

Cold Chain PHC Remote Guideline

Target Audience	All Clinical Employees
Jurisdiction	Primary Health Care Remote CAHS; Primary Health Care Remote TEHS
Jurisdiction Exclusions	N/A
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Purpose

Provide information regarding the principles of cold chain management for Primary Health Care staff to promote maintenance of potent vaccines, viable medicines and Point of Care consumables.

Guideline

1. General Information

The cold chain is the system of transporting and storing [vaccines](#), medicines and Point of Care (POC) Pathology consumables within the safe temperature range of 2°C to 8°C from the place of manufacture to the point of administration. This is to ensure people receive an effective vaccine / medicine / POC consumable that have retained their viability and have not had exposure to temperature excursions (ie affected by heat or cold).

The cold chain system requires that processes be in place to ensure that potent vaccines and viable medicines / POC consumables reach the recipients. Maintenance of a satisfactory temperature range will not only assure this occurs but will prevent potential costly wastage. This dual rationale warrants commitment of staff to the relevant processes.

Information in this document includes:

- [Vaccines](#)
- [Medicines](#)
- [Point of Care Pathology Consumables](#)
- [Transportation](#)
- [Purpose Built Temperature Controlled Refrigerators](#)
- [Cold Chain Monitoring](#)
- [Managing Cold Chain Monitor Changes / Breach in Cold Chain](#)
- [Quality Assurance](#) (QA)

Also see [Cold Chain Storage Check Forms](#) which describes relevant Quality Assurance (QA) activities.

2. Definitions

Cold Chain: a system of transporting and storing vaccines / medicines / POC consumables within the safe temperature range of 2°C to 8°C from the place of manufacture to the point of administration.

Freezing: a situation where vaccines / medicines / POC consumables experience temperatures at, or below, 0°C. Importantly vaccines may not appear frozen, but may have been damaged at these temperatures.

Freeze Monitor (FreezeAlert™): an electronic device that has been factory-set to detect exposure to < 2° C to meet Northern Territory requirements. An alarm is triggered if the temperature goes below the threshold setting.

Vaccine Time Temperature Monitor: a device that indicates exposure to temperatures > 10°C for differing periods (A, B, C indexes) or > 34°C (index D).

Medicines: for the purpose of this document this only includes medicines requiring cold chain monitoring.

Point of Care Pathology Consumables: for the purpose of this document this only includes POC consumables requiring cold chain monitoring.

3. Responsibilities

3.1 Clinical Staff

- Be familiar with, and apply, the principles of the cold chain and monitoring system
- Complete relevant vaccine provider qualifications and POC training
- Understand storage procedures and the operation of the Purpose Built Temperature Controlled Refrigerator and other refrigerators in the health centre
- Effectively participate in cold chain QA activities. See [Section 4.6](#)
- Be familiar with packing, unpacking and handling procedures of vaccines / medicines / POC consumables to be transported
- Complete a RiskMan incident report when there is a breach in the cold chain

3.2 Primary Health Care Manager (PHCM)

- Ensure standard cold chain maintenance and monitoring practices are observed by all staff, and assign staff to cold chain QA activities
- Support relevant professional development activities (vaccine provider qualifications and POC training)
- Ensure monthly submission of cold chain monitoring QA returns
- Ensure completed QA returns are placed into the QA Folder
- Maintain necessary equipment to ensure vaccines / medicines / POC consumables can be stored and maintained according to cold chain standards
- Investigate any breach of the cold chain occurring at health centre level, record in RiskMan and liaise with relevant personnel
- Liaise with the District Managers Administration Officer to facilitate refrigerator repairs / replacement

3.3 District Manager

- Follow up on cold chain issues with PHCMs as appropriate
- Ensure investigations in RiskMan are completed, recommendations attended and feedback provided to relevant staff
- Ensure staff have undertaken relevant training to provide vaccines and POC Testing
- Approve requests for refrigerator repairs / replacement
- Consider and approve the purchase of new Purpose Built Temperature Controlled Refrigerators as per [Standard Clinical Equipment Master List](#)

