

# Cold Chain PHC Remote Guideline

<b>Target Audience</b>	All Clinical Employees	
<b>Jurisdiction</b>	Primary Health Care Remote CAHS; Primary Health Care Remote TEHS	
<b>Jurisdiction Exclusions</b>	N/A	
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<b>GC/SharePoint ID: HEALTHINTRA-1880-10991</b>	PGC/Content Manager ID: EDOC2018/16412	
<b>Version Number:</b>    Version: 15.0	Approved Date: 10/10/2019	

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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 Alarm Alerts / Breaches in Cold Chain](#)

- [Quality Assurance](#) (QA)

Also see Cold Chain Storage Check Forms – [CAHS](#) | [TEHS](#) which describe relevant QA activities.

## 2. Procedure

PHC staff must be familiar with, and apply, the principles of the cold chain and monitoring system as described in this document.

### 2.1 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. At PHC centres, vaccines must be stored in purpose built vaccine refrigerators.

### 2.2 Medicines and Point of Care (POC) Consumables

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.

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.

Medicines requiring storage between 2°C to 8°C and POC consumables 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 items until a purpose built refrigerator becomes available. The temperature of the refrigerator must be monitored per the guidelines provided in [Section 2.6 Cold Chain Monitoring](#).

### 2.3 Transportation

A cold chain monitor must be used in the transportation of vaccines / medicines / POC consumables.

#### 2.3.1 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 esky containing vaccines / medicines will be accompanied by a cold chain monitor.

**PHC Remote CAHS:** vaccines / medicines may be delivered to the Peter Sitzler Building for ongoing transportation to health centres. When this occurs the cold chain monitor is to be removed from the vaccines / medicines package and the vaccines / medicines placed in the Purpose Built Temperature Controlled Refrigerator. When the vaccines / medicines are sent to the health centre, they must be accompanied by a new cold chain monitor.

#### 2.3.2 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 a cold chain monitor.

### 2.3.3 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](#), as referenced in [The Australian Immunisation Handbook](#).

A digital minimum-maximum thermometer must be used to monitor the temperature inside the 'esky' per [Strive for 5](#) guidelines. On return to the health centre the temperatures recorded on the minimum-maximum thermometer must be checked, and if there has been no breach, cold chain items may be returned to the refrigerator. **Staff must use this stock first.** Where a breach in the cold chain has occurred see [Section 2.7](#) for further information.

## 2.4 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 an uninterrupted power supply whenever possible.

Do not store 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.

### 2.4.1 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 and liaison to expedite repairs.

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 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. Requests 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.

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.

## 2.5 Cold Chain Monitoring

### 2.5.1 Vaccine Refrigerator Temperature Chart / Data Loggers

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. The [Strive for 5 Vaccine Refrigerator Temperature Charts](#) are to be uploaded to the RiskMan PHC Monthly Audit.

Data Loggers must be placed in all vaccine refrigerators. The PHC standard Data Logger is the EasyLog USB Data Logger. They must be set to record the temperature at 5 minute intervals. The data must be downloaded weekly using the EasyLog software and uploaded into the RiskMan PHC Monthly Audit monthly, with the Strive for 5 Vaccine Refrigerator Temperature Charts and Cold Chain Quality Checks. Their batteries must be changed annually and recorded on the Quality Checks form. Placement of the Data Logger should be on the middle shelf with a card labelled “Contains Data Logger – data to be downloaded weekly.” For further information about the use of EasyLog USB Data Loggers, or Data Loggers in general, see the manufacturer’s information and the [Strive for 5](#) guidelines.



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.

### 2.5.2 Cold Chain Monitor - TagAlert® - for Transportation of Vaccines

TagAlert® monitors are single use items and only used during transportation of vaccines / medicines / POC consumables that require refrigeration. They have been factory-set to trigger an alarm when exposed to temperatures outside of predetermined settings and temperature readings are recorded every 5 mins once the TagAlert® monitor is activated.

TagAlert® has a [TagAlert® Alarm feature](#) and a fail safe feature which means the monitor will go into reset mode (ie flashing screen) if there are any issues with the monitor. When this occurs, do not use the Tag Alert® and notify CDC.

