

Manitoba's Pneumococcal Immunization Program

Frequently Asked Questions & Answers for Health Care Providers

1. What is pneumococcal disease?

Streptococcus pneumoniae (*S. pneumoniae*) is a bacterium that can cause infections of the ears, sinuses or upper airways. It can also cause community-acquired pneumonia (CAP) and more serious infections of the blood or brain referred to as invasive pneumococcal disease (IPD).

Healthy individuals can carry *S. pneumoniae* in the nasopharyngeal region without any presence of infection. *S. pneumoniae* colonizes in the mucosal surfaces of the nasopharynx and upper respiratory airway, and symptoms of inflammation appear as the bacteria migrate into the sterile parts of the airway. When pneumococci migrate to the lungs, they can cause pneumonia (i.e. CAP), or can enter the blood stream and cause bacteremia or septicemia (i.e. IPD). *S. pneumoniae* is an important cause of bacterial co-infection in patients with influenza.

IPD is most common in the very young (those under the age of five, especially those under the age of two) as well as the elderly, and groups at high risk due to an underlying medical condition. Individual risk for getting IPD can also be impacted by environmental or lifestyle factors such as alcoholism, homelessness as well as smoking and illicit drug use.

2. What vaccines offer protection against pneumococcal disease?

There are two Health Canada approved vaccines available as part of Manitoba's Pneumococcal Immunization Program:

1. **Pneumococcal Conjugate (Pneu-C-13) vaccine (Pneumovax 13, Pfizer)**
2. **Pneumococcal Polysaccharide (Pneu-P-23) vaccine (Pneumovax 23®, Merck)**

The Pneu-C-13 vaccine protects against 13 different types of *S. pneumoniae* that cause the most severe infections of the more than 90 types that circulate. Pnevax[®]13 was first approved for pediatric use only. Its indications have since expanded to include adults of any age, without contraindications, for the prevention of IPD and CAP. In children less than five years of age, the effectiveness of the conjugate vaccine against IPD due to serotypes contained in the vaccine is estimated to range from 86% to 97%.

The Pneu-P-23 vaccine protects against 23 different serotypes. Pneu-P-23 vaccine efficacy against IPD is estimated to be 50% to 80% among the elderly and in high-risk groups. Immunogenicity and efficacy are decreased in certain groups at particularly high-risk of pneumococcal infection, such as persons with kidney failure, sickle cell anemia, or impaired responsiveness, including human immunodeficiency virus (HIV) infection.

.....
Antimicrobial resistance among some *S. pneumoniae* makes prevention through the use of vaccines vital.
.....

3. What are the differences between the Pneu-C-13 vaccine and the Pneu-P-23 vaccine?

The Pneu-C-13 vaccine has been shown in a randomized control trial (CAPiTA study) to decrease IPD and CAP in children and older adults caused by the 13 serotypes included in the vaccine.

Based on the literature and Canadian epidemiological data, the Pneu-P-23 vaccine is a safe and effective tool in preventing IPD in immunocompetent adults over 65 years of age.

Generally, conjugated vaccines (i.e. the Pneu-C-13 vaccine) induce longer lasting immunity than polysaccharide vaccines (i.e. the Pneu-P-23 vaccine). Additionally, polysaccharide vaccines are less immunogenic in children younger than 2 years of age.

4. Is the pneumococcal vaccine offered free-of-charge to adults?

The Manitoba Immunization Program provides vaccines free-of-charge to individuals registered with Manitoba Health, Seniors and Active Living (MHSAL), as per provincial Eligibility Criteria for Publicly Funded Vaccines:

<https://www.gov.mb.ca/health/publichealth/cdc/vaccineeligibility.html>.

MHSAL routinely offers the Pneu-C-13 vaccine free-of-charge to infants and children as part of Manitoba's routine childhood immunization schedule.

Adults with one or more of the following high-risk medical conditions are also eligible for publicly funded Pneu-C-13 vaccine:

- Hematopoietic stem cell transplant (HSCT) recipients
- Individuals with HIV
- Solid organ transplant recipients

Patients under the care of a haematologist or oncologist from CancerCare Manitoba (CCMB) who have the following conditions and have been provided a CCMB directed schedule may be eligible for the Pneu-C-13 vaccine **and** Pneu-P-23 vaccine:

1. Malignant neoplasms (solid tissue and haematological) including leukemia and lymphoma, or clonal blood disorder, and who will receive or have completed immunosuppressive therapy including chemo therapy or radiation therapy, **or**
2. Hypo- or asplenic (Sickle Cell Disease, etc.)

