Cold Chain Management Policy for Immunisation Services

Name of provider/clinic/department:	Amberley Medical Centre
Date:	July 2024
Name of our local immunisation coordinator and/or cold chain coordinator:	Canterbury Immunisation Jayne Thomas and Christine Varley
Contact number(s):	03 327 0270, cell 027 383 9332 (J) 027 383 9442 (C)
Name of our IMAC Regional Advisor:	Sue Rogers
Contact number(s):	027 242 2451

Designated staff with overall responsibility for cold chain management

First person (Authorised Vaccinator or GP or Pharmacist Vaccinator):	Lucinda Batchelor
Second person:	Chris Long

All staff are responsible for ensuring that the vaccines they administer are stored correctly and are expected to receive cold chain orientation.

1. Vaccine documents

The vaccine documents listed below provide detailed information to support our cold chain management and inform the development of this policy. The following documents are available or there is online access to:

- The current *Immunisation Handbook* https://www.health.govt.nz/publication/immunisation-handbook-2020
- Current *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* – available on the Ministry's website at www.health.govt.nz/coldchain
- *Annual Cold Chain Management Record* available on the Ministry's website at: www.health.govt.nz/coldchain
- Medsafe vaccine data sheets (available from the Medsafe website at: www.medsafe.govt.nz/Medicines/infoSearch.asp)
- A hard copy of these documents are located in the Cold Chain Folder in the Managers' Office

2. Cold Chain Accreditation

All immunisation providers, clinics and departments storing vaccines must achieve Cold Chain Accreditation (CCA) or Cold Chain Compliance (CCC) if appropriate. The documentation from our CCA visit is located in the Cold Chain folder. Our CCA is valid until 31 July 2024.

3. Vaccine stock requirements

All staff are aware of how much vaccine stock is required at any one time, based on the size of our vaccinating population, including both casual and enrolled patients/clients. To avoid overstocking and to ensure stock rotation, a minimum stock of National Immunisation Schedule vaccines of two weeks and no more than four weeks' worth of stock should be held at any given time.

3a. Our stock requirements

The number of:

240	Children aged under five years
67	Children aged 11 years[1,2]
67 101	Adults aged 45 and 65 years
1537	Adults aged 65 years and older (Influenza)

[1] Depending on whether there is a school-based programme delivered in your region.

[2] When ordering Tdap, take into consideration the number of vaccines you require for pregnant women.

The minimum and maximum vaccine stock levels are:

	DTaP-IPV-HepB/Hib	PCV	RV	Hib	MMR	Varicella	DTaP-IPV	MEN B
Minimum	9	9	6	3	6	3	3	10
Maximum	29	29	16	6	16	13	13	30

	Tdap	HPV	Shingrix	Influenza Adult	Influenza Child	Comirnaty 30MCG SDV	Comirnaty 30MCG MDV	Comirnaty 10MCG
Minimum	13	6	6	10	0	5 vials	5 vials	2 vials
Maximum	33	16	26	300	20	10 vials	10 vials	4 vials

3b. Vaccine ordering and stock keeping

We undertake a stock count two times per month on the second and fourth Thursday and order vaccines as appropriate.

All vaccines are logged in the vaccine register including their arrival date, name, batch number, expiry date and total number in stock. The vaccine register is stored in the Dispensary next to Fridge 1.

4. Receiving and storing vaccines

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

- Check that the vaccine delivery has been delivered to correct address (is it for your site?)
- Check the vaccines have arrived within the designated timeframe, are what was ordered and have a reasonable expiry date

- Check whether any vaccines have monitoring devices included and follow any instructions provided eg: include process for receiving Covid-19 vaccinations
- Where no monitoring device is included in the delivery, check the vaccines for any visible signs of exposure to high or freezing temperatures (eg, melted ice packs, damp packaging or ice visible on packaging or inside the vaccine).
- Record vaccine details (including date received, batch number and expiry day, month and year) in a vaccine register/log or stock management system.
- Document the date the vaccines arrived at the provider on the vaccine box or have a documented system for identifying when vaccines were delivered
- Leave the vaccines in their original boxes and place in the pharmaceutical refrigerator.
- Store vaccines in columns to allow optimum air circulation. Maintain a gap of at least 25 - 30 mm between the vaccine boxes and the fridge walls and back plate. Do not store vaccines in the perspex or wire container at the bottom of fridge.

