

# Protocols for Cold Chain Failure

## What is the Cold Chain?

The cold chain refers to the system of storing and transporting vaccines within the recommended safe temperature range of between 2°C to 8°C. *Immunisation service providers should maintain vaccine refrigerators as close as possible to 5°C, as this gives a safety margin of + or – 3°C.*

Maintaining the cold chain is an essential part of providing effective immunisation services to patients within your practice, as vaccines can become less effective or even destroyed if they are frozen or allowed to get too hot. The loss of vaccine effectiveness is cumulative and cannot be reversed. It is therefore very important for good patient care that your practice has a system of daily monitoring the vaccine refrigerator temperature to ensure that vaccines are maintained within the safe temperature range. It is also important that your practice has procedures of what to do if there has been a break in the cold chain.

## What is a break in the Cold Chain (Cold Chain Failure)?

Cold chain failure or a breach in the cold chain occurs when vaccines are exposed to temperatures outside the recommended range of 2°C – 8°C. This DOES NOT include deviations of up to 12°C for less than 15 minutes when restocking the fridge.

## Effects of Cold Chain Failure

Administering a vaccine that is inactive or has lost its effectiveness as a result of a cold chain failure could mean:

- The patient remains susceptible to disease,
- Wasted time, effort and money,
- Cost of revaccinating, and even
- The potential for legal liability.

## Effectiveness of Vaccines at Different Temperatures and Conditions

The vaccines *more* sensitive to cold, heat or light are:

### **DO NOT FREEZE\***

DTP containing vaccines  
Hib (except PRP-T vaccine)  
Hep B  
Hep A  
Influenza  
Pneumococcal  
Meningococcal C  
Japanese encephalitis  
All reconstituted vaccines  
All combinations of these  
Vaccine diluents

### **UNSTABLE AT ROOM TEMPERATURE**

MMR  
Varicella-Zoster  
Yellow Fever  
BCG  
All reconstituted vaccines

### **DO NOT EXPOSE TO LIGHT**

Reconstituted MMR  
Monovalent Rubella  
Varicella-Zoster  
Meningococcal C Conjugate  
Most DTPa containing vaccines  
Yellow fever  
BCG

\* These vaccines should be discarded if exposed to temperatures of 0°C or below.

In Australia freezing has been shown to be the major cause of vaccine damage.<sup>1</sup>

Some vaccines are sensitive to light, and should be protected from exposure to sunlight or fluorescent (neon) light. Often these vaccines are supplied in vials made from dark brown glass, which gives them some protection against light damage, but care must still be taken to keep them

covered and protected from strong light at all times. It is therefore recommended to keep vaccines in their packaging until use to help protect them against unnecessary light exposure.

### When can a break in the cold chain occur?

#### ➤ *During Transportation to Your Surgery:*

When vaccines are delivered to your surgery always check the Cold Chain Monitors (CCMs) that are placed with the vaccines. Cold Chain Monitors are both heat and freeze monitors and accompany all vaccines during transport. CCMs are attached to an index card with instructions, and they will indicate whether the vaccines have been exposed to temperatures below 0°C or above 8°C.

If vaccines arrive and the CCMs indicate they have been exposed to temperatures outside the safe range, contact the NSW Public Health Unit on Ph: 1300 066 055, to discuss what action should be taken. Isolate the vaccines in the refrigerator. Do not use these vaccines.

#### ➤ *During Storage in Your Vaccine Refrigerator:*

The temperature within your vaccine refrigerator may go outside the safe temperature range for vaccine storage because of a number of reasons:

- Vaccine refrigerator is operating at a temperature that is too cold → below 2°C
- Vaccine refrigerator is operating at a temperature that is too warm → above 8°C
- Refrigerator door left open
- Power to the refrigerator was turned off or unplugged
- Power failure

#### **POWER FAILURES**

##### *Domestic Refrigerator:*

- During a power failure of **4 hours or less**, keep the refrigerator door closed.
- If the power failure continues for **more than 4 hours**, store vaccines in an insulated container (cooler) with conditioned ice packs/gel packs to keep them cool. (Note: the vaccines must NOT be in direct contact with the ice packs as they may freeze).

##### *Purpose-Built Vaccine Refrigerator:*

- Monitor the temperature of your refrigerator. If vaccines are at risk use alternate storage arrangements (some refrigerators may not hold the temperature very long).

### What to do if there has been a Cold Chain Failure

⊗ **If vaccines are exposed to temperatures outside the safe temperature range of 2°C – 8°C** (this DOES NOT include deviations of up to 12°C for less than 15 mins when restocking):

- Isolate the vaccines in the refrigerator to prevent further use (e.g. sign on fridge door) and do not use them until advised otherwise
- Contact the NSW Public Health Unit on 1300 066 055 as soon as possible for advice
- Immediately inform the person within the practice who is responsible for vaccine storage
- If necessary, adjust the thermostat within the refrigerator to a more appropriate temperature setting (warmer or cooler depending on the temperature reading, the ideal operating temperature is 5°C)
- Recheck the temperature regularly (e.g. hourly to begin with) to make sure the temperature is being maintained within the correct range
- Do not discard any vaccine unless directed to do so by the Public Health Unit

- Do not place new vaccines into the refrigerator until the temperature is operating within the safe range

### **The NSW Public Health Unit: Ph:1300 066 055**

If your practice contacts the NSW Public Health Unit with concerns about vaccines being exposed to temperatures outside the recommended range, the Immunisation Coordinator will ask you a number of questions to determine whether the vaccines need to be discarded. If the Public Health Unit determines the refrigerator was operating at temperatures that were not safe, you will be advised to make alterations to the temperature.

Vaccines should only be re-ordered once the refrigerator is maintaining the appropriate temperature. Vaccines should not be discarded until the new stocks arrive because the refrigerator runs at a colder temperature when empty and new vaccines put into an empty refrigerator are then at risk of freezing. Once the refrigerator temperature is acceptable, and the new vaccines arrive, discard the vaccines affected by the cold chain failure into your sharps container. The Public Health Unit will then need to complete a vaccine wastage form with you.

#### **Acknowledgments:**

1. *National Vaccine Storage Guidelines, Strive for 5*, (2005) Commonwealth Department of Health and Ageing
2. *KISS Guide to Vaccine Management*, GP NSW
3. *Safe vaccine handling, cold chain and immunizations*, (1998) World Health Organisation, Geneva.
4. Rixon, Gay. *Vaccine Cold Chain Presentation* (2003) NSW Department of Health.