**Cold Chain Policy for Clinic Name Covid-19 Community Vaccination Centre**

This policy deals with Clinic Name Community Vaccination Centre cold chain management; fridge management, vaccine receipt and storage, staff responsibilities, transporting within cold chain, data logger download as well as details around the Covid-19 vaccination program.

Location of Vaccination Centre: Address

Cold chain accreditation expires on Date

## Designated staff with overall responsibility for cold chain management

|  |  |
| --- | --- |
| Clinic Name Community Vaccination Centre | |
| Date |  |
| DHB Immunisation Co-ordinator |  |
| Local Immunisation Co-ordinator |  |
| IMAC COVID Immunisation Advisor |  |
| Clinical Lead for COVID vaccination service |  |
| Second Person responsible |  |

## Site security

* The vaccines must be stored in a work area that has the constant presence of an authorised person during hours of operation and must not be within easy access of the public
* Delete if this line is not storing vaccine overnight: Security of vaccine stored overnight achieved with a secured building with a monitored alarm. Names of those who will be contacted by alarm company: *alternatively you may hire an overnight onsite security guard.*

## Vaccine documents

The vaccine documents listed below provide detailed information to support cold chain management around the COVID-19 vaccination programme. All documents are stored in the vaccination folder in the vaccine room.

* The .pdf version of the **Immunisation Handbook** has been downloaded and is available where. Pfizer vaccine information is printed and located in where.
* **National-Standards-for-vaccine-storage-and-transportation-for-immunisation-providers-sep19**. This is available on the Ministry’s website at: <https://www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017> *A printed copy is available where.*
* **2021 Addendum to National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition): COVID-19 Vaccine Immunisation Programme**. This is available on the Ministry’s website at: <https://www.health.govt.nz/publication/2021-addendum-national-standards-vaccine-storage-and-transportation-providers-2017-2nd-edition> *A printed copy is available where.*
* Annual Cold Chain Management Record is located in the: *cold chain shared folder AND hard copy printed is available where*
* Medsafe vaccine data sheets for the Pfizer Comirnaty Covid-19 vaccine are contained in the cold chain / vaccine folder alongside extra copies of the vaccine preparation and administration instructions.
* Ministry of Health Operating Guidelines, latest version found here: https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals

## Receiving Vaccinations – this is the HCL process, if receiving vaccine from DHB pharmacy, need to replace with DHB SOP information here.

The Clinical Lead (CL), who is a qualified vaccinator experienced in cold chain, must be available on site to accept deliveries. HCL will pack and ship the vaccine under cold chain conditions in Credo Cubes at +2°C to+8°C.

**CHECK PACKAGE**

The courier will hand the package to the site contact. Before signing for the package the CL will:

Confirm the Credo Cube is addressed to them/their site

Provide their photo identification to the courier for the courier’s confirmation

Conduct a check of the order immediately while the courier is present (see below)

**CHECK TEMPERATURE**

The CL must check the temperature logger included in the Credo Cube to confirm whether a temperature breach has occurred in transit.

The temperature logger will have a green light if the temperature has remained within limits or a red light if a breach has occurred.

**Where a breach has occurred the CL must quarantine the shipment in cold chain conditions while the logger is returned to HCL for reading. The site contact must call the MoH Logistics team on 0800 335 778.**

The Logistics team will talk the CL through the actions to be taken, such as urgent orders being placed and what will happen once the temperature data has been read. In this situation, the site contact will **not** sign for the package with the transport provider and it will be returned to HCL.

**CHECK VIALS**

The CL will open the Credo Cube and the internal vaccine packaging and conduct a visual check of the vials in each package to ensure vials are intact.

**Where over 20% of the vials are broken or spoiled, the site contact must contact the MoH Logistics team on 0800 335 778. The Logistics team will talk the site contact through the actions to be taken (e.g. disposing of the vaccine and sending out an urgent replacement shipment).**

Where over 80% of vials are intact and there are no concerns, the site contact will sign for the package.

**ADD VACCINES TO SITE COLD CHAIN**

The Clinical Lead will then store the vaccine at cold chain conditions in the internal packaging carton it arrived in (not the Credo Cube, but the white cardboard vaccine box) until the use-by date and time marked on the vaccine box is reached. Any vials that are not viable must be disposed of following the disposal process detailed in section 5 below.

