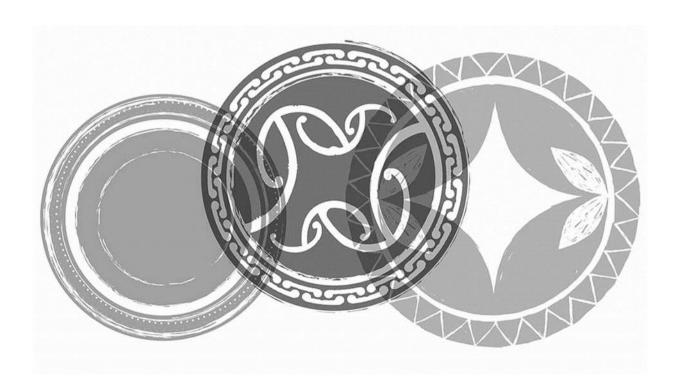


## National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017



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## **Contents**

Definitions and abbreviations						
Inti	oduc	etion	1			
1		ional Standards for Vaccine Storage and Transportation for nunisation Providers	2			
2	Bac	kground	4			
	2.1	Vaccine arrival and distribution	4			
	2.2	Vaccines are temperature sensitive	4			
	2.3	Cold chain excursion costs	5			
3	Col	d Chain Accreditation	6			
4	Col	d chain compliance	8			
5	Peo	ple	9			
	5.1	Requirements for all immunisation providers	ç			
	5.2	Designated cold chain management leads	10			
6	Systems and processes					
	6.1	Provider cold chain policy	11			
	6.2	Key requirements for immunisation providers for vaccine stock management	12			
	6.3	During a power outage or equipment failure	16			
	6.4	Process for vaccines stored outside +2°C to +8°C	17			
	6.5	Vaccine disposal	18			
7	Equ	ipment	19			
	7.1	Pharmaceutical refrigerator	19			
	7.2	Monitoring the temperature of the pharmaceutical refrigerator	20			
	7.3	Transporting vaccines using a chilly bin	21			
Bib	liogra	aphy	23			
App	endi	x 1: National Cold Chain Audit	<b>2</b> 4			
	Sun	nmary of instructions	<b>2</b> 4			
	Data	a collected	25			
App		x 2: Vaccine pharmaceutical refrigerator	26			
	Wha	at to consider when buying a new pharmaceutical refrigerator	26			
Anr	endi	x 3: Transporting or storing vaccines in chilly bins	27			

Storing and using ice packs	27
Packing vaccines for transport or storage in chilly bins	27
Appendix 4: Data loggers and digital minimum/maximum thermometers	29
Data loggers	29
Calibration of data loggers	30
Digital minimum/maximum thermometers	30
Accuracy testing (ice pointing)	30
Appendix 5: Key contacts	32
Regional immunisation advisors (IMAC)	32
Immunisation Advisory Centre (IMAC)	32
Regional distribution stores	32
Healthcare Logistics	33
Vaccine manufacturers	33
List of tables	
Table 1: Example of vaccine costs at a medium-sized general practice	5
Table 2: Example of vaccine costs at a youth clinic	5
Table 3: Example of vaccine costs for a routine chilly bin for a school-based immunisate programme	tion 5
Table 4: Two weeks' vaccine supply (number of doses), per population served by the general practice	13
Table 5: Four weeks' vaccine supply (number of doses), per population served by the general practice	14

## **Definitions and abbreviations**

**CCA reviewer**: someone who reviews an immunisation provider's cold chain management practices and processes and approves their achievement of CCA or CCC if appropriate. It is recommended that the reviewer has completed an appropriate assessor's programme. (Note: the CCA reviewer may be an immunisation coordinator.)

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  $+2^{\circ}$ C to  $+8^{\circ}$ 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 standards for safe vaccine storage and transportation. All immunisation providers must have their cold chain management accredited by an approved CCA reviewer.

**Cold Chain Compliance (CCC)**: issued when an immunisation provider achieves all of the standards for CCA but are unable to show the refrigerator's three-month continuous temperature monitoring records. CCC is a short-term arrangement for new providers or those providers who store vaccines for only a short time in the year.

**Cold chain breach**: an event that has led to the 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.

**Data logger**: an electronic device that continuously measures the current refrigerator temperature at preset intervals and records the information, which can then be downloaded.