If there are concerns about the condition of the delivered vaccines, quarantine the vaccines in the pharmaceutical refrigerator

- label the vaccines as not for use until a decision on whether to use the vaccines has been made
- notify the regional distribution store (or Healthcare Logistics in the case of influenza or non-funded vaccines)
- contact your immunisation coordinator
- do not return vaccines until you have authorisation to do so from the distributor
- advise coordinators of all returned vaccines

4a. COVID-19 vaccines:

- The 'count' should be checked off by a second person for an additional layer of security.
- It is good practice to 'sign out' these vials when removed from the fridge for use, allowing a running total of vials which should match stock on hand in the fridge.
- Highlight the date of expiry on the box label to identify the first box to be used
- Refer to the current version of the COVID-19 Vaccine Operating Guidelines for details.

5. National cold chain audit logger

All staff are aware they need to check each vaccine delivery for any national cold chain audit loggers and are aware that they will need to follow the instructions supplied.

6. Cold chain equipment – operation and maintenance

This service uses two pharmaceutical refrigerators to store vaccines (details on page 5).

All vaccinators are responsible for ensuring that the pharmaceutical refrigerator:

- is not used to store non-medical materials (eg, 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 around the condenser
- has nothing placed on the top of it, except the daily minimum/maximum recording charts
- has an independent power point

- 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.

We will contact our immunisation coordinator when purchasing new equipment or if we have any questions about cold chain equipment.

6a. Refrigerator temperature monitoring

The minimum and maximum vaccine refrigerator temperature is recorded daily from the inbuilt temperature monitor. Both refrigerators have an audible alarm. The minimum and maximum temperatures are reset after they have been recorded.

The minimum and maximum temperature is recorded at the same time of each working day morning. The current temperature records are kept in next to each refrigerator and archived as with other medical records for at least 10 years in the Archive box in the Dispensary. The *Annual Cold Chain Management Record* is used to document the clinics daily readings.

The data logger is set to record the refrigerator temperature every 5 minutes. This is downloaded weekly and reviewed alongside the daily minimum/maximum temperature for that week and any unusual variations are discussed promptly with the immunisation/cold chain coordinator. The data logger must also be downloaded in response to temperatures outside the +2°C to +8°C temperature range.

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 data is regularly backed up and is stored for a minimum of 10 years in the Log Tag Folder (P:\LogTag Data)

The following staff can download the data logger. See SOP at page 9 for instructions.

Name	Designation
Lucy Batchelor	Practice Nurse
Chris Long	Nurse Manager
Julie Hansen	Practice Nurse
Katie Croft	Practice Nurse
Hannah Wix	Practice Nurse
Sarah Egden	Practice Nurse
Megan Harrop	Practice Pharmacist
Hannah Hipkiss	Practice Nurse

6b. Monitoring chilly bins for transport and temporary storage

A minimum/maximum digital thermometer with audible alarm is used to measure the temperature of vaccines when using chilly bins to transport or temporarily store vaccines.

- Staff will check and record the minimum, maximum and current temperatures of the vaccines:
  - before transporting the vaccines
  - before unpacking them at the alternative storage area
  - every 20–30 minutes while transporting or temporarily storing them.

6c. Monitoring chilly bins for storage in offsite immunisation clinics

To monitor the temperature of vaccines stored in chilly bins for offsite immunisation clinics:

- a data logger with a probe, external display and alarm is used to monitor the temperature of the vaccines throughout the time they are stored in chilly bins at an offsite vaccination clinic
- staff will record the minimum, maximum and current temperatures every 20–30 minutes after putting the vaccines in the chilly bin
- the data logger is set to record the temperature every 5 minutes; the data is downloaded, reviewed and saved after returning to the clinic.

Providers must keep documentation associated with monitoring the temperature of vaccines in chilly bins for 10 years, along with the rest of the cold chain documentation.

The following staff can download the off-site data logger. See SOP at page 10 for off-site data logger instructions.

