Ontario

Ministry of Health

Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccines for Children Aged 6 Weeks to 17 Years

This fact sheet provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

NEW: Children 6 weeks to 17 years who are at high risk of IPD that have completed their Pneu-C-13 immunization series are now eligible to receive one dose of Pneu-C-20.

To determine the appropriate immunization schedule, refer to Figure 1: Immunization decision flowchart in the Appendices.

Pneumococcal vaccine programs in Ontario

There are three pneumococcal vaccine programs in Ontario:

1. Routine vaccination program for children aged 6 weeks to 4 years
2. Routine vaccination program for individuals aged 65 years and older
3. High risk vaccination program for individuals aged 6 weeks and older with certain medical or non-medical conditions who are at high risk for IPD

Infectious agent

The bacterium *Streptococcus pneumoniae* is the cause of invasive pneumococcal disease (IPD) and a common cause of respiratory infections including community acquired pneumonia (CAP) and acute otitis media (AOM).

Transmission

S. pneumoniae is transmitted by direct contact with respiratory droplets or indirect contact with respiratory secretions of infected or colonized persons. The incubation period for IPD has not been clearly defined and may be as short as 1 to 3 days.

Risk factors

IPD is most common in the very young, the elderly, and groups at high risk due to an underlying medical, environmental or living condition. Additionally, the incidence rate of IPD is significantly higher in northern Canada, including northern Ontario, compared to the rest of Canada.

Spectrum of clinical illness

Asymptomatic upper respiratory tract colonization with *S. pneumoniae* is common. Infection with *S. pneumoniae* may result in bronchitis, otitis media, sinusitis or invasive disease when *S. pneumoniae* invades normally sterile sites, such as the blood or central nervous system.

Bacteremia and meningitis are the most common manifestations of IPD in children 2 years of age and younger. Pneumococci cause 50% of all cases of bacterial meningitis. The case-fatality rate of pneumococcal meningitis is 8% among children and 22% among adults. Permanent neurologic damage is common among survivors. Pneumococcal pneumonia with or without bacteremia is the most common presentation among adults and is a common complication following viral infections. The case fatality rate of bacteremic pneumococcal pneumonia is 5% to 7% and is higher among elderly persons and those with multiple co-morbidities.

Pneumococcal vaccines are authorized for use in Canada

Type of Vaccine	Vaccine Name	Abbreviation	Eligible age groups in Ontario
Pneumococcal conjugate (Pneu-C)	Prevnar 13	Pneu-C-13	This vaccine is no longer publicly funded. Individuals previously eligible for this vaccine should receive either Pneu-C-15 or Pneu-C-20 depending if the individual is at low or high risk for IPD.
	Vaxneuvance	Pneu-C-15	Children 6 weeks to 4 years of age at low risk for IPD.
	Prevnar 20	Pneu-C-20	Individuals ≥6 weeks of age and older at high risk for IPD and individuals ≥65 years of age at low risk for IPD.
Pneumococcal polysaccharide (Pneu-P)	Pneumovax 23	Pneu-P-23	This vaccine is no longer publicly funded. Individuals previously eligible for this vaccine should receive Pneu-C-20.

Publicly funded vaccines for children aged 6 weeks to 17 years

Pneumococcal conjugate (Pneu-C) vaccines that will be available are:

- **Vaxneuvance** (Pneu-C-15) for those aged 6 weeks to 4 years at low risk for IPD
- **Prevnar 20** (Pneu-C-20) for those aged 6 weeks to 17 years at high risk for IPD

For additional information see Table 1: Pneu-C vaccines available in the Appendices.

Vaccine preparation and administration

See the individual vaccine product monographs for step-by-step directions on administration and expiry dates. To ensure the correct volume is accurately drawn up, refer to Table 1 in the Publicly Funded Immunization Schedules for Ontario for assistance in selecting appropriate needle length and gauge.

Vaccine storage and handling

The Vaccine Storage and Handling Guidelines details provincial requirements for the storage and handling of refrigerated vaccines. Please also refer to the product monographs (located in Table 1 of the Appendices) for additional information.

Recommendations for use

The immunization schedules in this document only take into consideration doses of publicly funded pneumococcal vaccines received. Individuals remain eligible for publicly funded pneumococcal vaccines regardless of receipt of privately purchased pneumococcal vaccines. Health care providers should take an individual's complete pneumococcal immunization history into consideration when determining if additional doses are recommended.

