Pneumococcal Conjugate Vaccine

June 18, 2024

Introduction

For more detailed information it is important for staff to refer to other program resources found in the AHS Immunization Program Standards Manual:

- AHS Vaccine Biological pages and/or Vaccine Product Monographs
- AHS Vaccine Storage and Handling e-learning modules and Standard
- Guidelines for the reporting of adverse events following immunization
- Reporting requirements and data collection guidelines
- Alberta Health Pneumococcal Immunization Program Policies

Pneumococcal Vaccine – History of Use in Alberta

1998 - Pneumococcal Polysaccharide vaccine has been offered nationally, focusing on persons 65 years of age and older and those under 65 eligible due to health conditions or living situation.

2001 - Prevnar™, Pneumococcal Conjugate vaccine, was introduced to the childhood immunization program. Later expanded to include persons with high-risk medical conditions.

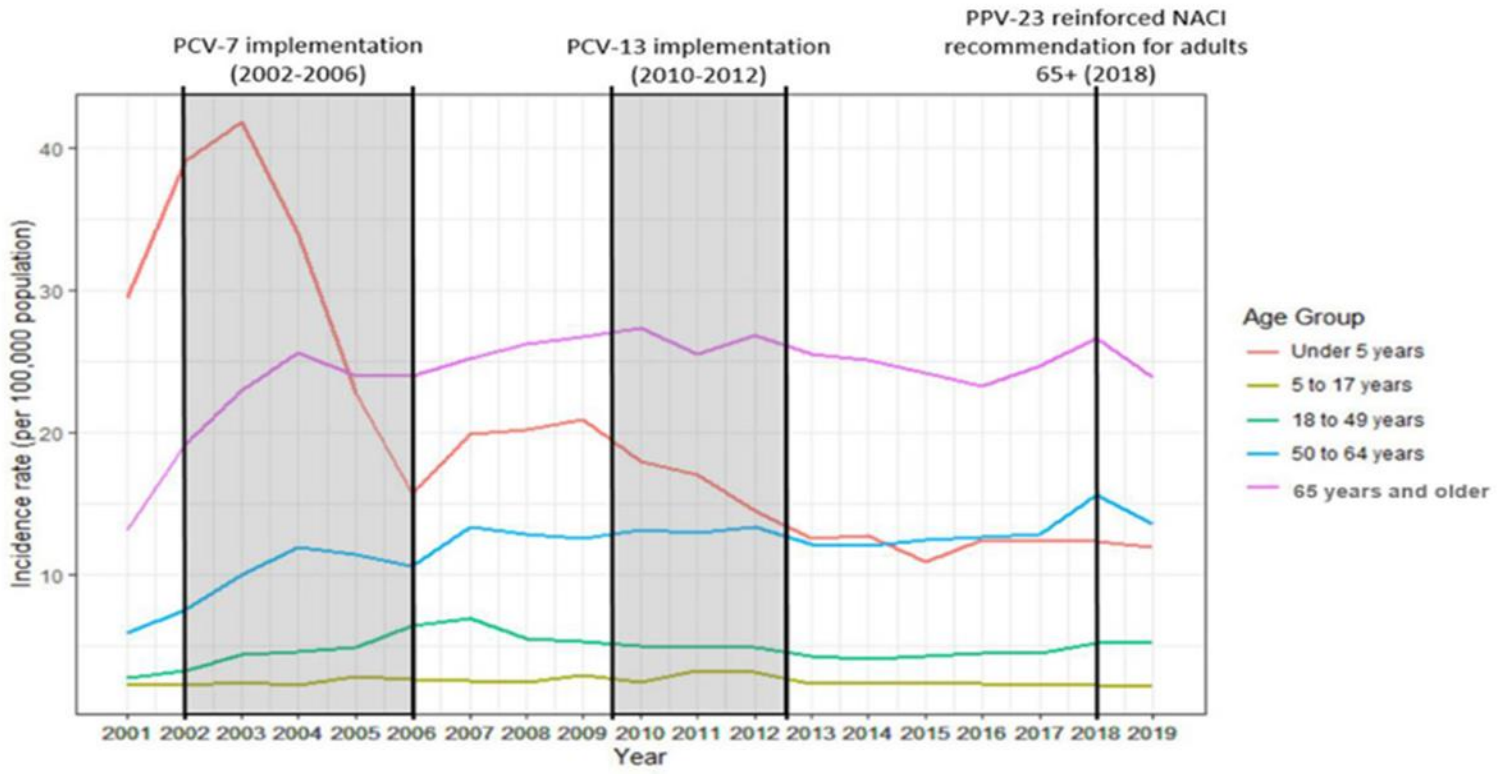
June 24, 2024 - Alberta will begin to offer Pneumococcal Conjugate 15, Vaxneuvance®, and Pneumococcal Conjugate 20, Prevnar 20™.