**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 coordinator**: the role as defined through the Ministry of Health's Crown Funding Agreement Service Specification. Referred to as immunisation facilitator in some areas.

**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.

**National Cold Chain Audit (NCCA)**: an audit that monitors National Immunisation Schedule vaccines through the cold chain, from the regional distribution stores to the immunisation provider.

**National Immunisation Schedule:** the series of vaccines that are offered free to babies, children, adolescents and adults. PHARMAC lists all publicly funded vaccines on the New Zealand Pharmaceutical Schedule. The Ministry of Health is responsible for implementing the Schedule.

**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.

**New Zealand Pharmaceutical Schedule**: a list of the prescription medicines and therapeutic products subsidised by the Government. PHARMAC is responsible for maintaining and managing the Pharmaceutical Schedule.

PHARMAC: Pharmaceutical Management Agency Ltd.

**Pharmaceutical refrigerators**: refrigerators designed and constructed specifically to store vaccines and medicines.

**PHO**: primary health organisation.

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

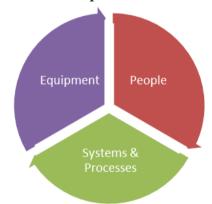
## Introduction

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. These standards supersede the *National Guidelines for Vaccine Storage and Distribution 2012* (Ministry of Health 2012) and the *Immunisation Handbook 2014* (Ministry of Health 2014).

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.

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

- 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 when the vaccine is administered to an individual.



All immunisation providers are required to achieve cold chain accreditation (or cold chain compliance if appropriate), the process that assesses a provider's ability to meet the required standards.

The review of these standards has been informed by the National Review of Cold Chain Management Practices commissioned by the Ministry of Health (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, following 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 an immunisation programme.
- 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 that contains 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:
  - store only medicines and vaccines
  - · are appropriately maintained and serviced
  - contain only vaccines and medicines stored in their original packaging and properly spaced within the pharmaceutical refrigerator.

Note: All pharmaceutical refrigerators have a limited life span, usually around 10 years. Immunisation providers are expected to actively plan for replacement and replace their refrigerator after 10 years rather than wait until the refrigerator fails to maintain temperature.

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 data logger. Every week the provider then downloads and reviews this information, takes appropriate action and stores 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 3 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 the pharmaceutical refrigerators
  - trial and test the capacity of their portable storage equipment.

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:
  - the daily minimum and maximum temperature recordings
  - · the weekly data logger downloads
  - temperature recordings from vaccines transported and stored in chilly bins
  - any 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 and tested equipment for this purpose.

See section 7.3 and Appendix 3 for further information.

For the details on how providers can meet these 10 standards, see sections 2 to 7. If an immunisation provider fails to comply with the standards, its district health board (DHB) or primary health organisation (PHO), medical officer of health or the Ministry will review its access to vaccines. Vaccine supply may also 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 vaccines listed on the New Zealand Pharmaceutical Schedule are delivered to the National Vaccine Store, where temperature monitoring continues to ensure that the vaccines remain within the required  $+2^{\circ}$ C to  $+8^{\circ}$ 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 in place to ensure the vaccine cold chain is maintained at all times during storage at their sites and during vaccine transportation to providers. The Ministry of Health Medicines Control team is responsible for auditing the cold chain practices at the National Vaccine Store and regional distribution stores.

Both the National Vaccine Store and regional distribution stores audit the maintenance of the cold chain during the delivery process by inserting data loggers in some vaccine deliveries. Information is provided for immunisation providers when a data logger has been included in their delivery. This includes instructions on how to check the data logger and return it to the distributor, or to the Immunisation Advisory Centre (IMAC) in the case of the National Cold Chain Audit (NCCA) logger. See Appendix 1 for information on the NCCA process.

## 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 the vaccines, so it is important to advise your immunisation coordinator of any cold chain breaches.

The immunisation coordinators have access to thermostability data for vaccines on the National Immunisation Schedule. However, when the temperature exposures are significant or occur over an extended period, the immunisation co-ordinator will need to get further information from the vaccine manufacturer. See section 6.4 for the process for managing vaccines stored outside the required  $+2^{\circ}\text{C}$  to  $+8^{\circ}\text{C}$  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. Some types of vaccines can cost up to \$170 a dose. Even a small immunisation provider stores thousands of dollars' worth of vaccines at one time.