Eligible group	Risk of IPD	Recommended schedule	Eligible vaccine
Starting at 2 months of age	Low risk	2, 4, and 12 months of age* See Table 2 and Figure 1	Pneu-C-15
Starting at 2 months of age	High risk⅄ Except HSCT	2, 4, 6 and 12 months of age* See Table 3 and Figure 1	Pneu-C-20
Starting 3-9 months post HSCT	High risk HSCT	See Table 4 and Figure 1	Pneu-C-20

⅄For a list of high-risk criteria that increase an individual's risk for IPD, see below.

* The number of doses required to complete a Pneu-C series for children with interrupted or incomplete schedules varies with the age of the child.

- HSCT: hematopoietic stem cell transplant recipients

Immunization with pneumococcal conjugate vaccine is not recommended for children 5 years of age and older who are at low risk for IPD. Children who are at low risk for IPD who have completed a vaccine series with Pneu-C-13 and/or Pneu-C-15 are not recommended for an additional dose of Pneu-C-15.

All children who are at high risk of IPD and have completed their immunization schedule with Pneu-C-13 should receive 1 dose of Pneu-C-20. Pneu-C-20 should be provided at a minimum interval of 8 weeks since the last dose of Pneu-C-13, or at least 1 year since

a dose of Pneu-P-23. Children at high risk of IPD who have completed a vaccine series that includes at least one dose of Pneu-C-20 do not require any additional doses of Pneu-C-20.

High-risk criteria that increases risk for IPD

As indicated by the National Advisory Committee on Immunization (NACI), the following medical or non-medical conditions increases an individuals' risk of IPD:

1. Asplenia (functional or anatomic), splenic dysfunction
2. Congenital (primary) 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
3. HIV infection
4. Immunocompromising therapy including use of long-term systemic corticosteroid, chemotherapy, radiation therapy, post-organ transplant therapy, certain anti-rheumatic drugs and other immunosuppressive therapy
5. Malignant neoplasms, including leukemia and lymphoma
6. Sickle-cell disease and other sickle cell hemoglobinopathies
7. Solid organ or islet cell transplant (recipient)
8. Hepatic cirrhosis due to any cause
9. Chronic renal disease, including nephrotic syndrome
10. Chronic cardiac disease
11. Chronic liver disease, including hepatitis B and C
12. Chronic respiratory disease, excluding asthma, except those treated with high-dose corticosteroid therapy
13. Chronic neurologic conditions that may impair clearance of oral secretions
14. Diabetes mellitus
15. Cochlear implant recipients (pre/post implant)
16. Chronic cerebral spinal fluid leak
17. Residents of chronic care facilities or wards
18. Hematopoietic stem cell transplant (HSCT) (recipient)

Intervals between vaccines and co-administration

Vaccine	Minimum intervals
Pneu-C and Pneu-C	8 weeks minimum, except post HSCT (See Table 4 for post HSCT intervals)
Pneu-P-23 and Pneu-C	1 year minimum
Vaccines not listed above	Pneu-C-15 **OR** Pneu-C-20 vaccines may be given at the same time with other vaccines, or at any time before or after other vaccines. If Pneu-C-15 **OR** Pneu-C-20 are given by injection at the same time as other vaccine(s), separate limbs should be used if possible. Alternatively, the injections may be administered into the same muscle separated by at least 2.5 cm (1”). Different immunization equipment (needle and syringe) must be used for each vaccine.

Contraindications and precautions

Do not administer a pneumococcal conjugate vaccine to:

- Persons with a history of anaphylaxis after previous administration of the vaccine, and/or
- Persons with proven immediate or anaphylactic hypersensitivity to any component of the vaccine, including diphtheria toxoid.

In situations of suspected hypersensitivity or non-anaphylactic allergy to vaccine components, investigation is indicated, which may involve immunization in a controlled setting. Consultation with an allergist is advised.

Administration of pneumococcal vaccine should be postponed in persons suffering from severe acute illness. Immunization should not be delayed because of minor acute illness, with or without fever.

Vaccine safety

Pneumococcal conjugate vaccines authorized for use in Canada are safe and well tolerated. As with other vaccines, they must be authorized for use by the Canadian regulator, Health Canada, following review of a product’s safety and how well it works (e.g., clinical trial and other evidence.)

Once a vaccine is authorized for use in Canada, provincial surveillance in Ontario and national surveillance coordinated by Health Canada and the Public Health Agency of Canada ensures ongoing monitoring of vaccine safety.