Prior to activation of the TagAlert® monitor it is recommended that the monitor be pre-conditioned by refrigeration prior to use for approximately two (2) hours.


Regional Centre – Pharmacy / Peter Sitzler Building	
	<p><b>Activate</b> TagAlert® by pressing the start / stop button for 5 seconds immediately prior to placing with refrigerated items for distribution. The Liquid Crystal Display (LCD) displays a flashing “Heart” indicating the TagAlert® is activated.</p> <p><b>Affix</b> the TagAlert® to the “<i>Reading an Enhanced TagAlert® Indicator</i>” card and record the date and time started.</p> <p><b>Place</b> TagAlert® with the refrigerated items in the esky immediately to prevent out of cold chain recordings on TagAlert prior to dispatch of items.</p>
Remote Health Centre	
	<p>On receipt of refrigerated items, press the start / stop button to stop the TagAlert® monitor and look at the LCD display.</p> <p>If the triangle points to the green “✓”, all refrigerated items travelling with this monitor are safe to use.</p>

## 2.6 Managing Cold Chain Monitor Alarm Alert / Breaches in Cold Chain

### 2.6.1 Vaccines

Vaccine efficacy and the shelf life of the vaccine may be affected when there is a breach of cold chain temperatures. CDC must be contacted and will provide clear direction for managing the vaccines following a breach in the cold chain. **Do not discard any vaccine prior to talking with CDC.**

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

	<p>If the numbers 1, 2, 3, and/or 4 are visible on the LCD display and the triangle points to the red "X", then the alarm has been triggered. Record numbers displayed on the "Reading an Enhanced TagAlert® Indicator" card. Contact CDC if alarm is triggered for further information.</p> <p><b>Vaccines:</b></p> <ul style="list-style-type: none"> <li>- isolate the vaccines and contact the Centre for Disease Control (CDC) for advice</li> <li>- complete the <a href="#">Vaccine Wastage Report Form</a> if vaccines are to be discarded</li> <li>- discard the TagAlert® after you receive advice from CDC.</li> <li>- complete a RiskMan incident report</li> </ul>
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### 2.6.2 Medicines

Where the cold chain monitor indicates 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.

### 2.6.3 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 2.8 Storage of Cartridges and Quality Controls and [Diabetes Care Analysers](#) for additional information.

### 2.6.4 Management of Cold Chain Breach During Refrigeration Failures, eg due to power outage, fault.

- Put a sign on the refrigerator stating 'Power out. Do not use. Keep refrigerator door closed'
- Cover the glass door with insulating material (cardboard, bubble wrap or a blanket) and place ice bricks in empty spaces, taking care not to place them alongside the items, and keep the door closed
- Closely monitor the refrigerator temperature using a minimum-maximum thermometer
- If the temperature rises to +8°C, move items to a prepared esky/ies
- Ensure all items are packed and monitored with a minimum-maximum thermometer
- Ensure you have a strategy in place for longer term storage, eg for a faulty fridge, transfer items to an alternative refrigerator and monitor with a minimum-maximum thermometer
- Contact relevant personnel for advice:
  - **Vaccines:** Centre for Disease Control (CDC) – with the downloaded data from the Data Logger
  - **Medicines:** PHC Pharmacists or supplying pharmacy
  - **POC consumables:** Professional Practice Nurse

## 2.7 Quality Assurance (QA)

Staff need to have adequate training and knowledge and to effectively participate in QA activities. This should be provided at orientation / health centre induction by staff with a relevant vaccine provider qualification.

Primary Health Care QA mechanisms comprise:

<a href="#">Cold Chain Storage Check PHC Remote CAHS Form</a> <a href="#">Cold Chain Storage Check PHC Remote TEHS Form</a>	to be completed monthly
<a href="#">Strive for 5 Vaccine Refrigerator Temperature Chart</a>	to be completed twice daily during the month <i>Note: write name of health centre on the chart and when completing more than one chart label which refrigerator.</i>
Data Logger	to be downloaded weekly using the EasyLog software

The completed Quality Check Forms, Temperature Chart/s, Data Logger data and any related documentary evidence (eg photos of deficits, emails regarding reporting of issues etc) are to be uploaded to the RiskMan PHC Monthly Audit. See [Quality Assurance Overview PHC Remote Guideline](#) and [RiskMan PHC Audit Process PHC Remote Information Sheet](#) for detailed information.