Tables 1–4 give examples based on past cold chain excursions. The total costs in each table indicates what the vaccines cost is to the DHBs.

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

Vaccine	No. of doses in stock
ADT	15
Tdap	10
23PPV	2
MMR	19
Hib	9
DTaP-IPV	10
RV5	19
HPV	10
PCV	18
DTaP-IPV-Hib/Hep B	19
Total costs	\$8,000

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

Table 3: Example of vaccine costs for a routine chilly bin for a school-based immunisation programme

No. of doses in stock			
100			
80			
\$7,700			

Note: The costs above were calculated in 2016.

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 Accreditation (CCA) is an audit tool used to assess the cold chain management practices and processes of immunisation providers to ensure they meet the standards for safe vaccine storage and transportation before offering an immunisation programme. To achieve CCA, the provider first conducts a self-assessment and then an approved CCA reviewer conducts a review.

All immunisation providers who store vaccines all year round 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.

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.

The CCA reviewer will assess the provider's past performance and current cold chain knowledge. Those 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. It can be awarded for up to three years.

CCA assessment is based on the following five areas:

- 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. vaccine stock management
- 4. requirements for temperature monitoring and refrigerator performance are understood and monitoring devices and processes are appropriate
- 5. storage and transport equipment meets requirements.

Immunisation providers must meet **all** the requirements for cold chain management to achieve CCA and **all** staff must be responsible for the cold chain.

If a provider fails to meet the CCA requirements, the CCA reviewer will work with the provider to develop a remedial plan for the provider 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 or Medicines Control (in the case of a pharmacy). Further actions may be taken if necessary, which may include placing vaccine deliveries on hold.

Each DHB is expected to work with the CCA reviewer and/or immunisation coordinator, PHO, medical officer of health, IMAC and other immunisation stakeholders to develop a process for working through issues where providers are not achieving 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 CCA requirements
- discussing the 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.

By 1 February 2018, all DHBs will be required to have a documented local process for addressing provider non-compliance. Each DHB needs to review this process annually and make the documentation available to the Ministry on request.

For the *CCA Provider Self-Assessment Form* and the *CCA Immunisation Provider Review Form*, go to the Ministry of Health's cold chain page (www.health.govt.nz/coldchain).

## 4 Cold chain compliance

A 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. This category can also be used when a new immunisation provider is setting up.

CCC is issued through the same process as CCA: that is, the provider conducts a self-assessment, and then the CCA reviewer undertakes an immunisation provider review before the provider can offer an immunisation programme or service. A local certificate is issued for CCC and 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.

If a provider offered an immunisation service in the previous year, it must produce its temperature recordings (daily recordings and data logger downloads) from that year for the CCC review; the CCA reviewer will randomly review at least a quarter of these recordings.

CCC may also be applied in hospital settings for areas stocking influenza vaccine only. Areas that stock vaccines all year round will need to achieve CCA.

If a provider fails to meet the CCC requirements, the CCA reviewer will work with the provider to develop a remedial plan for the provider to achieve the requirements. However, the provider will not be able to deliver an immunisation service until it has met the requirements.

## 5 People

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

While all clinical staff need a high level of knowledge about the cold chain principles and equipment, 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 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 recorded daily on a temperature recording chart (in the Annual Cold Chain Management Guide, for example) and that the minimum/maximum thermometer is reset at this time
- check the temperature recording chart for variations in temperature before using the 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, consistent with the Health (Retention of Health Information) Regulations 1996
- ensure that all relevant clinical staff know how to download, save and file the data logger recordings; 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 and contacting the immunisation coordinator; see section 6.4 for more information
- document the 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 should be an authorised vaccinator, general practitioner or a pharmacist vaccinator. Where this is not possible, the provider should discuss the issue with the CCA reviewer and appoint the most appropriate person.

