Ontario

Ministry of Health

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July 2, 2024

Dear Health Care Provider,

This letter is to inform you that Ontario's publicly funded pneumococcal vaccine program is transitioning to the following new pneumococcal vaccines:

- Pneumococcal 15-valent conjugate (Pneu-C-15), Vaxneuvance
- Pneumococcal 20-valent conjugate (Pneu-C-20), Prevnar 20

These two new pneumococcal conjugate vaccines will provide broader protection against invasive pneumococcal disease (IPD) compared to Pneu-C-13 and longer-term protection than Pneu-P-23, which are currently used in the provincial program.

The Pnue-C-15 vaccine is for use in the routine pediatric pneumococcal vaccine program and the Pneu-C-20 is for use in the high-risk programs and the routine adult program 65+. Please note eligibility for these programs in not changing and re-vaccination is not part of the product transition. Any future changes in eligibility will be communicated separately.

Please refer to the following attachments for additional information:

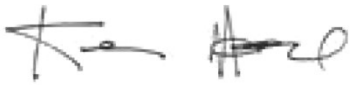
- Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccines for Children Aged 6 Weeks to 4 Years
- Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccine for High-Risk Individuals Aged 5 to 64 Years
- Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccine for Individuals Aged 65 Years and Older
- Vaccine Fact Sheet: Pneumococcal Vaccine Program for Individuals Aged 6 Weeks and Older
- Qs & As for Health Care Providers: Pneumococcal Vaccine Transition

The program transition is planned for July 29, 2024. Details on ordering Pneu-C-15 and Pneu-C-20 vaccines will be shared by your local public health unit.

Should you or your staff have any questions, please contact your local public health unit.

We thank you for your continued support and dedication to the publicly funded immunization program, protecting Ontarians against vaccine preventable diseases.

Sincerely,



Dr. Kieran Michael Moore, MD, CCFP(EM), FCFP, MPH, DTM&H, FRCPC, FCAHS
Chief Medical Officer of Health and Assistant Deputy Minister, Public Health

c: Dr. Daniel Warshafsky, Associate Chief Medical Officer of Health
Michael Sherar, President and Chief Executive Office, Public Health Ontario

Ontario

Ministry of Health

Vaccine Fact Sheet: Pneumococcal Vaccine Program for Individuals Ages 6 Weeks and Older

This document is intended for informational purposes only. It is not intended to provide medical or legal advice.

Importance of getting immunized with pneumococcal vaccines

Pneumococcal vaccines can prevent illness caused by many types of pneumococcal bacteria, which can cause serious and life-threatening infections like:

- Meningitis (infection of the lining of the brain)
- Septicemia (infection in the blood)
- Pneumonia (infection of the lungs)

More commonly, pneumococcal bacteria can cause:

- Otitis media (ear infections)
- Sinusitis (sinus infections)

Most pneumococcal infections are mild but can invade parts of the body that are normally bacteria-free. When this happens, a serious disease called invasive pneumococcal disease (IPD) can develop, which can cause serious symptoms, lifelong disability or even death. Meningitis, septicemia, and pneumonia caused by IPD can be fatal.

What pneumococcal conjugate vaccines protect against

The pneumococcal conjugate (Pneu-C) vaccines have been approved for use by Health Canada and are safe and effective products that protect against up to 20 different types of bacteria that cause pneumococcal disease. Vaccines protect you by building antibodies against a disease. The vaccines are provided for free to eligible individuals as part of the Ontario's publicly funded immunization program.

How pneumococcal disease is spread

Pneumococcal bacteria are very common. Many people have them in their nose and throat without getting sick, but they can still spread the bacteria through infected mucus or saliva. You may come in contact with infected mucus or saliva by:

- being near an infected person who coughs or sneezes
- having close contact with an infected person (for example, kissing or hugging)
- touching objects that were recently exposed to an infected person's mucus or saliva (such as shared utensils, cups, tissues or toys) and then rubbing your eyes, nose or mouth

Risk of pneumococcal disease

Anyone can get pneumococcal disease, but children under 2 years old, people with certain medical conditions or other risk factors, and adults 65 years or older are at the highest risk.