Why is pneumococcal conjugate vaccine important?

- Pneumococcal vaccines are used to prevent serious illnesses caused by the *Streptococcus pneumoniae* bacteria
- Worldwide, pneumococcal disease is a major cause of morbidity and mortality. In Canada, invasive pneumococcal disease (IPD) is most common among the very young and adults aged 65 years and older.
    - bacteremia and meningitis are the most common manifestations in children 2 years of age and younger.
    - Pneumococcal pneumonia with or without bacteremia is the most common presentation among adults.

Data taken from the National Advisory Committee on immunization Statement: **Public health level recommendations on the use of pneumococcal vaccines in adults, including the use of 15-valent and 20-valent conjugate vaccines (24 Feb 2023)**

Figure 1: Annual incidence rate of IPD by age group reported to Canadian Notifiable Disease Surveillance System, 2001-2019



What is pneumococcal vaccine?

- There are two types of pneumococcal vaccine, polysaccharide and conjugate.
- Pneumococcal conjugate vaccines provide an improved immune response due to immunologic memory resulting in higher levels of antibodies. They also have shown better efficacy against nasopharyngeal carriage and noninvasive pneumonia overall.
- Historically pneumococcal vaccines have been called the “pneumonia shot” by seniors.
- Vaxneuvance® will be provided by Public Health in Child Health Clinic.
- Prevnar 20™ will be provided throughout the year by Public Health and other community partners.

Pneumococcal Conjugate Vaccines

	VAXNEUVANCE® (Merck)	Prevnar 20™ (Pfizer)
Dosage/Route	0.5 mL/IM	0.5 mL/IM
Packaging	Single Dose: Pre-filled, single dose syringe (luer lock needles not included), 10 doses per package	Single Dose: Pre-filled, single dose syringe (luer lock needles not included), 10 doses per package
Indication	Children 2 months up to including 59 months of age not at high risk for IPD.	Individuals 65 years of age and older who have not previously received a Pneu-23 or Pneu-20 vaccine. Individuals 18 years and older who are at high risk of IPD and have not received previously recommended doses of pneumococcal conjugate and polysaccharide vaccines. Children 2 months to 17 years of age at high risk of IPD.
Ingredients	Serotypes1,3,4,5,6A,6B,7F,9V,14,18C,19A,19F,22F,23F and 33F Aluminum phosphate, polysorbate 80, sodium chloride, L-histidine, water for injection	Serotypes:1,3,4,5,6A,6B,7F,8,9V,10A,11A,12F,14,15B,18C,19A,19F,22F,23F and 33F Aluminum phosphate, polysorbate 80, sodium chloride, succinic acid, water for injection
Schedule	See biological page	See biological page

Pneumococcal 15 (Pneu-C15) vaccine eligibility

Children 2 months up to and including 59 months of age.

Children that are considered at high risk for invasive pneumococcal disease are recommended to receive Pneumococcal conjugate 20.