Adverse events

Mild to moderate reactions are more commonly seen including:

- Pain, swelling or redness at the injection site
- Low grade fever
- Fatigue
- Headaches
- Irritability
- Increased or decreased sleep
- Decreased appetite

Pneumococcal conjugate vaccines have been used in Ontario's publicly funded immunization programs for more than 20 years. Severe adverse effects are rare following immunization. In most cases, it does not cause any reaction. There is an extremely rare possibility (less than one in a million people) that anaphylaxis may occur.

Any unexpected or serious reaction to a vaccine should be reported to your local public health unit.

Guidance on reporting Adverse Events Following Immunization (AEFI)

To ensure the ongoing safety of vaccines in Ontario, reporting of AEFIs by physicians, nurses, pharmacists or other persons authorized to administer an immunizing agent is mandatory under the *Health Promotion and Protection Act*. Vaccine providers are asked to report AEFIs through local public health units using the Ontario AEFI Reporting Form. A list of public health units is available at: www.health.gov.on.ca/en/common/system/services/phu/locations.aspx.

Those administering vaccines should ensure that the vaccine recipients or their parents or guardians are aware of the need to immediately report AEFIs to their health care provider. Subsequently, health care providers should report any serious or unexpected adverse event felt to be temporally related to vaccination to their local public health unit.

Vaccine recipients or their parents or guardians should be advised to go to the nearest emergency department if severe reactions develop, including the following:

- Hives
- Swelling of the mouth or throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C)
- Convulsions (seizures)
- Other serious reactions

Observation period following immunization

NACI recommends a 15-minute post-vaccination observation period, as specified in the Canadian Immunization Guide (CIG). If there is a specific concern about possible vaccine allergy, 30 minutes is a safer interval.

Record of immunization

Each vaccine recipient should be provided with a permanent personal immunization record, the Yellow Immunization Card. Please write “Prevnar 20” (if Pneu-C-20 was administered) or “Vaxneuvance” (if Pneu-C-15 was administered) under the “vaccine brand name” column. Vaccine recipients, or their parents or guardians, should be instructed to keep the record in a safe place and to present it at every health care visit so that it can be updated.

Infants born prematurely

Premature infants in stable clinical condition should be immunized with a Pneu-C at the same chronological age and according to the same schedule (i.e., Table 3, Table 4 or Table 5) as full-term infants.

Persons with inadequate immunization records

Children with incomplete immunization records, or no immunization records, should be considered unimmunized and should receive pneumococcal vaccines on a schedule appropriate to their age and risk factors, regardless of possible previous immunization.

