MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand Government

National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)

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Definitions and abbreviations

Buffered probe: a temperature monitoring device in which the sensor is placed in a buffering medium (eg, glycol, solid nylon or glass beads) to slow the thermal response rate to more closely match the product being monitored.

Calibration: the comparison of measurement values delivered by a device under test with those of a calibration standard of known accuracy; adjustments are made as necessary. This test is usually carried out by a service accredited by International Accreditation New Zealand.

CCA reviewer: a person or organisation contracted by a DHB to review an immunisation provider's cold chain management practices and processes and confirm its achievement of meeting the National Standards requirements via CCA or CCC (if appropriate). Reviewers should have completed an appropriate assessor's programme (eg, NZ2752 New Zealand Certificate in Assessment Practice) and be locally approved by the Medical Officer of Health. (Note: the CCA reviewer may be an immunisation or cold chain coordinator.) For community pharmacies, the reviewer is a Medicines Control auditor.

CFA: Crown Funding Agreement.

Chilly bin: a generic term for a portable insulated container.

Cold chain: the system of transporting and storing vaccines within the required temperature range of +2°C to +8°C from the place of manufacture to the point of vaccine administration.

Cold Chain Accreditation (CCA): a tool used to ensure immunisation providers' cold chain management practices and processes meet the standard's requirements for safe vaccine storage and transportation.

Cold Chain Compliance (CCC): issued when an immunisation provider achieves all of the standards for CCA but is unable to show the refrigerator's three-month continuous temperature monitoring records.

Cold chain breach: an event that has led to vaccines being stored or transported in temperatures outside the required +2°C to +8°C range, without compromising the potency or stability of the vaccines.

Cold chain excursion: an event that has led to the vaccines being stored or transported in temperatures outside the required +2°C to +8°C range and, as a result, vaccines are compromised and need to be returned for destruction.

Cold chain failure: an event in which vaccines involved in a cold chain excursion are administered to patients.

Continuous monitoring services: also called cloud-based monitoring, web-based monitoring, external monitoring or real-time monitoring. Such services send temperature information from a sensor in a provider's refrigerator to software that can be viewed through a website. They may be in-built or separate, like a datalogger; records must be downloaded/accessed and reviewed weekly.

Datalogger: an electronic device that measures the current refrigerator temperature at preset intervals and records information that can then be downloaded/ accessed and reviewed weekly. Datalogger is used as the generic term for all devices that sample and store/transmit temperatures from within the refrigerator.

Digital thermometer: a digital minimum/maximum thermometer with a visible display used to measure the temperature range vaccines are being stored at and/or during transport.

DHB: district health board.

IMAC: Immunisation Advisory Centre.

Immunisation/Cold chain coordinator: referred to as 'immunisation facilitator' in some areas. This document uses 'coordinator' to refer to any roles that sit under the CFA, including CCA reviewer.

Immunisation provider: any provider storing and/or administering vaccines to individuals in New Zealand. Examples include but are not limited to: general practices, public health units, community pharmacies, corrections facilities, outreach immunisation services, travel clinics, emergency medical services, public and private hospital wards and departments/pharmacies, and occupational health services.

Medicines Control: a regulatory team within Medsafe at the Ministry of Health. Medicines Control regulates licence holders within the pharmaceutical supply chain in New Zealand, including community pharmacies and pharmaceutical wholesalers. Medicines Control regulates cold chain management in community pharmacies as part of the pharmacy licensing framework it administers.

National Cold Chain Audit (NCCA): an audit that monitors National Immunisation Schedule vaccines through the cold chain, from the regional distribution stores to immunisation providers over a set period of time.

National Immunisation Programme: aims to prevent diseases through vaccination and achieve immunisation coverage that prevents outbreaks and epidemics. The Programme provides national oversight of immunisation services, providers and agencies. It is managed by the Ministry of Health.

National Immunisation Schedule: the series of vaccines funded by PHARMAC for babies, children, adolescents and adults.

National Vaccine Store: manages the National Immunisation Schedule vaccine supply on behalf of PHARMAC. The National Vaccine Store is responsible for all vaccines from when they arrive at the store until they are distributed to the regional distribution stores or directly to immunisation providers.

Offsite clinic: any site at which multiple vaccines are required to be stored and dispensed from a chilly bin.

PHARMAC: Pharmaceutical Management Agency Ltd.

Pharmaceutical refrigerator: a refrigerator designed and constructed for the specific purpose of storing pharmaceuticals and vaccines between +2°C and +8°C, and has a built-in alarm set to activate if temperatures go outside this range. In this document, 'refrigerator' refers to a pharmaceutical refrigerator unless otherwise noted.

PHO: primary health organisation.

Refrigerator technician: A person employed and trained to install, service and repair refrigeration systems.

RIA: IMAC regional immunisation advisor.

Regional distribution store: stores and distributes vaccines at a regional level.

Validation: the act of checking or proving the validity or accuracy of temperature monitoring equipment, to confirm that a sensor is recording accurately. To do this the device needs to be checked alongside a known accurate device (calibrated) of the same medium (air or buffer).

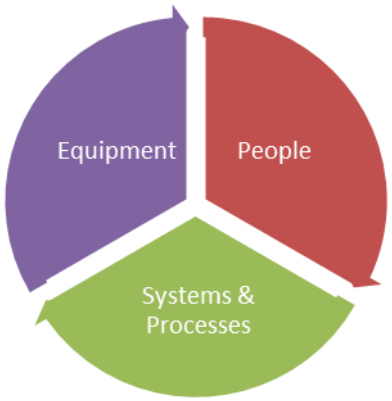
Introduction

This document defines the National Standards for Vaccine Storage and Transportation for all immunisation providers in New Zealand and outlines the requirements for providers to achieve the standards. The standards were reviewed and updated in 2019.

Cold chain is the process used to maintain required temperatures for vaccines. All vaccines must be stored within the +2°C to +8°C temperature range at all times during storage or transport, from the point of manufacture through to the point they are administered to an individual.

These standards may also be used to support cold chain management for the storage of other refrigerated medicines.

The integrity of the cold chain depends on three essential elements, which underpin the standards:



1. the **people** managing vaccine manufacture, storage and distribution and those managing the cold chain at the provider level
2. the **systems and processes** providers use to ensure they monitor the vaccine storage conditions and actions taken if the vaccines are exposed to temperatures outside the required range
3. the **equipment** used for storing, transporting and monitoring vaccines from the time the vaccine is delivered to an immunisation provider to the time the vaccine is administered to an individual.

All immunisation providers are required to achieve cold chain accreditation (CCA) or cold chain compliance (CCC) to confirm their ability to meet the required standards. Immunisation or cold chain coordinators assess immunisation providers' achievement of CCA or CCC. Previously, they also assessed community pharmacy compliance; this now occurs through the auditing activities of Medicines Control, the team within Medsafe that issues pharmacy licences. Immunisation or cold chain coordinators still provide community pharmacies with advice and support concerning the cold chain, and follow-up of cold chain breaches or excursions. They should report any concerns about a community pharmacy's cold chain management that poses a patient safety risk to Medicines Control.

The review of these standards has been informed by the earlier versions of the National Standards, the National Review of Cold Chain Management Practices commissioned by the Ministry in 2014/15; current evidence-based practice, including international policies; and feedback received from the immunisation sector. For more information, see the National Review of Cold Chain Practices Summary on the Ministry's website (**www.health.govt.nz/coldchain**).

1 National Standards for Vaccine Storage and Transportation for Immunisation Providers

Aim: To improve the health of all New Zealanders by protecting them from vaccine preventable diseases through an effective immunisation programme.

Objective: To ensure immunisation providers in New Zealand safely store and transport vaccines, using the 10 standards below to ensure all vaccines administrated are safe and effective.

1. All immunisation providers must hold cold chain accreditation or cold chain compliance before offering immunisation services.

2. All clinical staff must ensure continuity of the cold chain. They must also:
   - be competent in all aspects of vaccine storage and transportation to ensure that vaccines are kept within the required +2°C to +8°C temperature range at all times
   - take appropriate action when the cold chain is not maintained
   - take responsibility for ensuring that the vaccines they administer have been correctly stored
   - have read and understood, and comply with, the provider's cold chain policy.

