# Sample Template: Cold Chain Management Policy for Immunisation Services

*This template provides 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. You will need to adjust this template to suit your setting, ensuring that you meet the requirements for safe vaccine storage as required by the Ministry of Health (the Ministry). Contact your local immunisation/cold chain coordinator if you have any questions or need advice about your cold chain management or policy.*

*Information in blue is provided to assist you with inserting information that is specific to your immunisation service/clinic and would usually not form part of the completed document.*

*You should include instruction on how to use, download and review the data logger as an appendix to this policy.*

|  |  |
| --- | --- |
| Name of provider/clinic/department: |  |
| Date: |  |
| Name of our local immunisation coordinator and/or cold chain coordinator: |  |
| Contact number(s): |  |
| Name of our IMAC Regional Advisor: |  |
| Contact number(s): |  |

## Designated staff with overall responsibility for cold chain management

|  |  |
| --- | --- |
| First person (Authorised Vaccinator or GP or Pharmacist Vaccinator): |  |
| Second person: |  |

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

## 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*
* Access to the online versions of the Immunisation Handbook as this version is the most up-to-date information – available on the Ministry’s website at: www.health.govt.nz
* Current *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017*  – available on the Ministry’s website at [www.health.govt.nz/cold](http://www.health.govt.nz/cold)chain
* *Annual Cold Chain Management Record* available on the Ministry’s website at: [www.health.govt.nz/coldchain](http://www.health.govt.nz/coldchain)
* Medsafe vaccine data sheets (available from the Medsafe website at: www.medsafe.govt.nz/Medicines/infoSearch.asp)

These documents are located …………………… Please indicate where they are stored in this policy document. Note: these documents should be located in close proximity to your cold chain folder or on the desktop of the clinical computers and accessible to all vaccinators.

## 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 ……. Our CCA is valid until ……..--

## Vaccine 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 is recommended), and no more than (four weeks is recommended) worth of stock should be held at any given time.

*Refer to the dose requirements tables in the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 to calculate your vaccine stock levels.*

## Our stock requirements

*(Complete the tables below with the information relevant for your area)*

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 pregnant women.

The minimum and maximum vaccine stock levels are:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **DTaP-IPV- HepB/Hib** | **PCV** | **RV** | **Hib** | **MMR** | **Varicella** | **DTaP-IPV** |
| Minimum |  |  |  |  |  |  |  |
| Maximum |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Tdap** | **HPV** | **Td** | **Influenza** |  |  |  |  |
| Minimum |  |  |  |  |  |  |  |  |
| Maximum |  |  |  |  |  |  |  |  |

Also consider and outline your vaccine stock requirements for the following:

* Seasonal variations, special programmes, vaccines for special groups and disease outbreaks when ordering vaccines
* The amount of Tdap and HPV vaccines will depend on the number of children vaccinated in a Year 7 or 8 school-based immunisation programme
* The type and capacity of your pharmaceutical refrigerator
* The impact of the addition of new vaccines or changes in vaccine combinations as part of the National Immunisation Schedule
* Non-funded vaccine requirements, eg, travel vaccines, occupational health vaccines or the influenza vaccine.

## Vaccine ordering and stock keeping

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

All vaccines are logged in the vaccine register (or inwards goods process in the case of a pharmacy), including their arrival date, name, batch number, expiry date and total number in stock. Outline how your vaccine register can be accessed. The vaccine register may be hardcopy or electronic. An example of a vaccine register can be found on the IMAC website at [www.immune.org.nz](http://www.immune.org.nz). Please note that if your vaccine register is electronic, it must be backed up and saved for 10 years.

## Receiving and storing vaccines

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

* Vaccines are checked to ensure they have arrived within the indicated timeframe on the packaging.
* Vaccines are left in their original packaging, as this acts as insulation and protects vaccines sensitive to light.
* Vaccines are unpacked as quickly as is practical on arrival.
* Vaccine stock is rotated so that those with earlier expiry dates are used first.
* Vaccines are placed in the refrigerator in such a way as to allow for air circulation.

Refer to the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* for more information on receiving and storing vaccines.

## 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.

## Cold chain equipment – operation and maintenance

This service uses a pharmaceutical refrigerator to store vaccines (details on page # of your policy doc).

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.