The designated cold chain staff are responsible for:

- ensuring the daily and weekly temperature monitoring checks are undertaken and any cold chain breaches 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
- ensuring all relevant clinical staff know how to download and review the data logger information and know the actions to take if the recordings are outside the required range
- ensuring providers use temperature recording charts
- changing, when required, the refrigerator set point on advice from the pharmaceutical refrigerator technician or manufacturer (this must be documented)
- ensuring the refrigerator performance and daily temperature monitoring equipment are checked for accuracy on an annual basis for a minimum of 24 hours. (This should be done independently either as part of the refrigerator service and/or in conjunction with the immunisation coordinator using a calibrated data logger.)

## 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).

All immunisation providers must have a cold chain policy that contains the required information as 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. The policy should be:

- dated and signed by the relevant staff
- reviewed at least annually
- reviewed when the designated cold chain staff, vaccine equipment or processes change.

#### The policy should specify:

- the names of the designated staff members responsible for cold chain management (ie, two or more staff). The cold chain leads should be an authorised vaccinator, general practitioner or pharmacist vaccinator
- vaccine and stock requirements for the provider's programme or clinic
- vaccine ordering and stock taking processes (including a vaccine register)
- processes for receiving and storing vaccines
- 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)
- 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 as per the manufacturer's recommendations and cleaning schedule)
- processes for monitoring the pharmaceutical refrigerator temperature, including instructions on data logger use
- details of equipment to use for offsite vaccination clinics, including chilly bin(s), insulation material and temperature monitoring equipment
- process for temperature monitoring while vaccines are being stored in chilly bin(s) for offsite immunisation clinics
- action to be taken when the temperature recordings of the refrigerator or chilly bin(s) 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 providers are in areas regularly affected by power outages, they 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 and read the data logger
- a cold chain equipment replacement plan. All pharmaceutical refrigerators have a limited life span, usually around 10 years immunisation providers are expected to actively plan for replacement and replace their refrigerator after 10 years rather than wait until the refrigerator fails to maintain temperature.

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

The local CCA reviewer 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 of vaccines. Tables 5 and 6 can help to calculate this level.
- Many vaccines are dispatched in boxes with multiple doses. Table 6 has taken this practice into account for calculating the maximum level of stock.
- When ordering Tdap for the 11-year immunisation, also consider the number of vaccines required for your 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.

## Im munisation 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. The calculations are based on the:

- number of people enrolled in the practice, at a particular time, who are aged under 5 years, 11 or 12 years (depending on whether a school-based immunisation programme is delivered in the region) and 45 and 65 years, assuming 100 percent coverage for all scheduled vaccines
- number of times each vaccine is used on the Schedule.

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

<5-year-old population	50	100	250	500	1000	1250
DTaP-IPV-Hib/HepB and RV5	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 <sup>1</sup>	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 <sup>2, 3</sup>	1	1	2	4	8	10
HPV <sup>2,4</sup> (2 doses)	1	2	4	8	16	20
45- and 65-year-old population (combined)	20	40	100	200	400	500
ADT⁵	2	2	4	8	16	20

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; you will 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, take into consideration the number of vaccines your practice requires for pregnant women.
- 4 When ordering HPV, take into consideration the number of vaccines your practice requires for your 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 your practice and the number of patients seen for acute wound management. The numbers in the table above only take account of a combined population number for 45 and 65 years of age.

Table 5: Four weeks' vaccine supply (number of doses), per population served by the general practice

<5-year-old population	50	100	250	500	1000	1250
DTaP-IPV-Hib/HepB and RV5	3	5	12	24	47	58
RV1	2	4	8	16	31	39
PCV	4	7	16	31	62	77
DTaP-IPV	2	2	4	8	16	20
Hib and varicella <sup>1</sup>	2	2	4	8	16	20
MMR	2	4	8	16	31	39
Single year age group eg, 11-year-olds	10	20	50	100	200	250
Tdap <sup>2, 3</sup>	2	2	4	8	16	20
HPV <sup>2,4</sup> (2 doses)	2	4	8	16	31	39
45- and 65-year-old population (combined)	20	40	100	200	400	500
ADT⁵	4	4	8	16	32	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.

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- 2 Tdap and HPV numbers will depend on the number of children vaccinated in a school-based programme.
- 3 When ordering Tdap, take into consideration the number of vaccines your practice requires for pregnant women.
- 4 When ordering HPV, take into consideration the number of vaccines your practice requires for your 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 your practice and the number of patients seen for acute wound management. The numbers in the table above only take account of a combined population number for 45 and 65 years of age.