Name	**Designation**
Lucy Batchelor	Practice Nurse
Chris Long	Nurse Manager
Julie Hansen	Practice Nurse
Katie Croft	Practice Nurse
Hannah Wix	Practice Nurse
Megan Harrop	Practice Pharmacist
Hannah Hipkiss	Practice Nurse
Sarah Egden	Practice Nurse

7. Maintenance and replacement plan and schedule

This covers all cold chain equipment, including:

Equipment		Location in clinic	Maintenance and replacement plan
Refrigerator: Date purchased:	Rollex April 2015 Replace 2025	Dispensary room Replace by 2025 Model PSR273	Annual service by Pierson's Refrigeration. Annual check of Fridge performance and temp ranges by Canterbury Immunisation every 12 months. Annual service completed 1/3/2024 both fridges
Model: Refrigerator Date Purchased	PSR273 Rollex March 2022 Replace 2032	East Wing AMC Replace by 2032	
Minimum and maximum montioring device		Vaccine refrigerator	In built temperature recording device
Electronic temperature monitoring devices 5 x LogTag Model TRED30-16R for offi-site work 2 x LogTag Model TRID30-7R		File Room cupboard Two Vaccine refrigerators	The uploaded data is in shared P drive
Chilly bin/s: IKO20 for offsite and emergency. X2 Back up emergency is blue walled chilly bin + 4 large polystyrene bins	This equipment is used for storing vaccines when transporting them, defrosting your vaccine refrigerator, in the event of a power or equipment failure or for offsite vaccination clinics	Stored in Outside Storage shed 5 Log Tags for these chilly bins	Outline your plan for: Off Site see Cold Chain management storage and temperature monitoring when transporting and storing vaccines for offsite immunisation programmes defrosting refrigerators Maintaining the cold chain in the event of a power or equipment failure. *In the event of an emergency all vaccines to be placed in Blue walled chilly Bin with appropriate packaging and monitored with Log tag for transportation. Also include E logger in Chilly bin if all vaccines being transported*
Phase 5 cold sheets		Kept in freezer in outside shed	Phase 5 sheets are kept frozen in outside freezer in readiness for emergency storage of vaccines.
Insulation material			Bubble sheets and silicone fabric for packing are kept with the freezer in outside storage building.

8. **Process for vaccine stored outside +2°C to +8°C temperature range This process is taken from the *National Standards for Vaccine Storage and Transportation 2017.***

Vaccine temperatures are recorded outside required temperature range (below +2°C or above +8°C)*

*When one-off temperature variations of up to 12°C for less than 30 minutes occur for known reasons (eg, stocktake), you do not need to notify the immunisation/cold chain coordinator; however, you must document the variations in your records.

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Quarantine the vaccines.

- Label and quarantine all the vaccines involved.
- Ensure the vaccines are kept within the required temperature range of +2°C to +8°C. Seek alternative storage arrangements, if required, as per your cold chain policy.
- Communicate with colleagues to ensure the vaccines are not used until further notice.
- Document the incident.

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Confirm and define the incident.

- Review the refrigerator temperature records and download information from the data logger to clarify the cold chain before this event.
- Confirm current refrigerator temperatures.
- Check the refrigerator's service history to date.

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Collect as much information as possible.

- What monitoring has taken place (maximum, minimum and/or current thermometer readings)?
- For how long were the vaccines stored outside the required +2°C to +8°C range (minutes, hours or days)?
- Identify all vaccines stored in the refrigerator, the length of time they were stored, usual stock turnover and expiry dates.
- Identify any previous events involving these vaccines where the temperature has gone outside the required +2°C to +8°C range.
- Is it likely that any individuals received a compromised vaccine?

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Contact your local immunisation/cold chain coordinator with all the available information and work with them through to resolution. Ensure that you fully document the incident and outcomes.

8a. HANDLING TEMPERATURE BREACHES OF COVID 19 VACCINES

- Please refer to coloured table below for COVID vaccine temperature breaches of +8°C to +30°C (up to +25°C only for Nuvaxovid)
- Label the vaccines 'not for use'.
- If the refrigerator is currently running within the +2°C to +8°C range, leave the labelled vaccines in your refrigerator.
- If the refrigerator is not within the +2°C to +8°C range, look for obvious reversible causes (door open, power interruption).

