



Communiqué

Cold Chain

What is the Cold Chain?

“Cold chain” refers to the process used to maintain optimal conditions during the transport, storage and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client. The optimum temperature for refrigerated vaccines is between 2°C and 8°C.



Importance of Maintaining the Cold Chain

Vaccine must be stored maintaining the cold chain. Vaccines are sensitive biological products that may become less effective or even destroyed when exposed to temperatures outside the recommended range. Cold-sensitive vaccines experience an immediate loss of potency following freezing.

Vaccines exposed to temperatures above the recommended temperature range experience some loss of potency with each episode of exposure. Repetitive exposure to heat episodes results in a cumulative loss of potency that is not reversible.

By requesting publicly funded vaccines, providers accept responsibility for adequate cold chain storage. Losses must be accounted for by the Health Unit to the Ministry of Health and Long-Term Care.

In Haldimand and Norfolk, for the period of Jan. 1 to Oct. 1, 2008, a total of \$44,992.21 worth of vaccine has been wasted due to breaks in cold chain in physicians' offices and other health care agencies.

Maintaining the potency of vaccines is important for several of the following reasons:

- There is a need to ensure that an effective product is being used. Vaccine

failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine-preventable disease.

- Careful management of resources is important. Vaccines are expensive and can be in short supply. Loss of vaccines may result in the cancellation of immunization clinics resulting in lost opportunities to immunize.
- Revaccination of people who have received an ineffective vaccine is professionally uncomfortable and may cause a loss of public confidence in vaccines and/or the health care system.

An estimated 17% to 37% of health care providers expose vaccines to improper storage temperatures. Refrigerator temperatures are more commonly kept too cold rather than too warm. One study involving site visits showed that 15% of refrigeration units had temperatures of 1°C or lower.

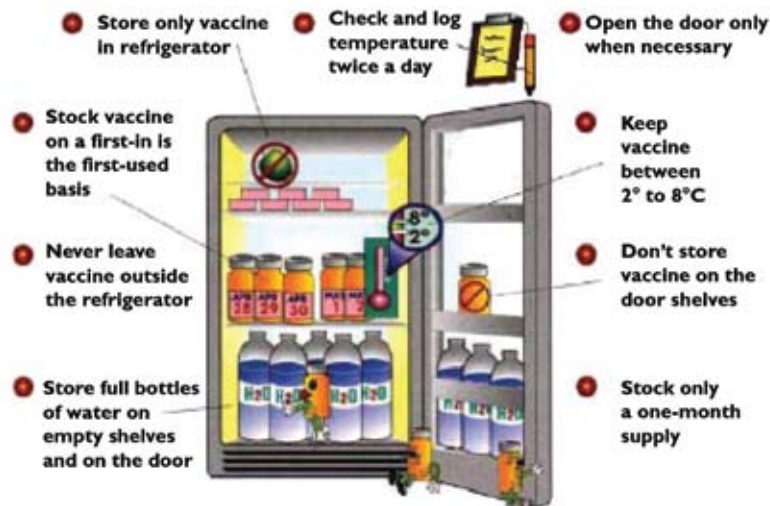
Temperatures falling outside the recommended range (2°C to 8°C) require immediate action to avoid loss of product. Notify a member of our Vaccine Preventable Disease Program at the Health Unit right away 519-426-6170 or 905-318-6623. We will consult with you regarding the type of vaccine, the duration and the temperatures reached during the exposure. Serological testing or revaccination of the vaccine recipient may be suggested.

Appropriate Vaccine and Diluents Storage Conditions

Proper vaccine storage and handling procedures include but are not limited to the following:

- A minimum of twice daily minimum and maximum temperature monitoring of the refrigerator(s).
- A minimum of twice daily recording on the temperature logs.
- Responding to storage temperatures outside the recommended range (2°C to 8°C) by notifying the Health Unit.
- Maintaining storage and handling equipment and records.
- Rotating vaccine stock so that vaccine closer to its expiration date will be used first.
- Monitoring expiration dates on vaccines and ensuring that expired vaccine is not administered to clients.
- Dating each multi-dose vial when opening and observing when potency will be lost; e.g. Tubersol 30 days after entering vial. If unsure, check product monograph.
- Ordering vaccines to maintain no more than a one-month supply (or quantity sufficient to meet seasonal or outbreak demands).

Figure 1: Organizing the Refrigerator



Organizing your Vaccine Refrigerator

Organization of your refrigerator must take into account convenience for staff, technical features of the refrigerators and vaccine requirements. In the refrigerator, vaccine should be stored in the middle of the compartment away from the coils, walls, floor and cold-air vent. The temperature near the floor of the refrigerator is not stable and differs from that in the middle of the compartment. For this reason, vaccine should never be stored in the vegetable bins. Vaccines should not be stored in the refrigerator door. The temperature in the door is not stable because door openings subject products in this location to frequent temperature fluctuations. Refrigerated vaccines should always be stored far enough away from the air venting from the freezer compartment to avoid freezing.

- Overseeing proper receipt, storage and transport of vaccine.

