Cold Chain Problem Solving

**Problem:** Abnormal temperature (outside 2° C and 8°C)

**Decision-Making Process**

- **If the abnormal reading is minimum, maximum or current temperature:** Abnormal minimum or current temperatures are most likely to indicate a problem. An abnormal maximum temperature may indicate a problem if it is noted in a period when the fridge is not in use (e.g., overnight) or if it registers several degrees too high.

- **If the abnormal temperature was noted at the a.m. reading or p.m. reading:**
  - If the maximum temperature is the abnormal reading and this only occurred during the hours in which the vaccine was used, then the increase in temperature would most likely to be due to opening the fridge. The ambient temperature of the fridge changes very quickly when the door is opened but it does not alter the temperature of the vaccine. The ministry suggests that if the door is open for several minutes and the thermometer reading rises above normal, then it is okay to clear it at this time.

- **When were the last normal temperatures recorded:**
  - Recurring abnormal temperatures may be indicative of a problem. However, if the exact same temperature is repeatedly documented, then the thermometer temperature is not cleared following the reading (e.g., minimum temperature repeatedly recorded as 4° C, or maximum temperature repeatedly recorded as 8° C. Push the clear button after each reading to reset the thermometer).

- **When was the battery last changed:**
  - It is advised to change the battery every six months. A weak battery will not give accurate temperatures. Replacement Battery is Duracell 303/357.

- **Other things to consider:**
  - Was the hydro out, was the fridge door found ajar, the age of the fridge, is it a bar fridge (temps fluctuate faster), or a kitchen style fridge, is the plug securely in place, does the fridge temperature need to be adjusted (a higher number on the dial will give a lower temperature), is the seal around the door in good condition, does the door close properly, is the probe placed in the middle of the fridge, are non-medical products being stored in the fridge?

- **Suggestions to help prevent fluctuating temperatures:**
  1. Have a tray with a working supply of vaccines (one box of each), so that you can quickly remove and return the tray when you need a vaccine, rather than keeping the door open while you search for the right vaccine.
  2. Place bottles of water in the door of the fridge and on the shelves if space is available. This will help to stabilize temperature in the refrigerator.
  3. Place the probe of the glycol thermometer in the center of the fridge.
  4. Change the thermometer battery every six months.
  5. If the fridge is more than five years old then it may need to be serviced.

**What to do When There is a Power Interruption/Failure or Refrigerator Failure**

When the electricity is disrupted for four hours or less:

- Keep the refrigerator door closed.

When the electricity disruption continues for more than four hours:

- Remove the vaccines from the non-functioning refrigerator and put them in an insulated container with ice packs and a thermometer.
- If possible, transfer the vaccines to a functioning refrigerator and monitor with a min-max thermometer: Have a contingency plan. Some facilities have generator back up and you may be able to arrange with them, in advance, to transfer your vaccine to their location. Some area locations with generator back ups are hospitals, Haldimand-Norfolk Health Unit’s Simcoe office and pharmacies. Vaccine may also be moved to an extra home refrigerator that is working and that you monitor with a min-max thermometer. Do not use a kitchen refrigerator because the temperature fluctuates every time the door is opened.
- If the vaccines cannot be transported to a functioning refrigerator, then leave them in the non-functioning one and if possible place frozen ice packs into the refrigerator to help maintain the correct temperature.
- Keep the refrigerator door closed.
- Keep the ambient temperature in the office low.
- Continue to monitor and record the temperatures twice daily.
- Transfer the vaccine to a functioning refrigerator as soon as possible.
- Call the Haldimand-Norfolk Health Unit at 519-426-6170 or 905-318-6623 for further advice.

Source: Vaccine Storage and Handling Guidelines 2006, Ministry of Health and Long term Care

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**Pneumococcal Polysaccharide Vaccine**

In response to several inquiries about pneumococcal polysaccharide vaccine and revaccination, information regarding this topic is included in this edition. Pneumococcal conjugate vaccine is part of the routine schedule for children beginning their immunization in early infancy. Pneumococcal polysaccharide vaccine (one dose) is recommended for all people 65 years of age and older regardless of medical condition.