- Contact your Immunisation Coordinator or Regional Immunisation Advisor for advice and further actions.
- Document the steps and actions you have taken.
- If advised to by your local co-ordinator or CL, pack your labelled vaccines into a chilly bin, with a temperature monitoring device and consider transporting to your back-up provider (see table in section 9 of this policy for details).

9. Emergency plan for dealing with equipment and power failures

In the event of a power failure and/or equipment failure, the refrigerator will be monitored using an independent digital thermometer or data logger with a visible display and the kept door closed. If the power failure extends beyond 4 hours or the internal refrigerator temperature is above +8^{o}C seek alternative refrigeration.

	Event	Action	Who responsible
Power failure or refrigerator failure	1. If failure is less than 4 hours and temperature remains between +2°C and +8°C.	• Keep refrigerator door closed and monitor refrigerator temperature. Do not remove any vaccines from the refrigerator unless temperature range is below +2°C degrees or above +8°C degrees.	Any Nurse
	2. If temperature remains stable between +2°C and +8°C but power failure is continuing beyond 4 hours.	• Contact immunisation/cold chain coordinator. • Pack vaccines for transport in accordance with the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* and take with log tagger to – Kaiapoi Family Doctors (alternative refrigeration site)	
	3. If the refrigerator temperature is below +2°C degrees	• Quarantine vaccines in the refrigerator, download the data logger. • Move your vaccines to your alternative refrigeration site. • Contact immunisation/cold chain coordinator for further advice.	

	4. If the refrigerator temperature is above +8°C	• Quarantine the vaccines. • Download the data logger. • Discuss with immunisation/cold chain coordinator. • Pack vaccines for transport in accordance with the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017,* and take with Log tagger to Kaiapoi Family Doctors (alternative refrigeration site)	
Location for alternative refrigeration – Kaiapoi *Family Doctors, 42 Charles Street,* Kaiapoi			
Contact details for alternative refrigeration – Kaiapoi 03 327 7474 (open 9am to 5pm Monday to Friday). Before transporting vaccines, check the alternative facility has storage capacity for the vaccines.			
Contact the local immunisation coordinator to inform them of the breach and for further advice.			

10. Vaccine disposal

Before disposing of vaccines (other than for expiry reasons), we will contact the local immunisation/cold chain coordinator. Refer to *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* for more information on vaccine disposal and returning vaccines for destruction.

All vaccines for disposal will be returned to ProPharma if advised by Immunisation Co-Ordinator

10a. Disposal of vaccines and consumables ordered via CIR portal

Disposal of consumables

Consumables should be disposed of according to existing procedures (e.g. disposal into sharps bin and/or biohazard bags). Follow your local procedures to arrange collection of the sharps bin.

Disposal of damaged, empty and expired vaccine vials

If a vial is expired, broken, damaged or not suitable for use, confirm destruction with clinical lead (who may obtain further advice from 0800 IMMUNE).

The process for destruction and disposal of expired vials is as follows:

a. Remove the lid.
b. Deface the vial.
c. Place the vial(s) in the Interwaste vial disposal bin.
d. Record the wastage in the CIR Inventory.

Interwaste will provide a 20-litre sized container in which to dispose expired (full), empty, broken or damaged vials. Expired vials should be defaced before disposal. When the container is almost full, contact

Interwaste on 0800 102 131 to arrange for pick-up. Interwaste will deliver a new disposal container at the same time and remove the existing container. Interwaste will destroy the vials in an appropriate manner.

Ensure the lid of the Interwaste disposal container remains closed when not in use.

Disposal of vaccines drawn up but not administered and empty vaccine syringes

Vaccine doses that have been drawn up but not administered must be disposed of in the sharps bin provided. Similarly, empty/used vaccine syringes should be disposed of in the sharps bin. Seal and remove sharps bins when filled and store in a secure area for transportation and final disposal.

Disposal of vaccine packaging

Ensure all packaging the vaccine is sent in is destroyed to ensure packages cannot be replicated. Once all vials in a packet have been used, black out all vaccine-related information on the label using a permanent marker. The vaccine box must be securely destroyed. Tear off the lid of the cardboard vaccine box which has the label on it and place in the shredding bin, secure document destruction bin or biohazard bag. The remainder of the non-identifiable cardboard box can be placed in normal waste.

11. Policy review

All new staff will be orientated to this cold chain management policy and our cold chain process. Staff training and information is recorded in their induction programme.