All vaccines should be stored with the caps on in their original boxes until they are needed. Light exposure may cause loss of potency in vaccines and other biologics. Therefore, these products should be protected from light exposure at all times.

Minimum and Maximum Thermometers

The Traceable Sentry Thermometer that has been provided by the Health Unit shows the current temperature and the minimum and maximum temperatures

that have been reached since the last time the thermometer was reset. Temperature fluctuations outside the recommended range (2° to 8°C) can be detected by referring to the minimum and maximum temperature readings. It is important to manually reset the thermometer each time the temperatures are recorded. The minimum/maximum thermometer must be reset regularly (after properly recording temperatures) for meaningful readings.

The minimum/maximum and current temperatures must be recorded twice daily – usually first thing in the morning and at the end of the day. The Health Unit must be notified as soon as possible if the temperature is out of the 2°C to 8°C range.

Thermometer Placement



The Sentry Thermometer has a detachable probe sensor and 10 feet of cable. The probe sensor is encased in a glycol medium that inhibits temperature fluctuations. The probe sensor must be placed in the centre of the vaccine fridge among the stored vaccine boxes. The digital part of the thermometer should be placed on the outside of the refrigerator where it can be read without opening the door. If for any reason the fridge door must remain open for extended periods, this should be indicated on the temperature log and the thermometer should be reset.

References:

National Vaccine Storage and Handling Guidelines for Immunization Providers (2007)
www.publichealth.gc.ca
 retrieved Sept. 16, 2008

Schedule of Health Unit Vaccine Clinics

With the exception of the month in which flu clinics are being held, the Health Unit schedules monthly vaccine clinics at the Caledonia and Simcoe locations. Appointments are required. Clients can call the Simcoe office of the Health Unit and speak to a member of the Vaccine Preventable Disease Team to book appointments. The purpose of the clinics is to catch up clients who are not up-to-date with their immunizations. This includes, but is not limited to, Hepatitis B, Meningococcal C and Human Papillomavirus (HPV).

Clinic schedules are as follows:

Simcoe location

First Tuesday of each month • 2 to 4 p.m.

Caledonia location

First Wednesday of each month • 2 to 4 p.m.

Influenza Immunization:

A Quick Reference for Health Care Providers

What is influenza immunization?

Each year, 20 to 25% of Canadians are infected by the influenza virus. Children under two years old and the elderly are at highest risk for influenza-related complications and deaths. In Canada, it is estimated that between 4,000 to 8,000 deaths are related to influenza each year.

In Ontario, influenza immunization is accomplished through the administration of a trivalent inactivated influenza vaccine. This vaccine contains three different influenza virus strains. These are selected annually to reflect the anticipated strains that will be circulating that upcoming influenza season. It takes approximately two weeks for most recipients to develop immunity following immunization.

Who should get the influenza vaccine?

Influenza immunization should be offered to everyone six months of age and older who lives, works or attends school in Ontario.

Special attention should be given to the following high-risk groups:

- Children six to 23 months of age.
- Adults 65 years of age and older.
- Adults and children with selected chronic health conditions.
- Residents of nursing homes and other chronic care facilities.
- Healthy pregnant women.
- Health care and other care providers in facilities and community settings who are capable of transmitting influenza disease to those at risk.
- Household contacts of people at high risk of influenza complications.
- Individuals who provide essential community services.
- People in direct contact during culling operations with poultry infected with avian influenza.

Effectiveness of influenza immunization

The effectiveness of influenza immunization

How is the influenza vaccine given?

The recommended period for administration of the influenza vaccine is prior to late October. However, the vaccine can still be given at any time up until the end of the influenza season (typically end of April).

Age	Dose (mL)	No. of Doses	Recommended Location†
6-35 months	0.25	1 or 2*	< 12 months old – thigh** ≥ 12 months old – deltoid
3-8 years	0.5	1 or 2*	deltoid
≥ 9 years	0.5	1	deltoid

* Children < 9 years old require two doses of influenza vaccine given four weeks apart if they are being immunized against influenza for the first time. Eligible children < 9 years old who have received one or more doses of the influenza vaccine in the past should receive one dose of influenza vaccine per season thereafter.

** Anterolateral aspect of thigh

† Given intramuscularly

varies depending on how well the influenza virus strains within the vaccine “match” the influenza virus strains circulating that season.

Healthy persons: Studies have shown that when the influenza vaccine was well matched, it prevented:

- Up to 80% of clinical influenza in healthy children.
- Up to 51% of influenza-induced otitis media in children.
- Up to 89% of lab-confirmed cases of influenza in healthy adults.
- Up to 44% of health care provider visits and 43% of days off work for upper respiratory symptoms in healthy adults.

Elderly persons: In adults 65 years of age and older, efficacy of the influenza vaccine diminishes, potentially due to a less responsive immune system. However, this should not prevent immunization since protection against influenza-related complications is still likely to occur.

Persons with respiratory disease:

Influenza immunization was found to decrease the number of chronic obstructive pulmonary disease (COPD) exacerbations and improve quality of life scores in people with asthma. Getting immunized with the influenza vaccine was not found to result in asthma exacerbations.

