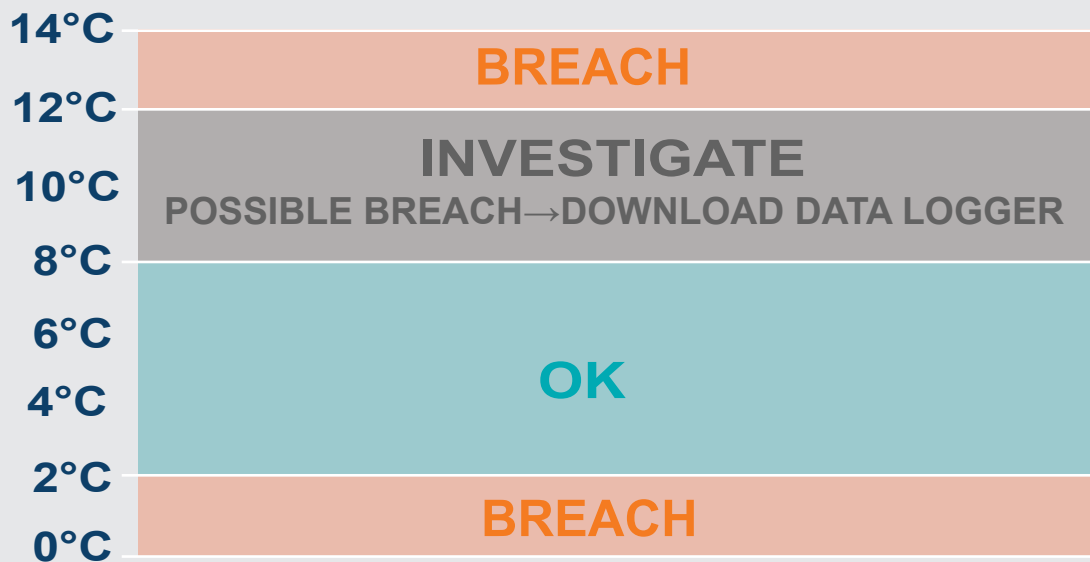


# COLD CHAIN BREACH

## WHAT ACTION SHOULD YOU TAKE?

### IS IT A COLD CHAIN BREACH?



#### < 2°C for any length of time



Contact PHU\*. Alert staff and put sign on fridge: **“Do not use or discard vaccines.”**

#### Between 8°C and 12°C for less than 15 minutes

No action required



#### Between 8°C and 12°C for more than 15 minutes

Contact PHU\*. Alert staff and put sign on the fridge: **“Do not use or discard vaccines.”**



#### >12°C for any length of time

Contact PHU\*. Alert staff and put sign on the fridge: **“Do not use or discard vaccines.”**



# COLD CHAIN BREACH



## Why report a cold chain breach?

Vaccines can become less effective or even destroyed if they are exposed to temperatures outside the recommended range of 2°C to 8°C. The loss of vaccine effectiveness is cumulative and cannot be reversed.

All cold chain breaches involving **government funded** vaccines **must be reported** to the Public Health Unit (PHU). Immunisation providers have a duty of care to ensure that all clients receive potent and effective vaccines and are protected from vaccine preventable diseases.

Prompt identification and reporting of a possible cold chain breach will prevent:

### Health Professional

- Loss of community confidence and credibility of profession
- Patient requires recall and re-vaccination – inconvenient and costly
- Potential legal liability

### Patient

- Remains susceptible to disease
- Requires recall and re-vaccination – inconvenient and costly
- Increase risk of experiencing adverse reaction

### Vaccine

- Freezing of vaccines can cause loss of potency which can never be restored.
- Cumulative effect on vaccine viability if exposed to heat.

### Cost Consideration

- Vaccines are expensive and in short supply
- Cost of revaccination – time spent recalling and revaccinating patients

## Public Health Unit:

The Public Health Unit (PHU) will advise which vaccines are still viable – “retain and label”, and which vaccines to discard. This will avoid administration of non-potent vaccines to patients.

Public Health Unit NSW local directory: 1300 066 055

## What is a Cold Chain Breach?

The **cold chain** refers to the transport and storage of vaccines within the recommended safe temperature range between 2°C to 8°C.

