

## Important notes

- This report summarises the COOL Project Report.
- Appendix 1: The *COOL Project Chilly Bin Packing Protocol* was developed from the findings of the COOL Project to support offsite vaccination programmes, also at [www.immune.org.nz/health-professionals/cold-chain](http://www.immune.org.nz/health-professionals/cold-chain).
- The recommendations in this report are based on the products tested as part of the COOL Project. The rationale behind the equipment selected for testing is described on page 5 under *Initial selection of equipment for tests*.
- There are other suppliers in New Zealand who provide similar equipment that immunisation providers may also consider when purchasing new equipment for vaccine storage and transportation. This information is intended to assist providers when they are planning to purchase new equipment or replace their current equipment. Providers are not expected to purchase these products now but 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.
- The *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* will be updated to reflect the findings of the COOL Project.

## 1. Project outcomes

### Equipment and supplies recommendations

These recommendations are based on the equipment tested in the table below, and relate to purchasing information and some set up information for small, medium and large chilly bin volumes.

CHILLY BIN	SMALL <20L	MEDIUM 20 – 40L	LARGE 40 -50L
Brand	Waeco/Dometic Cool-Ice	Waeco/Dometic Cool-Ice	Waeco/Dometic Cool-Ice
Size	13L	22L	41L
RRP (incl gst)	\$115	\$129	\$239
Weight	2.8kg	4.2kg	7.5kg
Dimensions (d x w x h)	386x 241 x 306mm	386 x 363 x 314mm	386 x 632 x 342mm
Available from	Burnsco, Hunting and Fishing, Bell technology, RV World <a href="http://dometic.com/en-nz/nz/find-a-dealer">dometic.com/en-nz/nz/find-a-dealer</a>		
COOLING PRODUCT			
Brand	Thermasorb Chill Wrap		
RRP (incl gst)	\$2.30 per sheet (1 sheet = 2x 3x4 cells; perforated)		
Volume	1x 3x4 cells	2x 3x4 cells	3x 3x4 cells
Approximate weight	453g	906g	1359g
Position of cooling product	Top only, above insulating matting		
Available from	Fishing Industry Services Limited <a href="http://fishindserv.co.nz/custform.htm">fishindserv.co.nz/custform.htm</a>		
Durability	Replace at least every year or earlier if deteriorating		
INSULATION			
Brand	Friedola Sympa Nova matting		
RRP (incl gst)	\$24.10/m 650mm wide		
Position	Above & below vaccine		
Bottom mat	Cut to size of bottom		
Top mat	Cut bigger to go 1-2cm up sides		
Available from	Mitre10, Bunnings, Para Rubber, Plastic Box <a href="http://bunnings.co.nz/search/products?q=sympanova">bunnings.co.nz/search/products?q=sympanova</a>		
DATA LOGGER			
Brand / Model	LogTag TRED30-16R		
RRP (incl gst)	\$172.50; software is free; USB interface costs \$103.50		
Position of logger	Outside of chilly bin; using Velcro dots allows for best position for reading logger		
Probe medium	In polyethylene foam block (or alternatively in a box of vaccines)		
Available from	Bell Technology		

Notes: Prices are approximate. Waeco has been bought by Dometic but the chilly bins remain the same.

## **Chilly bin packing protocol**

The packing protocol that was developed from the findings of the COOL Project is in Appendix 1.

## **2. Project criteria**

### **Purpose of project**

The Immunisation Advisory Centre (IMAC) undertook a project, on behalf of the Ministry of Health, in 2016 & 2017 to investigate, review, select and test equipment used for mobile/offsite immunisations.

### **Aims of project**

Report on:

- how School-Based Immunisation Programmes (SBIPs) are managing the cold chain
- the results of testing both current and alternative equipment and processes

Provide recommendations for:

- best practice in packing portable storage devices
- the purchase of portable storage devices
- the purchase of temperature monitoring equipment

### **Scope of project**

- Identify and select an agreed number of DHB offsite providers to be part of the review and testing
- Test an agreed range of portable storage devices for vaccine transportation
- Compare and evaluate methods of cold chain transportation between DHB/or offsite storage facility to the community vaccination programme where the vaccine is given
- Design and implement a protocol, including visual instructions, for the transportation of vaccines to non-clinical settings
- Write Standard Operating Procedures to provide to facilities and units involved in the study
- Analyse and report on data, including providing recommendations

## **3. Key principles used throughout the project**

- Do not freeze the vaccines
- Take a pragmatic approach in the choice of equipment and the development of a protocol for vaccines offsite transportation and monitoring

## 4. Activities and findings that led to the project outcomes

Three School-based Immunisation Programmes (SBIPs) collaborated on this project. These SBIPs ranged from very large to small providers and were located in different climate regions around New Zealand.