Publicly funded pneumococcal conjugate vaccines in Ontario

Type of Vaccine	Vaccine Name	Abbreviation
Pneu-C	Vaxneuvance	Pneu-C-15
	Prevnar 20	Pneu-C-20

Eligibility criteria for Pneu-C vaccines

Eligibility	Vaccine	# of doses	Schedule
6 weeks to 4 years of age who are **not** at increased risk for IPD	Pneu-C-15	Up to 3 doses	2, 4 and 12 months of age
6 weeks to 4 years of age who are at increased risk for IPD	Pneu-C-20	Up to 4 doses	2, 4, 6 and 12 months of age
5 to 64 years of age with certain medical and non-medical conditions that increase their risk for IPD	Pneu-C-20	1 lifetime dose	
65 years of age and older	Pneu-C-20	1 lifetime dose	

Catch-up immunizations are available to those who miss their scheduled doses. Individuals who have previously received all eligible publicly funded doses of pneumococcal vaccines based on their age and risk of IPD may not be eligible to receive additional doses of pneumococcal vaccines. Speak with your health care provider to determine your vaccine eligibility and schedule.

Vaccine safety

Pneu-C vaccines are approved for use by Health Canada and they are safe. They are not only used in Canada but are used worldwide. Pneu-C-vaccines have been used in Ontario's publicly funded immunization programs for more than 20 years.

Every approved vaccine must be shown to be safe and effective before it is approved for use in Canada. Once approved, vaccine safety is continuously monitored.

Possible reactions after receiving the vaccine

Many people have no side effects from Pneu-C vaccines. For those that do, they are usually mild and last one to two days. Serious side effects are very rare.

Common reactions to Pneu-C vaccines may include:

- Soreness, redness and/or swelling where the vaccine was given
- Fever
- Drowsiness
- Loss of appetite
- Headache
- Muscle or joint ache
- Chills
- Fussiness (irritability) - infants only

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy before, during, or after getting vaccinated and they can take extra precautions to ensure your safety.

As with any medicine, there is an extremely rare possibility (less than one in a million people) of a life-threatening allergic reaction called anaphylaxis. Signs of anaphylaxis can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness. For this reason, it is important to remain at your health care provider's office for at least 15 minutes after you have received your Pneu-C vaccine. If anaphylaxis occurs, you will be given medicine to treat the symptoms.

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

Managing side effects of the vaccine

To help with soreness and swelling, put a cool, wet cloth over the area where you had the needle.

There is medicine to help with a fever or pain. Check with a health care provider if you are not sure what medicine or dose to take. Follow the directions on the package.

Some people with health problems, such as a weak immune system, must call their health care provider if they get a fever. If you have been told to do this, call your health care provider even if you think the fever is from the vaccine.

What to do if a serious problem occurs

An allergic reaction could occur after someone leaves the place of vaccination. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get to the nearest hospital.

For other signs that concern you, call a health care provider.

Adverse reactions should be reported to a health care provider or your local public health unit.

When not to get the vaccine or when to delay immunizations

Speak with your health care provider if you have had a severe allergic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine including diphtheria toxoid.

In some cases, your health care provider may decide to postpone pneumococcal vaccine immunization until a future visit. People with minor illnesses, such as a cold, may be immunized. People who are moderately or severely ill should usually wait until they recover. Your health care provider can give you more information.

Vaccine record

Your health care provider should document your immunization in your Yellow Immunization Card. Please keep your Yellow Immunization Card in a safe place and bring it with you each time you receive a vaccine from your health care provider.

Privately purchasing vaccine for those that are not eligible for publicly funded Pneu-C vaccine

If you do not meet eligibility criteria for the publicly funded Pneu-C vaccine, you can speak to your health care provider to determine if the vaccine would be appropriate for you. The vaccine would need to be privately purchased; however, if you have a private insurance plan, you may connect with them to determine if Pneu-C vaccine is covered.

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Qs & As for Health Care Providers: Pneumococcal Vaccine Transition

This document will assist vaccine providers with the transition of the current pneumococcal conjugate 13-valent (Pneu-C-13) and pneumococcal polysaccharide 23-valent (Pneu-P-23) vaccines to the new pneumococcal conjugate 15-valent (Pneu-C-15) and 20-valent (Pneu-C-20) vaccines .

Which pneumococcal vaccines are authorized for use in Canada?

Type of Vaccine	Vaccine Name	Abbreviation
Pneumococcal conjugate (Pneu-C)	Prevnar 13	Pneu-C-13
	Vaxneuvance	Pneu-C-15
	Prevnar 20	Pneu-C-20
Pneumococcal polysaccharide (Pneu-P)	Pneumovax 23	Pneu-P-23

Which pneumococcal vaccines were previously publicly funded and what vaccines are currently publicly funded in Ontario?