A **cold chain breach** is when vaccine storage temperatures have been outside the recommended range of +2°C and +8°C.

This does not include temperature deviations or excursions up to +12°C lasting no longer than 15 minutes when stocktaking or restocking.



## Vaccine potency following cold chain breach

Vaccines are delicate biological substances that can become less effective or destroyed if they are frozen, allowed to get too hot and/or exposed to direct sunlight or fluorescent light.

### Freezing

Temperatures below +2°C or freezing of vaccine is the **most common** reason for vaccine damage and loss in Australia. For vaccines that are cold or freeze-sensitive, the loss of potency following freezing is **immediate** and these vaccines must not be administered until advice by the Public Health Unit.

In all instances where vaccines are **exposed to temperatures below +2°C**, immunisation providers are required to take the following steps:

1. Isolate vaccines
2. Label: "do not use, do not discard"
3. Keep vaccines refrigerated between +2° to +8°C
4. Contact the PHU for advice on vaccine efficacy

Freezing is a **greater danger** to vaccine efficacy than mild heat exposure.

### Heat

Heat impact on vaccines is cumulative, therefore, vaccines exposed to temperature ranges over +8°C will, in some instances, still be able to be administered but may have a shortened shelf life as a result of the heat exposure.

When vaccines are exposed to repeated episodes of heat, the loss of vaccine potency is cumulative and cannot be reversed.

In all instances where vaccines are **exposed to temperatures above +8°C** (excluding temperature deviations up to +12°C lasting no longer than 15 minutes) immunisation providers are required to take the following steps:

1. Isolate vaccines
2. Label: "do not use, do not discard"
3. Keep vaccines refrigerated between +2° to +8°C
4. Contact the PHU for advice on vaccine efficacy

### Further Information

- [National Vaccine Storage Guidelines - Strive for 5](#)
- HETI Vaccine Storage and Cold Chain Management training module available at [http://www.health.nsw.gov.au/immunisation/coldchain/story\\_flash.html](http://www.health.nsw.gov.au/immunisation/coldchain/story_flash.html)

Contact Central and Eastern Sydney PHN if you require training or further information about cold chain management:

#### **CESPHN Immunisation Support**

1300 986 991

[immunisation@cesphn.com.au](mailto:immunisation@cesphn.com.au)

<https://www.cesphn.org.au/programs/immunisation>

# ATTENTION!

## ISOLATED VACCINES

**1. DO NOT** use vaccines



**2. DO NOT** discard vaccines



**3. Await** instructions from your Public Health Unit

*For privately purchased vaccines (i.e. non NIP), contact manufacturer.*

# INFORMATION SHEET



## Power Failure Action Plan

### Alternative storage during a power failure

Each immunisation facility should have a back-up plan and alternative vaccine storage if a power failure or fridge failure occurs, such as:

- Back-up power supply e.g. Generator or battery/solar back up
- Cooler or esky (enough to fit all vaccines)

Keep in mind there may only be 20–30 minutes before the vaccine refrigerator temperature rises above +8°C when there is a power failure so alternative storage must be ready quickly.

### What to do when power goes off (if using cooler box/esky)

1. Immediately isolate the vaccines, keep refrigerated between +2°C to +8°C and put a sign on the refrigerator stating 'Power out. Do not use vaccines. Keep refrigerator door closed.'
2. Cover the glass door with insulating material (cardboard, bubble wrap or a blanket) and place ice bricks in empty spaces, taking care not to place them alongside vaccines, and keep the door closed.
3. Closely monitor the refrigerator temperature – if the inbuilt min/max thermometer is not working, use a battery powered min/max thermometer. If the temperature rises to +8°C, move vaccines to a prepared cooler boxes or eskies.