The COOL Project consisted of a series of activities, some of which were carried out concurrently or were repeated as more information came to light. The main activities are in the flow chart below:



### Surveying of providers

A survey was developed for SBIP providers to help inform the design of the equipment testing, requesting information around their equipment, processes and procedures in relation to their SBIPs.

Survey results showed that SBIPs are using:

- either iLog or LogTag data loggers
- a range of chilly bin packing methods
- a range of cooling products; mainly Envirofreeze and Chill Wrap
- a range of insulating products; mainly Sympa Nova matting but also includes shredded paper
- a wide range of chilly bin brands and sizes, but most are using Rubbermaid chilly bins dating back to at least 2005 after being purchased for the Meningococcal B school-based immunisation programme
- a range of maximum/minimum thermometers.

## Aligning COOL Project with the 2017 Standards

The *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* were reviewed to ensure the project supported criteria set out in the Standards. The criteria applicable to this project are shown below in italics with underlining added to the wording which is particularly relevant to this project. These criteria were considered and followed whenever possible when carrying out this project. Where they were not followed an explanatory footnote appears at the bottom of the page.

### 7.3 Transporting vaccines using a chilly bin:

(Page 22 of 2017 Standards)

#### General principles

- Use a more robust chilly bin for offsite clinics
- For each chilly bin, use sufficient ice packs and insulation material.
- 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

#### 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

### Appendix 3 Transporting or storing vaccines in chilly bins:

(Page 28 of 2017 Standards)

#### 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<sup>1</sup>
- 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)
- 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<sup>2</sup>

#### 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.<sup>3</sup>

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<sup>1</sup> The Chill Wrap cooling product used in the testing was frozen horizontally not vertically.

<sup>2</sup> These were not considered the best cooling product for mobile/offsite immunisations.

<sup>3</sup> This was not adhered to. It was found not to be in line with WHO documentation and will be changed in an update of 2017 Standards.<sup>4</sup> Polyethylene foam blocks were used for performance testing after being recommended by a collaborating SBIP and found to be effective in controlled set up test phase; approximate size 65x65x40mm. Same foam type as used to make pool noodles.

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.*<sup>4</sup>
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.*<sup>5</sup>
8. *Do not start travelling until the loaded chilly bin temperatures have stabilised at between +2°C and +8°C. 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.*<sup>6</sup>

## Review of overseas documentation

Packing and monitoring guidelines/standards from England, Scotland and Australia were reviewed. Publications from the World Health Organization were found to be focused more on managing the cold chain in developing countries and for transporting vaccines for longer periods than one day, and without data loggers.

## Initial selection of equipment for tests

The selection of equipment to be used in tests were in four categories:

- A chilly bin to transport and store the vaccines offsite
- A frozen cooling product to maintain the temperature of the vaccines when offsite
- An insulating product to protect the vaccines from being frozen by the cooling product
- A device to monitor and record the temperature of the vaccines while in the chilly bin

The equipment and supplies were selected for the testing according to a range of criteria including (depending on the item) price, weight, availability, history of effectiveness, acceptability and meeting the 2017 Standards. Those items selected are shown in the table below.

EQUIPMENT / SUPPLIES	BRAND / MODEL
Dataloggers	<ul style="list-style-type: none"> <li>• Logtag model TRED30-16R for chilly bin temperatures (new in 2017)</li> <li>• Logtag model TRID30-7R for room temperatures</li> </ul>
Chilly bins	<ul style="list-style-type: none"> <li>• Waeco Cool-Ice sizes 12, 22, 33 and 41 litres (new)</li> <li>• Rubbermaid Durachill 47 litres (new)</li> <li>• Rubbermaid 22 &amp; 42 litres (used)</li> <li>• Esky 12 litres (new)</li> </ul>
Cooling products	<ul style="list-style-type: none"> <li>• Chill Wrap</li> <li>• Gel packs as used by ProPharma in their vaccine deliveries</li> </ul>
Insulating matting	Sympa Nova Friedola matting
Probe medium	<ul style="list-style-type: none"> <li>• Polyethylene foam block</li> <li>• Glycol</li> <li>• Vaccine box</li> </ul>
Vaccine	Ten dose boxes of either Boostrix or Gardasil

<sup>4</sup> Polyethylene foam blocks were used for performance testing after being recommended by a collaborating SBIP and found to be effective in controlled set up test phase; approximate size 65x65x40mm. Same foam type as used to make pool noodles.

