Cold Chain Policy Management

Purpose:

This document contains the information required to assist immunisation providers to develop their own cold chain management policy. Each provider, clinic or department storing vaccines must have an individualised policy or set of standard operating procedures that cover off the required information/process.

Providers are not required to use this template but must ensure that their cold chain policy document covers the required details.

Instructions for use:

This template must be adjusted to suit your setting, (particularly areas highlighted in red) ensuring that you meet the requirements for safe vaccine storage as required by Te Whatu Ora – Health New Zealand (Te Whatu Ora). Contact your local immunisation/cold chain coordinator if you have any questions or need advice about your cold chain management or policy.

All immunisation providers storing and/or transporting vaccines must have a written, current cold chain management policy that is:

* dated and signed by relevant staff
* reviewed at least annually and when there are staff, equipment or process changes, copy of updated policy sent to immunisation/cold chain coordinator.

The policy should specify:

* the names of (at least two) designated staff members responsible for cold chain management
* vaccine and stock requirements for the provider’s programme or clinic
* vaccine ordering and stock taking processes
* processes for receiving and storing vaccines
* action to be taken if the provider receives a temperature monitoring device with their vaccine order
* the plan and schedule for cold chain equipment maintenance (servicing and cleaning) and equipment replacement plan
* processes for monitoring the refrigerator’s temperature, including instructions on datalogger use
* details of equipment and process for offsite vaccination clinics, including chilly bins, insulation material and temperature monitoring process and equipment
* action to be taken when the temperature recordings of the refrigerator or chilly bins are outside the + 2°C to + 8°C range and list equipment available.
* processes for vaccine disposal
* a documented cold chain orientation plan for new staff

The policy should also include space for all relevant staff to sign confirming that they have read and understood the cold chain policy.

Cold Chain Management Policy for *Clinic Name* Immunisation Services

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| --- | --- |
|  | |
| Clinic name, address and contact details (email and phone number)  **Cold Chain Accreditation / Compliance expiry date:** xx | |
| **Cold Chain policy date:** | **Policy annual review date:** |
| xx | xx |

This policy deals with ***Clinic’s name*** cold chain management, pharmaceutical fridge management, vaccine receipt and storage, staff responsibilities, transporting within cold chain, data logger download and details for vaccines as per the National Immunisation Schedule and COVID-19 vaccines.

|  |  |  |
| --- | --- | --- |
| **Contacts for Cold Chain Management** | | |
| **ROLE** | **NAME** | **CONTACT DETAILS** |
| Immunisation coordinator / cold chain coordinator | xx | xx |
| IMAC Regional Advisor | xx | xx |
|  | | |
| **Designated Staff with overall responsibility for cold chain management** | | |
| First Cold chain lead for Clinic  (Authorised Vaccinator or GP or Pharmacist vaccinator) | xx | xx |
| Second Cold chain lead | xx | xx |
|  | | |
| **Back up Provider details** | | |
| xx | xx | xx |
|  |  |  |

1. **COLD CHAIN ACCREDITATION**

We are committed to ensuring safe storage of vaccine and all equipment, system and processes are compliant with the National Standards for vaccine storage and transportation for immunisation providers 2017 (2nd edition).

## **SUPPORTING DOCUMENTS**

The vaccine documents listed below provide detailed information to support cold chain management around the National Immunisation schedule and COVID-19 vaccination programme and are available for staff to review and become familiar with, they are stored *(ie cold chain vaccination folder)* in the *where (ie vaccine room/computer location)*.

* The **Immunisation Handbook,** available online <https://www.health.govt.nz/our-work/immunisation-handbook-2020>
* **National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition) updated Sept 2019**. This is available on the Ministry’s website at: <https://www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017>
* **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>
* Annual Cold Chain Management Record available on Manatū Hauora Ministry of Health website [www.health.govt.nz/coldchain](http://www.health.govt.nz/coldchain) for download and printing
* Medsafe vaccine data are available from https://medsafe.govt.nz/Medicines/infoSearch.asp
* Te Whatu Ora COVID-19 vaccination Operating Guidelines, <https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines>

1. **VACCINE REQUIREMENTS, STOCKTAKING & ORDERING**

The Clinical lead / Cold Chain lead will be aware of how much vaccine stock is required at any one time, based on demand and consumer population served.