   See **section 5** for more information.

3. All immunisation providers must have a cold chain policy containing the required information outlined in **section 6.1**. The Ministry of Health has provided a cold chain policy template that providers can adapt and use for their facility (see **www.health.govt.nz/coldchain**).

4. All immunisation providers must have a stock management process that ensures they are not over- or under-stocked.

   See **section 6.2** for more information.

5. All immunisation providers must use one or more pharmaceutical refrigerators for vaccine storage that:
   - stores only medicines and vaccines
   - is appropriately maintained and serviced
   - contains only vaccines and medicines stored in their original packaging and properly spaced within the pharmaceutical refrigerator.

   See **section 7.1** for more information.

6. All immunisation providers must have two systems for monitoring the temperature that vaccines are being stored at:
   - a daily check device that records the minimum and maximum temperatures reached – for example, an inbuilt refrigerator monitor or digital minimum/maximum thermometer
   - a weekly check device that records the temperature at least every 10 minutes – for example, a datalogger. Every week the provider must then download/ access and review this information against other temperature recordings taken, take appropriate action and store the week's information.

   See **section 7.2** for more information.

7. All providers must have a cold chain process and equipment for ensuring safe temporary storage of vaccines if a power outage occurs or a refrigerator fails.

   See **section 6.3**, **section 7.3** and **Appendix 2** for more information.

8. All equipment used for storing, transporting and monitoring vaccines must be fit for the purpose, and appropriately maintained and tested. As part of this maintenance and testing, providers must:
   - arrange for annual servicing of pharmaceutical refrigerators
   - trial and test the capacity of their portable storage equipment
   - ensure that spatial logging of pharmaceutical refrigerators occurs at least every three years.

   See **section 7.1** and **Appendices 2**, **3** and **4** for more information.

9. All documentation associated with vaccine temperature monitoring must be kept for at least 10 years. This includes:
   - daily minimum and maximum temperature recordings
   - weekly datalogger downloads or records
   - temperature recordings from vaccines transported and stored in chilly bins
   - actions taken when a cold chain breach, excursion or failure occurs.

10. All immunisation providers who offer offsite immunisation clinics – for example, occupational health, school-based immunisation programmes and outreach immunisation services – must have appropriate, tested equipment for this purpose.

    Note: this situation is different from that involving temporary storage or transport following a power outage or refrigerator failure.

    See **section 7.3** and **Appendix 2** for further information.

For details on how providers can meet these 10 standards, see sections 2–7. If an immunisation provider fails to comply with the standards, it should refer to its district health board (DHB)'s Cold Chain Provider Non-Compliance Policy. Thereafter, the relevant DHB, primary health organisation (PHO) or medical officer of health; Medicines Control; or the Ministry will review the provider's access to vaccines. Vaccine supply may be suspended until the provider is able to meet the standards.

2 Background

2.1 Vaccine arrival and distribution

All vaccines used in New Zealand are manufactured overseas and shipped by air or sea in such a way that they remain at their required temperature for the entire journey. The National Immunisation Schedule vaccines are delivered to the National Vaccine Store, where temperature monitoring continues to ensure that the vaccines remain within the required +2°C to +8°C range.

Vaccines are distributed from the National Vaccine Store to the regional distribution stores in Whangarei, Auckland, Hamilton, Wellington, Christchurch and Dunedin, and from there to local immunisation providers. In some instances, the National Vaccine Store distributes vaccines (eg, influenza vaccines) directly to immunisation providers.

The National Vaccine Store and regional distribution stores have standard operating procedures to ensure the vaccine cold chain is maintained at all times during storage at their sites and during vaccine transportation to providers. Medicines Control audits licensed premises involved in the cold chain of medicines in New Zealand (including wholesalers and pharmacies).

Both the National Vaccine Store and regional distribution stores audit the maintenance of the cold chain during the delivery process by inserting dataloggers in some vaccine deliveries. Information is provided for immunisation providers when a datalogger has been included in a delivery. Any other wholesalers transporting vaccines are also expected to audit their cold chain processes including during delivery.

2.2 Vaccines are temperature sensitive

Vaccines can become less effective or be destroyed if they are:

- stored outside the +2°C to +8°C range
- exposed to sun or fluorescent light.

Temperatures above 8°C have a cumulative effect on the potency and stability of vaccines, and a temperature at or below 0°C will cause irreparable damage to some vaccines. In the event of either type of breach, it is important to advise the coordinator of the breach as soon as it is identified. All affected stock must be quarantined and the vaccines labelled as not for use until a decision on whether to use them has been made.

Coordinators have access to thermostability data for vaccines on the National Immunisation Schedule. However, when temperature exposures are significant or occur over an extended period, the coordinator will need to obtain further information from the vaccine manufacturer. See section 6.4 for the process for managing vaccines stored outside the required +2°C to +8°C range.

The impact of thermal damage (temperatures outside +2°C to +8°C) on vaccine potency is complex, and our knowledge of it is based on limited human data. The impact varies for each vaccine. Once a vaccine has been thermally compromised, its loss of potency cannot be reversed.

2.3 Cold chain excursion costs

PHARMAC procures vaccines on the National Immunisation Schedule on behalf of DHBs. Vaccines can cost up to $170 a dose. Even a small immunisation provider stores thousands of dollars' worth of vaccines at one time.

Tables 1 and 2 give examples of cold chain excursion costs based on past cold chain excursions. The 'total costs' row in each table indicates what the vaccines' total cost is to DHBs.

Table 1: Example of vaccine costs at a medium-sized general practice

Vaccine	No. of doses in stock
ADT	6
Tdap	5
23PPV	4
MMR	20
RV1	25
Infarix-Hexa	26
PCV10	24
Infarix-IPV	34
Varicella	23
Zostervax	16
HPV9	5
HepB 20 mcg	6
HepB 5 mcg	2
Total costs	**$6,200**

Key: D = diphtheria, T = tetanus, aP = acellular pertussis, IPV = inactivated polio vaccine, Hib = *Haemophilus influenzae* type b, HepB = hepatitis B, RV = rotavirus vaccine, PCV = pneumococcal conjugate vaccine, MMR = measles, mumps and rubella, d = adult type diphtheria, ap = adult type pertussis, HPV = human papillomavirus vaccine, ADT = adult type tetanus-diphtheria vaccine.

Table 2: Example of vaccine costs at a youth clinic

Vaccine	No. of doses in stock
Tdap	8
ADT	8
HPV	9
HepB 10 mcg	8
MMR	9
Total costs	**$1,650**

Key: D = diphtheria, T = tetanus, aP = acellular pertussis, IPV = inactivated polio vaccine, Hib = *Haemophilus influenzae* type b, HepB = hepatitis B, RV = rotavirus vaccine, PCV = pneumococcal conjugate vaccine, MMR = measles, mumps and rubella, d = adult type diphtheria, ap = adult type pertussis, HPV = human papillomavirus vaccine, ADT = adult type tetanus-diphtheria vaccine.

Note: The costs above were calculated in 2019.

The costs outlined in the tables above are only one part of the costs associated with a cold chain failure when compromised vaccines have been administered to patients. When these vaccines need to be re-administered, the same unit cost is again incurred. There is also the cost of staff time to contact and explain the events to patients, and the cost of time, equipment and possibly extra staff to re-vaccinate patients. Additionally, intangible costs may arise, such as loss of public confidence in the New Zealand Immunisation Programme and in the immunisation provider.

3 Cold Chain Accreditation

Cold chain management of an immunisation provider is assessed through the use of the audit tool Cold Chain Accreditation (CCA). In order to achieve CCA, an immunisation provider is required to demonstrate it has appropriate cold chain management practices and processes in place to meet the standards' requirements. The provider must be able to demonstrate it meets the requirements to hold CCA prior to offering immunisation services and at any point while offering an immunisation programme.