Vaccine program	Eligible age group	Previous vaccine	Current vaccine
Routine	6 weeks to 4 years of age	Pneu-C-13	Pneu-C-15
Routine	≥65 years of age	Pneu-P-23	Pneu-C-20
High risk	≥6 weeks of age and older	Pneu-P-23 and Pneu-C-13	Pneu-C-20

What serotypes do each of the vaccines protect against?

Serotypes	Pneu-C-13	Pneu-C-15	Pneu-C-20	Pneu-P-23
1	✓	✓	✓	✓
4	✓	✓	✓	✓
5	✓	✓	✓	✓
6B	✓	✓	✓	✓
7F	✓	✓	✓	✓
9V	✓	✓	✓	✓
14	✓	✓	✓	✓
18C	✓	✓	✓	✓
19F	✓	✓	✓	✓
23F	✓	✓	✓	✓
3	✓	✓	✓	✓
19A	✓	✓	✓	✓
6A	✓	✓	✓	
22F		✓	✓	✓
33F		✓	✓	✓
8			✓	✓
10A			✓	✓
11A			✓	✓
12F			✓	✓
15B			✓	✓
2				✓
9N				✓
17F				✓
20				✓

What is the difference between conjugate and polysaccharide vaccines?

Protection induced by polysaccharide vaccines wanes more quickly (within 5 years of vaccination) due to their T cell independent mode of action, than conjugate vaccines. In contrast, conjugate vaccines induce memory, provide longer duration of protection, and provide the ability for boosting by involving T cells.

Polysaccharide vaccines have also been associated with hyporesponsiveness (i.e., lower antibody titres against serotypes) with subsequent dosing. However, this has rarely been demonstrated to affect clinical outcomes. The conjugate vaccines have not been associated with hyporesponsiveness.

For the high-risk programs, is the protection from Pneu-C-20 vaccine expected to be better than that offered by the Pneu-P-23 vaccine?

Pneu-C-20 vaccine covers close to 90% of serotypes included in Pneu-P-23 vaccine. It also has the additional benefit of being a conjugate vaccine. Pneu-C-20 vaccine is expected to provide protection that is similar to Pneu-C-13 for the shared strains and will offer protection against the additional 7 strains.

Who is eligible for Ontario's high-risk pneumococcal immunization program?

Eligibility depends on age, previous pneumococcal immunization, and presence of specific medical and non-medical conditions that increase an individual's risk for IPD. Refer to Health Care Provider Fact Sheets for eligibility criteria and vaccine schedules.

List of high-risk criteria that increases an individual's 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 nursing homes, homes for the aged and chronic care facilities or wards
18. Hematopoietic stem cell transplant (HSCT) (recipient)

Would those who are eligible to receive Pneu-C-20 vaccine continue to be eligible for a Pneu-P-23 vaccine booster?

If a client receives Pneu-C-20 vaccine, a Pneu-P-23 vaccine booster is not recommended. Pneumococcal conjugate vaccines are more immunogenic and provide longer-lasting protection than the pneumococcal polysaccharide vaccine. Therefore, Pneu-C-20 vaccine can be offered as a single dose without a subsequent dose of Pneu-P-23 vaccine, which aligns with recommendations from the National Advisory Committee on Immunization (NACI).

Will Pneu-P-23 vaccine continue to be publicly funded?

Pneu-P-23 vaccine will no longer be publicly funded as it will be replaced with the Pneu-C-20 vaccine. NACI no longer recommends the use of Pneu-P-23 vaccine if Pneu-C-20 vaccine is available for individuals at high risk of IPD.

Will individuals at high risk for IPD who receive Pneu-C-20 vaccine require a booster dose of Pneu-C-20 vaccine in the future?

Currently, there are no recommendations for a booster dose of Pneu-C-20 vaccine.

Re-immunization using a same-valency conjugate vaccine following the completion of an age-appropriate schedule is not currently recommended since it is not known whether additional doses will confer an added benefit. For example, children at increased risk of IPD and hematopoietic stem cell transplant (HSCT) recipients who have completed a vaccine series that includes at least one dose of Pneu-C-20 do not require further doses and adults for whom Pneu-C-20 is indicated should only receive one dose of Pneu-C-20.

Why is Pneu-C-20 vaccine not being used for all pneumococcal vaccine programs?