3.4 District Manager Administration Officer

- Liaise with PHC staff to expedite repairs / replacement refrigerators as appropriate
- Arrange transportation of the refrigerator to and from the service provider as necessary

3.5 Professional Practice Nurse (PPN)

- Ensure reminder e-mails re QA activities are distributed to health centres monthly
- Maintain cold chain QA database and master records
- Identify deficits in health centre processes and advise of best practice to PHCMs
- Report QA issues as required to the relevant person, eg District Manager, Infrastructure Coordinator
- Provide reports on QA activities as required, to Management Team
- Distribute POC consumables in accordance with cold chain requirements

3.6 Centre for Disease Control (CDC): Clinical Nurse Manager, Immunisation

- Provide advice regarding vaccine cold chain management and vaccine wastage
- Respond to and advise action if there are breaches in the cold chain
- Monitor RiskMan reports
- Monitor return of the Vaccine Wastage Reports Form
- Review and update the Vaccine Wastage Report Form template as appropriate

3.7 Supplying Pharmacy

- Distribute vaccines / medicines in accordance with cold chain requirements

4. Procedure

4.1 Vaccines

Vaccines are delicate biological substances that can become less effective or destroyed if they are frozen, allowed to get too hot, exposed to direct sunlight or fluorescent light. Health practitioners have a professional responsibility for administering effective (potent) vaccines. This responsibility is primarily assured by the correct transport and storage of vaccines inherent in the cold chain process.

Completion of vaccine provider training is a mandatory requirement for remote clinical practice. NT registered nurses, midwives and Aboriginal and Torres Strait Islander Health Practitioners who need to complete immunisation training will be recommended to complete the South Australian (SA) online course titled 'Understanding Vaccines and the National Immunisation Program' or another approved interstate course as detailed in the [Gazette Notice Prescribed Qualifications to Supply or Administer or Possess Vaccinations](#). See the DoH [Immunisation – Health Professionals](#) website for further information and links to the SA online course.

4.2 Medicines

Some medicines require refrigeration to ensure their viability. These should be managed according to the cold chain protocols for transport, packaging, storage, monitoring as described in this document.

Different arrangements exist for the provision of medicines that are not room temperature stable, where clients receive medicines in a [Dose Administration Aids](#) (DAA). For local arrangements contact your [Section 100 pharmacy](#) provider.

Medicines requiring storage between 2°C to 8°C should be stored in a purpose built temperature controlled refrigerator that is separate to the vaccine refrigerator. Where this is not available, a dedicated domestic refrigerator could be used to store these medicines until a purpose built refrigerator becomes available. The temperature of the refrigerator must be monitored per the guidelines provided in Section 4.6 Cold Chain Monitoring. Note: Medicines and POC consumables may be stored in the same refrigerator.

4.3 Point of Care Consumables

POC consumables for [i-STAT® Analyser](#), [Diabetes Care Analysers](#) (DCA) and HemoCue Quality Controls (QCs) are used for POC testing in a number of remote health centres. POC Cartridges and QC are to be kept refrigerated at 2°C to 8°C until product expiry date.

i-STAT and DCA cartridges and QCs should be stored in a purpose built temperature controlled refrigerator that is separate to the vaccine refrigerator. Where this is not available, a dedicated domestic refrigerator may be used to store these consumables. The temperature of the refrigerator must be monitored per the guidelines provided in [Section 4.6 Cold Chain Monitoring](#). *Note: POC consumables and medicines may be stored in the same refrigerator.*

4.4 Transportation

Cold chain monitors must be used in the transportation and storage of vaccines / medicines / POC consumables.

4.4.1 Pharmacy Supplied Vaccines / Medicines

Distribution of vaccines / medicines from pharmacies occurs in an 'esky', with adequate insulation and cold packs for routine transport timelines. Each vaccine type / medicine will be accompanied by a freeze monitor and vaccine time temperature monitor.

4.4.2 Primary Health Care - Remote Supplied Point of Care Consumables

Distribution of POC consumables is completed using an 'esky' with adequate insulation and cold packs for routine transport timelines. Each POC consumable order will be accompanied by cold chain monitors.