All immunisation providers who store vaccines continuously must have current CCA. This includes but is not limited to general practices, outreach immunisation services, public health units, community pharmacies, corrections facilities, travel clinics, emergency medical services, public and private hospital wards and departments/ pharmacies, and occupational health services. In a secondary care services setting, the National Standards apply to all departments storing vaccines, and can also be used to support cold chain management for the storage of medicines. For general practices it is important to note that CCA is required to meet the Royal New Zealand College of General Practitioners Cornerstone® Standard (section 2, indicator 16) and the Foundation Standard.

All community pharmacies are deemed to hold CCA through their Licence to Operate Pharmacy, unless there are specific operating conditions preventing the pharmacy from offering this service (or refrigerated products in general).

In assessing CCA, a CCA reviewer will assess the provider's past performance and current cold chain knowledge. These findings help to determine the length of time CCA is awarded for; other considerations are the stability of the provider's workforce, the age of the equipment and the provider's cold chain history. CCA can be awarded for up to three years. Community pharmacies must apply for a Licence to Operate Pharmacy annually, and if they continue to provide immunisation services must ensure they continue to meet the requirements of the standards at all times.

CCA assessment is based on the following five components:

1. the provider has copies of or online access to appropriate vaccine reference information
2. the provider has an appropriate and documented cold chain policy
3. the provider carries out appropriate vaccine stock management
4. the provider understands requirements for temperature monitoring and refrigerator performance, and monitoring devices and processes are appropriate
5. storage and transport equipment meets the requirements of the National Standards.

Immunisation providers must meet **all** the National Standards for cold chain management and **all** staff must be responsible for the cold chain.

If a provider fails to meet the requirements, or is found to be noncompliant, of the National Standards, the CCA reviewer will work with the provider to develop a remedial plan to achieve the requirements. The provider may administer vaccines while the remedial plan is in place, if the required temperature range of +2°C to +8°C can be maintained at all times and the provider works within the agreed timeframes outlined in the plan. The maximum recommended timeframe for completing the remedial plan is three months.

If a provider is not willing to work on a remedial plan or does not keep to the agreed timeframes, the CCA reviewer will notify the PHO, DHB and medical officer of health, as appropriate. Medicines Control will manage the remedial process for community pharmacies. Where pharmacies are unable to demonstrate compliance with the National Standards, this may result in actions such as a condition being placed on a pharmacy's licence, which, for example, may prohibit the pharmacy from providing vaccination services.

Each DHB should work with the CCA reviewer and/or coordinator, PHO, medical officer of health, the Immunisation Advisory Centre (IMAC) and other immunisation stakeholders to develop a process for working through issues where providers are not achieving or maintaining CCA. This process may include steps such as:

- developing a provider remedial plan and timeframes
- undertaking a CCA reassessment
- following up appropriately if the provider does not complete requirements of the National Standards
- discussing issues with the IMAC regional immunisation advisor, medical officer of health and PHO clinical lead
- formally notifying and making recommendations to the provider
- revoking the existing CCA
- placing vaccine deliveries to the provider on hold.

All DHBs must have a Cold Chain Non-Compliance Policy; which documents the local process for addressing provider cold chain non-compliance. Each DHB must review this process annually and make the documentation available to the Ministry on request.

The Ministry publishes a *CCA Provider Self-Assessment Form* and a *CCA Immunisation Provider Review Form*. To access these, go to the Ministry of Health's cold chain webpage (**www.health.govt.nz/coldchain**).

4 Cold Chain Compliance

The existence of the category called 'Cold Chain Compliance' (CCC) acknowledges that a number of immunisation providers offer only short-term services for influenza vaccine.

CCC is issued only when an immunisation provider meets all of the requirements for CCA but are unable to show the three-month continuous temperature monitoring records, and when a new immunisation provider is setting up. It may also be applied in hospital settings for areas stocking influenza vaccine only.

CCC is issued through the same process as CCA: that is, the provider conducts a self-assessment, and then the CCA reviewer undertakes a review of the immunisation provider's cold chain management. A local certificate or letter is issued for CCC; this is valid for up to nine months. The expectation is that the CCC process will be undertaken before the provider begins its immunisation programme each year; where this is not feasible, the provider must complete the CCA self-assessment to confirm they meet the standards requirements and return this to the CCA reviewer for review prior to recommencing/ continuing the immunisation service.

If a provider offered an immunisation service in the previous year, it must produce its temperature recordings (daily recordings and datalogger downloads/records) for that year for the CCC review. All recordings from the previous year should be available, and the reviewer should be able to randomly select dates to view off-site clinic data and on-site refrigerator recordings (note: where the company is the same but the vaccinator contract to provide the services is not, this may not be possible).

CCC is not relevant to community pharmacies providing immunisation services, as their compliance with the National Standards is audited as part of Medicines Control's regulatory activities.

5 People

People play a key role in ensuring that vaccines are kept within the required +2°C to +8°C temperature range when they are stored and transported. All vaccinators are responsible for ensuring the vaccines they administer have been stored correctly.

All clinical staff need a high level of knowledge about cold chain principles and equipment. However, each provider must nominate at least two people to hold overall responsibility for vaccine storage and temperature monitoring.

All clinical staff must have read and understood, and must comply with, their provider's cold chain policy.

All relevant clinical staff must review cold chain records prior to accessing any vaccine, to ensure vaccine thermostability.

All relevant clinical staff are expected to take appropriate action if the cold chain is not maintained.

5.1 Requirements for all immunisation providers

All immunisation providers must:

- ensure that the minimum and maximum refrigerator temperatures are checked and recorded daily on a temperature recording chart and that the minimum/maximum thermometer is reset at this time
- check the temperature recording chart for variations in temperature before using vaccines
- store the minimum/maximum temperature recording chart by the refrigerator so that all vaccinators can check the recordings before taking the vaccines out of the refrigerators
- keep the temperature records for 10 years, consistently with the Health (Retention of Health Information) Regulations 1996
- ensure that all relevant clinical staff know how to download/access, save and file the datalogger recordings; can review the data and compare it with the minimum/maximum thermometer readings every week
- immediately act on temperature readings outside the required +2°C to +8°C range by following the process outlined in their cold chain policy; see **section 6.4** for more information
- document actions taken and reasons why temperature readings were outside the required +2°C to +8°C range.

5.2 Designated cold chain management leads

The provider's designated cold chain management leads (a minimum of two people) should be authorised vaccinators, general practitioners or pharmacist vaccinators. Where this is not possible, the provider should discuss the issue with the CCA reviewer and appoint the most appropriate people.

The designated cold chain staff are responsible for:

- ensuring the daily and weekly temperature monitoring checks are undertaken and documented, including ensuring the datalogger is rotated within the refrigerator
- reviewing records at the end of each month to check for seasonal fluctuations and trends
- ensuring that any cold chain breaches, excursions or failures have been followed up
- ensuring 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
- following up privately purchased vaccine thermostability following a cold chain breach (this should be discussed with the coordinator)
- ensuring all relevant clinical staff know how to download/access and review the datalogger information and know the actions to take if the recordings are outside the required range
- changing, when required, the refrigerator set point, only on advice from the pharmaceutical refrigerator technician, manufacturer or coordinator (this must be documented)
- ensuring the refrigerator performance and daily temperature monitoring equipment are checked for accuracy on an annual basis as part of the refrigerator service
- ensuring spatial logging of the provider's refrigerator occurs every three years by the coordinator.

5.3 Immunisation/cold chain coordinators

Immunisation coordination services are defined through the Crown Funding Agreement (CFA) Immunisation Coordination Services service specification between the Minister of Health and DHBs. This service specification outlines the DHB's role in ensuring that all those involved in immunisation provision offer a high-quality and safe vaccination experience. DHBs either directly contract/employ immunisation/cold chain coordinators or contract another organisation (eg, a PHO) to do so. Coordinators provide cold chain education, advice and support, and review cold chain management practices for all immunisation providers, under the CFA. This document uses 'coordinator' to refer to any roles that sit under the CFA, including CCA reviewer.

Coordinators need to be familiar with the standards – and, in particular, the principles behind the standards – so they are able to advise in situations that the standards do not specifically cover.