## Compliance

Monitoring of RiskMan Audits - PHC Monthly Check Report: 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.	Relevant District Manager <b>PHC CAHS:</b> Clinical Nurse Manager, Quality and Safety PHC CAHS <b>PHC TEHS:</b> Safety and Quality Manager PHC TEHS
Vaccine wastage will be monitored by return of the Vaccine Wastage Report Form to the 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 <b>PHC CAHS:</b> Clinical Nurse Manager, Quality and Safety <b>PHC TEHS:</b> Safety and Quality Manager

## Document Quality Assurance

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

## Key Associated Documents

Forms	<a href="#">Strive for 5 Vaccine Refrigerator Temperature Chart</a> <a href="#">Cold Chain Storage Check PHC Remote CAHS Form</a> <a href="#">Cold Chain Storage Check PHC Remote TEHS Form</a> <a href="#">Vaccine Wastage Report Form</a>
Key Legislation, By-Laws, Standards, Delegations, Aligned & Supporting Documents	<a href="#">Diabetes Care Analyser (DCA) PHC Remote Guideline</a> <a href="#">Dose Administration Aids PHC Remote Guideline</a> <a href="#">i-Stat 1 Analysers PHC Remote Guideline</a>

	<p><a href="#">Purchase Request PHC Remote TEHS Guideline</a></p> <p><a href="#">Quality Assurance Overview PHC Remote Guideline</a></p> <p><a href="#">Section 100 Pharmacy Arrangements PHC Remote Guideline</a></p> <p><a href="#">Standard Clinical Equipment PHC Remote Guideline</a></p> <p><a href="#">Stores and Ordering Overview PHC Remote CAHS Guideline</a></p> <p><a href="#">Vaccines PHC Remote Guideline</a></p> <p>Information Sheets:</p> <p><a href="#">RiskMan PHC Audit Process PHC Remote Information Sheet</a></p> <p><a href="#">Standard Clinical Equipment Contents PHC Remote Master List</a></p> <p><a href="#">Urgent Minor Repairs PHC Remote Information Sheet</a></p> <p>DoH <a href="#">Immunisation – Health Professionals</a> website</p> <p>G21 - <a href="#">Prescribed Qualifications for Aboriginal and Torres Strait Islander Health Practitioners to Supply, Administer or Possess Vaccines</a> (p 5-8)</p> <p>S25 - <a href="#">Prescribed Qualifications for Nurses and Midwives to Supply, Administer or Possess Vaccines</a> (p 4-6)</p> <p><a href="#">Immunise Australia Program</a></p> <p><a href="#">The Australian Immunisation Handbook</a></p> <p><a href="#">National Vaccine Storage Guidelines - Strive for 5, 3<sup>rd</sup> Edition</a></p> <p>Purpose Built Temperature Controlled (Vaccine) Refrigerators websites:</p> <p><a href="#">Arcus</a></p> <p><a href="#">Thermoline Scientific</a></p> <p><a href="#">Quirks Australia</a></p>
References	As above

## Definitions

Preferred Term	Description
<b>Breach:</b>	has occurred if vaccine storage temperatures have been outside the recommended range of +2°C to +8°C. It excludes deviations and may be caused by longer term power outages, faulty refrigeration units.
<b>Cold Chain:</b>	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.
<b>Data Logger:</b>	a small electronic device that continuously measures temperatures and keeps a record of the results. ( <a href="#">Strive for 5</a> )
<b>Deviation:</b>	is a fluctuation up to +12°C, lasting no longer than 15 minutes, as may occur when stock taking or restocking refrigerators.
<b>Freezing:</b>	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.
<b>Medicines:</b>	for the purpose of this document this only includes medicines requiring cold chain monitoring.

Preferred Term	Description
<b>Point of Care Pathology Consumables:</b>	for the purpose of this document this only includes POC consumables requiring cold chain monitoring.
<b>TagAlert® Monitor:</b>	an electronic device that has been factory-set to detect exposure to temperature outside cold chain standards. An alarm is triggered if the temperature goes outside the threshold settings.

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