NACI states that either Pneu-C-15 or Pneu-C-20 may be used for routine immunization of healthy children who are 6 weeks to 4 years of age and not at increased risk for IPD. Pneu-C-15, which is a higher-valent pneumococcal conjugate vaccine, can protect children against additional serotypes compared to Pneu-C-13 and is expected to further reduce the burden of IPD. NACI recommends that the Pneu-C-20 vaccine be used for individuals 6 weeks and older who are at increased risk of IPD and for programs for individuals 65 years of age and older.

Are there different pediatric pneumococcal vaccine schedules?

There are two pediatric pneumococcal vaccine schedules for children ages 6 weeks to 4 years:

1. Children **not** at increased risk of IPD: Pneu-C-15 vaccine is routinely administered using a 3-dose schedule at 2 months, 4 months and 12 months of age.
2. Children at increased risk of IPD: Pneu-C-20 vaccine is routinely administered using a 4-dose schedule at 2 months, 4 months, 6 months and 12 months of age.

Catch-up schedules for children who missed doses are detailed in the Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccines for Children Aged 6 Weeks to 4 Years. Refer to Table 3, Table 4 and Table 5.

Will catch-up programs for those who have previously completed their pneumococcal immunizations be considered?

The current transition for the pneumococcal program will focus on those who have not completed or have not received all eligible publicly funded pneumococcal vaccine(s) (e.g., Pneu-P-23 and/or Pneu-C-13).

The ministry is currently examining future catch-up programs for Pneu-C-20 vaccine for those who have received all eligible publicly funded pneumococcal immunizations.

How can I order Pneu-C-15 and Pneu-C-20 vaccines?

Vaccine providers should order vaccine from their usual vaccine supply source (i.e., public health unit or the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS)).

What should I do with my Pneu-C-13 and Pneu-P-23 vaccines?

The ministry may receive a credit for any unused Pneu-C-13 and/or Pneu-P-23 vaccines. It is important for you to return any unused pneumococcal vaccines to your usual vaccine supply source (i.e., public health unit or OGPMSS), once you have received doses of Pneu-C-15 and Pneu-C-20 vaccines.

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 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.

Where can I find the product monographs?

Product monographs are available from Health Canada:

- Pneu-C-15: Vaxneuvance
- Pneu-C-20: Prevnar 20

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Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccines for Children Aged 6 Weeks to 4 Years

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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).

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

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 increased 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.

Publicly funded vaccines for children aged 6 weeks to 4 years

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
Eligibility Criteria	Children 6 weeks to 4 years **not** at increased risk for IPD (low risk)	Children 6 weeks to 4 years at increased risk for IPD (high risk) (See Table 6)

Eligibility

Children aged 6 weeks to 4 years who have not completed or have not received all eligible publicly funded pneumococcal vaccine(s) (e.g., Pneu-P-23 and/or Pneu-C-13) are eligible for immunization with Pneu-C-20 vaccine according to appropriate age and high risk criteria (Table 1, Table 2, Table 3 and Table 4). Additional (catch-up) doses of Pneu-C-20 for those who have received all eligible publicly funded pneumococcal immunizations will be considered for future programming.

Recommendations for use

The following schedules 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.

Table 1: Recommended schedule and vaccine eligibility for those aged 6 weeks to 4 years

Eligible group	Risk of IPD	Recommended schedule	Eligible vaccine
Starting at 2 months	Low risk	2, 4, and 12 months of age See Table 2 and Table 3	Pneu-C-15
Starting at 2 months	High risk⅄ Except HSCT	2, 4, 6 and 12 months of age See Table 2 and Table 4	Pneu-C-20
Starting 3-9 months post HSCT	Post HSCT	See Table 2 and Table 5	Pneu-C-20

⅄ For a list of high-risk criteria that increase an individual's risk for IPD, see Table 6.

- HSCT: hematopoietic stem cell transplant recipients

Table 2: Schedule for Pneu-C for children aged 6 weeks to 4 years at according to prior pneumococcal vaccine history

Risk for IPD	History of publicly funded		Recommended # of Pneu-C dose(s) required and intervals
	Pneu-P-23	Pneu-C-13	
Low risk	Not eligible	0 doses or incomplete series	See Table 3
	Not eligible	Completed series	None