The standards identify certain roles and requirements for coordinators. In summary, coordinators:

- support providers to implement the standards, and ensure they have appropriate information
- assess providers' compliance with the standards (other than community pharmacies) using CCA/CCC
- spatially log all immunisation providers' refrigerators at least every three years (including community pharmacies), or at the time of CCA/CCC assessment
- provide advice to all immunisation providers in the event of an equipment or power failure
- respond and provide advice to all immunisation providers in the event of a cold chain breach, excursion or failure, including by providing thermostability advice on funded vaccines and by supporting providers to seek advice for privately purchased vaccines
- report all cold chain excursions to the IMAC Regional Immunisation Advisor (RIA) within one week, in addition to local PHO or DHB incident reporting processes
- report all suspected or confirmed cold chain failures to the RIA within one working day, in addition to local PHO or DHB incident reporting processes
- discuss issues of concern with appropriate contacts (eg, DHB, PHO, RIA, Ministry of Health)
- follow the Ministry's process in the event of a possible or confirmed cold chain failure (**section 6.4**).

6 Systems and processes

The systems and processes that immunisation providers use ensure the continuity of the cold chain and provide helpful information for all staff in the facility on the appropriate actions to take if a cold chain breach occurs in order to prevent a cold chain failure (that is, to prevent compromised vaccines from being administered to patients). These systems and processes may also support cold chain management for the storage of other refrigerated medicines.

All immunisation providers must have a cold chain policy that contains the required information outlined in the cold chain policy template (**www.health.govt.nz/coldchain**).

6.1 Provider cold chain 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
- reviewed when the designated cold chain staff, vaccine equipment or processes change, a copy of the this should be supplied to the 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 distributor's temperature monitoring device with their vaccine order (eg, influenza or non-funded vaccines)
- the plan and schedule for cold chain equipment maintenance (including refrigerator annual service according to the manufacturer's recommendations and cleaning schedule)
- processes for monitoring the refrigerator's temperature, including instructions on datalogger use
- details of equipment to use for offsite vaccination clinics, including chilly bins, insulation material and temperature monitoring equipment
- processes for temperature monitoring while vaccines are being stored in chilly bins for offsite immunisation clinics
- action to be taken when the temperature recordings of the refrigerator or chilly bins are outside the + 2°C to + 8°C range

- emergency plans and equipment to use if a refrigerator fails and/or a power outage occurs, including a nominated back-up provider (if practical, one that would not be affected by a local power outage, such as a power line being down). If a provider is in an area regularly affected by power outages, it should consider using uninterruptable power supply devices (eg, generators)
- processes for vaccine disposal
- the date when the next annual cold chain policy review is due
- a cold chain orientation plan for new staff, including how to download/access and read the datalogger, what to do and who to contact if there is a cold chain issue, and how to pack a chilly bin and move vaccines to an alternative provider
- a cold chain equipment replacement plan. All pharmaceutical refrigerators have a limited life span, usually around 10 years – immunisation providers must actively plan for replacement, and replace their refrigerator at or before 10 years of age rather than wait until the refrigerator fails to maintain temperature
- action to be taken when the provider receives a National Cold Chain Audit monitor (this only applies to providers who hold National Immunisation Schedule vaccine stock).

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

6.2 Key requirements for immunisation providers for vaccine stock management

Stock management principles

All immunisation providers should know how much vaccine stock they require at any one time, according to the size of their clinics, the population they are vaccinating and the size of the refrigerator.

Where a provider works with a defined population, it should base its vaccine stock requirements on the known population base, using a similar method to that of general practice.

Overstocking can lead to increased wastage in the event of cold chain breaches, vaccines reaching their expiry dates and insufficient airflow in the refrigerator.

If a provider finds that it is regularly returning expired vaccines, it should review its stock numbers and ordering process and adjust accordingly.

The coordinator can help with working out minimum and maximum stock levels.

General practice

General practices should keep a minimum of two weeks' supply but no more than four weeks supply of vaccines. Tables 3 and 4 can help to calculate appropriate levels.

Many vaccines are dispatched in boxes with multiple doses. Table 4 takes this into account.

When ordering Tdap for the 11-year immunisation, providers should also consider the number of vaccines they require for their population of pregnant women.

School-based immunisation programmes

School-based immunisation programmes should order vaccines taking into account school roll, consent form return and absenteeism.

Immunisation providers with non-defined populations, such as pharmacies and drop-in clinics

These providers should base their vaccine order volumes on minimum order numbers, previous numbers administered and space available in the refrigerator.

General practice dose requirements

General practices can use the calculation tables below to help them estimate the volumes of National Immunisation Schedule vaccines (excluding influenza) they need for their practice population. These calculations are based on:

- the number of people enrolled in the practice at a particular time, who are aged under five years, 11 years or 12 years (depending on whether a school-based immunisation programme is delivered in the region) and 45 years and 65 years, assuming 100 percent coverage for all scheduled vaccines
- the number of times each vaccine is used on the schedule.

Table 3: Two weeks' vaccine supply (number of doses), per population served by the general practice

<5-year-old population	**50**	**100**	**250**	**500**	**1,000**	**1,250**
DTaP-IPV-Hib/HepB	2	3	6	12	24	29
RV1	1	2	4	8	16	20
PCV	2	4	8	16	31	39
DTaP-IPV	1	1	2	4	8	10
Hib and varicella[1]	1	1	2	4	8	10
MMR	1	2	4	8	16	20
Single-year age group (eg, 11-year-olds)	**10**	**20**	**50**	**100**	**200**	**250**
Tdap[2, 3]	1	1	2	4	8	10
HPV[2,4] (2 doses)	1	2	4	8	16	20
45- and 65-year-old population (combined)	**20**	**40**	**100**	**200**	**400**	**500**
ADT[5]	2	2	4	8	16	20
VZV (65-year-old population only)[6]	1	1	2	4	8	10

Key: D = diphtheria, T = tetanus, aP = acellular pertussis, IPV = inactivated polio vaccine, Hib = *Haemophilus influenzae* type b, HepB = hepatitis B, RV = rotavirus vaccine, PCV = pneumococcal conjugate vaccine, MMR = measles, mumps and rubella, d = adult type diphtheria, ap = adult type pertussis, HPV = human papillomavirus vaccine, ADT = adult type tetanus-diphtheria vaccine.

Notes

1 The calculation for varicella is for the 15-month event only; providers need to consider the number of vaccines doses required for eligible 11-year-olds.

2 Tdap and HPV numbers will depend on the number of children vaccinated in a school-based programme.

3 When ordering Tdap, providers should consider the number of vaccines the practice requires for pregnant women.

4 When ordering HPV, providers should consider the number of vaccines the practice requires for 14-year-old catch-ups.

5 The volume of ADT stock required will depend on how many people aged 45 and 65 years are enrolled at the practice and the number of patients seen for acute wound management. The numbers in the table apply to a combined population number for people aged 45 and 65 years of age.

6 The volume of VZV stock is based on vaccinating only a population of people turning 65 years; providers need to consider how many vaccines they require for those eligible for catch-up.

Table 4: Four weeks' vaccine supply (number of doses), per population served by the general practice

<5-year-old population	**50**	**100**	**250**	**500**	**1,000**	**1,250**
DTaP-IPV-Hib/HepB	12	13	16	32	54	59
RV1	11	12	14	18	36	40
PCV	12	14	18	36	71	79
DTaP-IPV and Varicella[1]	11	11	12	14	18	20
Hib	2	2	4	8	16	20
MMR	11	12	14	18	36	40
Single year age group eg, 11-year-olds	**10**	**20**	**50**	**100**	**200**	**250**
Tdap[2, 3]	11	11	12	14	18	20
HPV[2,4] (2 doses)	12	13	16	32	54	59
45- and 65-year-old population (combined)	**20**	**40**	**100**	**200**	**400**	**500**
ADT[5]	12	12	14	18	36	40
VZV (65-year-old population only)[6]	11	12	14	18	36	40

Key: D = diphtheria, T = tetanus, aP = acellular pertussis, IPV = inactivated polio vaccine, Hib = *Haemophilus influenzae* type b, HepB = hepatitis B, RV = rotavirus vaccine, PCV = pneumococcal conjugate vaccine, MMR = measles, mumps and rubella, d = adult type diphtheria, ap = adult type pertussis, HPV = human papillomavirus vaccine, ADT = adult type tetanus-diphtheria vaccine.

