

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

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

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