Risk for IPD	History of publicly funded		Recommended # of Pneu-C dose(s) required and intervals
	Pneu-P-23	Pneu-C-13	
High risk✢ See criteria 1 to 9 in Table 4	O to 2 doses	0 doses or incomplete series	See Table 4 Dose(s) of Pneu-C-20 should be given 1 year after last dose of Pneu-P-23 (if applicable)
	1 dose	Complete series	1 dose of Pneu-C-20, 1 year after last dose of Pneu-P-23 and 8 weeks after last dose of Pneu-C-13
	2 doses	Complete series	None
High risk✢ See criteria 10 to 17 in Table 4	O to 1 dose	0 doses or incomplete series	See Table 4 Dose(s) of Pneu-C-20 should be given 1 year after last dose of Pneu-P-23 (if applicable)
	1 dose	Complete series	None
Post HSCT	O to 2 doses	0 doses or incomplete series	See Table 5 Dose(s) of Pneu-C-20 should be given 1 year after last dose of Pneu-P-23 (if applicable)
	1 dose	Complete series	1 dose of Pneu-C-20, 1 year after last dose of Pneu-P-23 and 8 weeks after last dose of Pneu-C-13
	2 doses	Complete series	None

Notes:

✢ For a list of high-risk criteria that increase an individual's risk for IPD, see Table 6.

- Pneu-C-13: pneumococcal conjugate 13-valent vaccine (Prevnar 13)
- If a child started their immunization series with one Pneu-C (e.g., Pneu-C-13), it is acceptable to complete the series with another Pneu-C (e.g., Pneu-C-15 or Pneu-C-20).
- For children at high risk of IPD who started their immunization series with Pneu-C-13 or Pneu-C-15, it is recommended to complete the series with Pneu-C-20.

Table 3: Schedule for PNEU-C-15 for children at LOW-RISK who have not completed or have not started their pneumococcal immunizations

Child's current age	History of publicly funded Pneu-C-13	Recommended # of PNEU-C-15 dose(s) required to complete series and recommended intervals
2 to 6 months	0 doses	1st dose at age ≥ 2 months 2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose and at age ≥12 months
	1 dose (1st dose)	2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose and at age ≥12 months
	2 doses (1st and 2nd dose)	3rd dose, 2 months after 2nd dose and at age ≥12 months
7 to 11 months	0 doses	1st dose 2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose and at age ≥12 months
	1 dose (1st dose)	2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose and at age ≥12 months
	2 doses (1st and 2nd dose)	3rd dose, 2 months after 2nd dose and at age ≥12 months
12 to 23 months	0 doses	1st dose 2nd dose, 2 months after 1st dose
	1 dose (1st dose) at age <12 months	2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose
	1 dose (1st dose) at age ≥12 months	2nd dose, 2 months after 1st dose
	1 dose (1st dose) at age <12 months + 1 dose (2nd dose) at age ≥12 months	3rd dose, 2 months after 2nd dose
	2 or more doses at age <12 months	1 dose, 2 months after most recent dose
24 to 59 months	0 doses	1 dose
	Any incomplete series	1 dose, 2 months after most recent dose

Table 4: Schedule for PNEU-C-20 for children at HIGH-RISK□ (except HSCT) who have not completed or have not started their pneumococcal immunizations

Child's current age	History of publicly funded Pneu-C-13	Recommended # of PNEU-C-20 dose(s) required to complete series and recommended intervals
2 to 6 months	0 doses	1st dose at age ≥ 2 months 2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose 4th dose, 2 months after 3rd dose and at age 12-15 months
	1 dose (1st dose)	2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose 4th dose, 2 months after 3rd dose and at age 12-15 months
	2 doses (1st and 2nd dose)	3rd dose, 2 months after 2nd dose 4th dose, 2 months after 3rd dose and at age 12-15 months
7 to 11 months	0 doses	1st dose 2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose and at age 12-15 months
	1 dose (1st dose)	2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose and at age 12-15 months
	2 doses (1st and 2nd dose)	3rd dose, 2 months after 2nd dose and at age 12-15 months
12 to 23 months	0 doses	1st dose 2nd dose, 2 months after 1st dose
	1 dose (1st dose) at age <12 months	2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose
	1 dose (1st dose) at age ≥12 months	2nd dose, 2 months after 1st dose
	1 dose (1st dose) at age <12 months + 1 dose (2nd dose) at age ≥12 months	3rd dose, 2 months after 2nd dose
	2 or more doses at age <12 months	1 dose, 2 months after most recent dose

Child's current age	History of publicly funded Pneu-C-13	Recommended # of PNEU-C-20 dose(s) required to complete series and recommended intervals
24 to 59 months	0 doses	1 dose
	Any incomplete series	1 dose, 2 months after most recent dose

Notes:

- For a list of high-risk criteria that increase an individual's risk for IPD, see Table 6.
- For post HSCT schedule, see Table 5