Individuals two to < 65 years of age who are high-risk of IPD, are eligible for the Pneu-P-23 vaccine. This includes:

- Residents of a personal care home or long-term care facility
- Chronic cerebral spinal fluid (CSF) leak
- Cochlear implants (including those children who are to receive implants)
- Chronic cardiac or pulmonary disease
- Diabetes mellitus
- Chronic kidney disease
- Chronic liver disease (including hepatic cirrhosis due to any cause)
- 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
- Asplenia (functional or anatomic)
- Immunocompromising therapy including use of long-term corticosteroids, post-organ transplant therapy, and certain anti-rheumatic drugs
- HIV infection
- HSCT recipients
- Solid organ or islet transplant (candidate or recipient)
- Chronic neurologic condition that may impair clearance of oral secretions
- Nephrotic syndrome
- Alcoholism
- Homelessness
- Illicit drug users*

**In light of the current increase in illicit drug use via injection in Manitoba, health care providers are encouraged to make every effort to offer the Pneu-P-23 vaccine to individuals with lifestyle and/or environmental risk factors.*

Individuals up to the age of 65 who are at highest risk for IPD are eligible for one lifetime booster dose. Individuals 65 years of age and older who are newly diagnosed as being at highest risk of IPD are eligible for one lifetime booster dose. This includes people with the following medical conditions:

- Asplenia (functional or anatomic)

- Sickle cell disease
- Hepatic cirrhosis
- Chronic renal failure
- Nephrotic syndrome
- HIV infection
- Immunosuppression related to disease or therapy

All individuals aged 65 years and older are eligible to receive a dose of Pneu-P-23 vaccine, regardless of risk factors or previous pneumococcal vaccination.

Refer to question 5 for information pertaining to minimum intervals between pneumococcal vaccines.

5. Does the National Advisory Committee on Immunization (NACI) recommend ALL adults receive the Pneu-C-13 vaccine?

No. NACI recommends adults with immunocompromising conditions resulting in one or more of the following high-risk conditions receive the Pneu-C-13 vaccine:

- Sickle cell disease, congenital or acquired asplenia, or splenic dysfunction
- 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
- Immunocompromising therapy including use of long-term corticosteroids, chemotherapy, radiation therapy and post-organ transplant therapy

- HIV infection
- HSCT (recipient)
- Malignant neoplasms, including leukemia and lymphoma
- Nephrotic syndrome
- Solid organ or islet transplant (candidate or recipient)

See question 4 to determine MHSAL eligibility for Pneu-C-13 vaccine for adults.

According to 2015 data, in adults aged 65 years and older, approximately 30% of IPD cases and 10% of all-cause CAP requiring hospitalization are caused by Pneu-C-13 serotypes. Immunization with the Pneu-C-13 vaccine may be considered on an individual basis for pneumococcal vaccine-naïve, healthy adults aged 65 years and older for the prevention of CAP and IPD. This would require a prescription because it is not a funded cohort under The Manitoba Pneumococcal Immunization Program at this time (see question 10).

6. Why is Pneu-C-13 vaccine not recommended for ALL adults aged 65 years and older?

At this time, NACI recommends against routinely publicly funding the Pneu-C-13 vaccine for healthy adults 65 years of age and older at the population-level. NACI considered disease burden, herd immunity effects and the results of economic evaluation.

NACI's recommendation for adults aged 65 years and older, without other risk factors increasing their risk of IPD, is based on the epidemiology of circulating serotypes causing IPD and CAP in Canada and the evidence of changing incidence of pneumococcal disease following the

implementation of childhood pneumococcal immunization programs. Although there is clinical trial evidence for Pneu-C-13 vaccine efficacy in older adults for preventing IPD and CAP, currently within the Canadian context, such a publicly funded program would not significantly decrease the disease burden in a cost-effective manner.

7. What is the recommended interval between the Pneu-C-13 vaccine and Pneu-P-23 vaccine?

In situations where a health care provider recommends both the Pneu-C-13 vaccine and Pneu-P-23 vaccine, the Pneu-C-13 vaccine should be provided first, followed by the Pneu-P-23 vaccine **eight weeks** later. The purpose of administering Pneu-P-23 vaccine to an individual who has already received Pneu-C-13 vaccine is to expand the breadth of serotypes against which an individual is protected.

Adults who have previously received the Pneu-P-23 vaccine can receive the Pneu-C-13 vaccine **one year** after the Pneu-P-23 vaccine. The minimum interval is due to the theoretical potential for a decrease in antibody titres following immunization with Pneu-P-23.

