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and Long-Term Care**

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MEMORANDUM

TO: Health Care Providers

RE: Introducing Prevnar[®]13 for Immunization Against Invasive Pneumococcal Disease (IPD) for Infants and Children

This letter is to inform you that a new pneumococcal conjugate vaccine known as Prevnar[®]13 is now available and is publicly funded in Ontario for infants and children. The vaccine was approved for use in Canada in December 2009 and provides broader protection against invasive pneumococcal disease (IPD).

The Vaccine

Prevnar[®]13 is a 13-valent pneumococcal conjugate vaccine indicated for 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.

The vaccine provides protection against 6 more serotypes (1, 3, 5, 6A, 7F and 19A) than the serotype coverage provided in the Prevnar[®] (7-valent) vaccine and 3 more serotypes than the coverage provided in the Synflorix[™] vaccine.

The unique serotypes contained in Prevnar[®]13 which are not in either Prevnar[®] (7-valent) or Synflorix[™] are **3, 6A and 19A**.

Background

In 2005, Ontario introduced a publicly funded pneumococcal conjugate immunization program with Prevnar[®] (7-valent) vaccine for all infants and children < 2 years of age to protect against pneumococcal serotypes 4, 6B, 9V, 14, 18C, 19F and 23F. In 2009, Synflorix[™] vaccine replaced Prevnar[®] (7-valent) to provide protection against 3 additional serotypes (1, 5 and 7F).

Since the introduction of the pneumococcal immunization program in Ontario, there has been a dramatic shift in the epidemiology of IPD. While there has been a decline in the incidence of pediatric IPD caused by serotypes contained in the Prevnar[®] (7-valent) vaccine, the incidence of IPD caused by non-vaccine serotypes has increased, particularly for one and two-year old children. Across Canada and the United States, the incidence of disease due to non vaccine strains, in particular serotypes 3 and 19A that are now contained in Prevnar[®] 13, have increased.

Please refer to the following attachments and links for additional information:

- Eligibility criteria and detailed schedules for Prevnar[®]13 (Attachment A):
 - Table 1: Routine pneumococcal conjugate immunization
 - Table 2: Catch-up pneumococcal conjugate immunization
 - Table 3: Prevnar[®] 13 schedules for low risk children
 - Table 4: Prevnar[®] 13 schedules for high risk children
- Qs & As for Health Units (Attachment B)
- Qs & As for Health Care Providers (Attachment C)
- Fact sheet on pneumococcal conjugate vaccine and invasive pneumococcal disease
http://www.health.gov.on.ca/english/public/pub/immun/pnem_conjugate.html
- Publicly Funded Immunization Schedules for Ontario
<http://www.health.gov.on.ca/english/providers/program/immun/pdf/schedule.pdf>
- Prevnar[®]13 product monograph
http://www.wyeth.ca/en/products/Product%20Monographs%20PDFs/Prevnar_13_Product_Monograph_Dec_21_2009_EN.pdf

Kindly share this information with appropriate staff in your practice. Should you or your staff have any questions, please contact your local public health unit. A list of health units can be found at: http://www.health.gov.on.ca/english/public/contact/phu/phuloc_mn.html.

We thank you for your continued support with and commitment to the publicly funded immunization program and protecting our children against vaccine preventable diseases.

Sincerely,

Original signed by Dr. David Williams

David Williams, MD, MHSc, FRCPC
Associate Chief Medical Officer of Health, Health Protection & Prevention

Attachments

c: Vaccine Preventable Diseases Managers, Ontario Public Health Units

Prevnar®13 Eligibility

Table 1: ROUTINE Pneumococcal Conjugate Immunization

| Eligible age cohort | Health status | Recommended doses of Prevnar®13 | Recommended schedule |
|----------------------|--|---------------------------------|------------------------------|
| Starting at 2 months | Low risk (healthy with no medical conditions that increase the risk of IPD) | 3 doses | 2, 4, and 12 months of age |
| Starting at 2 months | High risk† | 4 doses | 2, 4, 6 and 15 months of age |

Table 2: CATCH-UP Pneumococcal Conjugate Immunization

| Eligible age cohort | Health status | History of pneumococcal conjugate vaccine | Recommended dose(s) of Prevnar®13 | Recommended schedule |
|---|---|--|---|--|
| 2 months to 59 months (<5 years) | <ul style="list-style-type: none"> • Low risk or • High risk† | <ul style="list-style-type: none"> • Any incomplete series with pneu-C-7 and/or pneu-C-10 | 1 to 3 doses depending on age at first dose | See Table 3 and Table 4 for schedules |
| 12 months to 59 months (<5 years) | <ul style="list-style-type: none"> • High risk† | <ul style="list-style-type: none"> • Completed series with pneu-C-7 and/or pneu-C-10 | 1 catch-up dose | ≥8 weeks after the last dose of pneumococcal conjugate vaccine |
| Eligible starting January 2011 2 years old or turning 2 years old in 2011 | <ul style="list-style-type: none"> • Low risk | <ul style="list-style-type: none"> • Completed series with pneu-C-7 and/or pneu-C-10 | 1 catch-up dose | ≥8 weeks after the last dose of pneumococcal conjugate vaccine |