Pneu-C15 schedule

Healthy Children presenting at:

- 2 months up to 11 months of age (3 doses)
  - Dose 1: 2 months of age
  - Dose 2: 4 months of age
  - Dose 3: 12 months of age
- 12 months up to and including 23 months of age (2 doses)
  - Dose 1: Day 0
  - Dose 2: 8 weeks after dose 1
- 24 months up to and including 59 months of age
  - 1 dose
- Dose 1 may be administered as early as 6 weeks of age
- The recommended interval between doses 1 and 2 for children younger than one year of age is eight weeks. However, the interval may be shortened to four weeks.
- For children 2 months up to and including 11 months of age, the third dose should be given in the second year of life (12 months of age or older) , and at least 8 weeks from second dose.
- The minimum interval between doses for children receiving immunization after 12 months of age is eight weeks.

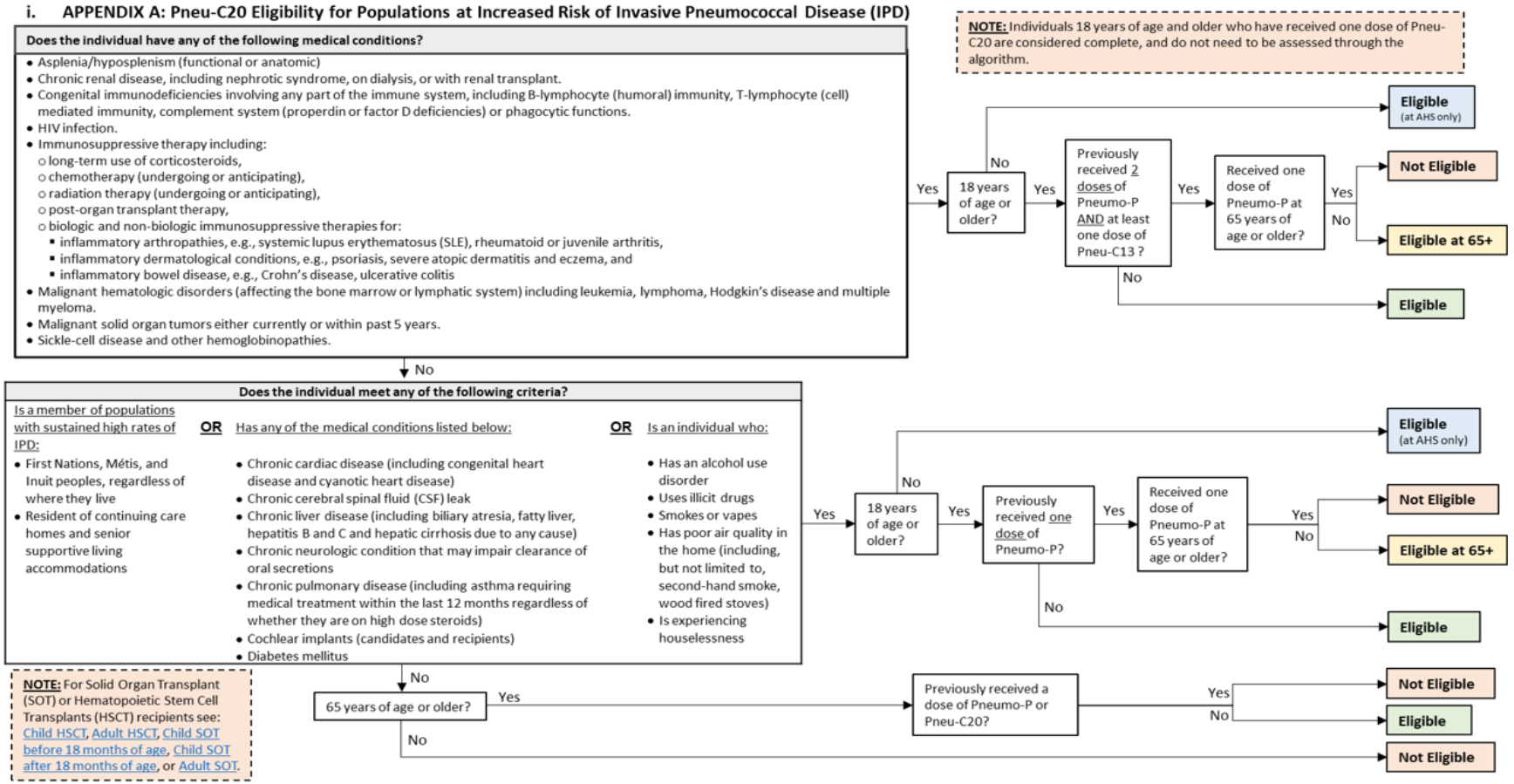
Pneumococcal 20 (Pneu-C20) vaccine eligibility