Our cold chain policy is reviewed and updated annually and when changes are made to designated cold chain staff or the vaccine documents.

The immunisation/cold chain coordinator will be contacted:

- when there is a significant change in staff responsible for cold chain management
- before purchasing a new pharmaceutical refrigerator or cold chain equipment, including chilly bins and temperature monitoring equipment
- in the event of a cold chain breach* before disposing of vaccines
- for cold chain management advice.

The undersigned accept this document as this services cold chain management policy.

Signature of 1st designated staff member:	Signature of 2nd designated staff member:
Position: Nurse Manager	Position: Practice Nurse
Name: Chris Long	Name: Lucy Batchelor
Date policy approved: July 2024	
Date of next cold chain policy review: August 2025	

SOP – Cold Chain weekly download of log-tags

Subject	Weekly download of log-tags from vaccine fridges
Purpose	Maintain the integrity of the cold chain
Responsibility	Authorised Vaccinator

This SOP is to be undertaken by an Authorised Vaccinator every Monday morning (or day after following a public holiday) to manage the Cold Chain integrity of our vaccination fridges.

1. **Vaccine Fridge # 1**

    a. **Log in to CL's PC**
        i. The Log tag analyser is visible on the desktop screen (top left side of screen)
            1. Double click on Analyser3 icon – It will appear on the screen

    b. **Prepare the Log Tagger**:
        i. Retrieve Log Tag from Vaccine fridge # 1
            1. Place Log Tag into cradle (after point 3 is achieved)
                a. The analyser will update the recordings for the previous week and record in file path: P:\LogTag Data

    c. **Download data from Log Tagger:**
            1. Go to the ribbon and click on 'log tag' and choose 'configure'
            2. After it completes its first run, click on 'configure' again (bottom of blue box)
            3. The Log Tag in the cradle is beeping briefly and is preparing to record the temperature
            4. Place the Log Tag back in the vaccine fridge on a different rack
            5. Check that the downloaded records has been saved in the Log Tag file P:\LogTag Data (it may take a couple of minutes to appear in the downloads)

2. **Vaccine Fridge # 2**
    a. Repeat as above

Amberley medical centre

SOP – Managing the Off-Site Cold Chain

Subject	Setting up the temp logger for transportation of vaccines & retrieving data after the event
Purpose	Maintain the integrity of the cold chain whilst vaccines off site
Responsibility	Authorised Vaccinator

This SOP is to be undertaken by the Authorised Vaccinator designated to run and manage the Cold Chain integrity for offsite vaccination clinics.

1. **Prepare the vaccine bins for going offsite**:
    a. Load bins with 4 x phase 5 freezing pads

2. **Prepare the log tagger**:
    a. Log in to CL's PC
        i. The Log tag analyser is visible on the desktop screen (top left side of screen)
        ii. Double click on Analyser3 icon – It will appear on the screen
    b. Place Log Tag into cradle (after point 3 is achieved). The analyser will say that there aren't any readings. That's ok
        i. Look at the top ribbon and click on the Log Tag
        ii. Choose to configure from the drop-down box
        iii. The Log Tag in the cradle will beep
        iv. Sometimes you will see a small blue box that pops up and says that the DATE-TIME start time is 2 minutes in the future. Click yes
        v. At the bottom of the blue box on the screen click on Configure again
        vi. You will see that the Log Tag in the cradle is beeping and is preparing to record the temperature in a few minutes.
    c. You can go and plug this into the Chilly Bin, and it will start to record after a few minutes
    d. Record the readings onto the Temperature Log page every 30 minutes

3. **Returning from offsite clinic:**
    a. Unload the remaining vaccines and return to vaccine fridge.
    b. Disconnect the Log Tag and take to CL's desk.
        i. Open the Analyser again as above. Once it appears on the screen
    c. Place the Log Tag in the cradle.
        i. The analyser will immediately download the data.
        ii. A graph will appear on the page showing the data for the period off site.
        iii. On the top ribbon you will see the "print" tab.
        iv. Click on this and choose the colour printer.
        v. At the bottom of the screen, you will see the "Summary". Print that as well, you have to click on print twice it seems
    d. Attach the paperwork to the handwritten record of the temperature made whilst off site