#### 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 at risk from a cold chain excursion. Influenza vaccine comes in boxes of 10.

#### 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). The

online order process has an audit trail, and is less susceptible to errors and is faster than the alternative of faxing an order.

Healthcare Logistics distributes influenza vaccine orders to immunisation providers once the vaccine becomes available at the start of the influenza programme (usually in March). The minimum order for influenza vaccine is 60 doses at the beginning of the programme, reducing to 30 and then 10 doses towards the end of the programme. There are no limits on the number of influenza vaccine deliveries a provider is entitled to receive but providers should calculate their requirements in order to reduce multiple small influenza vaccine orders and deliveries because wasted chilly bins have an impact on the environment (they cannot be returned for reuse).

You can order influenza vaccine from the Healthcare Logistics website (www.hcl.co.nz). The online order process has an audit trail, and is less susceptible to errors and is faster than the alternative of faxing an order. For more information, 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, for example, an NCCA or distributor data logger; follow any instructions provided on using those devices
- check the vaccines delivered are those that 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 arrival date at the provider on the vaccine box
- 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 (for example, 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 local immunisation coordinator
- not return vaccines until they have written authorisation to do so from the distributor
- record information on the vaccines returned to the distributor (including batch numbers and expiry dates) in the provider's vaccine register or system and forward this to the immunisation coordinator.

Immunisation providers who are unsure of how to read the NCCA monitor should contact their local immunisation coordinator for advice before using the vaccines that came with the card. They must keep the vaccines within the  $+2^{\circ}$ C to  $+8^{\circ}$ C range while this occurs.

#### Placing vaccines in a pharmaceutical refrigerator

Place vaccines 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 expiry dates visible to ensure those with the shortest expiry date are used first. In addition:
- if the vaccines are put into plastic containers, these must have holes in the side and bottom to allow air to flow
- the refrigerated vaccines must not exceed 90 percent of the available refrigerator storage space.

Do not store vaccines in plastic bags, in solid containers, in the refrigerator door, in the drawer at the bottom of the refrigerator or on the bottom (floor) of the refrigerator.

Under the Medicines Act 1981, section 47, 'Storage and delivery of medicines', providers must not store vaccines in a cupboard, box or shelf, or store food in the 'for vaccines only' refrigerator. Vaccines should not be prepared in any room or on any table or bench that is used for packing, preparing or consuming any food or drink.

Laboratory specimens should not 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 data logger with external display to monitor the internal refrigerator temperature.
- If the internal refrigerator temperature rises above +8°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 immunisation coordinator before moving vaccines as there will need 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 immunisation 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)\*



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.



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 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.
- Is it likely that any individuals received a compromised vaccine?



Contact your local immunisation coordinator with all of the available information and work with them through to resolution.

#### 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 immunisation coordinator; however, it must document the variations in its records.

Additional notes: If staff do not follow up cold chain breaches and the provider does not contact the immunisation 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 it leads to a cold chain failure (ie, vaccines in a cold chain excursion are administered to patients), then the immunisation coordinator, along with the provider, is required to involve the IMAC regional immunisation advisor, PHO clinical lead, DHB lead and the local medical officer of health. The immunisation coordinator must notify the Ministry of Health immunisation team by email, on immunisation@moh.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 being referred for competence review by their regulatory body, this is particularly relevant where a cold chain failure could have been prevented if action had been taken.

## 6.5 Vaccine disposal

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

The 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 the requirements under the Resource Management Act 1991. Please do not dispose of unused vaccines in sharps containers.

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.

Providers should return any vaccines for disposal to the regional distribution store for safe destruction. To prepare the vaccines for the regional distribution store:

- clearly label them and attach the regional distribution store's 'Vaccines for Destruction' sticker (which you 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 (for example, 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 you are sending them for destruction, for example, due to a cold chain excursion or expired vaccine.

## 7 Equipment

All equipment used for storing, transporting and monitoring vaccines must be fit for the purpose, appropriately maintained and tested.

All immunisation providers must have a pharmaceutical refrigerator for vaccine storage. 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.