1. Check fridge temperature and have vaccine register ready along with marker pen
2. Log vaccines into the vaccine register, including vaccine arrival date, name, batch number, expiry date and total number in stock. The vaccines are unpacked as soon as possible after arrival on the premises. The ‘count’ should be checked off by a second person for an additional layer of security.
3. It is good practice to ‘write 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.
4. The date of arrival of the vaccines needs to be written on the vaccine box in permanent marker. This is to ensure that the oldest stock is used first. The CL can then identify the first box to be used with a green sticker *or include your site process to ensure stock rotation*.
5. 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 container at the bottom of fridge.

## Disposable of Pfizer Vaccine and Consumables

**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). Dispose the unusable vial into the Interwaste Bin and complete the MoH incident report form.

Interwaste will provide a 20 litre-sized container in which to dispose empty, broken or damaged vials. 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 so they can destroy the vials in an appropriate manner.

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

**Disposal of vaccines drawn up but not administered & 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 can be disposed of in the sharps bin.

**Disposal of vaccine packaging**

Ensure all packaging the vaccine is sent in is destroyed so 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. Tear off the lid of the cardboard vaccine box which has the label on it and place the packaging in the shredding bin. Remainder of the non identifiable cardboard box can be placed in normal waste.

**Shelf Life of Vaccine**

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| --- | --- | --- |
|  | **At +2˚C to +8˚C** | **At ambient temperature (up to +30˚C)** |
| **Undiluted vaccine vials** | **31 days** from time of removal from ULT.  **Note:** Transportation time (max 12 hours) at +2°C to+8°C is included in the 31-day limit. This expiry printed on vaccine box. | **2 hours\*** |
| **Diluted Vaccine** | **6 hours\*\*** | |
| **\*** undiluted vaccine should not be routinely stored outside +2˚C to +8˚C, it should only be removed from the refrigerator in preparation for being diluted.  \*\*unless used immediately store syringes in a pre-cooled, data logger monitored pre-cooled chilly bin. | | |

## Cold chain equipment – operation and maintenance

Clinic Name Community Vaccination Centre uses one pharmaceutical refrigerator to store vaccines. This fridge is a enter fridge details here. *Moving the fridge from where it was first assessed for CCA or obtaining new equipment such as dataloggers or chilly bins, will require an updated policy to be submitted and signed off.*

All vaccinators are responsible for ensuring that 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 around the condenser
* has nothing placed on the top of it, except the daily minimum/maximum recording folder
* has an independent power point with a surge protector
* the fridge is serviced on an annual basis by a technician from name of service provider. This is due DATE
* is not more than 10 years old
* the CL will contact our immunisation coordinator when purchasing new equipment or if we have any questions about cold chain equipment.

## Refrigerator temperature monitoring and Data Logger review

* Minimum requirements for monitoring refrigerators that store Comirnaty are two monitoring systems, run on two different sensors. This is usually min/max thermometer which is checked daily and a continuous (24 hour) monitoring system (data logger or cloud-based system) which is reviewed weekly. All staff should be taught how to download the continuous monitoring system and who and when does the weekly review.
* The CL (or acting CL) is to record minimum and maximum daily fridge temperature in the Annual Cold Chain Management Guide every morning the clinic is open at the same time each day. The minimum and maximum temperatures are reset after they have been recorded. All vaccinating staff are able to do this recording. Directions are contained in cold chain folder on how do this.
* The current temperature records are recorded in the Annual Cold Chain Management Record which is kept on top of the fridge.
* A year’s worth of recordings is stored in archives for 10 years.
* The Datalogger is set to record the refrigerator temperature every 5 minutes. The Datalogger temperature information is reviewed weekly by the CL (or acting CL) and reviewed alongside the daily minimum/maximum temperature for that week. Any unusual variations are discussed promptly with the immunisation/cold chain coordinator, as listed on page one. The Datalogger temperature information is also reviewed in response to temperatures outside the +2°C to +8°C range.
* Any unusual variations from the Datalogger temperatures are recorded in the ‘Breaches Reported’ spreadsheet found in the following folder: Vaccine Folder in desktop of Laptop 3 and noted on the daily min /max sheet
* The data is regularly backed up and is stored for a minimum of 10 years in the following file: Vaccine Folder where
* The person completing the Datalogger temperature review should also note this on the ‘Annual Cold Chain Management Record’ that is kept on top of the fridge. If there are any temperatures that appear out of the +2˚C to +8˚C range, the person doing the Datalogger review should check the ‘Annual Cold Chain Management Record’ for those dates to see if any vaccines had arrived or a vaccine stocktake undertaken, which may account for the temperature deviation.