4.4.3 Vaccines / Medicines / POC consumables used outside the health centre

Vaccines / medicines / POC consumables transported for use outside the health centre are to be packed according to guidelines in [Strive for 5](#) pp 34-38, as referenced in [The Australian Immunisation Handbook 10th Ed.](#) pp 24-25.

The same freeze monitor and vaccine time temperature monitor are to remain with this stock at all times ie during transportation and storage in the fridge. On return to the health centre these cold chain items are to be returned to the refrigerator as appropriate. **Staff are to use this stock first.** Where cold chain monitors indicate a breach in the cold chain see [Section 4.7](#) for further information.

The use of a digital minimum-maximum thermometer to monitor the temperature inside the 'esky' is to be considered when items may be out of the refrigerator for extended periods. (See [The Australian Immunisation Handbook 10th Ed.](#), pp 29 & 31).

4.5 Purpose Built Temperature Controlled (Vaccine) Refrigerators

Purpose Built Temperature Controlled Refrigerators are manufactured for the purpose of storing cold chain items under optimum conditions and provide:

- a stable, uniform, controlled temperature unaffected by ambient temperature
- defrost cycle without raising the cabinet temperature
- standard alarm and safety features for fluctuations in cabinet temperature

Each remote health centre will have a Purpose Built Temperature Controlled Refrigerator/s and these are to be connected to a 24 hour power supply whenever possible.

Avoid storing other medical products, eg medicines and POC consumables with vaccines. This minimises the risk of overcrowding the vaccines and reduces the frequency of door openings for the refrigerator. Only when absolutely necessary may other temperature sensitive medical products (requiring storage at 2-8°C) be stored in the vaccine storage refrigerator. Food, drinks and other non-medical products must never be stored in the Purpose Built Temperature Controlled Refrigerator or dedicated medicines / POC consumables refrigerator.

4.5.1 Maintenance / Repairs / Replacement Refrigerators

Staff must complete the monthly Cold Chain Storage Check PHC Remote Form (CAHS | TEHS) and notify PHCM if any issues are identified during the check. Ensure that the interior and exterior (including door seals) are clean. Clean with soapy water as needed.

When a Purpose Built Temperature Controlled Refrigerator requires repair, the PHCM is to report this to the District Managers Administration Officer for action. The relevant staff member will liaise with health centre staff to expedite repairs.

When a domestic refrigerator used to store medicines and POC consumables requires repairs this should not be repaired but replaced with a Purpose Built Temperature Controlled Refrigerator utilising the Purchase Request process. See [Standard Clinical Equipment Master List](#).

The District Managers Administration Officer will liaise with the service provider (with a qualified refrigeration mechanic) who may discuss the issues and provide advice via the telephone to the PHCM. In the event a qualified refrigeration mechanic is available in the community (eg providing routine air conditioner maintenance), the service provider may request the mechanic to investigate the fault. To facilitate payment to the service provider this request **must** be arranged with the Administration Officer prior to commencing the work.

When a refrigerator needs to be transported to a regional centre for repair, the PHCM should liaise with the District Managers Administration Officer. A replacement refrigerator may be available and should be arranged through the Administration Officer with the service provider repairing the Temperature Controlled Refrigerators.

Requests for Temperature Controlled Refrigerators must be in line with the [Standard Clinical Equipment Master List](#) in order to maintain standardisation in the type of Temperature Controlled Refrigerator in health centres.

4.6 Cold Chain Monitoring

4.6.1 Vaccine Refrigerator Temperature Chart

Monitoring and maintaining a safe temperature for vaccine / medicine / POC consumables storage from the time of manufacture to their final administration to clients is crucial to the cold chain process.

Temperature Controlled Refrigerators are fitted with electronic temperature monitoring equipment, which records the minimum and maximum temperatures within the refrigerator. A [Strive for 5 Vaccine Refrigerator Temperature Chart](#) is used to record the temperatures within the refrigerator, and minimum and maximum temperatures should be checked and recorded twice daily (ie the start and close of each working day). Temperature settings must be reset following each reading.