Notes

1 The calculation for varicella is for the 15-month event only; providers need to consider the number of vaccines doses required for eligible 11-year-olds.

2 Tdap and HPV numbers will depend on the number of children vaccinated in a school-based programme.

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4 When ordering HPV, providers should consider the number of vaccines the practice requires for 14-year-old catch-ups.

5 The volume of ADT stock required will depend on how many people aged 45 and 65 years are enrolled at the practice and the number of patients seen for acute wound management. The numbers in the table apply to a combined population number for people aged 45 and 65 years of age.

6 The volume of VZV stock is based on vaccinating only a population of people turning 65 years; providers need to consider how many vaccines they require for those eligible for catch-up.

Influenza vaccine volume requirement

The number of influenza vaccine doses an immunisation provider requires depends on its service and/or enrolled population, and whether it provides:

- funded influenza vaccine to pregnant women, those aged under 65 years with certain medical conditions and those aged 65 years and over
- privately purchased influenza vaccines, or
- an occupational health vaccination service.

Providers should consider the size of their pharmaceutical refrigerators when ordering influenza vaccines, because overstocking a refrigerator places **all** the vaccines in the refrigerator at risk from a cold chain excursion.

Ordering vaccines

Immunisation providers are entitled to two free deliveries each month for National Immunisation Schedule vaccines.

For online schedule vaccine order forms, go to the regional distribution stores' National Immunisation Schedule Funded Vaccines website (**www.fundedvaccines.co.nz/vaccines**). Ordering vaccines online provides an audit trail, is less susceptible to errors and is faster than faxing.

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**). Ordering vaccines online provides an audit trail, is less susceptible to errors and is faster than faxing. For more information about ordering influenza vaccine, see **www.influenza.org.nz**.

Receiving vaccines

When a vaccine delivery arrives at an immunisation provider's premises, a designated staff member should:

- check the vaccines have arrived within the designated timeframe (check the packing label for time dispatched and timeframe)
- check whether any vaccines have monitoring devices included (eg, a distributor datalogger) and follow any instructions provided on using/returning those devices
- 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). See the end of this section for more information on what to do in this situation
- check the vaccines delivered are those the provider ordered
- check all vaccines are at least one month before their expiry date
- 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 but remove them from the transport container.

If a provider has concerns about the condition of the delivered vaccines (eg, there is evidence of exposure to high temperatures such as melted ice packs and the vaccines are warm to touch, or the vaccines are extremely cold), they should:

- 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 the coordinator
- not return vaccines until they have authorisation to do so from the distributor
- advise coordinators of all returned vaccines.

If providers are unsure of how to read a monitoring device transported with a vaccine order they should contact the appropriate distributor or their coordinator for more information. They must keep the vaccines in quarantine within the cold chain while this occurs.

Placing vaccines in a pharmaceutical refrigerator

Place vaccines (and other refrigerated pharmaceuticals) in the pharmaceutical refrigerator:

- without any packing material except their original box
- with a 2–3 cm gap between vaccine boxes and the refrigerator walls or plates
- with the delivery date written on the box or a documented system for identifying when vaccines were delivered
- with the expiry dates visible (where possible), to ensure vaccines with the shortest expiry date are used first.

In addition:

- if the vaccines are put into plastic containers, these containers must have holes in the side and bottom to allow air to flow
- other refrigerated pharmaceuticals may be packaged in such a way that the packaging will not interfere with airflow in the refrigerator. A large interior space may be required to ensure adequate airflow; this should be discussed with the refrigerator technician
- the refrigerated vaccines must not exceed 90 percent of available refrigerator storage space.

No food, drink or laboratory specimens should be stored in the pharmaceutical refrigerator.

6.3 During a power outage or equipment failure

Pharmaceutical refrigerators do not hold their temperatures when the power supply is interrupted, so it is important to monitor the temperature and to respond to rising temperatures. The following practices are recommended when a power outage occurs or equipment fails.

- Use an external digital minimum/maximum thermometer or datalogger with external display to monitor the internal refrigerator temperature (this should be checked and documented every 30 minutes).
- If the internal refrigerator temperature rises above +7.5°C, seek alternative storage, following the provider's cold chain policy.
- If the internal temperature of the refrigerator falls below +2°C, remove the vaccines and place them in alternative storage, following the provider's cold chain policy.
- If the power outage is widespread, such as across the region or city, contact the coordinator before moving vaccines; there needs to be a priority system for back-up vaccine storage.

6.4 Process for vaccines stored outside +2°C to +8°C

When a provider finds vaccines have been stored in temperatures outside the required +2°C to +8°C range, it must collect information on the temperature breach and discuss the issue with the coordinator to confirm vaccine stability before using the vaccines or returning them for destruction. The steps below outline the initial process a provider should follow.

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

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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 the providers 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/access information from the datalogger 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)?
- How long were the vaccines stored outside of 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.
- Check whether it is likely that any individuals received a compromised vaccine.

⇩

Contact the coordinator, provide them with all of the available information and work with them through to resolution. Complete all required documentation.

Note

* When one-off temperature variations of up to 12°C for less than 30 minutes occur for known reasons (eg, stocktake), a provider does not need to notify the coordinator; however, it must document the variations in its records. This does not apply to buffered probes.

If staff do not follow up cold chain breaches and the provider does not contact the coordinator, CCA or CCC may be withheld or revoked and vaccine delivery suspended. If a provider fails to take actions following a cold chain excursion and this failure leads to a cold chain failure (ie, vaccines in a cold chain excursion are administered to patients), then the coordinator, along with the provider, is required to inform the IMAC regional immunisation advisor, PHO clinical lead, DHB lead and the local medical officer of health (as appropriate). The coordinator must notify the Ministry of Health immunisation team by email, on **immunisation@health.govt.nz,** when a cold chain failure has occurred.

Failure to follow up and document temperatures that are outside the required range may result in clinical staff (and, in the case of community pharmacy, the pharmacy premises) being referred for competence review by their regulatory body (in the case of community pharmacy, to Medicines Control), particularly where a cold chain failure could have been prevented if appropriate action had been taken.

6.5 Vaccine disposal

Providers must return all unwanted, discontinued, expired or thermally compromised vaccines to their regional distribution store for secure destruction, including private market vaccines.

Regional distribution stores use a medical waste facility in which vaccines are heat sterilised to make them inactive, and then crushed and buried in a sterile landfill, consistent with requirements under the Resource Management Act 1991.

Providers must contact their immunisation coordinator before disposing of any vaccines, and for help in managing events that result in vaccine wastage, except in cases where vaccines have expired or been discontinued.

To prepare the vaccines for return to the regional distribution store, providers should:

- clearly label them and attach the regional distribution store's 'Vaccines for Destruction' sticker (which providers can download from the regional distribution stores' website: **www.fundedvaccines.co.nz/vaccines**)
- pack them using the standard health and safety precautions that apply to medical sharps waste (eg, using an approved sharps container, or the insulated container in which the vaccines were delivered, and removing all needles other than those attached to unused prefilled syringes; the latter should remain sheathed)
- mark them with the reason the provider is sending them for destruction; for example, due to a cold chain excursion or because they have expired
- record the vaccines as returned for destruction in the provider's vaccine register.

7 Equipment

All equipment used for storing, transporting and monitoring vaccines must be fit for the purpose, appropriately maintained and tested according to the manufacturer's recommendations and the requirements outlined in the National Standards.

All immunisation providers must have a pharmaceutical refrigerator for vaccine storage at each site where they store vaccines. They must replace it every 10 years.

All immunisation providers must have appropriate equipment for transporting and storing vaccines if a power outage occurs or equipment fails. For more information refer to **section 6.4**.

All immunisation providers who offer offsite immunisation clinics – for example, occupational health, school-based immunisation programmes and outreach immunisation services – must have appropriate, tested equipment for this purpose. For more information refer to **section 7.3**.

7.1 Pharmaceutical refrigerator

All immunisation providers must use a pharmaceutical refrigerator to store vaccines.