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

## 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
- be plugged into an independent power point; if not hard wired, then the plug needs a power point protector and/or a large, bright notice should be used to tell people not to unplug the refrigerator, to help prevent the power cords from accidentally being removed
- not be in direct sunlight or against a heat source
- be in a ventilated room that is kept at a temperature above 5°C and below 32°C all of the time
- be at least 4 cm but preferably 10 cm away 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 by an approved/licensed refrigerator technician and documented.

Note: External surge protectors should be in place if the refrigerator manufacturer recommends or requires them. It is also recommended that providers (particularly community-based providers) put a notice at the meter box advising 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 are expected to actively plan for their replacement and replace their refrigerator after 10 years rather than wait until the refrigerator fails to maintain temperature. See Appendix 2 for matters to consider in relation to 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 data logger 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.

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

Each refrigerator must have two forms of temperature monitoring equipment.

## 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, if not using glycol solution).

Staff should take minimum and maximum temperature readings and record them once a day, preferably 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 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 staff review the electronic temperature recordings device data weekly and also whenever the daily check minimum/maximum recordings indicate that the refrigerator temperatures have been outside the  $+2^{\circ}$ C to  $+8^{\circ}$ C range.

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

#### 2a. A data logger

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

- measure the current refrigerator temperature at preset intervals and record that information, which can be downloaded
- are powered separately from the refrigerator and the minimum/maximum thermometer
- should be preset to record the current temperature at least every 10 minutes (a fiveminute interval is recommended if the logger has the capacity)
- should have their information downloaded every week and compared with the daily minimum and maximum recordings to check for any unexplained temperature variations, with appropriate action then taken, including informing the immunisation 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 regularly)
- should have their battery checked and replaced before it runs out, if that is possible.

OR

#### 2b. External monitoring services

At least two pharmaceutical refrigerator suppliers are offering online (external or cloud storage-based) temperature monitoring and alerting devices. These devices record and store the temperature recordings at set intervals (not more than 10 minutes, a five-minute interval is recommended) from your pharmaceutical refrigerator in the cloud and can be set up 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
- access for the provider to download and review the data every week and compare it
  with the daily minimum and maximum recordings to check for any unexplained
  variations in temperature.

For more information on minimum/maximum thermometers and data loggers, see Appendix 4.

## 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**

- Store vaccines between +2°C and +8°C at all times.
- Only use polystyrene 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).
- Use a more robust chilly bin 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 audible alarm or a data logger with probe and an external display (depending on the reason for using the chilly bin). It must be possible to read the temperature without opening the chilly bin.
- Providers are expected to trial their equipment and be able to show that they can maintain the temperatures between +2°C and +8°C at all times.

See Appendix 3 for more information on storing ice packs and preparing chilly bins.

Note: You will need to start cooling the chilly bin at least 30 minutes before you put vaccines inside it.

#### Monitoring chilly bins for transport and 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, for example, during a power outage or refrigerator servicing.
- Staff should 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 vaccines stored in chilly bins for offsite immunisation clinics:

- use a data logger with a probe, external display and alarm 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
- record the minimum, maximum and current temperatures every 20–30 minutes after putting the vaccines in the chilly bin
- set the data logger to record the temperature every five minutes; download, review and save the data 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.

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# **Appendix 1: National Cold Chain Audit**

The Pharmaceutical Management Agency Ltd (PHARMAC) and the Ministry of Health commission the National Cold Chain Audit (NCCA) to monitor National Immunisation Schedule vaccines, from the time that the regional distribution stores distribute the vaccines and up to two weeks in an immunisation provider's refrigerator. The Immunisation Advisory Centre (IMAC) is responsible for managing and reporting on the NCCA.

NCCA temperature loggers are used to monitor up to 10 percent of vaccines distributed from regional distribution stores. The loggers stay with the box of vaccines they are allocated to, until either the last dose of vaccine is used or two weeks have passed, whichever occurs first.

The loggers used are yellow ECONOLOG loggers.

A sticker on the vaccine delivery container indicates to the provider that an NCCA logger is enclosed and that they should follow the enclosed instruction sheet before unpacking the vaccines into the refrigerator.

## **Summary of instructions**

When the vaccine arrives at the immunisation provider's facility, one of the two lights will be flashing; this is the only time the provider is required to check the logger.