All vaccinating staff are able to review the Datalogger information. The CL is the person primarily responsible for reviewing the datalogger on a weekly basis on a Monday is preferred day and if away, will nominate someone to do this in their place.

* The following staff are able to download the data logger (minimum of two staff required, all vaccinators should know how to do this, and it must be included on the new clinical staff orientation process):

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| --- | --- | --- |
| Name | Designation | Date |
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1. **Maintenance and replacement plan and schedule**

This covers all cold chain equipment, including:

| **Equipment** | | **Location in clinic** | **Maintenance and replacement plan** |
| --- | --- | --- | --- |
| This table needs local clinic information, enter details as they apply to your clinic, if the fridge or other equipment is moved, this table must be updated and policy resubmitted for approval | | | |
| Refrigerator:  Date purchased: | Type |  | Yearly maintenance / check by NAME, replacement by DATE  Any issues with fridge call 24/7 service  NUMBER & EMAIL CONTACT |
| In-built or portable minimum and maximum monitoring device *depends on make/model of vaccine fridge, delete* *what not applicable* | | Vaccine refrigerator | Probe is in the fridge and is set to record temperatures at 10-minute intervals. |
| Electronic temperature monitoring devices:  Device eg data logger model | | Vaccine refrigerator |  |
| Defrosting Refrigerators | |  | Vaccine fridge is self-defrosting. |

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| **Equipment for portable storage** | **Location in clinic** |
| Chilly bin/s:  Include type, size and date of purchase |  |
| Ice packs:  Type eg Cool-Pac Ice Pads and normal ice pads | The Cool-Pac pads are kept frozen in the freezer along with the normal ice pads. |
| Insulation material  Eg Polystyrene pieces and foil insulation, shredded paper/rubber mat | Kept in sealed box in vaccination room |
| Data logger/s  Type, date purchased  Data loggers with visible external display must be used for off site clinics |  |
| If the refrigerator or other equipment is moved, this table must be updated. | |

### Monitoring and Preparing chilly bins for transport or temporary storage for offsite immunisation

Before transporting vaccines offsite, the chilly bin must be cooled and the vaccines packed appropriately.

**How to precool the chilly bin**

* Remove the required amount of ice packs from the freezer where they are kept and remove any ice build up.
* Place half the amount of ice packs on paper towels on a bench or desk to condition it (ie allow ‘frost’ to form and melt off).
* Place the bottom insulation matting in the empty chilly bin.
* Place the data logger inside
* Place the top insulation matting in the chilly bin covering the probe and the bottom insulation matting.
* Place the remaining ice packs (those that aren’t conditioning) in the chilly bin on top of the insulation matting and close the chilly bin.
* Start the data logger (with a 15-minute start delay, avoiding initial over temperature alarms).
* After 15 minutes, review, document and begin to monitor the temperature in the chilly bin.
* Once the temperature is below +5°C assess the stability of the temperature. When the temperature changes less than +0.5°C between 3–5-minute readings, it can be considered stable enough to add the vaccine.
* When the temperature has stabilised open the chilly bin and remove the ice packs, the top insulation matting and the probe and pack the vaccine you will be transporting into the chilly bin.
* Document how long the precooling took as that we can allow for this when transporting vaccines offsite.