The refrigerator must:

- be used to store medicines and vaccines only, consistent with the Medicines Act 1981, section 47
- be left on at all times (unless empty of stock; in this case, before storing vaccines again, a provider must monitor the temperature for a minimum of 24 hours with a datalogger)
- be plugged into an independent power point
- have a plug protected through a power point protector and/or a large, bright notice that tells people not to unplug the refrigerator
- not be in direct sunlight or against a heat source
- be in a ventilated room and operated in ambient temperature conditions according to the manufacturer's recommendations
- be installed at least 4 cm but preferably 10 cm away (or according to the manufacturer's requirements) from surrounding surfaces, to allow air to circulate around the condenser
- be levelled in a way that allows the door to close automatically if left ajar
- have door seals in good condition to allow the door to close easily and securely

- have grille-type shelves to allow the air to circulate
- be serviced annually (including validation of refrigerator temperature monitoring equipment) by an approved/licensed refrigerator technician and documented.

Note: External surge protectors should be in place for all pharmaceutical refrigerators. In addition, providers (particularly community-based providers) should put a notice at the meter box advising staff not to turn off the power before consulting the person responsible for vaccine management.

All pharmaceutical refrigerators have a limited life span: usually around 10 years. Immunisation providers must actively plan for their replacement, and replace their refrigerator at or before 10 years rather than wait until the refrigerator fails to maintain temperature. See **Appendix 1** for more information about pharmaceutical refrigerators.

7.2 Monitoring the temperature of the pharmaceutical refrigerator

Either the manufacturer or the provider must monitor every new refrigerator on site using a minimum/maximum thermometer and datalogger for a minimum of 24 hours before use, to ensure that the refrigerator is maintaining the +2°C to +8°C range, before placing vaccines into it. Where this is not practical (eg, due to ongoing vaccine storage requirements), the provider should download/access the datalogger at the end of the business day after the refrigerator has been installed, and again prior to the vaccines being used in the morning of the next day, to confirm that cold chain has been maintained.

The provider should keep temperature recordings for the pharmaceutical refrigerator for at least 10 years.

Each refrigerator must have two forms of temperature monitoring equipment, as follows.

1. **The daily check device using a minimum/maximum thermometer with externally visible display**
    - If the manufacturer considers it appropriate, the provider may use the inbuilt refrigerator temperature recording device.
    - Otherwise the provider can use an external digital minimum/maximum thermometer with audible alarm (placing the probe inside a vaccine box (or skillet) in glycol solution or a foam block).

    Staff should take minimum and maximum temperature readings and record them once a day – ideally first thing in the morning – and then reset the monitoring device.

2. **The weekly check device using an electronic temperature recording device**

The weekly check device (datalogger or equivalent: see 2a and 2b below) does not override the need for the provider to check and record the daily minimum and maximum temperatures.

Providers should also be aware of where the sensor is for both daily and weekly check devices. The devices should measure the temperature in different parts of the refrigerator, and must not share a sensor.

Providers must ensure that the electronic temperature recordings device data is reviewed weekly and also whenever the daily check minimum/maximum recordings indicate that the refrigerator temperatures have been outside the +2°C to +8°C range. Please note that buffer materials (eg, glycol solution) are less sensitive to short-term changes in temperature.

The data from the weekly check device may be stored electronically (provided it is backed up) or on a paper system recording daily minimum and maximum recordings (the system must allow access to the actual logger's readings at a later date).

2a. **A datalogger**

Dataloggers are self-contained temperature recording devices; they come in many shapes and sizes. It is necessary to configure them on a computer before placing them in the refrigerator. Dataloggers:

- measure the current refrigerator temperature at preset intervals and record that information, which can be downloaded/reviewed
- are powered separately from the refrigerator and the minimum/maximum thermometer (and have a back-up power system if they are not battery operated)
- should be preset to record the current temperature at least every 10 minutes (a five-minute interval is recommended if the logger has the capacity)
- must have their information downloaded/accessed every week and compared with the daily minimum and maximum recordings to check for any unexplained temperature variations; in this case providers should take appropriate action, including informing the coordinator
- should have the rollover function enabled to ensure the most recent data is kept if their memory becomes full (this usually occurs if the data is not downloaded/accessed regularly)
- should be rotated through the interior of the refrigerator to check for any temperature variations unless the manufacturer instructs otherwise
- although not required, should be calibrated according to manufacturers' requirements
- should have their battery checked and replaced before it runs out. If a provider is unable to change the battery, it should replace the datalogger (according to the manufacturers' recommendations) before it runs out of battery.

2b. **Continuous monitoring services**

A number of suppliers offer online (external or cloud storage-based) temperature monitoring and alerting services. These devices record refrigerator temperature and store/send the resulting recordings at set intervals (not more than 10 minutes; a five-minute interval is recommended). Providers can set up these services to send SMS or email alerts if the system picks up recordings outside the preset range.

The service should offer:

- detailed and accurate records of temperature history that the provider can access
- the ability for the provider to download/access and review the data every week and compare it with daily minimum and maximum recordings, to allow them to check for any unexplained variations in temperature
- an indicator for when the battery in the monitoring device needs replacing, if applicable
- a monitoring device powered separately from the refrigerator and the minimum/maximum thermometer (or have a back-up power system)
- back-up of information for at least 10 years.

3. **Cold room temperature monitoring**

Some sites, including DHB hospital pharmacies, may use a cold room or large walk-in chiller to store vaccines. These storage rooms/chillers do not need to be replaced every 10 years. However, to meet the requirements for CCA they must have:

- a suitable continual monitoring plan (eg, specifying documented six-monthly maintenance checks by the service provider)
- 24-hour-a-day monitoring systems via either a datalogger or an external monitoring (cloud-based) system that allows daily minimum and maximum recordings to be downloaded weekly and reviewed
- an external alarm system set to activate if temperatures go below +2°C to or over +8°C degrees
- an appropriate documented response process, back-up power supply and processes in place for alternative storage if the room/chiller malfunctions and cannot store the vaccine within the required temperature ranges.

For more information on minimum/maximum thermometers and dataloggers, see Appendix 3.

7.3 Transporting vaccines using a chilly bin

Immunisation providers must use temperature-monitored chilly bins to store vaccines when:

- transporting vaccines to another provider
- defrosting refrigerators
- a power outage occurs or equipment fails
- running offsite clinics, for example school-based immunisation programmes, outreach immunisation services or workplace settings.

General principles

General principles providers should adhere to when using chilly bins are as follows.

- Store vaccines between +2°C and +8°C at all times.
- Only use polystyrene or hard-walled chilly bins for temporary storage during refrigerator maintenance or for transport to another provider (either planned or as a result of a power outage or equipment failure).
- A hard walled/robust chilly bin must be used for offsite clinics.
- For each chilly bin, use sufficient ice packs and insulation material.
- For each chilly bin, monitor the temperature using either a digital minimum/maximum thermometer with an audible alarm or a datalogger with a probe and an external display (depending on the reason for using the chilly bin: for further guidelines on chilly bins used at offsite clinics, see the following section). It must be possible to read the temperature without opening the chilly bin. If using a datalogger:
  - providers should consider pursuing the ability to download/access the datalogger remotely, if a review function is not available on the logger
  - providers should set dataloggers to record the temperature every five minutes, and should download/access, review and save the data after returning to clinic.
- Carry out trials of the equipment, and be able to show that it can maintain temperatures between +2°C and +8°C at all times.

See Appendix 2 for more information on storing ice packs and preparing chilly bins. If a provider has any questions as to which type of chilly bin and monitoring system it requires, it should discuss this with its coordinator, who can advise on the most appropriate equipment that meets both the principles underlying the standards and the needs of the provider.

Note: The provider will need to start cooling the chilly bin at least 30 minutes (depending on the size of the chilly bin) before putting vaccines inside it.