Individuals who are not eligible for publicly funded vaccines

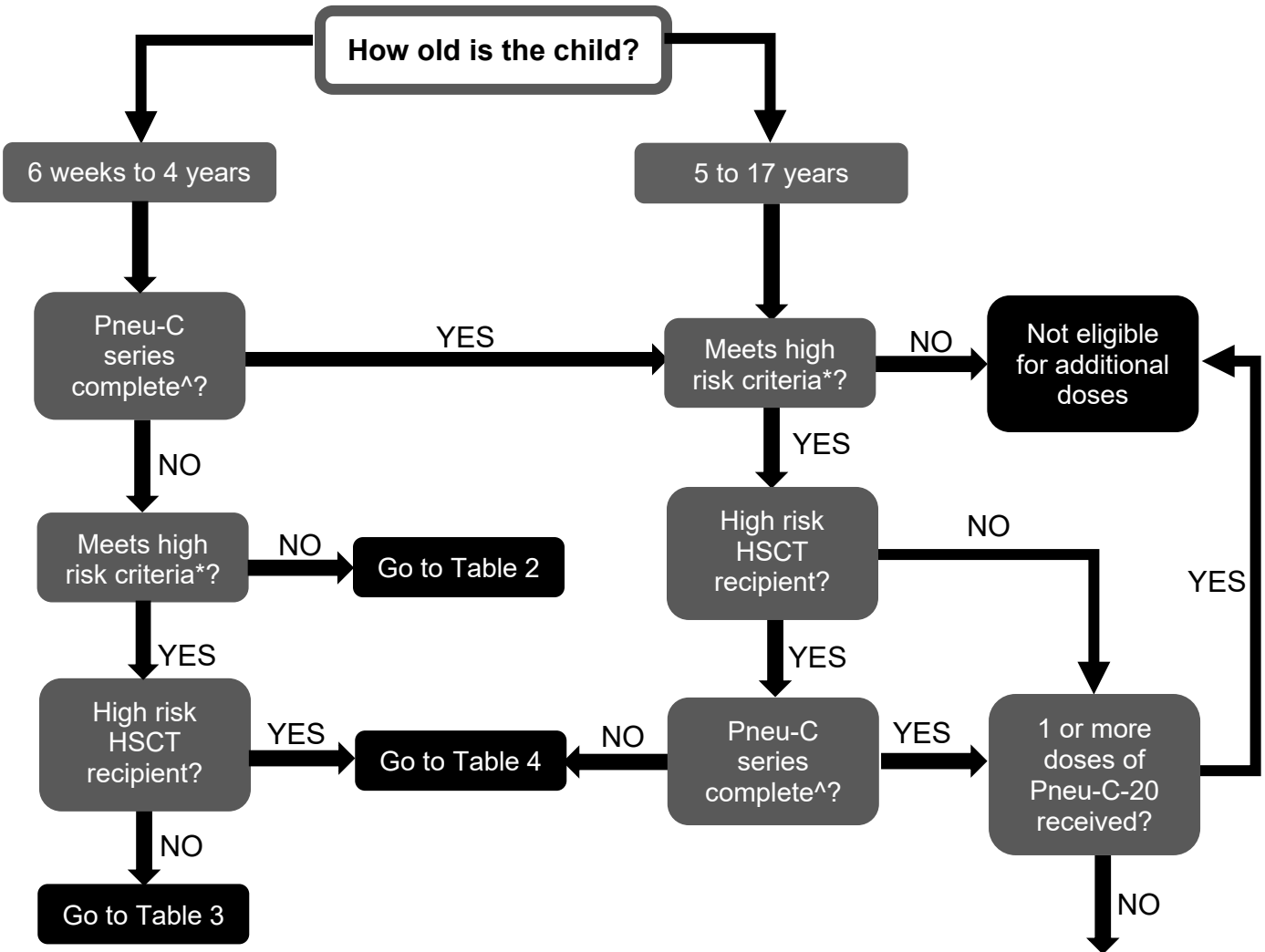
NACI provides recommendations on the use of pneumococcal conjugate vaccines. Individuals who are not eligible for publicly funded Pneu-C-15 or Pneu-C-20 can privately purchase pneumococcal conjugate vaccines.

Appendices

Table 1: Pneu-C vaccines

Vaccine	Pneumococcal Conjugate 15-valent	Pneumococcal Conjugate 20-valent
Vaccine abbreviation	Pneu-C-15	Pneu-C-20
Vaccine name	Vaxneuvance	Prevnar 20
Manufacturer	Merck	Pfizer
Protects against	IPD	IPD
***Streptococcus* pneumoniae serotypes**	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F	1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F
Dosage	0.5 mL	0.5 mL
Route of administration	Intramuscular Injection (IM)	Intramuscular Injection (IM)
Package format	1 prefilled syringe 10 prefilled syringes	10 prefilled syringes
Package size (cm) **L x W x H**	1 syringe: 4.9 x 3.2 x 13.3 10 syringes: 11.4 x 5.2 x 12.4	12.45 x 9.91 x 5.33
Specific storage considerations	N/A	Syringes should be stored **horizontally** to minimize the re-dispersion time.
Product monograph	Vaxneuvance	Prevnar 20
Eligibility Criteria	Children 6 weeks to 4 years **not** at low risk for IPD (low risk)	Individuals 6 weeks and older at high risk for IPD (high risk) and adults 65 years and older

Figure 1: Immunization decision flowchart for individuals 6 weeks to 17 years



***High-risk criteria for those at risk for IPD:** 1. Asplenia (functional or anatomic), splenic dysfunction, 2. Congenital (primary) 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, 3. HIV infection, 4. Immunocompromising therapy including use of long-term systemic corticosteroid, chemotherapy, radiation therapy, post-organ transplant therapy, certain anti-rheumatic drugs and other immunosuppressive therapy, 5. Malignant neoplasms, including leukemia and lymphoma, 6. Sickle-cell disease and other sickle cell hemoglobinopathies, 7. Solid organ or islet cell transplant (recipient), 8. Hepatic cirrhosis due to any cause, 9. Chronic renal disease, including nephrotic syndrome, 10. Chronic cardiac disease, 11. Chronic liver disease, including hepatitis B and C, 12. Chronic respiratory disease, excluding asthma, except those treated with high-dose corticosteroid therapy, 13. Chronic neurologic conditions that may impair clearance of oral secretions, 14. Diabetes mellitus, 15. Cochlear implant recipients (pre/post implant), 16. Chronic cerebral spinal fluid leak, 17. Residents of chronic care facilities or wards, 18. Hematopoietic stem cell transplant (HSCT) (recipient)