<sup>5</sup> Clips can be purchased from a hardware store and added to current chilly bins if not present.

<sup>6</sup> Ice packs were not placed round the sides of chilly bins as part of this project.

## **Field performance testing**

The three collaborating SBIPs all tested one new Rubbermaid and four new Waeco chilly bins as part of their normal vaccinating activities, using them on a total of 55 offsite trips. They provided data loggers' temperature information and both objective and subjective feedback on each of the chilly bins.

## **Set up testing**

This testing was carried out to determine a range of variables to be used in the controlled performance tests including:

- Type, volume, placement and surface temperature of cooling product
- Position and medium of data logger probe
- Impact of insulating matting
- Time and method for precooling of chilly bins
- Volume of vaccine

The 33L Waeco chilly bin was dropped from the test process after the collaborating SBIPs provided negative feedback based on their field testing.

## **Controlled performance testing**

To determine which transport containers were most effective at maintaining cold chain temperatures, the testing variable was chilly bins, with all other factors remaining as consistent as possible within a small, medium or large chilly bin size category. These factors included the packing method, placement of data logger probes, volume and types of vaccines, schedule and timings of removing and replacing vaccines into the transport containers, cooling and insulation products.

Eight chilly bins, both new and used were tested, and subjected to prolonged periods of hot and cold temperatures in order to differentiate their performance. Chill Wrap was chosen as the cooling product with the data logger probes in the chilly bins being in polyethylene foam blocks.

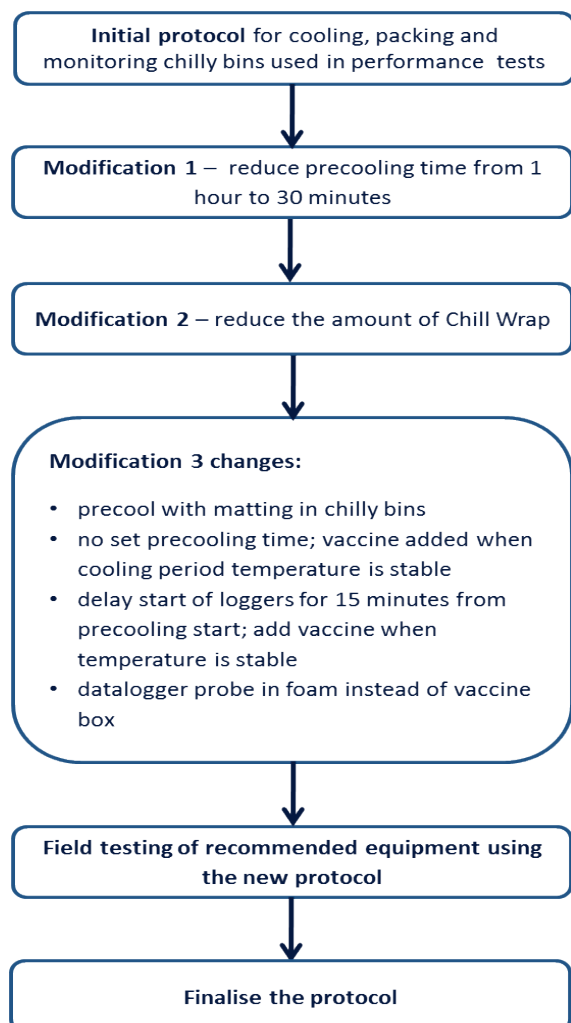
Based on historical New Zealand climate information from the National Institute of Water and Atmospheric Research, the atmospheric temperature targets for the duration of these tests were +5°C or cooler for cold testing and +25°C or hotter for hot testing. Hot temperatures were achieved by heating a small office and cold temperatures by using a small chiller truck.

A schedule of timing of openings and vaccine volumes for each size category of chilly bin was designed so as to be a realistic time frame over a day of vaccinating. No cooling product was added or removed during the tests' durations. Small chilly bins were tested with vaccine in them for 5.5 hours with six openings and medium and large chilly bins for 8.5 hours with five openings.