Monitoring chilly bins at offsite immunisation clinics

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

- use a datalogger with a probe, external display and alarm to monitor the temperature of the vaccines throughout the time they are stored in a chilly bin, and consider using a secondary back-up device (eg, digital minimum/maximum thermometer), in case the datalogger gets damaged
- record the minimum, maximum and current temperatures at least every 30 minutes after putting the vaccines in the chilly bin
- set the datalogger to record the temperature every five minutes, and download, review and save the data after returning to the clinic (an exception to this is that a minimum/maximum digital thermometer with audible alarm can be used to measure the temperature of a vaccine during transport to a single patient (eg, an influenza vaccine for an elderly person at home) when the time the vaccine will be in the chilly bin is expected to be less than 120 minutes).

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.

Monitoring chilly bins for transport or temporary storage

Providers should adhere to the following principles when monitoring chilly bins for transport or temporary storage.

- Providers must have a minimum/maximum digital thermometer with audible alarm to measure the temperature of vaccines when using chilly bins to transport or temporarily store vaccines.
- Staff should check and record the minimum, maximum and current temperatures of vaccines:
  - before transporting the vaccines
  - before unpacking them at the alternative storage area
  - at least every 30 minutes while transporting or temporarily storing them (when it is safe to do so).
- In addition, providers can use a minimum/maximum digital thermometer with audible alarm to monitor temperature in the following circumstances:
  - transport within a hospital setting/site when a vaccine is being transferred from the pharmacy to a ward (or vice versa) within 120 minutes or less. In this setting, where transport time is expected to be less than 30 minutes, providers may consider the use of pre-cooled chilly bins with ice packs removed and no monitoring equipment, if trials show the temperature remains above 2˚C and below +12°C.
  - vaccines stored in a chilly bin for no more than four hours in a clinical room (in this situation, the provider must transfer the vaccine doses back to the refrigerator if the chilly bin is not maintaining the required temperature range).

Note: in all these situations, providers need to record the minimum/maximum temperature and store this documentation for 10 years.

Bibliography

Australian Government. 2019. *National Vaccine Storage Guidelines: Strive for 5* (3rd ed). Canberra: Australian Government Department of Health.

Centers for Disease Control and Prevention. 2019. *Vaccine Storage & Handling Toolkit*. Atlanta: US Department of Health and Human Services.

Grassby PF. 1993. Safe storage of vaccines: problems and solutions. *Pharmaceutical Journal* 241: 323–7.

Ministry of Health. 2009. *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods. Part 4: Wholesaling of medicines and medical devices*. Wellington: Ministry of Health.

Ministry of Health. 2017a. *National Guidelines for Vaccine Storage and Transportation for Immunisation Providers 2017*. Wellington: Ministry of Health.

Ministry of Health. 2017b. *Immunisation Handbook 2017* (2nd ed). Wellington: Ministry of Health.

World Health Organization. 1996a. *Guidelines for Establishing or Improving National, Regional and District Vaccine Stores*. Geneva: World Health Organization.

World Health Organization. 1996b. *Managing Cold Chain Equipment: A guide for national logistics officers*. Geneva: World Health Organization.

Appendix 1: Vaccine pharmaceutical refrigerator

What is a pharmaceutical refrigerator?

A pharmaceutical refrigerator has been designed and constructed for the specific purpose of storing pharmaceuticals and vaccines between +2°C and +8 °C, and has a built-in alarm set to activate if temperatures go outside this range.

What to consider when buying a new pharmaceutical refrigerator

When looking to buy a new pharmaceutical refrigerator, providers should consider the following.

- What are the requirements for vaccine stock, including seasonal vaccines?
  - Is it possible to add more shelves within the refrigerator?
  - Can the shelf height be varied?
  - What space is available in the facility? For example, will two small refrigerators fit better than one large one?
  - What size does the manufacturer recommend for the provider's maximum stock levels and influenza vaccine requirements?
- An alarm system is required. Consider an alarm system that can notify the provider of temperature breaches when staff are offsite.
- The refrigerator must have a 'door left open' alert.
- It must be possible to adjust the refrigerator's feet so the door self-closes.
- An inbuilt minimum/maximum thermometer with external display is preferable to an additional device.
- Ensure the refrigerator can operate in a local variable ambient room temperature – can it maintain internal temperatures between +2°C and +8°C in that environment?
- Does the refrigerator have a solid or a transparent door? Remember vaccines need to be protected from light.

- Can it be cleaned easily? Does it have any special cleaning requirements?
- What is covered in the warranty, and what time period does the warranty cover?
- What are the refrigerator's service requirements, and what is the service provider's response time?
- Does the supplier offer a recycling service for old refrigerators?
- What is the expected lifetime of the refrigerator? Remembering that they need to be replace at or before 10 years of age.
- Does the manufacturer carry out spatial temperature logging (mapping of the warmer and cooler spots in the refrigerator), and provide a report on its findings? This must be completed before a provider stores vaccines in the refrigerator.

Appendix 2: Transporting or storing vaccines in chilly bins

Immunisation providers must consider the following factors when transporting or storing vaccines in chilly bins, to ensure the vaccines are kept at +2°C to +8°C. Providers will need a datalogger(s), ice packs, insulation sheets and a chilly bin to transport the vaccines, or any other trialled system (eg, Cryopaks).

For advice on selecting the right equipment, providers can refer to IMAC's website at **www.immune.org.nz/health-professionals/cold-chain**, where they can read the COOL Project stakeholder summary.

Datalogger probe placement in a chilly bin

Providers should set datalogger alarms at +2°C (low alarm point) and +8°C (high alarm point).

The logger probe can be placed in a block of polyethylene foam approximately 60 x 60 x 40mm or an empty vaccine box or in glycol solution, and placed in the chilly bin.

Providers should monitor the temperature in the middle of, and ideally at the same level as, the boxes of vaccine closest to the cooling product in the chilly bin.

If an audible low temperature alarm sounds, or a manual temperature reading is at +3°C or lower, the provider should remove ice packs and continue to monitor every 3–5 minutes until the temperature stabilises at a higher point. If the temperature continues to drop, they should remove all ice packs and leave the chilly bin open until the temperature stops dropping and increases to +3°C or higher (but below +7°C).

If an audible high temperature alarm sounds, or a manual temperature reading is at +7°C or higher, the provider should add ice packs and continue to monitor every 3–5 minutes until the temperature stabilises at a lower point (but above +3°C).

Note: The datalogger temperature reading should be used as an early warning as to what could happen inside the boxes of vaccine if action is not taken to either reduce or increase the chilly bin's temperature.

Storing and using ice packs and other cooling products

Large sheets of gel pack ice replacement are the recommended cooling product (the generic term 'ice pack' is used throughout this document). Where traditional ice packs are used, they should be the flat bottle type, about 35 mm thick. Slimmer models tend to thaw out more quickly.

Ice packs must be frozen, not refrigerated. When freezing traditional ice packs, set them on their edge in the freezer and space them to allow for even freezing.

The number of ice packs needed to keep the vaccines at +2°C to +8°C throughout the time they are transported or stored will depend on:

- the size of the container
- the length of time storage is required
- environmental conditions.

Providers should have enough ice packs to ensure the temperature within the chilly bin remains within the +2°C to +8°C range.

Ice packs should be frost-free before the provider places them in the chilly bin (ie, ice should no longer form on the surface).

There is a risk of vaccines freezing if ice packs are not used correctly. Note that fewer commercial ice packs may be required to achieve the required temperature range of +2°C to +8°C. Additives in some commercial ice packs depress their melting point.

To transport vaccines over longer periods (eg, for a school-based immunisation programme or an outreach immunisation service), providers should take an extra transport container of ice packs to top up the chilly bin containing the vaccines as necessary to maintain the temperature in the +2°C to +8°C range.

Packing vaccines for transport or storage in chilly bins

The amount of vaccine to be transported or stored will determine the size of the chilly bin required.

In hotter weather, additional ice packs may be needed for precooling to reach the acceptable temperature within 30 minutes. Alternatively, precooling ice packs can be left in the chilly bin overnight.

Providers need to trial any alternative equipment and show that they can maintain a temperature of between +2°C to +8°C at all times.

Packing requires two pieces of insulation mat: one for below the vaccine and one for above. The bottom mat should fit the chilly bin; the top mat should be cut larger to allow for 1–2 cm to go up the sides of the chilly bin. A full packing and monitoring protocol can be found in the COOL Project stakeholder summary on the IMAC website: **www.immune.org.nz/health-professionals/cold-chain**.

