerator and used within the hour. An additional pack is retrieved only once the previous pack has been used.

Evaluation:

- Temperature measurements of cold chain refrigerator.
- Incident Management system.
- Weekly central fridge monitoring system report comparisons.
- Inspection of vaccine delivery conditions and reports on abnormal conditions to IPCC, and via the incident system. Condition standards are evaluated against that of the National Standards for storage and transportation.

Associated Appendices

- Appendix One: Maintenance and Replacement Plan and Schedule.
- Appendix Two: Process for Vaccine Stored Outside +2°C and 8°C Temperature Range.
- Appendix Three: Emergency Plan for Dealing with Equipment and Power Failures.
- Appendix Four: Ordering and Delivery of Cold Chain Vaccines.
- Appendix Five: Fridge Monitoring Remotely, Suite 22.

Associated Documents

The vaccine documents listed below provide detailed information to support our cold chain management and inform the development of this policy.

- *Immunisation Handbook*, www.health.govt.nz
 - *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* Ed. 2. www.health.govt.nz
 - *Annual Cold Chain Management Record* www.health.govt.nz
 - Medsafe vaccine data sheets www.medsafe.govt.nz/Medicines/infoSearch.asp
- Immunisation Advisory Centre: www.immune.org.nz