Three Waeco Cool-Ice chilly bins, sized 13, 22, and 41 litres, proved to be the most stable in the cold and hot temperature tests. The used Rubbermaid chilly bins performed acceptably but were less stable than the Waeco chilly bins. The three Waeco chilly bins were also tested for 30 minutes in sub-zero temperatures down to -6.5°C and maintained an average internal temperature of +4.6°C. This test was included because temperatures inside SBIPs vehicles can sometimes, in cooler regions of New Zealand, be close to zero degrees Celsius at the start of a journey associated with offsite vaccinations.

## Development of chilly bins' precooling, packing and monitoring protocol

The collaborating SBIPs provided input as to what were practical and effective methods for preparing to travel with vaccine in a chilly bin. Some of this input came from their long term general experience and some arose from field testing the new chilly bins selected for this project. The SBIPs input led to a series of protocol modifications and tests as shown in the following flowchart.

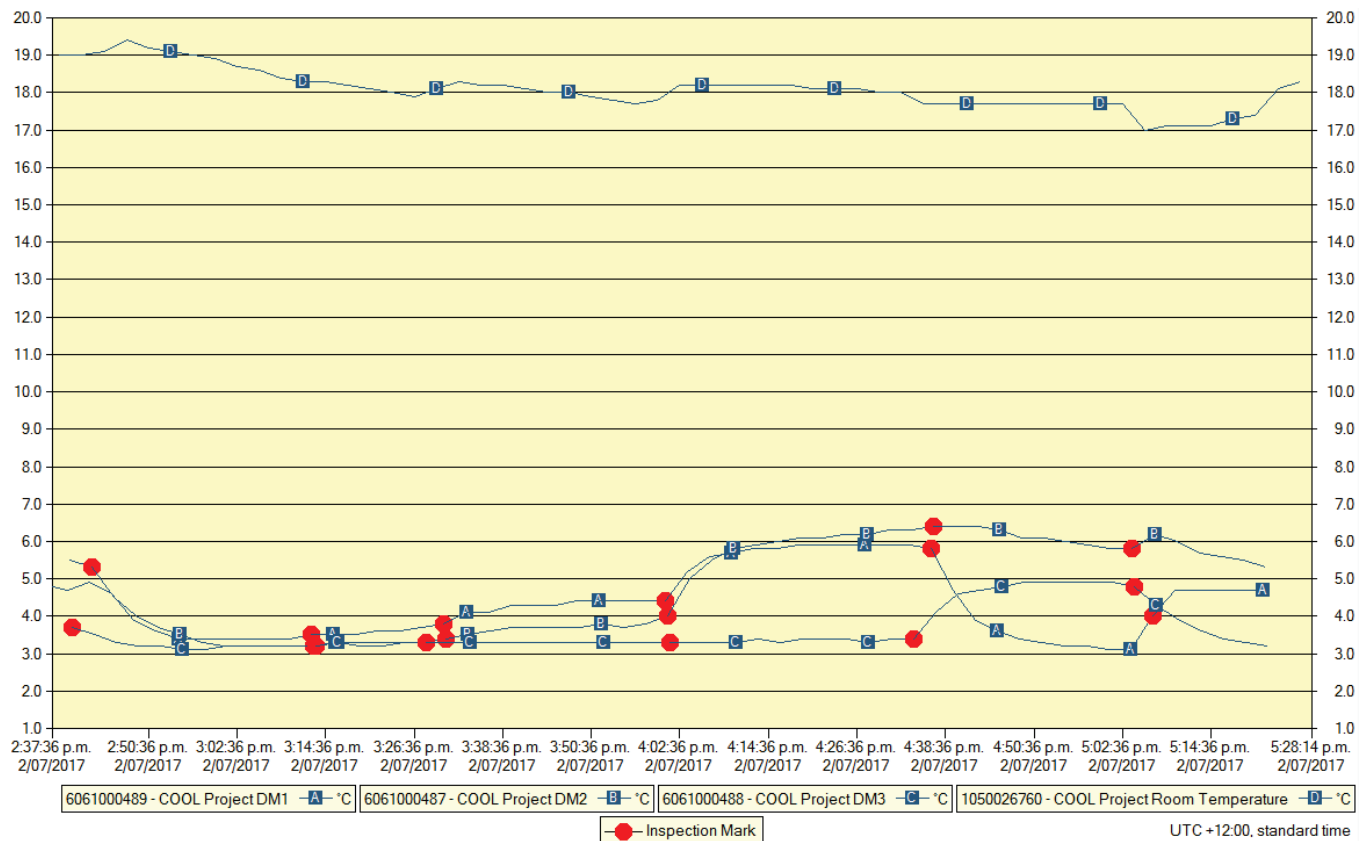


Refer to Appendix 1 for the resulting *Chilly bin packing protocol for offsite immunisations*.

