Pneumococcal conjugate 13-valent vaccine (Prevnar®13) for adults with high risk medical conditions: Q&A for health care providers

This questions and answers sheet for health care professionals provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment.

Updates:

Effective December 2014, Ontario has expanded its publicly funded high risk pneumococcal immunization program to include conjugate pneumococcal 13-valent vaccine (Pneu-C-13 or Prevnar®13) for adults 50 years of age and older with the following high risk medical conditions related to invasive pneumococcal disease: hematopoietic stem cell transplants (HSCT); HIV infection; and other immunosuppressive conditions.

What is invasive pneumococcal disease (IPD)?

IPD is a bacterial infection caused by *Streptococcus pneumoniae*. IPD most often presents in adults as bacteremic pneumonia, meningitis and other clinical manifestations such as endocarditis, or septic arthritis. In children, IPD usually occurs as bacteraemia without a clinical focus, pneumonia and meningitis (3). Symptoms of pneumonia in adults may include: a sudden onset with shaking chills, fever, shortness of breath or rapid breathing, chest pain and a productive cough. In infants and young children symptoms may not be specific and may include fever, cough, rapid breathing and grunting.

Meningitis due to pneumococcus in persons over 2 years of age presents with high fever, headache and stiff neck, which can develop over several hours or in 1-2 days. Other symptoms include nausea, vomiting, discomfort with bright lights, confusion and sleepiness. In newborns and small infants the above symptoms may be absent but they could present with irritability, feeding poorly, vomiting and inactivity.

The bacteria that cause IPD can live at the back of the nose and throat without causing symptoms. People of all ages can be healthy carriers of pneumococci bacteria. The bacteria are spread through droplets in the air from coughing or sneezing. Bacteria can also be spread through the saliva of an infected person when common items are shared, e.g., beverages (bottles, straws) or eating utensils.

What is the epidemiology and serotype distribution of IPD in Ontario?

IPD became reportable in Ontario in 2002. According to Ontario's integrated Public Health Information System (iPHIS), 10,962 cases of IPD were reported between 2003 and 2012. During this period, the

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incidence of IPD increased slightly in Ontario, from 8.3 cases per 100,000 population in 2003 to 9.4 cases per 100,000 population in 2012. Overall, national incidence followed a similar trend over the same period of time. There is some seasonal variation with the lowest number of cases occurring in the summer months of July and August, and the highest number of cases reported in winter.

In 2012, 1,273 cases of IPD were reported in Ontario. The highest incidence of IPD was observed in adults aged 65 years and older, followed by adults aged 60-64 years and infants less than one year of age. Males were consistently at higher risk for IPD compared to females among adolescents and adults. Hospitalization was reported for 69.5% of the cases reported in 2012, with 156 reported deaths (12.3% of all cases).

More than ninety distinct capsular serotypes have been identified worldwide, however, only a few serotypes cause the majority of invasive disease. Between 2007 and 2012, a decrease in IPD incidence due to serotypes 4, 6B, 9V, 14, 18C, 19F and 23F (serotypes contained within the pneumococcal 7 valent conjugate vaccine [Pneu-C-7]) was observed among children less than five years of age in Ontario. Additionally, incidence due to Pneu-C-13 serotypes (Pneu-C-7 serotypes plus serotypes 1, 3, 5, 6A, 7F and 19A) declined between 2009 and 2012 among children less than five years of age. Similar trends were observed among adults 65 years and older, suggesting a herd effect in other age groups not targeted for pneumococcal conjugate immunization. In contrast, IPD incidence due to serotypes unique to 23-valent pneumococcal polysaccharide vaccine (Pneu-P-23) demonstrated a consistent increase since 2007 among adults aged 65 years and older.

About the publicly funded pneumococcal vaccines

Ontario publicly funds two types of pneumococcal vaccines that protect against IPD:

1. The pneumococcal conjugate 13-valent (Pneu-C-13) vaccine, Prevnar®13, is authorized for use for the prevention of IPD; specifically for the active immunization against *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. *Streptococcus pneumoniae* are the most common cause of bacterial infection in immunocompromised adults and the vaccine can prevent these infections. Pneu-C-13 vaccine has been publicly funded for the immunization of infants and children under 5 years of age in Ontario since 2005. For more information about Prevnar®13, refer to the vaccine product monograph available at: www.pfizer.ca/en/our_products/vaccines/monograph/232.

2. Pneumococcal polysaccharide 23-valent (Pneu-P-23) vaccine (Pneumovax®23) is authorized for use to prevent pneumonia and other infections caused by 23 serotypes of the *Streptococcus pneumoniae*. These 23 types account for approximately nine out of 10 cases of pneumococcal disease. The vaccine is recommended for people with the medical conditions listed below, and routinely for people 65 years of age and older. Pneu-P-23 vaccine has been used in Canada since 1983 and publicly funded for high risk groups in Ontario since 1996. For more information about this program, visit www.health.gov.on.ca/en/public/publications/immune/pnem.aspx.

Who is eligible to receive the publicly funded Pneu-C-13 vaccine in Ontario and when should they receive it?