- All Individuals 65 years of age and older who have not previously received a dose of Pneu-P or Pneu-C20
- Individuals 2 months to 17 years of age who are at increased risk of IPD
- Individuals 18 years of age and older who are at increased risk for IPD and have not previously received pneumococcal conjugate or polysaccharide vaccines (Refer to the Pneu-C20 Eligibility for Populations at Increased Risk of Invasive Pneumococcal Disease (IPD) algorithm)

Note:

- Individuals 25 months of age and older who have already received one dose of Pneu-C20 are not eligible for a second dose. Re-immunization using a same-valency conjugate is not currently recommended as it is not known whether additional doses will provide additional benefit
- With the exception of adult HSCT and SOT recipients, individuals 18 years of age and older of age who previously received another pneumococcal conjugate vaccine series, and the recommended dose(s) of Pneu-P are considered complete and are not eligible for Pneu-C20.

Pneu-C20 vaccine eligibility



Groups at Increased Risk for Invasive Pneumococcal Disease (IPD)

Groups with sustained high rates of IPD:

- Residents of continuing care homes and supportive living accommodations
- First Nations, Métis, and Inuit peoples, regardless of where they live
  - It is acknowledged that individuals residing in communities and settings experiencing sustained high IPD rates are likely to benefit from an extensive pneumococcal vaccine program. Alberta Health, in partnership with Indigenous Services Canada and AHS, explored the burden of IPD in First Nations peoples and the burden of disease is higher when compared to the rest of the Alberta population. For this reason, Alberta Health has included First Nations, Métis, and Inuit peoples, regardless of where they live, as individuals eligible for the Pneu-C20 vaccine.

Groups at Increased Risk for Invasive Pneumococcal Disease (IPD)

Individuals with the following medical conditions:

- Asplenia/hyposplenism (functional or anatomic) See Special Situations for Immunization – Immunization of Specific Populations
- Chronic cardiac disease (including congenital heart disease and cyanotic heart disease).
- Chronic cerebral spinal fluid (CSF) leak.
- Chronic liver disease (including biliary atresia, fatty liver, hepatitis B and C and hepatic cirrhosis due to any cause).
- Chronic neurologic condition that may impair clearance of oral secretions.
- Chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).
- Chronic renal disease, including nephrotic syndrome, on dialysis, or with renal transplant.
- Cochlear implants (candidates and recipients).
- 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.
- Diabetes mellitus.

Groups at Increased Risk for Invasive Pneumococcal Disease (IPD)

- Immunosuppressive therapy including:
  - long term use of corticosteroids
  - chemotherapy (undergoing or anticipating),
  - radiation therapy (undergoing or anticipating),
  - post-organ transplant therapy,
  - biologic and non-biologic immunosuppressive therapies for:
    - inflammatory arthropathies, e.g., systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,
    - inflammatory dermatological conditions, e.g., psoriasis, severe atopic dermatitis and eczema, and
    - inflammatory bowel disease, e.g., Crohn's disease, ulcerative colitis

Note: Individuals prescribed eculizumab (Soliris®) or other complement C5 inhibitors are at increased risk of serious infections, especially with encapsulated bacteria, such as *Streptococcus pneumoniae*; therefore, they should receive PneuC-20 at least two weeks before receiving the first doses of complement C5 inhibitors if possible.