The final revised protocol was tested at IMAC using 10 dose boxes of expired Boostrix vaccine in the three most stable (Waeco) chilly bins simultaneously – 40 doses of vaccine in 13L chilly bin, 80 doses in 22L chilly bin and 140 doses in 41L chilly bin. The data loggers were set to alarm below +2°C and above +8°C.

Vaccines were added or removed from all three chilly bins within a five minute period each time the chilly bins were opened. Openings occurred at five time points during the 2.5 hour protocol test period and vaccines were added or removed.

The chilly bin temperatures remained between +3°C and +6.5°C for the 2.5 hour duration test without adding or removing any Chill Wrap. This is illustrated in the following graph of the four data loggers' temperatures.



Key: A is the 13L chilly bin, B is the 22L chilly bin, C is the 41L chilly bin and D is room temperature.

The protocol was also tested by two of the collaborating SBIPs and was found to be acceptable.



## Appendix 1: Chilly bin packing protocol for offsite immunisations

### Purpose of this protocol

This protocol details best practice guidelines arising from the products tested as part of the COOL Project. Providers using alternative packing methods and equipment can continue to do so provided that the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* (the 2017 Standards) are adhered to.

It is important to note that following these recommendations does not remove the onus on the immunisation provider to trial their equipment and be able to show that they can maintain the temperatures between +2°C and +8°C at all times.

### Recommendations relating to the data logger probe

- Have data logger alarms set at +2°C (low alarm point) and +8°C (high alarm point).
- Place logger probe either in a block of polyethylene foam approximately 60x60x40mm, with the metal part of the probe in the foam, OR in a box of vaccines.
- Monitor the temperature in the middle of, and ideally at the same level, as the top of the boxes of vaccine closest to the Chill Wrap in the chilly bin.

### Precooling the chilly bin before adding vaccine

The initial amount of cooling required is dependent on the size of the chilly bin.

CHILLY BIN SIZE	FROZEN CHILL WRAP REQUIRED of 3 cell x 4 cell sheets
Large chilly bin 41L	6 (3 sheets for precooling & 3 for maintaining temperature in chilly bin)
Medium chilly bin 22L	4 (2 sheets for precooling & 2 for maintaining temperature in chilly bin)
Small chilly bin 13L	2 (1 piece for precooling & 1 for maintaining temperature in chilly bin)

Note: in hotter weather an extra piece of 3x4 Chill Wrap may be needed for precooling only, to reduce the chilly bin temperature to an acceptable temperature within 30 minutes. An alternative in hot weather is to leave the frozen Chill Wrap in the chilly bin during night before packing.

### Steps for precooling the chilly bin

1. Remove the required amount, according to the table above, of Chill Wrap from the freezer.
2. Place half the amount of Chill Wrap on paper towels on a bench or desk to condition it.



3. Place the bottom insulation matting in the empty chilly bin.
4. Place the probe (in the foam block if one is being used) lying on its side on the middle of the insulation matting.



5. Place the top insulation matting in the chilly bin covering the probe and the bottom insulation matting.
6. Place the remaining sheets of Chill Wrap (those that aren't conditioning) in the chilly bin on top of the insulation matting and close the chilly bin.
7. Start the data logger (with a 15 minute start delay to avoid initial over temperature alarms).
8. After 15 minutes, review, document and begin to monitor the temperature in the chilly bin.
9. Once the temperature is below +5°C assess the stability of the temperature. When the temperature changes less than +0.5°C between 3 - 5 minute readings it can be considered stable enough to add the vaccine.
10. When the temperature has stabilised open the chilly bin and remove the Chill Wrap, the top insulation matting and the probe and pack the vaccine you will be transporting into the chilly bin.

## Packing the chilly bin with vaccine

Note: for all three sizes of chilly bin, this packing method uses insulation matting above and below the vaccines, and Chill Wrap above the vaccines only. Refer to page 12 *Recommended maximum vaccine volumes in chilly bins* for information on vaccine capacities of chilly bins.