Pevnar[®]13 Schedules

Table 3: Pevnar[®]13 schedule for LOW RISK children who have not completed or have not started their series

| Child's current age | Vaccination history of pneumococcal conjugate vaccine | Recommended Pevnar [®] 13 dose(s) required to complete series |
|----------------------------|---|--|
| 2 to 6 months | 0 doses | 1st dose (now) 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose and ≥12 months of age |
| | 1 dose (1st dose) | 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose and ≥12 months of age |
| | 2 age-appropriate doses (1st and 2nd dose) | 3rd dose, ≥8 weeks after 2nd dose and ≥12 months of age |
| 7 to 11 months | 0 doses | 1st dose (now) 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose and ≥12 months of age |
| | 1 dose (1st dose) | 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose and ≥12 months of age |
| | 2 doses (1st and 2nd dose) | 3rd dose, ≥8 weeks after 2nd dose and ≥12 months of age |
| 12 to 23 months (<2 years) | 0 doses | 1st dose (now) 2nd dose, ≥8 weeks after 1st dose |
| | 1 dose (1st dose) at <12 months of age | 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose |
| | 1 dose (1st dose) at ≥12 months of age | 2nd dose, ≥8 weeks after 1st dose |
| | 1 dose (1st dose) at <12 months of age + 1 dose (2nd dose) at ≥12 months of age | 3rd dose, ≥8 weeks after 2nd dose |
| | 2 or more doses at <12 months of age | 1 dose, ≥8 weeks after most recent dose |
| 24 to 59 months (<5 years) | 0 doses | 1 dose, ≥8 weeks after most recent dose (if applicable) |
| | Any incomplete series | |

For a list of medical conditions that increase an individual's risk for IPD, see page 3.

Prevnar®13 Schedules

Table 4: Prevnar®13 schedule for HIGH RISK† children who have not completed or have not started their series

| Child's current age | Vaccination history of pneumococcal conjugate vaccine | Recommended Prevnar®13 dose(s) required to complete series |
|----------------------------|---|---|
| 2 to 6 months | 0 doses | 1st dose (now) 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose 4th dose, ≥8 weeks after 3rd dose and ≥15 months of age |
| | 1 dose (1st dose) | 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose 4th dose, ≥8 weeks after 3rd dose and ≥15 months of age |
| | 2 age-appropriate doses (1st and 2nd dose) | 3rd dose, ≥8 weeks after 2nd dose 4th dose, ≥8 weeks after 3rd dose and ≥15 months of age |
| 7 to 11 months | 0 doses | 1st dose (now) 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose and ≥15 months of age |
| | 1 dose (1st dose) | 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose and ≥15 months of age |
| | 2 doses (1st and 2nd dose) | 3rd dose, ≥8 weeks after 2nd dose and ≥15 months of age |
| 12 to 23 months (<2 years) | 0 doses | 1st dose (now) 2nd dose, ≥8 weeks after 1st dose |
| | 1 dose (1st dose) at <12 months of age | 2nd dose, ≥8 weeks after 1st dose 3rd dose, ≥8 weeks after 2nd dose |
| | 1 dose (1st dose) at ≥12 months of age | 2nd dose, ≥8 weeks after 1st dose |
| | 1 dose (1st dose) at <12 months of age + 1 dose (2nd dose) at ≥12 months of age | 3rd dose, ≥8 weeks after 2nd dose |
| | 2 or more doses at <12 months of age | 1 dose, ≥8 weeks after most recent dose |
| 24 to 59 months (<5 years) | 0 doses | 1st dose (now) 2nd dose, ≥8 weeks after 1st dose |
| | Any incomplete series | 1 dose, ≥8 weeks after most recent dose |

† Medical conditions that increase an individual's risk for IPD:

- Chronic respiratory disease (excluding asthma, except those treated with high-dose corticosteroid therapy)
- Chronic cardiac disease
- Cirrhosis
- Chronic renal disease or nephrotic 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)

Note: Children 24 to 59 months of age and at high risk of IPD should also receive a dose of pneumococcal polysaccharide vaccine after the pneumococcal conjugate vaccine. Refer to the current *Publicly Funded Immunization Schedules for Ontario* at www.health.gov.on.ca/english/providers/program/immun/pdf/schedule.pdf

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 6 additional serotypes than in Pevnar[®] (7-valent) (4, 6B, 9V, 14, 18C, 19F, 23F) and 3 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 3 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, 1212 cases were reported in Ontario, up from 1065 cases in 2008. This increase in cases may be due in part to changes to the case definition starting in 2009. In the past 2 years, 2.2% 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 1212 cases reported in 2009 in Ontario, serotype results were available for 64%. 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 pneumo-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 their series if they have started their 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 their opportunity to receive their publicly funded dose(s), can they 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 pneumo-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: <http://www.phac-aspc.gc.ca/im/aeffi-form-eng.php>. Send the completed form to your local public health unit. A list of health units can be found at: http://www.health.gov.on.ca/english/public/contact/phu/phuloc_mn.html.

References:

1. Vaccine Product Monograph; Prevnar®13, ©Wyeth Canada, December 21, 2009. http://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.