**Packing vaccines for transport or storage in chilly bins**

* Precool the chilly bin as described above. However, cooling can take longer if it is a large chilly bin. This is why a test of how long the chilly bin takes to cool, must be done prior to ANY vaccine taken offsite so that the cooling time is already known.
* Place the boxes of vaccine to be relocated into the precooled chilly bin, sitting on the bottom insulation matting. The boxes of vaccine can be packed in any orientation and in multiple layers, leaving space in the middle for data logger.
* Place the data logger in between two boxes in the middle, ideally with the top of the foam level or just below the top of the boxes of vaccine. Place the probe into a box of vaccine which is in the middle top position of the boxes of vaccine.
* Some data loggers sit on top of the chilly bin as they have a visual temperature display and the probe is fed through a hole in the chilly bin lid. If this is the case, place the probe into a box of vaccine.
* Cover the boxes of vaccine and the data logger with the insulation matting and then add the ice packs that have been conditioning for at least 15 minutes on top of insulation. Wipe these conditioned ice packs dry before use. Make sure the vaccines are not frozen by contact with or exposure to the ice packs.
* Close the chilly bin and secure the lid using the clips on the container.
* Complete the relevant paperwork, the ‘Off-Site Immunisation Chilly Bin Temp Log’. Must have a hard copy of these documents every time vaccine is transported away from base. Temperature must be recorded every 30 minutes while chilly bin holds vaccine.
* If you need to leave your base before the chilly bin temperature is stable you must continue to monitor the temperature every 3-5 minutes until it is stable (and document this).
* Place the ice packs that were used for precooling back in the freezer. It is strongly recommended to take extra ice packs out for the day in a separate chilly bin in you need further ice packs to reduce the temperature.
* Do not start travelling until the loaded chilly bin temperatures have stabilised at between +2°C and +8°C.

**Note:** It may be necessary to place ice packs and/or insulation material around the side of the insulated container if it is a large space; you will need to experiment to find the best combination for your equipment. Any chilly bin (small or large) may require material e.g. cardboard or matting, to protect vaccine boxes from moving around whilst travelling.

## Handling refrigerator temperature breaches

The following advice applies to handling the Comirnaty™ vaccine (mRNA vaccine by Pfizer/BioNTech). In its thawed and undiluted state can be stored at room temperature (+8°C to +30°C) for up to 2 hours (120minutes). This time is accumulative.

* If your refrigeration fails and your data logger readings confirm your vaccine has been exposed temperature above +8°C you need to:
* 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). If no cause found, pack your labelled vaccines into a chilly bin, with a temperature monitoring device and consider transporting to your back-up provider

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| --- | --- |
| **Back up provider details** | *Before transporting vaccines, check alternative facility has storage capacity for the vaccines* |
| Location and hours of operation for alternative refrigeration | complete |
| Contact details for alternative refrigeration | complete |

* Contact your COVID Regional Advisor for advice and further actions.
* Document the steps and actions you have taken.

## 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 door kept closed. If the power failure extends beyond 4 hours or the internal refrigerator temperature is above +8⁰C seek alternative refrigeration.

|  |  |  |
| --- | --- | --- |
| Event | Action | Who responsible |
| Power failure or equipment failure and temperature rises above +7.5˚C | * Pre-cool chilly bin ready for transport to back up provider. * Contact immunisation coordinator * Pack vaccines for transport in accordance with the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 2nd Ed and take with a data logger to back up site. | Clinical Lead |
| Equipment failure and refrigerator temperature is below +2°C degrees | * Quarantine vaccines in the refrigerator, download the data logger. * Move your vaccines to your alternative refrigeration site, if datalogger temperature confirms temperatures below +2˚C. * Contact immunisation coordinator for further advice. |
| 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 2nd Ed, and take with a Jaycar Min/Max thermometer to |
| Location for alternative refrigeration – | | |
| Before transporting vaccines, check the alternative facility has storage capacity for the vaccines and is in a secure location. | | |

## Policy review

All new staff will be orientated to this cold chain management policy and our cold chain process. Staff will sign the back page to acknowledge that they have received cold chain specific training and information.

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 service’s cold chain management policy.

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| --- | --- | --- | --- | --- |
| Signature of 1st designated staff member: | | | Signature of 2nd designated staff member: | |
| Position: | Authorised/Pharmacist Vaccinator | | Position: |  |
| Name: |  | | Name: |  |
| Date policy approved: | |  | | |
| Date of next cold chain policy review: | |  | | |

Clinical staff who have been orientated to the cold chain process and policy for this service. All vaccinators working at this site under this cold chain policy have read and understood this document.

By signing this, I acknowledge that I have received training and information in relation to Clinic Name’s cold chain policy and processes.

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