Table 5: Schedule for Pneu-C-20 for HSCT recipient aged 6 weeks to 4 years who have not completed or have not started their Pneu-C-13 vaccine series post-transplant

History of publicly funded Pneu-C-13	Recommended # of Pneu-C-20 doses required to complete series and recommended intervals
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-transplant and 6-12 months after 3rd dose
1 dose post HSCT (1st dose)	2nd dose, 4 weeks after 1st dose 3rd dose, 4 weeks after 2nd dose 4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose
2 doses post HSCT (1st and 2nd doses)	3rd dose, 4 weeks after 2nd dose 4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose
3 doses post HSCT (1st, 2nd and 3rd dose)	4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose

Table 6: List of high-risk criteria that increases a child's 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)

Table 7: Intervals between vaccines

Risk of IPD	Previous publicly funded vaccine	Interval to Pneu-C vaccine
High risk⅄	Pneu-C-13	8 weeks minimum
	Pneu-P-23	1 year minimum
All	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 vaccines 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.

⅄For a list of high-risk criteria that increase an individual’s risk for IPD, see Table 6.

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.

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 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 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 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 vaccine 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 and adults 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

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

Ontario

Ministry of Health

Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccine for Individuals Aged 5 to 64 Years at High Risk for Invasive Pneumococcal Disease

This document is intended for informational purposes only. It is not intended to provide medical or legal advice.

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).

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.

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 increased 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.

Publicly funded vaccine for individuals aged 5 to 64 years who are at high risk for IPD

Vaccine	Pneumococcal Conjugate 20-valent
Vaccine abbreviation	Pneu-C-20
Vaccine name	Prevnar 20
Manufacturer	Pfizer
Protects against	IPD and pneumonia
***Streptococcus* pneumoniae serotypes**	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
Route of administration	Intramuscular Injection (IM)
Package format	10 prefilled syringes
Package size (cm)	12.45 (l) x 9.91 (w) x 5.33 (h)
Eligibility Criteria	Individuals aged 5 to 64 years who are at high risk for IPD

Eligibility

Individuals aged 5 to 64 years at high risk for IPD who have not completed or have not received all eligible publicly funded pneumococcal vaccine(s) (e.g., Pneu-P-23 and/or Pneu-C-13) are eligible for immunization with Pneu-C-20 vaccine according to appropriate age and high risk criteria (Table 1, Table 2 and Table 3). Additional (catch-up) doses of Pneu-C-20 for those who have received all eligible publicly funded pneumococcal immunizations will be considered for future programming.

Recommendations for use

The following schedules 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.

Table 1: Recommended schedule and vaccine eligibility for those aged 5 to 64 years

Eligible age group	Risk of IPD	Recommended schedule	Eligible vaccine
5 to 64 years	High risk⅄ except HSCT	See Table 2	Pneu-C-20
5 to 64 years	Post HSCT	See Table 2 and Table 3	Pneu-C-20

Notes:

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

- HSCT: hematopoietic stem cell transplant recipients

Table 2: Schedule for Pneu-C-20 for those aged 5 to 64 years at HIGH-RISK according to prior pneumococcal vaccine history

Eligible age group	High risk criteria	History of publicly funded		Recommended # of Pneu-C-20 dose(s) required and intervals
		Pneu-P-23	Pneu-C-13	
5 to 49 years	See criteria 1 to 9 in Table 4	O to 1 dose	N/A*	1 dose, 1 year after last dose of Pneu-P-23 (if applicable) and 8 weeks after last dose of Pneu-C-13 (if applicable)
		2 doses	N/A*	None
	See criteria 10 to 17 in Table 4	O doses	N/A*	1 dose, 1 year after last dose of Pneu-P-23 (if applicable)
		1 dose	N/A*	None

Eligible age group	High risk criteria	History of publicly funded		Recommended # of Pneu-C-20 dose(s) required and intervals
		Pneu-P-23	Pneu-C-13	
50 to 64 years	See criteria 1 to 7 in Table 4	O to 2 doses	O doses	1 dose, 1 year after last dose of Pneu-P-23 (if applicable)
		0 to 1 dose	1 dose	1 dose, 1 year after last dose of Pneu-P-23 (if applicable) and 8 weeks after last dose of Pneu-C-13
		2 doses	1 dose	None
	See criteria 8 to 9 in Table 4	O to 1 dose	Not eligible	1 dose, 1 year after last dose of Pneu-P-23 (if applicable)
		2 doses	Not eligible	None
	See criteria 10 to 17 in Table 4	O doses	Not eligible	1 dose, 1 year after last dose of Pneu-P-23 (if applicable)
		1 dose	Not eligible	None
5 to 64 years	Post HSCT	0 to 2 doses	0 doses or incomplete series	See Table 3 Dose(s) of Pneu-C-20 should be given 1 year after last dose of Pneu-P-23 (if applicable)
		1 dose	Complete series	1 dose, 1 year after last dose of Pneu-P-23 and 8 weeks after last dose of Pneu-C-13
		2 doses	Complete series	None

Notes:

- For a list of high-risk criteria that increase an individual's risk for IPD, see Table 4.