Health care providers: Many health care providers who have serological evidence of influenza infection do not recall having symptoms of influenza or a respiratory infection. Unfortunately, they can continue to transmit the virus to their patients during these periods. Immunization helps decrease their risk of getting the disease as well as passing it on.

Contraindications and precautions

- Individuals with a previous true allergic reaction to the influenza vaccine (reported incidence of 27 cases per million doses given) should avoid vaccination.
- Individuals with severe anaphylactic allergies to eggs, egg products, or any component of the influenza vaccine should avoid vaccination.
- For individuals with severe febrile illness, immunization can be deferred until the condition has improved or stabilized.
- Minor illness, with or without fever, is NOT a contraindication.
- Pregnancy or breastfeeding is NOT a contraindication. Immunization can occur during any trimester.

Side effects and harm

- The most frequent side effect of influenza immunization is soreness at

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Herpes Zoster Vaccine for the Prevention of Shingles

Health Canada approved Zostavax vaccine for the prevention of shingles for use in individuals 60 years of age and older on August 26, 2008. The herpes zoster (HZ) vaccine, Zostavax, has been approved for use in the United States since 2006. The vaccine is expected to be available in Canada sometime in 2009 through physicians and pharmacists. At the time of this publication no information is available regarding cost.

Zostavax, is a live, attenuated vaccine containing Oka/Merk strain VZV. The vaccine is similar to the varicella vaccine, Varivax, except the minimum plaque-forming units (PFU)-content of the Zostavax is at least fourteen-fold higher than the minimum PFU-content of Varivax.

In the Shingles Prevention Study (SPS) 2005, of 38,546 subjects 60 years of age or older, the shingles vaccine reduced the risk of developing herpes zoster compared with placebo by 64% in people aged 60 to 69 and by 51% for all age groups.

The vaccine also reduced the incidence of severe and long-lasting zoster-associated pain by 73% compared with placebo. In addition, among vaccinated individuals who developed zoster, the vaccine reduced zoster-associated pain compared with placebo by 22%. The efficacy of the vaccine in the SPS was maintained through four years of follow-up and a long-term follow-up study involving a subset of the SPS population is ongoing.

At present only a single injection of the zoster vaccine is recommended and there is no need for a booster shot at this point in time. Zoster vaccination is not recommended for persons of any age who have received varicella vaccine.

However, health care providers do not need to inquire about varicella vaccination history before administering zoster vaccine

because virtually all persons currently or soon to be in the recommended age group have not received varicella vaccine (Varivax II, the first fridge-stable chickenpox vaccine was licensed for use in Canada in August of 1999). Routine vaccination with Zostavax in individuals 60 years of age or older is recommended for several reasons.

First, zoster causes substantial morbidity in the United States, with approximately 1,000,000 new cases occurring annually. Many of these cause debilitating pain, and when Post-Herpetic Neuralgia (PHN) develops, the pain can last for months or even years. Other complications include involvement of the eye that can threaten sight, bacterial super-infections and disfiguring facial scarring. Second, although effective antiviral medications for treatment of zoster are available, administration must be initiated within 72 hours of rash onset for maximum benefit. Many patients might not obtain such rapid diagnosis and treatment, and even when they do, the treatment is only partially effective at alleviating the symptoms and shortening their duration. Third, available treatments for PHN often do not completely alleviate the pain and might be poorly tolerated by the older patients.

Finally, available evidence suggests the cost-effectiveness of zoster vaccine is within the range of some other public health interventions.

Look for more information on the Herpes Zoster vaccine in upcoming issues of the *communiqué* once the vaccine becomes available.

References:

- Morbidity and Mortality Weekly Report, www.cdc.gov/mmwr, June 6, 2008/vol. 57/RR-5
Public Health Agency of Canada, www.publichealth.gc.ca Canada Communicable Disease Report (CCDR) weekly, May 23, 2008, vol. 1

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the injection site. This typically lasts less than two days and rarely interferes with normal activities.

- Individuals may complain of other side effects from immunization such as fever, malaise or other systemic symptoms. However, most of these side effects occurred regardless of whether the individual received the influenza vaccine or a placebo injection.
- **Guillain-Barré Syndrome (GBS):** Data is conflicting as to whether a causal relationship exists between modern influenza vaccines and GBS. If one exists, the risk is estimated to be very low (no more than one to two cases per million doses). Since the introduction of universal influenza immunization in Ontario, there has been no detectable increase in the number of new cases of GBS requiring hospitalization at the population level. However, it may be prudent to avoid immunization in any individual known to have developed GBS within eight weeks of getting the influenza vaccine previously.
- **Thimerosal:** Most influenza vaccines available in Canada contain minute amounts of the preservative thimerosal. No studies have demonstrated an association between thimerosal-containing vaccines and adverse neurodevelopmental outcomes.

Reference: www.gettheflushot.ca
retrieved Nov. 4, 2008

Communiqué is a newsletter distributed by the Haldimand-Norfolk Health Unit for those who work in the area of Vaccines and Vaccine Preventable Diseases. If you have ideas or suggestions of topics for future *Communiqués*, please contact the Health Unit.



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