To avoid overstocking and to ensure stock rotation, a minimum stock of National Immunisation Schedule vaccines of **two** weeks is required, and no more the **four** weeks’ worth of stock should be held at any given time.

**The minimum and maximum stock levels are: (This is worked out using the tables in the National Standards, edit/add to tables as needed for your population and for special groups).**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **DTaP-IPV- HepB/Hib** | **PCV** | **RV** | **Hib** | **MMR** | **Varicella** | **DTaP-IPV** | **HPV** |
| Minimum | x | x | x | x | x | x | x | x |
| Maximum | x | x | x | x | x | x | x | x |
|  | **Tdap** | **Influenza - adult** | **Influenza - child** | **Shingrix** |  |  |  |  |
| Minimum | x | x | x | x | x | x | x | x |
| Maximum | x | x | x | x | x | x | x | x |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Comirnaty**  **(30mcg)** | **Comirnaty**  **(10mcg)** | **Nuvaxovid**  **(5mcg)** |
| Minimum | x | x | x |
| Maximum | x | x | x |

**3a NATIONAL IMMUNISATION SCHEDULE VACCINES**

We undertake a stock count xx times per month on xx (eg, second and fourth Tuesday of the month) and order vaccines as appropriate.

For online schedule vaccine order forms, go to the regional distribution stores’ National Immunisation Schedule Funded Vaccines website [www.fundedvaccines.co.nz/vaccines](http://www.fundedvaccines.co.nz/vaccines)

Healthcare Logistics distributes influenza vaccine orders to immunisation providers once the vaccine becomes available at the start of the funded influenza programme (from 1 April each year). Providers can order influenza vaccine from the Healthcare Logistics website ([www.hcl.co.nz](http://www.hcl.co.nz)). For more information about ordering influenza vaccine, see [www.influenza.org.nz](http://www.influenza.org.nz).

All vaccines are logged in the vaccine register which is accessed where (i.e. cold chain folder in cold chain room/computer.)

**3b COVID VACCINES delete if not required**

Stock management, demand, forecasts and allocation are monitored by in the CIR Inventory portal.

Vaccine stocktake is completed daily and entered electronically into the COVID Immunisation Register (CIR) Inventory portal. Vaccine demand is estimated on daily reporting of:

* Stock on hand
* Stock movements including ordering, transfers, wastage, consumption and stock adjustments
* Stock consumption
* Stock waste

Refer to the current version of the [COVID-19 Vaccine Operating Guidelines](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines) for details.

## **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 date) 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

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.
* Outline the process to identify the first box to be used eg with a coloured sticker

**4a COVID-19 VACCINES**

Refer to the current version of the [COVID-19 Vaccine Operating Guidelines](https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines) for details.

1. **DISPOSAL OF NATIONAL SCHEDULE VACCINES**

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.

## **5a DISPOSAL OF COVID VACCINES 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).

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

* + - 1. Remove the lid.
      2. Deface the vial.
      3. Place the vial(s) in the Interwaste vial disposal bin.
      4. 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. Remainder of the non-identifiable cardboard box can be placed in normal waste.

**6. TEMPERATURE MONITORING AND DATALOGGER REVIEW**

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

* Minimum requirements for monitoring refrigerators that store vaccines. National Schedule Immunisation vaccines and / or COVID-19 vaccines 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.