Appendix 3: Dataloggers and digital minimum/maximum thermometers

Dataloggers

Electronic temperature recording devices (dataloggers) and continuous monitoring systems are recommended as the gold standard for immunisation providers to monitor the cold chain of the vaccines they store and/or transport. If a power outage or a cold chain breach occurs, dataloggers provide a means of identifying how long the vaccines have been exposed to temperatures outside the required range.

Dataloggers are a self-contained temperature recording device; they come in many shapes and sizes. It is necessary to configure them on a computer before placing them in the refrigerator.

Dataloggers should be preset to record the current temperature every 10 minutes in refrigerators (a five-minute interval is recommended, if the logger has the capacity) and every five minutes in chilly bins. Providers need to reconnect the datalogger to a computer to download/access and save the information the datalogger records. They must review the information every week and compare it with recordings from the minimum/maximum thermometer.

With a cloud-based continuous monitoring system, providers need to log in via the web portal to review the information being sent via the logger in the refrigerator. Providers with cloud-based monitoring must review this data at least weekly and compare it with recordings from the minimum/maximum thermometer; they should document this in their cold chain records.

Providers should be aware that because dataloggers and digital thermometers usually monitor different areas of the refrigerator, the recordings should be consistent but will not be exactly the same.

Immunisation coordinators or CCA reviewers use their own calibrated dataloggers (three) to concurrently monitor different areas within a refrigerator during the CCA or CCC process (or three-yearly for community pharmacies). This concurrent monitoring indicates if the temperature varies within the refrigerator, and is an independent validation of the refrigerator temperature monitoring system that is required for CCA. Other monitoring equipment can be validated at the same time (eg, a minimum/maximum thermometer or datalogger could be put into the fridge during the same time period).

An increasing number of brands of electronic dataloggers are available. They have the following characteristics in common. (Note that providers should always be aware of the individual manufacturer's specifications.)

- The manufacturers' guarantees range from one to three years, usually.
- The loggers' accuracy at 0°C ranges from ±0.2°C to ±0.3°C at temperatures of –10°C to +70°C.
- The life span for loggers will depend on the environment in which they are being used (eg, the temperature range they are exposed to, the sample rate/logging interval and the number of uses) and whether they are being used correctly.

When buying a datalogger, providers should request a manufacturer's certificate of accuracy – either an in-house certificate or through International Accreditation New Zealand. Note: Use of a datalogger does not replace the requirement for minimum/maximum daily recordings; both are required to monitor refrigerator temperatures.

Community pharmacies must be able to demonstrate that they check all devices they use for temperature monitoring for accuracy on a regular basis. Method and frequency of validation will be specific to the device, and should be based on reputable information, where available, or a commonly accepted method, where reputable information is not available. Pharmacies should refer to the current Medsafe 'Pharmacy Equipment' document. Coordinators will spatially log community pharmacy refrigerators every three years; if it is a vaccinating pharmacy, it is the pharmacy's responsibility to contact the coordinator to arrange this.

Calibration of dataloggers

These standards do not require but recommend that immunisation providers to have their dataloggers calibrated. However, a provider may wish to do so to gain additional certainty their equipment is accurate.

If there is a concern about the cold chain process or a significant difference between the two monitoring systems (minimum/maximum thermometer and the datalogger), a provider will be required to send its logger for calibration or checking.

If dataloggers are calibrated, an independent laboratory that is International Accreditation New Zealand accredited should undertake the task and issue a certificate.

The dataloggers of immunisation coordinators and CCA reviewers must be calibrated annually or according to the manufacturer's recommendations and be able to provide evidence of calibration if requested by a provider.

Digital minimum/maximum thermometers

Providers must have a digital minimum/maximum thermometer available to:

- measure their daily refrigerator temperatures if the manufacturer considers that the refrigerator display function is not appropriate
- use during a power outage (if their datalogger does not have a visible display)
- use when transporting vaccines if equipment fails or a power outage occurs.

Such thermometers are a low-cost means of monitoring the ambient air temperatures of refrigerators.

A number of digital minimum/maximum thermometers are available. Most have the following characteristics in common.

- The manufacturer's guarantee often applies for one year only.
- Their accuracy at 0°C ranges from ±0.5°C to ±1.0°C.
- The battery must be replaced every one to two years.
- Their life span will vary depending on use.

Note: Providers may opt to use their digital minimum/maximum thermometers for additional refrigerator monitoring when they are not in use to monitor chilly bins. This is very helpful during a power outage if the datalogger does not have a display, as in this case the fridge display will not be visible either. A battery-powered digital thermometer will continue to monitor and display the current and minimum/maximum temperatures during a power outage. If using digital minimum/maximum thermometers in this way, providers should reset the min/max memory daily.

Accuracy testing (ice pointing)

Providers should test the accuracy of all minimum/maximum thermometers and dataloggers (if possible) after buying them, after the battery is changed and every 12 months.

Performing an ice point test

Providers can perform an ice point test as follows.

- Take about a cup of ice and remove any white frosty parts by rinsing it in water.
- Crush the ice cubes to pea size.
- Place the ice cubes in a cup without water.
- Place the probe in the ice.
- Leave for approximately five minutes, or until the reading stabilises.
- The thermometer should read 0°C (ice point) plus or minus the manufacturer's stated accuracy specification.

Appendix 4: Key contacts

Regional immunisation advisors (IMAC)

Northern:	Phone: 027 497 6971 Email: **rianorthern@auckland.ac.nz**
Midland:	Phone: 027 232 4567 Email: **riamidland@auckland.ac.nz**
Central:	Phone: 027 292 4174 Email: **riacentral@auckland.ac.nz**
South Island:	Phone: 027 242 2451 Email: **riasouth@auckland.ac.nz**

For contact details of immunisation coordinators and CCA reviewers, see **www.immune.org.nz/health-professionals/regional-advisors-and-local-coordinators**.

Immunisation Advisory Centre (IMAC)

Phone: (0800) IMMUNE (466 863)

Regional distribution stores

ProPharma provides a vaccine distribution service only, not a technical inquiry and assistance service. Direct all technical inquiries to your local immunisation coordinator or IMAC regional immunisation advisor in the first instance.

For ProPharma vaccine order forms and to place vaccine orders, go to: **www.fundedvaccines.co.nz/vaccines**.

Alternatively, providers can get National Immunisation Schedule vaccine order forms from ProPharma regional stores and fax them to the following numbers:

ProPharma Whangarei	(09) 438 9681
ProPharma Auckland	(09) 915 9581
ProPharma Hamilton	(07) 957 3840
ProPharma Palmerston North	(06) 952 0035
ProPharma Wellington	(04) 576 1811
ProPharma Nelson	(03) 547 6455
ProPharma Christchurch	(03) 389 5459
ProPharma Dunedin	(03) 474 5061

Healthcare Logistics

The Healthcare Logistics customer service number is 09 918 5100.

Healthcare Logistics distributes seasonal influenza vaccine orders on behalf of the manufacturers.

To order influenza vaccine online, go to: **www.hcl.co.nz**.

Alternatively, you can use the seasonal influenza vaccine order form in the annual *Everything you need to know about FLU* kit, which you can download from **www.influenza.org.nz**.

Medicines Control

To contact Medicines Control please call 0800 163 060 or email **medicinescontrol@health.govt.nz**.

Vaccine manufacturers

The vaccine manufacturing companies also provide technical assistance with cold chain problems. The coordinator is responsible for requesting and following cold chain advice from vaccine companies for National Immunisation Schedule vaccines on behalf of the provider.

The companies supplying vaccines for the National Immunisation Schedule are:

- GlaxoSmithKline (GSK) (phone 0800 822 2463)
- Merck, Sharp & Dohme (NZ) Ltd (MSD) (phone 0800 500 673)
- Sanofi-Aventis (NZ) Ltd (phone 09 580 1810)
- Seqirus (New Zealand) (phone 0800 502 757)

- Pfizer (New Zealand) (phone 0800 736 363)
- Mylan (phone 0800 737 271).