***** Those born on or after 2003 would have been eligible to receive doses of publicly funded doses of Pneu-C vaccine between the ages of 6 weeks and 4 years. The receipt of publicly funded Pneu-C doses prior to the age of 4 years does not impact their Pneu-C-20 eligibility and is therefore not taken into consideration.

- Pneu-P-23: pneumococcal polysaccharide 23-valent vaccine (Pneumovax 23).
- Pneu-C-13: pneumococcal conjugate 13-valent vaccine (Prevnar 13).

Table 3: Schedule for Pneu-C-20 for HSCT recipient aged 5 to 64 years who have not completed or have not started their Pneu-C-13 vaccine series post-transplant

History of publicly funded Pneu-C-13	Recommended # of Pneu-C-20 doses required to complete series and recommended interval
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-transplant and 6-12 months after 3rd dose
1 dose post HSCT (1st dose)	2nd dose, 4 weeks after 1st dose 3rd dose, 4 weeks after 2nd dose 4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose
2 doses post HSCT (1st and 2nd doses)	3rd dose, 4 weeks after 2nd dose 4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose
3 doses post HSCT (1st, 2nd and 3rd dose)	4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose

- If an individual started their immunization series with one Pneu-C (e.g., Pneu-C-13), it is recommended to complete the series with Pneu-C-20.

Table 4: List of high-risk criteria that increases an individual's 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 nursing homes, homes for the aged and chronic care facilities or wards
18. Hematopoietic stem cell transplant (HSCT) (recipient)

Table 5: Intervals between vaccines

Age group	Previous publicly funded Vaccine	Interval to Pneu-C-20 vaccine
5 to 17 years	Pneu-C-13	8 weeks minimum
	Pneu-P-23	1 year minimum
18 to 64 years	Pneu-C-13	8 weeks minimum
	Pneu-P-23	1 year recommended 8 weeks, if rapid completion is required
5 years of age and older	Vaccines not listed above	Pneu-C-20 vaccine may be given at the same time with other vaccines, or at any time before or after other vaccines. If given by injection at the same time, 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.

Adverse events

Mild to moderate reactions that are commonly seen include:

- 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 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 should 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 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 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” 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.

Persons with inadequate immunization records

Individuals 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

The National Advisory Committee on Immunization (NACI) provides recommendations on the use of pneumococcal vaccines. Individuals who are not eligible for publicly funded Pneu-C-20 vaccines can privately purchase pneumococcal conjugate vaccines.

Ontario

Ministry of Health

Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccine for Individuals Aged 65 Years and Older

This document is intended for informational purposes only. It is not intended to provide medical or legal advice.

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).

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

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 increased 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.

Publicly funded vaccine for individuals aged 65 years and older

Vaccine	Pneumococcal Conjugate 20-valent
Vaccine abbreviation	Pneu-C-20
Vaccine name	Prevnar 20
Manufacturer	Pfizer
Protects against	IPD and pneumonia
***Streptococcus* pneumoniae serotypes**	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
Route of administration	Intramuscular Injection (IM)
Package format	10 prefilled syringes
Package size (cm)	12.45 (l) x 9.91 (w) x 5.33 (h)
Eligibility Criteria	Individuals aged 65 years and older

Eligibility

Adults aged 65 years and older who have not completed or have not received all eligible publicly funded pneumococcal vaccine(s) (e.g., Pneu-P-23 and/or Pneu-C-13) are eligible for immunization with Pneu-C-20 vaccine according to appropriate age and high risk criteria (Table 1, Table 2 and Table 3). Additional (catch-up) doses of Pneu-C-20 for those who have received all eligible publicly funded pneumococcal immunizations will be considered for future programming.

Recommendations for use

The following schedules 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.