#### If the light is flashing green

- A flashing green light indicates the temperature is within limits the temperature has remained between +2°C and +8°C. After checking them, place the vaccines into your refrigerator, with the logger attached, for use.
- Return the logger to IMAC in the prepaid envelope either after using the last vaccine from the box it is attached to or two weeks after the delivery date if you still have the box of vaccine in your refrigerator. Complete the bottom of Section E on the instruction sheet and send that was well.

#### If the light is flashing red

- A flashing red light indicates the temperature is **out of limits** the temperature has NOT remained between +2°C and +8°C during the delivery period. Quarantine all of the vaccines in the delivery, in the pharmaceutical refrigerator. DO NOT USE.
- Call your local immunisation coordinator as soon as possible for advice on what to do next.

If your immunisation coordinator(s) is unavailable, please contact IMAC on (09) 923 2075. You will get advice on how to proceed.

You should also follow the steps above if you notice that the logger has a red light flashing while it is being stored in your refrigerator.

#### **Data collected**

When the loggers are returned to IMAC, an administrator downloads and reviews their data. If the administrator notes any temperatures outside the range of +2°C to +8°C, they will contact the IMAC National Manager, the IMAC regional immunisation advisor or the immunisation coordinator, depending on where the excursion has occurred. Further action is then taken, including advising the provider.

IMAC analyses the data collected from the loggers and reports to the Ministry on a six-monthly basis. It provides a summary of the information for key immunisation stakeholders.

For more information on the NCCA, see www.immune.org.nz/health-professionals/cold-chain, or contact your IMAC regional immunisation advisor or your immunisation coordinator.

# Appendix 2: Vaccine pharmaceutical refrigerator

# What to consider when buying a new pharmaceutical refrigerator

- 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 your maximum stock levels and influenza vaccine requirements?
- An alarm system is required. Consider an alarm system that can be connected to a system to notify you when you 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.
- Do you need an auto defrost feature?
- An inbuilt minimum/maximum thermometer with external display is preferable to using 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 it have a solid or glass 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 it cover?
- What are the service requirements and what is the response time from the service provider?
- Does the supplier offer a recycling service for old refrigerators?
- What is the expected lifetime of the refrigerator (most are up to 10 years)?
- Does the manufacturer carry out spatial temperature logging (mapping of the warmer and cooler spots in the refrigerator) and provide a report? This must be completed before storing vaccines in the refrigerator.

# Appendix 3: Transporting or storing vaccines in chilly bins

An immunisation provider must consider the following factors when transporting or storing vaccines in chilly bins.

## Storing and using ice packs

- Ice packs must be frozen, not refrigerated. When freezing the required 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.
- You should have enough ice packs to ensure the temperature within the insulated container remains within the +2°C to +8°C range.
- Ice packs should be frost-free before you place them in the insulated container (ice should no longer form on their 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.
- Ice packs should be the flat bottle type, about 35 mm thick, or the large gel pack variety. Slimmer models tend to thaw out more quickly.
- To transport vaccines over longer periods (for example, for a school-based immunisation programme or an outreach immunisation service), 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.

- 1. The volume of vaccine should be no more than one-third of the container's capacity.
- 2. Cool each chilly bin by placing ice packs inside it, usually around 30 minutes before using it. However, cooling can take longer if it is a large chilly bin.
- 3. Once the container has cooled, remove these ice packs and insert approved insulation material along the bottom of the container. For a large chilly bin, you can keep the ice packs in place and put a layer of insulation over the top.

- 4. Add the vaccine stock. Place the probe of the temperature monitoring device you are using in one of the boxes of vaccine or an empty vaccine box, closest to the ice packs. If the probe sits in glycol, put it with the vaccines closest to the ice packs.
- 5. Place a layer of insulation on top of all the vaccines, to ensure vaccines are not frozen by contact with or exposure to the ice packs.
- 6. Place the required number of ice packs on top of the insulation to reach a temperature of between +2°C and +8°C.
- 7. Secure the lid using the clips on the container.
- 8. Do not start travelling until the loaded chilly bin temperatures have stabilised at between +2°C and +8°C. (Cool vaccine from the refrigerator may cause the temperature of the chilly bin to drop. If so, you should adjust the number of ice packs before travelling).