The Pneu-P-23 lifetime booster dose has a minimum **five-year** interval after any previous dose of Pneu-P-23 vaccine.

The following table illustrates the minimum interval between pneumococcal vaccines, depending on the order in which pneumococcal vaccines are given.

Order of pneumococcal vaccine given	Minimum Interval
Pneu-C-13, then Pneu-P-23	8 weeks
Pneu-P-23, then Pneu-C-13	1 year
Pneu-P-23, then Pneu-P-23	5 years

8. Are booster doses recommended and funded?

Booster doses outside of the initial primary series (either a one dose, three dose or four dose series) for the Pneu-C-13 vaccine are not indicated at this time.

However, the Pneu-P-23 vaccine is less immunogenic than the Pneu-C-13 vaccine. Following immunization with Pneu-P-23 vaccine, antibody concentrations decline after five to 10 years; the duration of immunity is unknown. Therefore, a second lifetime (“booster”) dose of Pneu-P-23 vaccine is recommended and provided free-of-charge for those at highest risk of IPD, as per the following conditions:

- Asplenia (functional or anatomic) including sickle cell disease
- Hepatic cirrhosis
- Chronic renal failure
- Nephrotic syndrome
- HIV infection
- Immunosuppression related to disease or therapy (a listing is available at:

www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-

[guide-part-3-vaccination-specific-populations.html?page=8](#)).

If a booster dose is recommended, it should be administered at least five years after any previous dose of Pneu-P-23 vaccine and eight weeks after any previous dose of Pneu-C-13 vaccine.

All individuals should receive a dose of Pneu-P-23 vaccine at ≥ 65 years of age, regardless of risk factors or previous pneumococcal vaccination (provided the minimum 5-year interval between Pneu-P-23 vaccines is followed as well as the minimum eight week interval after any previous doses of Pneu-C-13 vaccine). Individuals at highest risk may therefore receive up to three publicly funded Pneu-P-23 vaccine doses.

9. Please provide examples of pneumococcal vaccine recommendations and eligibility including dosing and minimum intervals.

Example 1: pneumococcal vaccine-naïve, 40-year-old male diagnosed with HIV-infection.

Offer patient one dose of Pneu-C-13 vaccine free-of-charge, followed 8 weeks later by a publicly funded dose of Pneu-P-23 vaccine. Five years later (when patient is approx. 45 years of age), offer a second dose of Pneu-P-23 vaccine. When the patient turns 65 years of age, offer a dose of Pneu-P-23 vaccine free-of-charge.

Example 2: *previously unimmunized 66-year-old female with COPD.*

Offer patient one publicly funded dose of Pneu-P-23 vaccine.

Example 3: *70-year-old female, asplenia as of 1980, previously immunized with two doses of Pneu-P-23 vaccine in 1990 and 1995.*

Consider recommending a dose of Pneu-C-13 vaccine (out-of-pocket expense; prescription required) followed eight weeks later by a publicly funded dose of Pneu-P-23 vaccine.

Example 4: *70 year-old female, recently in renal failure; previously received a dose of Pneu-P-23 vaccine at 65 years of age.*

Offer patient one publicly funded dose of Pneu-P-23 vaccine; ensure it is five years after previous dose of Pneu-P-23 vaccine.

Example 5: *62 year-old, unimmunized male who recently started living at the Deer Lodge Centre (personal care home).*

Offer patient a publicly funded dose of Pneu-P-23 vaccine upon admittance to the personal care home. Five-years thereafter, offer a second dose of Pneu-P-23 vaccine (when patient is approximately 67 years of age).

10. If a patient is ineligible for Pneu-C-13 vaccine under MHSAL eligibility criteria, how can they get immunized?

Those ineligible for publicly funded Pneu-C-13 vaccine can obtain a prescription from a licensed health care provider, purchase the vaccine at a pharmacy and then make an appointment with any health care provider that offers non-funded immunization services.

Prior to issuing/dispensing a prescription for purchase by a client, it is important that eligibility for the publicly-funded Pneu-C-13 vaccine be confirmed by the health care provider or dispensing pharmacy because Departmental policy states that MHSAL does not reimburse individuals who pay out of pocket for a vaccine that is provided free-of-charge. Moreover, publicly funded Pneu-C-13 vaccine is provided to health care providers for the sole purpose of administering MHSAL's Pneumococcal Immunization Program. Pneumococcal vaccines ordered from the provincial distribution warehouse must be used solely for administering the vaccine to eligible patients, as per MHSAL's Eligibility Criteria for Publicly Funded Vaccines:

<https://www.gov.mb.ca/health/publichealth/cdc/vaccineeligibility.html>.