It is advisable to use an additional digital minimum-maximum thermometer in the vaccine storage refrigerator as a cross checking measure, and will be of value in the event of an electronic malfunction or power failure. Mercury thermometers are not authorised due to the potential Workplace Health and Safety risk of mercury spills.

When medicines and POC consumables are stored in a domestic refrigerator, a digital minimum-maximum thermometer **must** be kept in the refrigerator and the minimum and maximum temperatures within the refrigerator **must** be recorded on a cold chain graph twice daily.

[Strive for 5 Vaccine Refrigerator Temperature Charts](#) are to be returned monthly to the PPN.

In order to accurately read the cold chain monitors, staff need to have adequate training and knowledge and to effectively participate in QA activities. This should be provided at orientation / health centre induction and by staff obtaining a relevant vaccine provider qualification.

4.6.2 Vaccine Time Temperature Monitor

The vaccine time temp monitor, specific to each supply of vaccines must remain with, and be easily differentiated from other supplies of vaccines at all times, ie during transportation and storage in the fridge, until stock is completely used.

The date and time must be recorded on the [vaccine time temperature monitor](#) when:

- the vaccines / medicines / POC consumables arrive at the health centre
- the vaccines / medicines / POC consumables are taken from the health centre (eg outstation visits) and are returned

Dispose of the monitor when the associated batch of vaccines / medicines / POC consumables are completely used (or no longer required).


4.6.3 Freeze Monitor (FreezeAlert™)

The freeze monitor, specific to each supply of vaccines must remain with, and be easily differentiated from other supplies of vaccines at all times, ie during transportation and storage in the fridge, until stock is completely used.

The date and time must be recorded on the [Freeze Monitor](#) when:

- the vaccines / medicines / POC consumables arrive at the health centre
- the vaccines / medicines / POC consumables are taken from the health centre (eg outstation visits) and are returned
- the monitor alert has been activated, indicating vaccines / medicines / POC consumables have been frozen

FreezeAlert™ monitors will be activated for use by the Pharmacy / PPN prior to dispatch with vaccines and medicines / POC consumables. If the start button on the FreezeAlert™ monitor is accidentally pressed after it has been activated, this will not affect nor change the function of the monitor.

The new FreezeAlert™ monitor uses a simple  or X to indicate if the accompanying vaccines / medicines / POC consumables have been frozen.

FreezeAlert™ monitors are disposable, single-use products and can be disposed of into general waste.

4.7 Managing Cold Chain Monitor Changes / Breaches in Cold Chain

4.7.1 Vaccines

Instances where changes occur in the Cold Chain Monitor may affect vaccine efficacy and the shelf life of the vaccine.

The Vaccine Cold Chain Monitor Card and Vaccine Freeze Alert Monitor accompanying vaccines provide clear direction for managing the vaccines following a breach in the cold chain. See [Vaccine Time Temp Monitor](#) and [Vaccine Freeze Monitor](#) for details.

Please refer to CDC if there is any uncertainty on how to manage a vaccine where changes have occurred on Vaccine Time Temperature Monitors or FreezeAlert™ Monitors. **Do not discard any vaccine prior to talking with CDC.**

When there is a breach in cold chain, the following protocol should be followed:

Immediately isolate the vaccines within the refrigerator and label *do not use*

- Check the cold chain and take corrective action, including investigation to correct the problem and prevent reoccurrence
- Complete a [Vaccine Wastage Report Form](#)
- Discard the Vaccines
- Complete a RiskMan incident report
- Contact CDC for advice as required

Any breach of the cold chain must be reported via RiskMan and a [Vaccine Wastage Report Form](#) completed.

Reporting all vaccine wastage via the Vaccine Wastage Report Form provides an indication of PHC vaccine wastage across all health centres and enables accurate reporting to CDC and the Australian Government.

4.7.2 Medicines

Where monitors indicate a breach in cold chain (either below 2°C or above 8°C), the supplying pharmacy must be contacted to advise on viability of the medicine.

4.7.3 Point of Care Consumables

Where monitors indicate a breach in cold chain, the relevant PPN should be contacted to advise on the viability of the POC consumables. See [I-STAT Analysers](#) section 4.8 Storage of Cartridges and Quality Controls and [Diabetes Care Analysers](#) section 4.8.3 Storage, for additional information.