1. Add the boxes of vaccine that are being taken out for the day in the precooled chilly bin. The boxes of vaccine can be packed in any orientation and in multiple layers, leaving space in the middle for data logger. Complete the relevant paperwork, for example chilly bin vaccine log and vaccine fridge register. Take a hard copy of this document, or an equivalent, every time vaccine is transported away from base:

[Initial steps in a cold chain breach, IMAC fact sheet, October 2017](#)

2. Place the data logger probe (still in the foam block, if used) in between two boxes in the middle, ideally with the top of the foam level or just below the top of the boxes of vaccine. The foam should be arranged so that the probe tip is pointing towards the top insulation matting and Chill Wrap. If foam is not used place the probe into a box of vaccine which is in the middle top position of the boxes of vaccine.



3. Cover the boxes of vaccine and the probe with the insulation matting and the Chill Wrap that has been conditioning for at least 15 minutes.



*13L packed chilly bin*



*22L packed chilly bin*



*41L packed chilly bin*

4. Close the chilly bin and clip the latches.
5. Place the Chill Wrap that was used for precooling in another chilly bin to take out for the day for use as additional cooling if required.

## Monitoring the chilly bin temperature when it contains vaccine

1. Monitor the chilly bin temperature. When the temperature has stabilised, the chilly bin is ready to travel. If you need to leave your base before the chilly bin temperature is stable you must continue to monitor the temperature every 3-5 minutes until it is stable (and document this). Remember to take out another chilly bin containing additional Chill Wrap in case more is needed later in the day.
2. Continue to monitor and document the chilly bin maximum, minimum and current temperatures as shown on the data logger at least every 30 minutes and any time vaccine is being removed or added throughout the time vaccine is in the chilly bin. Remove Chill Wrap if the temperature is noted to be +3°C or lower, OR any time the audible low temperature alarm is triggered. You must continue to monitor the temperature every 3-5 minutes until it is stable (and document this). If the temperature continues to drop remove all Chill Wrap and leave the chilly bin open until the temperature has stopped dropping and has increased to +3°C or higher (but below +7°C).
3. Add Chill Wrap, from your 'additional cooling' chilly bin, if the temperature is noted to be +7°C or higher, OR any time the audible high temperature alarm is triggered. You must continue to monitor the temperature every 3-5 minutes until it is stable (and document this).
4. Closely monitor the chilly bin temperature after Chill Wrap is either added or removed, i.e. more frequently than every 20 minutes as the temperature can go out of range quite quickly.
5. When the temperature has stabilised revert back to checking the data logger at least every 30 minutes.
6. For any temperatures outside of +2°C and +8°C range follow the guidance provided in this document:

[Initial steps in a cold chain breach, IMAC fact sheet, October 2017](#)

## Unpacking the chilly bin after returning to base

1. On return to base check the data logger for the final time and document the maximum, minimum and current temperatures.
2. Download the data logger and review the temperature readings.
3. For any temperature breaches which have not been noticed and/or resolved earlier in the day follow the guidance provided in this document: [Initial steps in a cold chain breach, IMAC fact sheet, October 2017](#)



4. Open the chilly bin, remove the boxes containing unused vaccines and return them to the vaccine fridge. If any of these vaccines have been subject to a cold chain breach note the date and duration of the breach on the vaccine box before placing in the fridge. These boxes of vaccine will need to be placed in quarantine and your Immunisation Coordinator will need to be informed immediately.
5. Complete any required documentation.
6. Return the Chill Wrap to the freezer and do not reuse for at least 24 hours.
7. Spray and wipe out the chilly bin and insulation matting as required by your organisation's infection control policies and/or procedures.

## Recommended maximum vaccine volumes in chilly bins

Vaccine boxes can be oriented in any direction when packed and placed in more than one layer. Before packing in several layers, consider packing in one layer with the boxes on the ends, such as in the first photo below. This will result in each box being approximately the same distance from the Chill Wrap above it. However, this is not always possible and is not a requirement.

The photos below show the maximum amount of Boostrix and/or Gardasil which can be packed in the recommended chilly bins.

### Waeco 13L chilly bin



*Boostrix only = 12 boxes*



*Gardasil only = 5 boxes*



*equal Boostrix & Gardasil = 4 boxes of each*

### Waeco 22L chilly bin



*Boostrix only = 24 boxes*



*Gardasil only = 9 boxes*



*equal Boostrix & Gardasil = 6 boxes of each*

### Waeco 41L chilly bin



*Boostrix only = 43 boxes*



*Gardasil = 18 boxes*



*equal Boostrix & Gardasil = 14 boxes of each*

Note: gap in 41L chilly bin photo is because not enough boxes of vaccine were available to fill the gap.