

Guidelines for the Storage and Handling of Vaccines

For Physicians, Hospitals,
and Long-Term Care Homes

Perth District Health Unit



Adapted with permission from the Brant County Health Unit

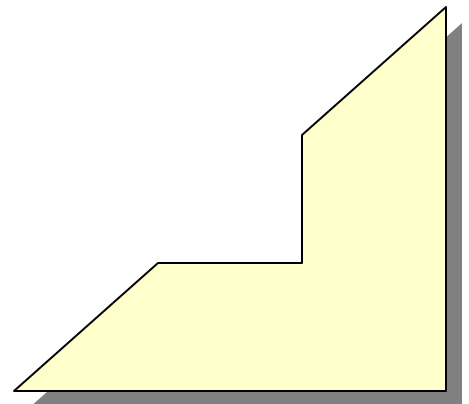


Table of Contents

Why Do Vaccines Need to Be Stored at 2-8°C?	2
When Do You Record Temperatures?	2
What Do You Do When Temperatures Go Out of the 2-8°C Range?	2
What Happens if the Fridge Temperature Rises Above 8°C Briefly?	3
What is the Difference Between an Exposure and a Failure?	3
Troubleshooting A Fridge that Has Trouble Maintaining Temperatures	4
Other Rules for the Storage and Handling of Vaccines	4
How to Read a Min/Max Thermometer	5
Vaccine Utilization.....	5
Other	5
References.....	6
Appendix One: Log Sheet Examples	7
Checklist for Safe Vaccine Storage and Handling	9

Why Do Vaccines Need to Be Stored at 2-8°C?

All vaccines are sensitive biological substances that lose their potency over time. However, loss of potency can be accelerated when vaccines are exposed to extremes in temperature, specifically outside of the 2-8°C range.

Vaccine which are not stored in this temperature range risk losing potency and may produce an unsatisfactory immune response incapable of protecting the individual from infection. This criteria has been accepted worldwide by the World Health Organization, Health Canada and the Ontario Ministry of Health and Long-Term Care.

Vaccines commonly contain adjuvants, which enhance immune response. If temperatures fall below 2°C adjuvants such as aluminum can be precipitated from the vaccine. This means that the aluminum component will no longer be able to aid in producing an adequate immune response.

If temperatures go above 8°C there is evidence that those vaccines which contain protein could be inactivated. Again this could result in an inadequate immune response.

When Do You Record Temperatures?

All facilities storing vaccine must record fridge temperatures twice daily according to the Ontario Ministry of Health Guidelines. These temperatures must be documented in a log book along with the date and time of the reading. If there are multiple people who check fridge temperatures in your facility then initials should also accompany the temperature reading.

If your office is only open for a half day it is still necessary to check fridge temperatures twice, upon arrival and departure from office. It is understandable that over the weekend or days when the office is closed the temperatures will not be checked. Please indicate the office was closed in your log.

What Do You Do When Temperatures Go Out of the 2-8°C Range?

If the fridge temperature has gone out of the 2-8°C range then you must call the Public Health Unit and report. A nurse specializing in cold chain will evaluate the problem and assess vaccine stability. At this time you will receive direction for your next steps.

If your fridge is currently not operating properly (power outage, etc) then consider moving your vaccine to an alternate fridge. Note: In order for the vaccine to be placed in a fridge the fridge must have shown three days of temperatures within the recommended range.

Do not immunize a client with a vaccine that has been part of a fridge failure or exposure. If you have inadvertently immunized a client with exposed vaccine, contact the Health Unit for advice.

What Happens if the Fridge Temperature Rises Above 8°C Briefly?

Sometimes when you open the fridge door the temperature may rise about 8°C briefly. Vaccines can be exposed safely for a very brief period of time to a slightly high temperature (<8.5°C for under five minutes). When this does occur shut the fridge door and wait until the temperature returns to normal range. If this is less than five minutes of time then clear the Min/Max thermometer and resume practice. **This does not mean that when you check temps in the morning you can ignore a reading up to 8.5°C! This only applies to exposure that can be verified as brief.**

If this sort of problem happens often consider making slight adjustments to your fridge's temperature settings.

What is the Difference Between an Exposure and a Failure?

An exposure means that your vaccine has been exposed to temperatures outside of the 2-8°C range once. Typically, exposed vaccines are marked with a red dot. Most vaccines can withstand one exposure; however circumstances vary so you still must check with the Public Health Nurse. (Note: Varicella vaccine Varivax is wasted after one exposure).

A failure means that vaccine has been exposed to out of range temperatures twice. At this time all vaccine must be wasted. Once you have had a fridge failure you are not able to order any new vaccine until you have proven that your fridge has had seven consecutive days of good temperatures. You must fax your fridge logs to the Health Unit every Monday by noon for four consecutive weeks. At the time of your failure you will receive a letter and a package from the Health Unit. A fridge inspection will be completed three months following the failure.

Note: Often sterile diluents are stored in the fridge. When red dotting exposed vaccines it is not necessary to red dot the diluent. The diluent is comprised of sterile water and does not contain components that would be subject to separation or precipitation.