**Indications and Clinical Use**

According to the Publicly Funded Schedules for Ontario, February 2005, the High-Risk Criteria for Pneumococcal Vaccine is as follows:

**A. Pneumococcal Conjugate Vaccine and/or Pneumococcal Polysaccharide Vaccine (depending on age):**

1. **Pneumococcal conjugate vaccine:** All children under five years of age with the medical conditions listed below.
2. **Pneumococcal polysaccharide vaccine:** All persons two years of age and older with the medical conditions below.

**Medical Conditions:**

- Chronic respiratory disease (excluding asthma, except those treated with high-dose corticosteroid therapy).
- Chronic cardiac disease.
- Cirrhosis or alcoholism.
- Chronic renal failure or nephritic syndrome.
- Diabetes mellitus.
- Asplenia, splenic dysfunction, sickle-cell disease and other sickle cell haemoglobinopathies.
- Chronic cerebrospinal fluid leak.
- Primary immune deficiency.
- HIV infection and other conditions associated with immunosuppression (malignancies, long term systemic corticosteroids and other immunosuppressive therapy).
- Solid organ transplant recipients.
- Cochlear implant recipients (pre/post implant).

For high risk children 24-59 months of age, the conjugate vaccine should be given first followed by the pneumococcal polysaccharide vaccine eight weeks later (minimum acceptable time interval is four weeks). See the National Advisory Committee on Immunization (NACI) guidelines for the immunization of high-risk children with the pneumococcal vaccines.

**B. Pneumococcal Polysaccharide Vaccine**

1. All residents of nursing homes, homes for the aged and chronic care facilities or wards.
2. All persons 65 years of age and older regardless of medical condition.

Pneumococcal Polysaccharide Vaccine is indicated in persons two years of age or older for the prevention of invasive infection, such as bacteraemia, pneumonia or meningitis, caused by the serotypes of pneumococci contained in the vaccine.

A single dose of pneumococcal polysaccharide vaccine is recommended for all individuals over 65 years of age including those with unknown vaccination histories.

Following polysaccharide pneumococcal immunization, serotype-specific antibody levels decline after five to 10 years and decrease more rapidly in some groups than in others. The duration of immunity is not precisely known. Revaccination should be considered in some individuals.

**Contraindications**

Immunization with Pneumococcal polysaccharide vaccine should be deferred in the presence of any acute illness, including febrile illness, to avoid superimposing adverse effects from the vaccine on the underlying illness or mistakenly identifying a manifestation of the underlying illness as a complication of vaccine use. A minor illness such as mild upper respiratory infection is not a reason to defer immunization.

Allergy to any component of Pneumococcal polysaccharide vaccine, its container or an anaphylactic or other allergic reaction to a previous dose of Pneumococcal polysaccharide vaccine are contraindications to vaccination.
**Warnings**

Pneumococcal polysaccharide vaccine will not immunize against types of pneumococci other than those contained in the vaccine.

In patients receiving antibiotic prophylaxis against pneumococcal infection, such prophylaxis should not be discontinued after immunization with Pneumococcal polysaccharide vaccine. Intramuscular injections should be given with care in persons suffering from coagulation disorders or on anticoagulant therapy because of the risk of hemorrhage.

Pneumococcal polysaccharide vaccine should not be administered into the buttocks due to the varying amount of fatty tissue in this region, nor by the intradermal route, since these methods of administration may induce a weaker immune response. Where possible, the vaccine should be given at least 10 to 14 days before splenectomy or initiation of chemotherapy or immunosuppressive therapy or early in the course of HIV infection.

Immunocompromised persons (whether from disease or treatment) may not obtain the expected immune response. If possible, consideration should be given to delaying vaccination until after the completion of any immunosuppressive treatment. If Pneumococcal polysaccharide vaccine is given less than 14 days prior to splenectomy or initiation of chemotherapy, it may not elicit the expected immune response.

As with any vaccine, immunization with Pneumococcal polysaccharide may not protect 100% of susceptible individuals.