One dose of Pneu-C-13 is now publicly funded for individuals aged 50 years and older with the following high risk conditions (with an exception for hematopoietic stem cell transplant recipients noted below):

- Hematopoietic stem cell transplants (HSCT) *
- HIV infection
- Immunosuppressive conditions, specifically:
    - Asplenia (anatomical or functional);
    - Sickle cell disease or other hemoglobinopathies;
    - Congenital immunodeficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, complement system (properdin, or factor D deficiencies), or phagocytic functions;
    - Immunosuppressive therapy including use of long term corticosteroids, chemotherapy, radiation therapy, post-organ-transplant therapy, biologic and non-biologic immunosuppressive therapies for rheumatologic and other inflammatory diseases;
    - Malignant neoplasms including leukemia and lymphoma; or
    - Solid organ or islet cell transplant (candidate or recipient).

* Note: HSCT recipients should receive 3 doses of Pneu-C-13 starting 3-9 months after transplant. These doses should be administered at least 4 weeks apart.

Why has the ministry expanded the publicly funded high risk pneumococcal immunization program to include high risk adults 50 years and older?

Until recently, Pneu-C-13 was only indicated for active immunization of infants and children under 5 years of age. The vaccine age indications have recently been expanded to 6 weeks of age and older, and National Advisory Committee on Immunization recommends this vaccine for use among individuals with certain high risk medical conditions to prevent pneumonia, bacteraemia and meningitis caused by *Streptococcus pneumoniae*.

The ministry is now publicly funding the vaccine for individuals 50 years of age and older with high risk medical conditions as these individuals have the highest number of reported cases and incidence of IPD, and would be considered at higher risk of disease compared to other groups.

When should the Pneumococcal Polysaccharide 23-valent vaccine also be given?

Following immunization with the Pneu-C-13 vaccine (Prevnar®13), high risk adults aged 50 years and older who meet any of the criteria listed above, should also receive pneumococcal polysaccharide 23-valent (Pneu-P-23) vaccine, or Pneumovax®23 if not previously immunized with Pneu-P-23.

- For Adults with HSCT: one dose of Pneu-P-23 vaccine should be given 12 to 18 months post transplant (6-12 months after the last dose of Pneu-C-13).
- For all other high risk groups: one dose of Pneu-P-23 vaccine should be given 8 weeks after the dose of Pneu-C-13. The Pneu-C-13 dose should be administered at least one year after any previous dose of Pneu-P-23.

For more information on the Pneu-P-23 vaccine, visit www.health.gov.on.ca/en/public/publications/pub_immun.aspx. For more information about the high risk pneumococcal immunization program, please contact your health care provider or local public health unit.

Who should not receive the vaccine?

Individuals with a history of anaphylaxis after a previous dose of a pneumococcal conjugate vaccine, and individuals with proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its container should not receive the vaccine.

Precautions should be taken for individuals who:

- has any present or past medical problems after any dose of 7-valent pneumococcal conjugate vaccine (Synflorix®) or Prevnar® 13
- are sick with a high fever
- have bleeding disorder or taking blood-thinning medications

What is the vaccine ordering process?

Order the vaccine through your regular vaccine supply source (i.e., public health unit or Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS)). Information about your public health unit can be found at: http://www.phdapps.health.gov.on.ca/PHULocator.

How should the Pneu-C-13 vaccine be stored?

In order to ensure optimal protection, the Pneu-C-13 vaccine (like other publicly funded vaccines) must be maintained at a temperature between +2°C to +8°C from the time of manufacture until the vaccine is administered to individuals. This temperature must be monitored and maintained at all times. For additional information on provincial vaccine storage and handling requirements please consult the Vaccine Storage and Handling Guidelines available at: http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/guidance/guide_vaccine_storage.pdf.

What should be done for adverse events following immunization (AEFIs)?

Under section 38 of the ***Health Protection and Promotion Act, R.S.O. 1990***, Ontario physicians, nurses, pharmacists and other health care providers (as listed under the section) are required to inform the person who consents to immunization of the importance of immediately reporting to a physician or a registered nurse in the extended class (nurse practitioner) of any reaction that may be a reportable event. Local public health units should subsequently be notified of the adverse event. The AEFI reporting form can be found on the Public Health Ontario (PHO) website along with a questions and answers fact sheet, available at: www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/Immunization-Resources.aspx. Please send the completed form to your local public health unit.

This information is monitored and reviewed on an ongoing basis by PHO and reported to the Public Health Agency of Canada (PHAC) to support national vaccine safety surveillance. Health care providers are required to report AEFIs to their local public health unit. A list of public health units in Ontario is available at: www.health.gov.on.ca/en/common/system/services/phu/locations.aspx

Who can I contact for more information?

- Further information, including Ontario's publicly funded immunization schedule, is available on the Ministry of Health and Long-Term Care's website for health care professionals at: www.health.gov.on.ca/en/pro/programs/immunization.
- If you have further questions, please contact your local public health unit. To find your local public health unit, visit: www.phdapps.health.gov.on.ca/PHULocator.
- Immunization information is available at: www.ontario.ca/vaccines.