4.8 Quality Assurance (QA)

Primary Health Care Vaccine QA mechanisms comprise:

- [Cold Chain Storage Check PHC Remote CAHS Form](#) - complete monthly
- [Cold Chain Storage Check PHC Remote TEHS Form](#) - complete monthly
- [Strive for 5 Vaccine Refrigerator Temperature Chart](#) - complete monthly and return to the PPN.

(Note: write name of health centre on the chart and when completing more than one chart label which refrigerator)

Compliance

Monthly quality assurance activities will be monitored by return of the Cold Chain Storage Check PHC Remote Form (CAHS TEHS) and Vaccine Refrigerator Temperature Chart.	PHC CAHS: Professional Practice Nurse PHC TEHS: relevant District Manager
Vaccine wastage will be monitored by return of the Vaccine Wastage Report Form by the Clinical Nurse Manager, Immunisation, Centre for Disease Control (CDC)	Clinical Nurse Manager, Immunisation, CDC
Adverse incidents will be recorded in client's electronic health record, entered into RiskMan and will be followed up by the relevant Manager.	Relevant Manager PHC CAHS: Clinical Nurse Manager, Quality and Safety PHC TEHS: Safety and Quality Manager

Document Quality Assurance

	Method	Responsibility
Implementation	Document will be accessible via the Policy Guidelines Centre and Remote Health Atlas Notification will be by e-mail distribution	Health Policy Guidelines Program
Review	Document is to be reviewed within three years, or as changes in practice occur	Atlas Development Officer, Primary Health Care CAHS
Evaluation	Evaluation will be ongoing and informal, based on feedback.	Atlas Development Officer, Primary Health Care CAHS

Key Associated Documents

Forms	<p>Strive for 5 Vaccine Refrigerator Temperature Chart</p> <p>Cold Chain Storage Check PHC Remote CAHS Form</p> <p>Cold Chain Storage Check PHC Remote TEHS Form</p> <p>Vaccine Freeze Monitor } supplied with vaccines / medicines by the Vaccine Time Temp Monitor } Pharmacy and POC consumables by the PPN</p> <p>Vaccine Wastage Report Form</p>
Key Legislation, By-Laws, Standards, Delegations, Aligned & Supporting Documents	<p>Diabetes Care Analyser (DCA) PHC Remote Guideline</p> <p>Dose Administration Aids PHC Remote Guideline</p> <p>i-Stat 1 Analysers PHC Remote Guideline</p> <p>Purchase Request PHC Remote TEHS Guideline</p> <p>Quality Assurance Overview PHC Remote Guideline</p> <p>Section 100 Pharmacy Arrangements PHC Remote Guideline</p> <p>Standard Clinical Equipment PHC Remote Guideline</p> <p>Stores and Ordering Overview PHC Remote CAHS Guideline</p> <p>Vaccines PHC Remote Guideline</p> <p>Information Sheets:</p> <p>Standard Clinical Equipment Contents PHC Remote Master List</p> <p>Urgent Minor Repairs PHC Remote Information Sheet</p> <p>Centre for Disease Control: Immunisation Project Officer, ph 08 8922 8044</p> <p>DoH Immunisation – Health Professionals website</p> <p>Gazette Notice Prescribed Qualifications to Supply or Administer or Possess Vaccinations</p> <p>Immunise Australia Program</p> <p>The Australian Immunisation Handbook 10th Ed.</p> <p>National Vaccine Storage Guidelines - Strive for 5, 2nd Ed.</p> <p>FreezeAlert™ Sensitech website</p> <p>Pharmacy Guild of Australia, Standard 9 - Receiving, Unpacking, Pricing and Storing Stock</p> <p>Purpose Built Temperature Controlled (Vaccine) Refrigerators websites:</p> <p>Arcus</p> <p>Thermoline Scientific</p> <p>Quirks Australia</p>
References	As above

Evidence Table

Reference	Method	Evidence level (I-V)	Summary of recommendation from this reference
N/A	N/A	N/A	N/A