Providers are expected to trial and document their transport and portable storage equipment to ensure it is capable of maintaining the  $+2^{\circ}$ C to  $+8^{\circ}$ C range at all times.

Opening the container more frequently, opening it for periods longer than one minute, or transporting vaccines in a hot motor vehicle is likely to reduce the time the temperature can be maintained within the recommended range.

Diluents should be transported within the cold chain, in the chilly bin.

It may be necessary to place ice packs and/or insulation material around the side of the insulated container if it is a large space; you will need to experiment to find the best combination for your equipment.

# Appendix 4: Data loggers and digital minimum/maximum thermometers

#### **Data loggers**

Data loggers 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, data loggers provide a means of identifying how long the vaccines have been exposed to temperatures outside the required range.

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

Data loggers should be preset to record the current temperature at least every 10 minutes in refrigerators (a five-minute interval is recommended if the logger has the capacity) and every five minutes in chilly bins. To see this information, you will need to reconnect the data logger to the computer to download and save the information. You must review the information every week and compare it with the recordings from the minimum/maximum thermometer.

With a cloud-based monitoring system, you will need to log in via the web portal to review the information being sent via the logger in the refrigerator. Do this every week and compare the information with the recordings from the minimum/maximum thermometer.

Be aware that because the data logger and the digital thermometer 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 data loggers (three) to concurrently monitor different areas within a refrigerator during the CCA or CCC process. 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.

An increasing number of brands of electronic data loggers are available for use. 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  $\pm 0.2$ °C to  $\pm 0.3$ °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 (for example, 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 data logger, providers should request a manufacturer's certificate of accuracy – either an in-house certificate or through International Accreditation New Zealand.

Note: The use of the data logger does not replace the requirement for minimum/maximum daily recordings, as both are required to monitor your refrigerator temperatures.

## Calibration of data loggers

These standards do not require immunisation providers to have their data loggers calibrated annually. 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 data logger), a provider will be required to send its logger off for calibration or checking.

If data loggers are calibrated, an independent laboratory that is International Accreditation New Zealand (IANZ) accredited should undertake the task and issue a certificate.

The data loggers of immunisation coordinators and CCA reviewers must be calibrated annually or according to the manufacturer's recommendations and a certificate issued.

## 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 data logger 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 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  $0^{\circ}$ C ranges from  $\pm 0.5^{\circ}$ C to  $\pm 1.0^{\circ}$ C.
- The battery must be replaced every one to two years.
- Their life span will vary depending on use.

## **Accuracy testing (ice pointing)**

Test the accuracy of all minimum/maximum thermometers and data loggers (if possible) after buying them, after the battery is changed and every 12 months.

#### Performing an ice point test

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 them 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 o°C (ice point) plus or minus the manufacturer's stated accuracy specification.					

## **Appendix 5: Key contacts**

## Regional immunisation advisors (IMAC)

Northern: Phone: 027 497 6971

Email: rianorthern@imac.org.nz

Midland: Phone: 027 232 4567

Email: riamidland@imac.org.nz

Central: Phone: 027 232 4567

Email: edcentral@imac.org.nz

South Island: Phone: 027 242 2451

Email: riasouth@imac.org.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)**

PO Box 17 360 Greenlane Auckland 1546

Phone: (0800) IMMUNE (466863) or (09) 373 7599

#### **Regional distribution stores**

ProPharma currently 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. The online order process has an audit trail, and is less susceptible to errors and is faster than the alternative of faxing an order.

Alternatively, you 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) 570 1081

 ProPharma Hamilton
 (07) 957 3850

 ProPharma Wellington
 (04) 576 1811

 ProPharma Christchurch
 (03) 389 5459

 ProPharma Dunedin
 (03) 474 5061

#### **Healthcare Logistics**

The Healthcare Logistics customer service number is 0508 425 358.

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

#### Vaccine manufacturers

The vaccine manufacturing companies also provide technical assistance with cold chain problems. The immunisation 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 o800 822 2463)
- Merck, Sharp & Dohme (NZ) Ltd (MSD) (phone o800 500 673)
- Sanofi-Aventis (NZ) Ltd (phone og 580 1810)
- Segirus (New Zealand) (phone 0800 502 757)
- Pfizer (New Zealand) (phone o800 736 363)
- Mylan (phone o800 737 271).