For additional information see: Immunization of Specific Populations.

- Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma, Hodgkin's disease and multiple myeloma.
- Malignant solid organ tumors either currently or within last 5 years.
- Sickle-cell disease and other hemoglobinopathies.

Groups at Increased Risk for Invasive Pneumococcal Disease (IPD)

Individuals who:

- Have an alcohol use disorder
- Use illicit drugs
- Smoke or vape
- Have poor indoor air quality in the home (including, but not limited to, second-hand smoke, wood fired stoves)
- Are experiencing houselessness
    - Definition: At the time of immunization assessment, the individual did not have an address or home (apartment, townhouse, etc.). This would include people staying in shelters, cars, etc.

Adult Hematopoietic stem cell transplant (HSCT) and/or CAR T-cell therapy and/or Solid Organ Transplant

- See Immunization for Adult HSCT Transplant Recipients.
- See Immunization for Adult SOT Candidates and Recipients.

Child Hematopoietic stem cell transplant (HSCT) and/or CAR T-cell therapy and/or Solid Organ Transplant

- See Immunization for Child HSCT Transplant Recipients.
- See Immunization for Children Expecting SOT Before 18 months of Age or Immunization of Children Expecting SOT After 18 Months of Age.

Pneu-C20 schedule

Individuals 65 years of age and older who have not received a Pneu-P or Pneu-C20 vaccine dose.

- 1 dose

Individuals with high-risk conditions presenting at:

2 months up to 6 months of age (4 doses)

- Dose 1: 2 months of age
- Dose 2: 4 months of age
- Dose 3: 6 months of age
- Dose 4 (reinforcing): 12 months of age and a minimum of 8 weeks after the previous dose.

7 months up to and including 11 months of age (3 doses)

- Dose 1: Day 0
- Dose 2: 8 weeks after dose 1
- Dose 3(reinforcing): 12 months of age and a minimum of 8 weeks after the previous dose

12 months up to and including 24 months of age (2 doses)

- Dose 1: day 0
- Dose 2: eight weeks after dose 1

25 months and older

- 1 dose

Pneu-C20 schedule

- Dose 1 may be administered as early as 6 weeks of age
- The recommended interval between doses 1, 2 and/or 3 for children younger than one year of age is eight weeks. However, the interval may be shortened to four weeks.
- The reinforcing dose should be given in the second year of life (12 months of age or older), and at least 8 weeks from third dose.
- The minimum interval between doses for children receiving immunization after 12 months of age is eight weeks.
- High-risk children who started a series with another pneumococcal conjugate vaccine:
  - Complete series with Pneu-C20
  - Count previous doses
  - Do not restart series
- Children at increased risk of developing IPD who previously completed a series with another pneumococcal conjugate vaccine and/or received the recommended doses of Pneu-P, are eligible for 1 dose of Pneu-C20 if they have not yet received a dose of Pneu-C20. It is recommended that this dose be given at least 8 weeks since the last pneumococcal vaccine dose or at least 1 year after their last dose of Pneu-P.

Pneu-C20 schedule

18 years of age and older at high-risk for IPD
Individuals who did not previously receive the recommended dose(s) of Pneu-P or Pneu-C20, see biological page and the Pneu-20 Eligibility for Populations at Increased Risk of IPD algorithm for additional information:

- 1 dose

Note:

- If possible, vaccine should be administered at least 14 days before splenectomy or initiation of immunosuppressive therapy.
- If the vaccine cannot be administered before initiation of immunosuppressive therapy, generally a period of at least 3 months should elapse between therapy cessation and administration of the vaccine.
- If immunosuppression is long-term/ongoing and/or for those with malignant solid organ tumors or malignant hematological disorders currently undergoing immunosuppressive therapy, the vaccine should be administered as soon as possible.