### Preparing your cooler box or esky

1. Place **one layer** of ice/gel packs at bottom of the esky (do not condition\* ice/gel packs in time sensitive cases such as power failure)
2. Place **two layers** of insulating material (i.e. bubble wrap) on top of ice/gel packs (ensure vaccine stock is **not in direct contact** with ice/gel packs)
3. Place vaccines on top of insulating material
4. Place the probe of min/max battery-operated thermometer inside a vaccine box in the centre of the vaccine stock
5. If practical, move data logger to esky
6. Place two layers of insulating material on top of vaccines
7. Place one layer of ice/gel packs on top of insulating material and seal the lid of the esky
8. Place min/max battery-operated thermometer on top of the cooler and monitor the temperature on the NSW Health "[Vaccine Cooler Temperature Chart](#)":
  - i. Monitor every 5 minutes for the first 30 minutes
  - ii. Monitor every 15 minutes for the second 30 minutes
  - iii. Monitor hourly thereafter (provided the temperatures are stable)

**Remember to reset the thermometer after each reading**

\*Condition – see [National Vaccine Storage Guidelines – Strive for 5](#) Section 9.2 - Freezing and conditioning ice packs and gel packs (page 33)

### When power is returned

1. Record the refrigerator min/max temperature then **reset** the thermometer
2. Ensure the refrigerator temperature has returned to between +2°C and +8°C before returning vaccines to the refrigerator
3. Download and analyse data logger information to assess for cold chain breach

### Reporting a cold chain breach

If a cold chain breach has occurred, report it to Public Health Unit (PHU) immediately on 1300 066 055. Isolate vaccines **do not use or discard vaccines** until advice is received from the PHU.

## What is a cold chain breach?

A 'cold chain breach' has occurred if vaccine storage temperatures have been outside the recommended range of +2°C to +8°C. It excludes fluctuations up to +12°C, lasting no longer than 15 minutes. When vaccines are repeatedly exposed to temperatures outside the +2°C to +8°C range, the loss of potency is cumulative and cannot be reversed.

## Responsibilities of safe vaccine storage and management

How often	Action required
Twice daily	<ul style="list-style-type: none"><li>Record current, minimum and maximum temperature of vaccine refrigerator on chart</li><li>Record in the morning and in the evening, at opening and closing of practice</li><li>Reset thermometer after each reading</li><li>Check that temperatures have remained between the +2°C to +8°C range</li><li>This must be done every day the practice is open, including weekends</li></ul>
Once a week	<ul style="list-style-type: none"><li>Download and review data logger</li><li>Download data, save to computer, and review data</li><li>Check that temperatures have remained between the +2°C to +8°C range</li></ul>
Annually	<ul style="list-style-type: none"><li>Service vaccine refrigerator– contact manufacturer</li><li>Calibrate thermometers/data loggers and change batteries</li><li>Perform <a href="#">vaccine storage self-audit</a> (<i>Appendix 2 of National Vaccine Storage Guidelines - Strive for 5</i>).</li></ul>
If breach identified	<ul style="list-style-type: none"><li>Report temperatures outside the +2°C to +8°C range to your Public Health Unit.</li><li>Do not use or discard vaccines until advice is received from the Public Health Unit.</li></ul>

## Further information

- [National Vaccine Storage Guidelines - Strive for 5](#)
- HETI Vaccine Storage and Cold Chain Management training module available at [http://www.health.nsw.gov.au/immunisation/coldchain/story\\_flash.html](http://www.health.nsw.gov.au/immunisation/coldchain/story_flash.html)
- Contact Central and Eastern Sydney PHN if you require training or further information about cold chain management:

**Public Health Unit:** 1300 066 055

**CESPHN Immunisation Support:** 1300 986 991

[immunisation@cesphn.com](mailto:immunisation@cesphn.com)

<https://www.cesphn.org.au/general-practice/help-my-patients-with/immunisation>



# Managing a Cold Chain Breach

Check and record vaccine fridge temperatures twice daily

If temperatures have gone below 2°C OR above 8°C

ISOLATE  
VACCINES

AND

ALERT &  
DO NOT USE

AND

DO NOT  
DISCARD

Ensure vaccines can continue to be stored between +2°C to +8°C.  
Vaccines may need to be transferred to an alternative monitored fridge or cooler

\*Record temperatures on the NSW Health Vaccine Cooler  
Temperature Chart available at [www.health.nsw.gov.au/manage-ccb](http://www.health.nsw.gov.au/manage-ccb)

DOWNLOAD DATA LOGGER  
AND INVESTIGATE

- Investigate cause
- Download and review data logger readings
- Review twice daily min/max temperature chart
- Identify if vaccines have been affected by a previous breach

Temperature above +8°C to less than +12°C for less than 15 minutes?