## Refrigerator temperature monitoring

The minimum and maximum vaccine refrigerator temperature is recorded daily from the inbuilt temperature monitor or specify alternative. This device should 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 (first thing in the morning is recommended to pick up any cold chain breaches that may have occurred over night). The current temperature records are kept in (close to the refrigerator is recommended) and archived as with other medical records for at least 10 years (where?). The *Annual Cold Chain Management Record* is used to document the clinics daily readings or specify alternative if one is used.

The data logger is set to record the refrigerator temperature every 5–10 minutes (5 minutes is recommended). 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 specify file.

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)

|  |  |  |
| --- | --- | --- |
| Name | Designation | Date |
|  |  |  |
|  |  |  |
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### 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.

### 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 consider using a secondary back-up device, eg, digital minimum/maximum thermometer, in case the data logger gets damaged
* consideration should be given to having the ability to download the data logger while away from base, if a review function is not available on the logger
* 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 download, 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.

## Maintenance and replacement plan and schedule

This covers all cold chain equipment, including: *(location and model numbers of all refrigerators and data loggers need to be noted, you also need a replacement plan for each piece of equipment dependent on their anticipated lifespan, eg, refrigerators are required to be replaced at least every 10 years)*

| **Equipment** | | | **Location in clinic** | **Maintenance and replacement plan** |
| --- | --- | --- | --- | --- |
| Refrigerator:  Date purchased: |  | |  | Annual service according to manufacturer’s recommendations. Annual check of refrigerator performance and temperature ranges by your local immunisation/cold chain coordinator or refrigerator manufacturer. Refrigerator replacement plan |
| Model: |  | |
| Minimum and maximum montioring device | | | Vaccine refrigerator | This maybe the inbuilt min/max unit in the refrigerator or it may be separate from the refrigerator. It must not be the only device in the refrigerator, as you need a minimum of two temperature monitoring devices for each refrigerator. |
| Electronic temperature monitoring device, eg, data logger: Type  Date purchased: | | | Vaccine refrigerator | This device is set to record the internal refrigerator temperature every 5–10minutes. It is separate from the unit that is used to record the daily minimum and maximum temperature readings.  Calibrate the device as per manufacture’s recommendations, please note that not all loggers require calibration. |
| Chilly bin/s:  The type of chilly bin your require will depend on whether or not you offer offsite vaccination clinics | | 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  Refer to section 7.3 in the *National Standards for Vaccine Storage and Transportation for Immunisation Provider 2017* for the minimum requirements*.* |  | Outline your plan for:  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.  Your plan should include the number of portable storage devices, eg, chilly bins that will be required for transporting your vaccine stocks and temperature monitoring devices with a visible display.  Refer to section 7.3 in the *National Standards for Vaccine Storage and Transportation for Immunisation Provider 2017* for the minimum requirements*.* |
| Ice packs | |  | Ice packs are kept frozen, in which freezer  Document the number of ice packs required, date purchased and replacement date. |
| Insulation material | |  |  |
| Digital thermometer/s or data loggers with visible display (you need to be able to see the current and min/max temps reached, without having to download or open the chilly bin) | |  | Your type of temperature monitoring device will depend on what whether or not you offer offsite vaccination clinics.  Please outline your processes around the following:  How many digital thermometers or data loggers with visible display do you have (one per chilly bin)?  Battery (changed according to manufacturer’s recommendations or removed when not in use).  Calibration and ice pointing undertaken if required or recommended by manufacture. |

## Process for vaccine stored outside +2⁰C to +8⁰C temperature range

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 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. |
|  |
| 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. |

## 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 +8⁰C 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. | *Complete* |
| 1. 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 temperature recording device to – *your alternative refrigeration site* |
| 1. 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. |
| 1. 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 temperature recording device to – *complete* |
| Location for alternative refrigeration – *complete* – | | | |
| Contact details for alternative refrigeration – complete –  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. | | | |

## 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 please complete your local ProPharma or your pharmacy arrangement details here.

## 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. If you use another process for recording staff training then please notes this here.

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.

\*One-off vaccine temperature variations of up to 12˚C for less than 30 minutes that occur for known reasons (eg stock take) do not need to be notified to the immunisation coordinator, however it must be documented in the your records.

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: |  | | 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 (policy date) for this service

|  |  |  |
| --- | --- | --- |
| Name | Designation | Date |
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By signing this, I acknowledge that I have received training and information in relation to clinic name cold chain policy and processes.

HP 6572