

Pneumococcal 13 Valent Conjugate Vaccine (Pevnar[®]13) Program

Questions and Answers for Health Care Providers

The Ministry of Health and Long-Term Care (the “ministry”) is replacing the current pneumococcal conjugate vaccine with **Pevnar[®]13** for enhanced protection against invasive pneumococcal disease (IPD) for Ontario infants and children.

About the pneu-C-13 vaccine (Pevnar[®]13):

Q1: What does the pneu-C-13 vaccine protect against?

A1: The newest pneumococcal conjugate vaccine, approved for use in Canada in December 2009, is Pevnar[®]13. The vaccine is indicated for the active immunization against *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F which are responsible for causing invasive pneumococcal disease (including sepsis, meningitis, bacteraemic pneumonia, pleural empyema, and bacteraemia).

The vaccine provides protection against six additional serotypes than in Pevnar[®] (7-valent) (4, 6B, 9V, 14, 18C, 19F, 23F) and three additional serotypes than the coverage provided in Synflorix[™] (1, 5, 7F). Pevnar[®]13 will not protect against serotypes that are not included in the vaccine.

Q2: What is the age indication for the Pevnar[®]13 vaccine?

A2: Pevnar[®]13 is approved by Health Canada for infants and children from 6 weeks to <6 years of age. In Ontario, it is currently publicly funded for infants and children as per the eligibility criteria outlined in Attachment A:

- Table 1: Routine pneumococcal conjugate immunization
- Table 2: Catch-up pneumococcal conjugate immunization

Q3: Where do I find more information about the vaccine such as common side effects, contraindications, storage recommendations, and where to inject the vaccine?

A3: Refer to the vaccine product monograph for Pevnar[®]13

About the publicly funded program:

Q4: Why has the province had three different pneumococcal conjugate vaccines since the publicly funded program began and why are we switching pneumococcal vaccines again?

A4: The manufacturing of the pneumococcal conjugate vaccine has advanced to provide broader protection against emerging serotypes that cause invasive pneumococcal disease (IPD), such as 19A. Surveillance has identified an increase in the incidence of IPD due to serotype 19A, most notably in children one to two years of age. This serotype has been responsible for drug resistant disease.^{2,3} The ministry wants to ensure the best and most appropriate vaccine is available to protect Ontario infants and children through the publicly funded program.

Q5: What is the epidemiology and serotype distribution of IPD in Ontario?

A5: IPD became reportable in Ontario in 2002. From 2004 to 2008 an average of 987 cases were reported each year. In 2009, 1,212 cases were reported in Ontario, up from 1,065 cases in 2008. This increase in cases may be due in part to changes to the case definition starting in 2009. In the past two years, 2.2 per cent of IPD cases have died.

Ninety distinct capsular serotypes have been identified worldwide, however, only a few serotypes produce the majority of invasive disease. In young children, studies have shown serotypes/groups 6 (A, B), 14, 18 (C), 19 (A, F) and 23 (F) are more common. Of the 1,212 cases reported in 2009 in Ontario, serotype results were available for 64 per cent. Serotype 19A was the most frequently reported serotype across all age groups (<2 years, 2-4 years, 5-64 years, 65+).

Data from the Toronto Invasive Bacterial Diseases Network indicated cases of serotype 6B and 14 decreased for children less than two years old after the introduction of the pneumococcal conjugate vaccine in January 2005; however, since 2004 cases of the non-vaccine strain 19A emerged, although the overall incidence of IPD was lower than the pre-vaccine period.

Ontario serotype data for 2008 and 2009 shows that there was an increase in reporting for serotypes 19A, 3 and 7F and for one to four year olds from 2008 to 2009 with the greatest increase in one and two year olds.

Q6: Who is eligible to receive the publicly funded pneu-C-13 vaccine and when should they receive it?

A6: The Ministry of Health and Long-Term Care is now offering Prevnar[®] 13 through the publicly funded program as per the eligibility criteria outlined in Attachment A:

- Table 1: Routine pneumococcal conjugate immunization
- Table 2: Catch-up pneumococcal conjugate immunization

Q7: When routine immunization with Prevnar[®]13 begins in November 2010, how should a child complete his/her series if the child had started the pneumococcal immunization series with Prevnar[®]7 or Synflorix[™]?

A7: Prevnar[®]13 should be given for the next and subsequent scheduled dose(s).

Q8: What are the detailed schedules for infants and children who have not completed or have not started their pneumococcal conjugate immunization series?

A8: See detailed schedules for Prevnar[®]13 outlined in Attachment A:

- Table 3: Prevnar[®]13 schedules for low-risk children
- Table 4: Prevnar[®]13 schedules for high-risk children

- Q9:** If a child missed his/her opportunity to receive publicly funded dose(s), can the child receive Prevnar®13 vaccine at a later date?
- A9:** Yes, children who were previously eligible to receive Prevnar®13 as outlined in Attachment A (refer to table 1 and table 2) but missed their opportunity to receive the vaccine will continue to be eligible to receive the vaccine (in the age-appropriate number of doses) up to 59 months of age (<5 years old).
- Q10:** What is the vaccine ordering process?
- A10:** Order the vaccine through your regular vaccine supply source (i.e., local public health unit or Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS)).
- Q11:** When routine immunization with Prevnar®13 begins in November 2010, what should be done with our existing stock of Prevnar®7 and/or Synflorix™?
- A11:** As the ministry will receive credit for any unused pneumococcal conjugate vaccines, it is important for you to return any unused Prevnar® (7-valent) and/or Synflorix™ vaccine to your vaccine supply source (i.e., public health unit or OGPMSS) when the routine pneu-C-13 program begins in November 2010.
- Q12:** How should Prevnar®13 be recorded in the yellow immunization record?
- A12:** When checking off “pneumo conjugate” vaccine, write “Prevnar®13” under the “Vaccine brand name” column.
- Q13:** What should be done for adverse events following immunization (AEFIs)?
- A13:** Under section 38 of the *Health Protection and Promotion Act, R.S.O. 1990*, physicians or other persons authorized to administer an immunizing agent are required to inform the person who consents to immunization of the importance of immediately reporting to a physician 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 Agency of Canada website along with a User Guide at: www.phac-aspc.gc.ca/im/ae-fi-form-eng.php. Send the completed form to your local public health unit.

A list of health units can be found at:
www.health.gov.on.ca/english/public/contact/phu/phuloc_mn.html.

References:

1. Vaccine Product Monograph; Prevnar®13, ©Wyeth Canada, December 21, 2009.
www.wyeth.ca/en/products/Product%20Monographs%20PDFs/Prevnar_13_Product_Monograph_Dec_21_2009_EN.pdf
2. CDC. Emergence of antimicrobial-resistant serotype 19A *Streptococcus pneumoniae* – Massachusetts, 2001-2006. MMWR Oct 19, 2007, 56(41):1077-1080.
3. Pichichero ME, Casey JR. Emergence of a multiresistant serotype 19A pneumococcal strain not included in the 7-valent conjugate vaccine as an otopathogen in children. *JAMA* 2007;298(15):1772-1778.