**Daily**

* The cold chain staff record minimum and maximum daily fridge temperature, from the inbuilt temperature monitor, on each vaccine fridge and document in the Annual Cold Chain Management Guide (ACCMR) every morning the clinic is open at the same time each day. The minimum and maximum temperatures are reset after they have been recorded. (If the Provider has more than one vaccine fridge onsite, each fridge has its own ACCMR with name of fridge written clearly on top) All vaccinating staff are able to do this recording. Directions are *(ie contained in cold chain folder)* on how do this.
* The current temperature records are recorded in the Annual Cold Chain Management Record (ACCMR) which is kept on top of the fridge. **Ensure all relevant clinical staff are trained on how to check and reset the minimum/maximum thermometer and how to record the minimum and maximum temperatures**, and know what to do if the temperature is outside the +2°C to +8°C range

# **Weekly**

* The datalogger is set to record the refrigerator temperature every 5 minutes. The datalogger temperature information is reviewed weekly by the Clinical Lead or Cold Chain Lead 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 data is regularly backed up.

**OR**

* Review continuous monitoring data weekly and review alongside the daily minimum/maximum temperature readings
* Any unusual variations are discussed promptly with the immunisation/cold chain coordinator.
* The person completing the datalogger temperature review should also note this on the ACCMR 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 ACCMR for those dates to see if any vaccines had arrived or a vaccine stocktake undertaken, which may account for the temperature deviation.

All temperature records whether manual or electronic must be stored for 10 years.

# **Cold Chain Breach**

* The data logger is downloaded and reviewed in response to any temperature breach outside +2°C to +8°C range. The local immunisation advisor must be notified to advise next steps
* All vaccinating staff can review the datalogger information. The Clinical Lead is the person primarily responsible for reviewing the datalogger on a weekly basis on *Monday (is the recommended day or first day after any period of being of being closed)* and if away, will nominate someone to do this in their place.

The following staff have been trained 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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**7. COLD CHAIN EQUIPMENT- OPERATION AND MAINTENANCE**

*Clinic Name* uses *one* pharmaceutical refrigerator(s) to store vaccines. The fridge(s) are *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, with ambient temperature monitoring / recording
* 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 Clinical Lead will contact our immunisation coordinator when purchasing new equipment or if we have any questions about cold chain equipment.

| **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 5 minute intervals. |
| Electronic temperature monitoring devices:  *Device eg data logger model*  *MATOS* | | Vaccine refrigerator | Expected replacement date: *xx* |
| Defrosting Refrigerators | |  | Vaccine fridge is self-defrosting |

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| --- | --- |
| **Equipment for portable storage and transport** | **Location in clinic** |
| Chilly bin/s:  *Include type, size and date of purchase* | Check monthly for wear and tear  Expected replacement date: *xx* |
| Ice packs:  *Type eg Cool-Pac Ice Pads and normal ice pads* | *The Chill wrap / 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*  Replaced minimum 6 monthly |
| Data logger/s  *Type, date purchased*  *Data loggers with visible external display must be used for off site clinics* | Expected replacement date: |
| If the refrigerator or other equipment is moved, this table must be updated. | |

**8. MONITORING AND PREPARING CHILLY BINS FOR OFFSITE TRANSPORTATION AND STORAGE**

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

**How to pre-cool 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 so that we can allow for this when transporting vaccines offsite.

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

* Pre-cool 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 pre-cooled 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 probe level or just below the top of the boxes of vaccine or 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 20-30 minutes while chilly bin holds vaccine.
* Do not start travelling until the loaded chilly bin temperatures have stabilised at between +2°C and +8°C.
* Note: 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 pre-cooling 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.

**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, shredded paper or matting, to protect vaccine boxes from moving around whilst travelling.

**Ambient temperature:** all providers must have a system in place for measuring and recording the ambient air temperature when storing COVID vaccines at room temperature, this includes in Outreach & drive thru settings.

## **9. HANDLING TEMPERATURE BREACHES OF NATIONAL SCHEDULE IMMUNISATION VACCINES**

This process is taken from the *National Standards for Vaccine Storage and Transportation 2017*

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| --- |
| Vaccine temperatures are recorded outside required temperature range (below +2°C or above +8°C)\*  \*When one-off temperature variations, involving National Schedule Immunisation Vaccines, 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. **This does not apply to buffered probes eg probe in glycol solutions.** |
|  |
| 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. |
|  |
| 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. |
|  |
| 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? |
|  |
| 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. |

## **9a 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 COVID Regional 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).