**Precautions**

The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated. Epinephrine Hydrochloride Solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. Health-care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management. Before administration, take all appropriate precautions to prevent adverse reactions. This includes a review of the patient’s history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindications to immunization and current health status.

Before administration of Pneumococcal polysaccharide vaccine, health-care providers should inform the patient, parent or guardian of the benefits and risks of immunization, inquire about the recent health status of the patient and comply with any local requirements regarding information to be provided to the patient before immunization. It is extremely important that the patient, parent or guardian be questioned concerning any symptoms and/or signs of an adverse reaction after a previous dose of vaccine. Do not inject into a blood vessel.

Use a separate sterile needle and syringe, or a sterile disposable unit, for each individual dose to prevent disease transmission.

Pneumococcal polysaccharide vaccine is not recommended for children under two years of age.

**Pregnancy and Lactation**

Animal reproductive studies have not been conducted with Pneumococcal polysaccharide vaccine. Clinical trials using Pneumococcal polysaccharide vaccine have been conducted in pregnant women during the third trimester and no significant adverse events were recorded. According to the Canadian Immunization Guide, neither pregnancy nor breastfeeding is a contraindication to either the polysaccharide or the conjugate pneumococcal vaccine. The benefits versus the risks of administering Pneumococcal polysaccharide in pregnancy should carefully be evaluated.

Breastfeeding is not a contra-indication to pneumococcal polysaccharide vaccines.

**Drug Interactions**

Pneumococcal polysaccharide vaccine should not be mixed in the same syringe with other parenterals. If any other vaccines are administered during the same visit, they must be given at separate sites and with separate syringes.

Pneumococcal polysaccharide vaccine may be given simultaneously with influenza, meningococcal and Hib conjugate vaccines at separate sites with separate syringes.

According to the Canadian Immunization Guide, there are obvious practical advantages to giving more than one vaccine at the same time, especially in preparation for foreign travel or when there is doubt that the patient will return for further doses of vaccine. Most of the commonly used antigens can safely be given simultaneously. No increase in the frequency or severity of clinically significant side effects has been observed. The immune response to each antigen is generally adequate and comparable to that found in patients receiving these vaccines at separate times.
**Dosage and Administration**

The immunizing dose is a single injection of 0.5 mL given intramuscularly or subcutaneously.

**Revaccination:** one injection of 0.5 mL

According to NACI, people for whom re-vaccination with pneumococcal polysaccharide vaccine should be considered include those with functional or anatomic asplenia or sickle cell disease; hepatic cirrhosis; chronic renal failure or nephrotic syndrome; HIV infection; and immunosuppression related to disease or therapy. A single revaccination is recommended after five years in those who received their first pneumococcal vaccine after age 10 years and after three years in those who received their first pneumococcal vaccination at less than 10 years of age.

**Immunization Schedule in Conjunction with the Pneumococcal Conjugate Vaccine**

Children who have completed the pneumococcal conjugate vaccination series (PCV7) before they are two years of age, and who are among the risk groups for which Pneumococcal polysaccharide vaccine is already recommended, should receive one dose of Pneumococcal polysaccharide vaccine at two years of age (more than 8 weeks after the last dose of pneumococcal conjugate vaccine).

The Ministry of Health and Long Term Care indicates there is a good supply of Pneumo® 23 so order according to office demand. The Ministry is supplying Health Units and Doctors office with a single dose prefilled syringe with a needle. Safety engineered syringes are not mandatory and these facilities are not yet required to use these syringes.

If you have any questions regarding vaccine, do not hesitate to call Maria or Rose at the Haldimand-Norfolk Health Unit at 519-426-6170.

Submitted by Rose Huyge Public Health Nurse

Source: Pneumococcal Polysaccharide Vaccine Product Monograph Sanofi Pasteur Limited Toronto Ontario, Canada 083-Pneumo® 23

Canadian Immunization Guide 2006, Seventh Edition

Publicly Funded Immunization Schedule for Ontario- February 2005.

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*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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