^Pneu-C series can be completed with:

- High risk for IPD: Pneu-C-13 and/or Pneu-C-20
- Low risk for IPD: Pneu-C-13 and/or Pneu-C-15

Table 2: PNEU-C-15 vaccination series for children aged 6 weeks to 4 years at LOW-RISK for IPD

Child's current age	# of previously received Pneu-C$^{\beta}$ doses	# of PNEU-C-15 dose(s) required to complete series	Intervals between doses$^{\curlyvee}$
2 to 11 months	0 doses	2 doses **+** 1 dose at age ≥12 months	2 months
	1 dose	1 dose **+** 1 dose at age ≥12 months	2 months
	2 doses	1 dose at age ≥12 months	2 months
12 to 23 months	0 doses	2 doses	2 months
	1 dose at age <12 months	2 doses	2 months
	1 dose at age ≥12 months	1 dose	2 months
	1 dose at age <12 months **+** 1 dose at age ≥12 months	1 dose	2 months
	≥2 doses at age <12 months	1 dose	2 months
	Completed series	0 doses	N/A
24 to 59 months	0 doses	1 dose	N/A
	Any incomplete series	1 dose	2 months
	Completed series	0 doses	N/A

$^{\curlyvee}$ Recommended interval between doses is 2 months and the minimum is 8 weeks
$^{\beta}$ Unless noted any Pneu-C vaccine can be used

Table 3: PNEU-C-20 vaccination series for children aged 6 weeks to 17 years at HIGH-RISK for IPD⅄ (except HSCT see Table 4)

Child's current age	# of previously received Pneu-Cβ doses	# of PNEU-C-20 dose(s) required to complete series	Intervals between dosesϒδ
2 to 6 months	0 doses	3 doses + 1 dose at age ≥12 months	2 months
	1 dose	2 doses + 1 dose at age ≥12 months	2 months
	2 doses	1 dose + 1 dose at age ≥12 months	2 months
7 to 11 months	0 doses	2 doses + 1 dose at age ≥12 months	2 months
	1 dose	1 dose + 1 dose at age ≥12 months	2 months
	2 doses	1 dose at age ≥12 months	2 months
12 to 23 months	0 doses	2 doses	2 months
	1 dose at age <12 months	2 doses	2 months
	1 dose at age ≥12 months	1 dose	2 months
	1 dose at age <12 months + 1 dose at age ≥12 months	1 dose	2 months
	≥2 doses at age <12 months	1 dose	2 months
	Completed series with 0 doses of Pneu-C-20	1 dose	2 months
	Completed series with ≥1 dose of Pneu-C-20	0 doses	N/A
24 to 59 months	0 doses	1 dose	2 months
	Any incomplete series	1 dose	2 months
	Completed series with 0 doses of Pneu-C-20	1 dose	2 months
	Completed series with ≥1 dose of Pneu-C-20	0 doses	N/A
5 to 17 years	0 doses of Pneu-C-20	1 dose	2 months
	≥1 dose of Pneu-C-20	0 doses	N/A

⅄ For a list of high-risk criteria that increase an individual's risk for IPD, see pages 3-4

β Unless noted any Pneu-C vaccine can be used

ϒ Recommended interval between doses is 2 months and the minimum is 8 weeks

δ Pneu-C-20 should be given 1 year after last dose of Pneu-P-23

Table 4: Pneu-C-20 vaccination series for HIGH-RISK HSCT recipients aged ≥6 weeks

# of previously received Pneu-C$^{\beta}$ doses	# of Pneu-C-20 dose(s) required to complete series and intervals$^{\delta}$
0 doses post HSCT	1st dose, 3-9 months post HSCT 2nd dose, ≥4 weeks after 1st dose 3rd dose, ≥4 weeks after 2nd dose 4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
1 dose post HSCT	2nd dose, ≥4 weeks after 1st dose 3rd dose, ≥4 weeks after 2nd dose 4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
2 doses post HSCT	3rd dose, ≥4 weeks after 2nd dose 4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
3 doses post HSCT	4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
4 doses post HSCT with 0 doses of Pneu-C-20	1 dose, 12-18 months post HSCT and 8 weeks after last dose of Pneu-C
4 doses post HSCT with ≥1 dose of Pneu-C-20	0 doses

δ Pneu-C-20 should be given 1 year after last dose of Pneu-P-23
β Unless noted any Pneu-C vaccine can be used