Troubleshooting a Fridge that is not Maintaining Temperatures

We realize getting your fridge to stay between 2-8°C can be frustrating. Here are some helpful hints to make it easier for you:

1. Any fridge/freezer combinations result in a blast of cold air being pushed from the freezer compartment into the main fridge compartment. This can cause a fluctuation in air temperature to below 2°C. To avoid this place the thermometer probe in an empty vaccine box. Avoid placing your probe on the back wall of the fridge.
2. If your temperature probe is not already attached to a water bottle or inside a vaccine box doing so may help to regulate your temperatures, as well as giving you a better picture of your fridge temperatures.
3. If your fridge has a small quantity of vaccine fill the empty space (shelves, door) with water bottles. This gives your fridge liquid bulk which helps keep your fridge temperatures more stable especially with the opening and shutting of the door.
4. If your fridge temperatures have been greater than 8°C when you are not going in and out of the fridge, this may be due to the fridge door not closing tightly. If you suspect the seal around your fridge door is not sealing, a latch can be purchased that will keep the door closed tightly
5. Sometimes fridges still have trouble maintaining temperatures despite all necessary precautions being taken. If you have tried everything please consider having your fridge serviced.

Other Rules for the Storage and Handling of Vaccines

1. All fridges storing vaccine should be maintained at a temperature between 2-8°C.
2. All facilities should use a digital Min/Max thermometer to monitor fridge temperature twice daily.
3. Only the required amount of vaccine should be removed from the fridge for vaccination and then immediately returned.
4. Fridges should only be used to house vaccine. If there is no alternate specimen fridge then specimens can be placed below the vaccine in a plastic bag. At no time should food items be placed in the fridge.
5. Vaccines should be stored in the middle of the refrigerator never in the vegetable crispers or the door.
6. Vaccines should also be organized according to product with the longest expiry dates at the back.
7. Multi-dose vials should be marked with the date they have been opened.
8. The vaccine fridge should be in a room where there is low traffic. The outlet should not be easily accessible and a sign reading "Do Not Unplug" should be posted. Ideally the room where the fridge is held should be locked at the end of the day.
9. Defrost the fridge when there is more than 1cm of ice in the freezer compartment. For fridges with auto defrost cycles contact the Health Unit to determine if your vaccine stock can tolerate the cycle.

How to Read a Min/Max Thermometer

The Min/Max thermometer has a digital readout and a wire probe that is long enough to go into the fridge. The probe should be attached to a water bottle or inside an empty vaccine box. The digital readout should be in an easy to read location (not in the fridge). Temperatures are to be checked twice a day.

1. Ensure that the In/Out switch is set to "Out" this will give you the reading of the air from inside the fridge.
2. First record the current temperature.
3. Press the Min/Max button once record the Min temperature, once the temperature is read then press clear.
4. Press the Min/Max button again and record the Max temperature, once the temperature is read then press clear.

Vaccine Utilization

Any facility administering vaccine should only be ordering a maximum of one month's supply. This protocol is based on the Ministry of Health Guidelines for vaccine Handling and Storage. Ordering more than this can often result in wastage due to expired vaccine. Also if you have more stock in your fridge the cost of vaccine wastage is far greater in the event of a failure.

Other

If you have any questions or require further literature please contact the Health Unit at 271-7600 x263.

References

Guidelines for the Storage and Handling of Vaccines. Brant County Health Unit. May 2005

Immunization, Keep it Cool: The Vaccine Cold Chain. Guidelines for Immunization Providers on Maintaining the Cold Chain, 2nd Edition. Commonwealth of Australia. 2001

Vaccine Distribution, Storage and Handling Protocol: Vaccine Preventable Diseases. Mandatory Health Program and Services Public Health Branch. January 1998.

Public Health Division: Vaccine Storage and Handling Guidelines. August 2005.

Checklist for Safe Vaccine Storage and Handling

Here is a list of 16 practices that help ensure you are keeping your vaccine supply safe. Use this as a means of assessing your current vaccine storage and handling procedures.

	Yes	No
1. We have a designated person in charge of the handling and storage of our vaccines	_____	_____
2. We have a back-up person in charge of the handling and storage of our vaccines	_____	_____
3. Our fridge is in a low traffic area, and the door to the room can be locked.	_____	_____
4. The refrigerator temperature is maintained between 2-8°C	_____	_____
5. We always keep a Min/Max thermometer in the fridge with the probe attached to a water bottle or in an empty vaccine box.	_____	_____
6. We keep ice packs in the freezer to help maintain the temperature and to be used for vaccine transport.	_____	_____
7. Fridge temperatures are checked and recorded twice a day (making sure the Min/Max thermometer is cleared every time the temperature is checked).	_____	_____
8. Our refrigerator only holds vaccines, not other medical products or food items	_____	_____
9. We store vaccines in the middle of the refrigerator, not in the door	_____	_____
10. We fill any empty space in the fridge with water bottles (shelves, doors)	_____	_____
11. We rotate our vaccine supply so the oldest vaccine is used first	_____	_____
12. Multi dose vials are marked with the date the bottle was first opened	_____	_____
13. Vaccines are never left out of the fridge for longer than necessary.	_____	_____
14. We have a "Do Not Unplug" sign next to the refrigerator's electrical outlet.	_____	_____
15. A vaccine inventory log is maintained that documents		
<input type="checkbox"/> Vaccine name and number of doses received	_____	_____
<input type="checkbox"/> Date the vaccine was received		
<input type="checkbox"/> Arrival condition of vaccine (any red dotted?)		
<input type="checkbox"/> Vaccine lot number and expiry date		
16. In the event of a fridge failure, we take the following steps:		
<input type="checkbox"/> We report fridge failure to the health unit	_____	_____
<input type="checkbox"/> We assure that the vaccines are safe, and if necessary move to a back-up location		
<input type="checkbox"/> We separate vaccines to be wasted and place in a bag that says "Do Not Use."		