Table 1: Recommended schedule and vaccine eligibility for those aged ≥65 years

Eligible age group	Risk of IPD	Recommended schedule	Eligible vaccine
65 years and older	Low risk	See Table 2	Pneu-C-20
	High risk✦ except HSCT	See Table 2	Pneu-C-20
	Post HSCT	See Table 2 and Table 3	Pneu-C-20

✦For a list of high-risk criteria that increase an individual's risk for IPD, see Table 4.

- HSCT: hematopoietic stem cell transplant recipients

Table 2: Schedules for Pneu-C-20 for those aged ≥65 years according to prior pneumococcal immunization

Risk of IPD	History of publicly funded		Recommended # of Pneu-C-20 dose(s) required and intervals
	Pneu-P-23	Pneu-C-13	
Low risk	0 doses	Not eligible	1 dose
	1 dose at age ≥65 years	Not eligible	None
High risk✦ See criteria 1 to 7 in Table 4	0 to 3 doses	0 doses	1 dose, 1 year after last dose of Pneu-P-23 (if applicable) and 8 weeks after last dose of Pneu-C-13 (if applicable)
	0 to 2 doses	1 dose	
	3 doses, with at least 1 dose at age ≥65 years	1 dose	None
High risk✦ See criteria 8 to 9 in Table 4	0 to 2 doses	Not eligible	1 dose
	3 doses, with at least 1 dose at age ≥65 years	Not eligible	None

Risk of IPD	History of publicly funded		Recommended # of Pneu-C-20 dose(s) required and intervals
	Pneu-P-23	Pneu-C-13	
High risk[⅄] See criteria 10 to 17 in Table 4	0 to 1 dose	Not eligible	1 dose, 1 year after last dose of Pneu-P-23 (if applicable)
	2 doses, with at least 1 dose at age ≥65 years	Not eligible	None
Post HSCT	0 to 3 doses	0 doses or incomplete series	See Table 3 Dose(s) of Pneu-C-20 should be given 1 year after last dose of Pneu-P-23 (if applicable)
	0 to 2 doses	Completed series	1 dose, 1 year after last dose of Pneu-P-23 (if applicable) and 8 weeks after last dose of Pneu-C-13
	3 doses, with at least 1 dose at age ≥65 years	Completed series	None

Notes:

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

- Pneu-P-23: pneumococcal polysaccharide 23-valent vaccine (Pneumovax 23)
- Pneu-C-13: pneumococcal conjugate 13-valent vaccine (Prevnar 13)

Table 3: Schedule for Pneu-C-20 for HSCT recipient aged ≥65 years who have not completed or have not started their Pneu-C-13 vaccine series post-transplant

History of publicly funded Pneu-C-13 post HSCT	Recommended # of Pneu-C-20 doses required to complete series and recommended interval
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-transplant and 6-12 months after 3rd dose
1 dose post HSCT (1st dose)	2nd dose, 4 weeks after 1st dose 3rd dose, 4 weeks after 2nd dose 4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose

History of publicly funded Pneu-C-13 post HSCT	Recommended # of Pneu-C-20 doses required to complete series and recommended interval
2 doses post HSCT (1st and 2nd doses)	3rd dose, 4 weeks after 2nd dose 4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose
3 doses post HSCT (1st, 2nd and 3rd dose)	4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose

- If an individual started their immunization series with one Pneu-C (e.g., Pneu-C-13), it is acceptable to complete the series with another Pneu-C (e.g., Pneu-C-20).

Table 4: List of high-risk criteria that increases an individual's 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 nursing homes, homes for the aged and chronic care facilities or wards
18. Hematopoietic stem cell transplant (HSCT) (recipient)

Table 5: Intervals between vaccines

Risk of IPD	Previous publicly funded vaccine	Interval to Pneu-C-20 vaccine
High risk⅄	Pneu-C-13	8 weeks minimum
	Pneu-P-23	1 year recommended 8 weeks, if rapid completion is required
All	Vaccines not listed above	Pneu-C-20 vaccine may be given at the same time with other vaccines, or at any time before or after other vaccines. If given by injection at the same time, 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.

⅄For a list of high-risk criteria that increase an individual’s risk for IPD, see Table 4.

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.

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 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 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 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" under the "vaccine brand name" column. Vaccine recipients 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.

Persons with inadequate immunization records

Individuals 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

The National Advisory Committee on Immunization (NACI) and the Ontario Immunization Advisory Committee (OIAC) provides recommendations on the use of pneumococcal vaccines. Individuals who are not eligible for publicly funded Pneu-C-20 vaccines can privately purchase pneumococcal conjugate vaccines.