**Shelf Life of Covid-19 Vaccines according to type:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Vaccine:** | **Pfizer/BioNTech (30mcg) 12+Yrs** *Comirnaty* | **Pfizer/BioNTech (10mcg) 5-11yrs** *Comirnaty Paediatric* | **Novovax**  *Nuvaxovid* |
| **Refrigerator (+2°C to +8°C)** | Undiluted 31 days with expiry printed on box label | Undiluted 10 weeks with USE BY on box label | 6 months |
| **Room Temp (+2°C to +30°C)** | Stable for 2 hours prior to adding diluent, or 6 hours from adding diluent | Stable for 2 hours *prior* to adding diluent, 12 hours *from* adding diluent.  Doses kept in syringes may be stored for up 6 hours cumulatively. | Opened: up to 6 hours **(+2°C to +25°C only)** |
| **Use by (i.e: administer to patient)** | Must use by 6 hours from time diluent added (+2°C to +30°C) | Must use by 6 hours from time diluent added (+2°C to +30°C) | Must be used within 6 hours from first opening vial |

## **10. EMERGENCY PLAN FOR HANDLING POWER OR EQUIPMENT FAILURE**

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** | **Responsibility** |
| 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. |  |
| Equipment failure and refrigerator temperature is below +2°C degrees | * Quarantine vaccines in the refrigerator, download the data logger. * If datalogger temperature confirms temperatures below +2˚C, prepare to move your vaccines to your alternative refrigeration site as listed below * 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 min/max thermometer to: |  |
| **Back up provider details**: *name of provider (must also have current CCA or CCC):*  Location and hours of operation for alternative refrigeration: *complete details*  Contact details for alternative refrigeration: *complete name & ph number* | | |
| **Before transporting vaccines, check the alternative facility has storage capacity for the vaccines and is in a secure location.** | | |

## **11. 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.

**This cold chain policy is reviewed and updated annually or when changes are made to designated cold chain staff, equipment or processes (whichever comes first).**

**The immunisation/cold chain coordinator will be informed:**

* 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.

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

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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| --- | --- | --- | --- |
| **Name** | **Designation** | **Date** | **Signature** |
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# **Appendix 1: Instructions on how to use, download and review the data logger**

Must have this.

# **Appendix 2: Vaccine documents**

# If printed

# **Appendix 3: Patient demographic stock min/max level based on**

The number of:

|  |  |
| --- | --- |
|  | Children aged under five years (including casuals) |
|  | Children aged 11 years1,2(including casuals) |
|  | Children aged 12 years1 (including casuals) |
|  | Adolescents aged 14 years who have not received HPV in a school-based programme |
|  | Adults aged 45 and 65 years |
|  | Adults aged 65 years and older (Influenza) |
|  | Individuals eligible for influenza vaccine (those with medical conditions & pregnant women) |

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 those who are pregnant.

Refer to Table 3 and Table 4 in the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition) to complete this chart

# **Appendix 4: Offsite vaccination storage, possible links, references**

<https://www.immune.org.nz/sites/default/files/resources/Written%20Resources/StandardOffsiteVaccineMgt20181009V02Final.pdf>

<https://www.immune.org.nz/sites/default/files/resources/Written%20Resources/ColdChainOffSiteTempLog20181008V01Final.docx>

<https://www.immune.org.nz/sites/default/files/Conferences/COOL%20Project%20Stakeholder%20Summary%20Report%20_FINAL%20December%202017%20updated%206%20Dec%202019%20with%20suppliers%20added.pdf>

**Appendix 5: Staff Orientation**

<https://www.immune.org.nz/sites/default/files/Health%20Proffessionals/ColdChainOrientationGuideCheck%20updated%20May%202020_0.docx>