Note: It is recommended that individuals wait at least 8 weeks since their last pneumococcal conjugate vaccine dose or at least one year since their last Pneumo-P vaccine before receiving Pneu-C20.

Reactions to Pneu-C15 and Pneu-C20 vaccines

	Vaxneuvance®	Prevnar 20™
Common	• Pain, redness, swelling and induration at injection site • Headache, myalgia, arthralgia • Irritability, fatigue, somnolence, decreased appetite • Fever • Urticaria	• Irritability, drowsiness/increased sleep, fatigue • Pain, redness, swelling at injection site • Fever, myalgia, arthralgia, chills • Vomiting, diarrhea • Headache • Joint pain • Rash
Uncommon		• Hypersensitivity reaction, including face edema, dyspnea, bronchospasm • Nausea, • Rash, angioedema • Vaccination site pruritis and urticaria, lymphadenopathy • Urticaria or urticaria like rash • Seizures
Rare	• Anaphylaxis • Allergic reaction	• Anaphylaxis • Allergic reaction

Contraindications

Pneumococcal conjugate vaccine is contraindicated for the following people:

- People who have experienced anaphylaxis to a previous dose of pneumococcal conjugate vaccine or any diphtheria toxoid-containing vaccine
- People who have a known severe hypersensitivity to any component of the vaccine
- Children under 6 weeks of age

Note: Pneu-C20 and Pneu-C15 will not protect against serotypes not included in the vaccine.

Commitment to Comfort

Needle Fears

- This can affect people to a degree that they avoid immunization

Alberta Health Services Commitment to Comfort is five principles to improve the immunization experience, health outcomes, satisfaction and encourage repeat attendance to healthcare encounters.

- Make a comfort plan
- Use positive language
- Use comfort positions
- Shift attention
- Use numbing cream

Reporting of adverse events following immunization (AEFI)

An adverse event following immunization is defined as a serious or unexpected event temporally associated with immunization.

Local reactions are the most reported event following immunization. A local reaction of pain and/or swelling is ONLY reportable if:

1. the onset of swelling is within 48 hours following immunization;

AND

2. swelling extends past the nearest joint

OR

3. severe pain that interferes with the normal use of the limb lasting greater than 4 days

OR

4. reaction requires hospitalization

AEFI reporting (cont'd)

Any of the following are also reportable adverse events:

- Anaphylaxis
- Other allergic reactions
- Any reaction outside of what is expected

Consult with AHS Adverse Event Following Immunization (AEFI) Team at AEFI@ahs.ca or call 1-855-444-2324 as soon as possible for any case where there is uncertainty as to whether a symptom following immunization is related to the immunization.

Severe reactions (anaphylaxis and death) should be reported within 24 hours and all other reactions within 3 days to the AEFI Team. "Reportable AEFIs" are reported to Alberta Health, and in turn to the National Surveillance Program.

Anaphylaxis

Alberta Health Services employees need to ensure they have completed the Anaphylaxis Management | Insite (albertahealthservices.ca) learning module.

Covenant Health employees need to ensure they have completed Covenant Health Anaphylaxis Learning Module found on CLiC.

All other providers must have Anaphylaxis Management Guidelines in place.

- Additional information available in the Canadian Immunization Guide – Vaccine Safety

Infection Prevention and Control (IPC)

IPC's mandate is to reduce the incidence of healthcare associated infections in patients, residents, and clients by:

- process and outcome surveillance
- outbreak identification and management
- consultation and education
- guideline, policy, and procedure development
- Research

For more information go to the AHS IPC website at:

https://www.albertahealthservices.ca/info/page6410.aspx

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