NO

YES

REPORT

Record temperatures  
Reset min/max thermometer  
Wait until fridge is within +2°C to +8°C  
No further action required

Government funded vaccines

Private vaccines/medications

Report to the Public Health Unit (PHU)  
**Business hours:** 1300 066 055  
**After hours:** Isolate vaccines & contact PHU  
next business day

For privately purchased vaccines and  
medications, contact the manufacturer for  
advice

Complete and return the \*Cold Chain Breach  
Reporting Form to the PHU and await advice

Download the CCB form at  
[www.health.nsw.gov.au/ccb](http://www.health.nsw.gov.au/ccb)

For more information visit [www.health.nsw.gov.au/manage-ccb](http://www.health.nsw.gov.au/manage-ccb)

**COLD CHAIN BREACH REPORTING FORM**  
 Sections marked with an \* are mandatory



**\*SECTION 1: IMMUNISATION PROVIDER DETAILS**

<b>Facility Name</b>	<b>Vaccine Account Number</b>
<b>Address</b>	<b>Phone</b>
<b>Number of GPs in the practice</b>	<b>Person Reporting the breach</b>
<b>Email</b>	

**\*SECTION 2: DETAILS OF COLD CHAIN BREACH (CCB)**

<b>1. Type of refrigerator</b>	<input type="checkbox"/> Vaccine Specific refrigerator <input type="checkbox"/> Domestic refrigerator	
<b>2. Date of cold chain breach</b>		
<b>3. Date CCB identified</b>		
<b>4. Select the reason for the CCB</b>	<input type="checkbox"/> Refrigerator malfunction <input type="checkbox"/> Power outage <input type="checkbox"/> planned <input type="checkbox"/> unplanned <input type="checkbox"/> Human error <input type="checkbox"/> Unknown/other	
<b>5. Additional information about the CCB</b>		
<b>6. Data logger temperature</b>	<b>Min</b>	<b>Max</b>
<b>7. Duration outside 2° C to 8° C (hrs/mins)</b>		
<b>8. Is this the first CCB for these vaccines?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No, what is the date of the previous CCB?	
<b>9. Was anyone vaccinated with potentially affected vaccines?</b>	<input type="checkbox"/> Yes (Public Health Unit to provide advice) <input type="checkbox"/> No	
<b>10. Select current vaccine management policies and procedures in place</b>	<input type="checkbox"/> Vaccine management protocol ( <i>refer to 'Strive for 5' Guidelines</i> ) <input type="checkbox"/> Accessible Cold Chain Breach Protocol <input type="checkbox"/> Completion of the <a href="#">NSW Health Cold Chain Training Module</a> by all staff <input type="checkbox"/> Annual vaccine storage self-audits Date of last audit:	



**COLD CHAIN BREACH REPORTING FORM**  
 Sections marked with an \* are mandatory



**SECTION 3: FRIDGE AND COLD CHAIN MONITORING DETAILS**

Section 3 must be completed if there has been a refrigerator malfunction or the cause of the cold chain breach is unknown

**3.1 Refrigerator details**

Date of refrigerator purchase	
Date of last refrigerator service	

**3.2 Data logger details**

Type of data logger	<input type="checkbox"/> Inbuilt <input type="checkbox"/> Portable
Date of purchase	
Date of last battery change	
Date of last calibration/ service	

**3.3 Minimum/maximum thermometer details**

Type of min/max thermometer	<input type="checkbox"/> Inbuilt <input type="checkbox"/> Battery operated
Date of purchase	
Date of last battery change	
Date of last accuracy check i.e. ice slurry	

**3.4 Alternative vaccine storage details**

Is there an alternative fridge for vaccine storage?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Type of alternative fridge used for back up vaccine storage	<input type="checkbox"/> Vaccine specific refrigerator <input type="checkbox"/> Domestic refrigerator

# COLD CHAIN BREACH REPORTING FORM

Sections marked with an \* are mandatory



## \*SECTION 4: VACCINE DETAILS

Enter the number of doses of each vaccine brand on hand at the time of the cold chain breach  
**Vaccines exposed to a second breach should be recorded as follows:**  
**Total number of doses exposed to first breach (total number of doses exposed to second breach), example:**

Vaccine	*Doses	PHU advice	Vaccine	*Doses	PHU advice
MMRII	5 (5)	Retain 5 (Discard 5)	Infanrix	13 (2)	Retain 13 (Discard 2)

Vaccine	*Doses	PHU advice	Vaccine	*Doses	PHU advice
Act-HIB			IPOL		
Adacel			Menactra		
Afluria Quad			Menitorix		
Boostrix			MMR II		
Boostrix IPV			Neis-Vac C		
Energix B (adult)			Nimenrix		
Energix B (paed)			Pneumovax 23		
Fluad			Prevenar 13		
Fluarix Tetra			Priorix		
Fluquadri			Priorix Tetra (MMRV)		
Fluquadri Jnr			Proquad		
Fluzone			Quadracel		
Gardasil			Rabies		
Gardasil 9			Rotarix		
Havrix 1440			Tripacel		
Hep B VaxII - adult			Vaqta Paed		
Hep B VaxII - paed			Varilrix		
Infanrix – Hexa			Varivax		
Infanrix IPV			Zostavax		
Infanrix DTPa					
<b>Additional advice</b>					

**Vaccines that can be retained, should be clearly labelled. Any further cold chain breaches should be reported to your local public health unit as each breach is assessed on a case by case basis.**

**COLD CHAIN BREACH REPORTING FORM**  
Sections marked with an \* are mandatory



**Attachments required**

All providers are required to provide the following items on the checklist

- Data logging for the duration of the cold chain breach (graph and temp log required)
- Vaccine refrigerator min/max temperature chart
- Min/max temperature chart used during transfer of vaccines e.g. esky (if applicable)
- Last refrigerator service report (required if there has been a fridge malfunction)

**Public Health Unit Use Only**

PHU Contact person:

Action(s) taken:

Vaccines Quarantined:  Yes  No

Fridge service requested:  Yes  No

Service report received:  Yes  No

HETI module recommended:  Yes  No

Certificates received:  Yes  No

Stop placed on vaccine account:  Yes - Date:  No

Comments:

This form should be completed and returned to your local public health unit in the event of a cold chain breach. Your local public health unit will provide advice on cold chain management and vaccine disposal.

Please email or fax this form to your local public health unit. You can contact your local public health unit on 1300 066 055.

## VACCINE COOLER TEMPERATURE CHART

**Facility name:**
**Vaccine Account Number:**

**MAINTAIN TEMPERATURE RANGE: +2°C to +8°C and Strive for 5°C**  
**If the cooler temperature is outside +2°C to +8°C please contact your local public health unit on 1300 066 055 for further advice**

 If the ice packs **HAVE** been \*conditioned and the cooler has been pre-chilled

 If the ice packs have **NOT** been \*conditioned and the cooler has **NOT** been pre-chilled

Monitor and record the temperature every 15 minutes for the first hour, then hourly (provided temperatures are stable) using a battery operated minimum/maximum or data logger and reset the thermometer after each reading for accuracy

Monitor the cooler every 5 minutes for the first 30 mins then every 15 minutes for the second 30 mins then hourly (provided the temperatures are stable) using a battery operated minimum/maximum or data logger and reset the thermometer after each reading for accuracy

**DATE:**

TIME	COOLER 1			COOLER 2			COOLER 3			COMMENT/ACTION	SIGNATURE
	Current	Min	Max	Current	Min	Max	Current	Min	Max		
ANY COLD CHAIN BREACHES IDENTIFIED			Y / N	ANY ACTION REQUIRED			Y / N	DATE:			SIGNATURE:

# COLD CHAIN BREACH



## Cold Chain Breach Labels

Vaccines subject to cold chain breaches that are assessed by your local public health unit as **safe and effective to administer** within their expiry date will need to be identified with a label:



Labels should be dated with the **date of the breach** and placed on the vaccine box. The label should not conceal the name of the vaccine and expiry date.

Any future cold chain breaches must be reported to your local public health unit as each one is assessed on a case by case basis.

### Where to order more Cold Chain Breach Labels

Additional labels can be ordered from the Better Health Centre on (02) 9887 5450.

### Contacting your Public Health Unit

Public Health Unit (PHU): 1300 066 055

### Further information:

[Cold Chain Breach Protocol](#) – NSW Health

[Vaccine storage and cold chain management](#) – NSW Health