

Recommendations: New Health Canada Authorized Pneumococcal Conjugate Vaccines for Adults Aged ≥ 18 Years

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Notice: Following the release of this Ontario Immunization Advisory Committee (OIAC) statement, the Public Health Agency of Canada [revised the Canadian Immunization Guide \(CIG\) chapter on pneumococcal vaccines](#) on May 3, 2024, to update the list of population groups at risk of invasive pneumococcal disease (IPD) and align pneumococcal vaccine advice, including re-immunization guidance and minimum intervals between vaccines, across age groups. In July 2024, Ontario transitioned its publicly-funded pneumococcal vaccine program to PCV20 for children and adults at increased risk of IPD and all adults 65 years of age and older. **Immunizers should consult the Ontario Ministry of Health website for [current eligibility and recommendations for publicly-funded pneumococcal vaccines](#).**

Overview

Pneumococcal disease (PD), caused by the *Streptococcus pneumoniae* bacterium, encompasses a clinical spectrum ranging from non-invasive infections to invasive pneumococcal disease (IPD). IPD leads to significant morbidity, mortality and economic impact globally. Ontario currently uses two pneumococcal vaccines in the publicly-funded vaccination program, the 23-valent pneumococcal polysaccharide vaccine (PPV23) and the 13-valent pneumococcal conjugate vaccine (PCV13). The adult pneumococcal program offers PPV23 to eligible adults (i.e., ≥ 65 years and adults that meet certain high-risk criteria), and PPV23 in addition to PCV13 to immunocompromised adults ≥ 50 years.¹

In November 2021 and May 2022, two new pneumococcal conjugate vaccine products, 15-valent (PCV15) and 20-valent (PCV20), respectively, were authorized by Health Canada for adults aged ≥ 18 years. These vaccines provide the benefits of conjugate vaccines while also protecting against additional serotypes not included in PCV13.

The Ministry of Health (MOH) requested the Ontario Immunization Advisory Committee (OIAC) provide recommendations on the use of PCV15 and PCV20 for Ontario adults aged ≥ 18 years. On October 11, 2022, OIAC initiated discussion on the use of PCV15 and PCV20 for Ontario adults. Following this meeting, on October 22, 2022, the Public Health Agency of Canada (PHAC) distributed an advanced copy of the National Advisory Committee on Immunization (NACI) statement outlining public health level recommendations on the use of PCV15 and PCV20 to all provinces and territories, which was officially published on February 24, 2023.² The OIAC reconvened on four dates (November 23, 2022; December 6, 2022; January 25, 2023; February 22, 2023) to review and discuss vaccine program considerations, including NACI recommendations on the use of PCV15 and PCV20 for Canadian adults by age group and risk, Ontario IPD epidemiology, evidence on vaccine immunogenicity and safety, and cost-effectiveness of these products. Although Ontario's pediatric program includes routine and high risk eligibility for

PCV13 and PPV23, recommendations for the use of new pneumococcal conjugate vaccines in the pediatric population were outside the scope of the request and have not yet been discussed by OIAC. This document provides a summary of considerations, evidence and the OIAC's recommendations.

Recommendations

1. For adults who have not previously received pneumococcal vaccine or whose previous pneumococcal vaccination status is unknown, OIAC supports the NACI recommendation for the use of PCV20 for the following adults at a higher risk of IPD:
 - a. Adults aged ≥ 18 years living with immunocompromising conditions (Table 1 Group 2)
 - b. Adults aged 50-64 years living with risk factors placing them at higher risk of pneumococcal disease, including:
 - i. Persons living with diabetes mellitus; chronic heart, lung, liver or kidney disease; a chronic neurologic condition impairing clearance of oral secretions; asthma requiring medical care in the preceding 12 months; cochlear implants, including those who are to receive implants; and chronic cerebrospinal fluid (CSF) leaks
 - ii. Social risk factors, including individuals
 - who smoke
 - who use unregulated drugs (previously/sometimes known as 'illicit drugs')
 - with alcohol use disorder
 - who are unhoused/underhoused
 - who live in communities or settings experiencing sustained high IPD rates, which may include some Indigenous communities, in which case consultations with these communities are necessary
 - c. All adults aged ≥ 65 years
2. For adults who have not previously received pneumococcal vaccine or whose previous pneumococcal vaccination status is unknown, OIAC also recommends PCV20 for adults aged 18-49 years at high risk for IPD who:
 - a. Are living with renal failure requiring dialysis
 - b. Are unhoused/underhoused
 - c. Have a cochlear implant or a chronic CSF leak
3. For adults previously vaccinated with a pneumococcal vaccine, OIAC supports the NACI recommendation of the use of PCV20 for all adults aged ≥ 65 years, including those previously vaccinated with PCV13 and/or PPV23. The OIAC also recommends PCV20 for other adults (as noted above in recommendations #1 and #2) if previously vaccinated with PCV13 and/or PPV23.

4. The following intervals are recommended between past doses and PCV20:
 - a. ≥ 5 years for those previously immunized with PPV23 (with or without PCV13)
 - b. ≥ 1 year for those who have received PCV13 alone
 5. The OIAC recommends the systematic recording of adult immunization data in an immunization registry, which offers both clinical benefits and, through linkage to other data sources, could inform evidence-based decisions at a population health level. Should PCV20 receive public funding, it will be important to have a robust tracking system in place to support immunization program monitoring and evaluation. Until such a registry is developed, OIAC recommends that the OHIP Schedule of Benefits include both pneumococcal polysaccharide and pneumococcal conjugate vaccine billing codes that can be used for the analysis of health administrative data.
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Background

Pneumococcal disease (PD), including invasive pneumococcal disease (IPD), is caused by the *Streptococcus pneumoniae* bacterium, which has over 100 known serotypes. However, only a few of these serotypes account for the majority of disease. IPD leads to substantial morbidity, mortality, and economic burden worldwide.³ Older adults and adults living with non-immunocompromising and immunocompromising medical conditions are at an increased risk for IPD (Table 1, Group 1 & 2).³ Certain social risk factors may also contribute to an increased risk of IPD (Table 1, Group 3).

NACI has identified specific populations considered to be at high risk of IPD that should be offered pneumococcal vaccination outside of the routine age-based recommendation for those aged ≥ 65 years ([Table 1](#)).

Table 1. Individuals at high risk of IPD adapted from the National Advisory Committee on Immunization Statement on PCV15 and PCV20 vaccines

Non-Immunocompromising Conditions (Group 1)	Immunocompromising Conditions (Group 2)	Social Risk Factors (Group 3)
<ul style="list-style-type: none"> • Chronic diseases, including: <ul style="list-style-type: none"> • Heart disease • Liver disease • Lung disease • Asthma requiring medical care in the preceding 12 months • Neurologic condition impairing clearance of oral secretions • Kidney disease • Diabetes mellitus • Cochlear implants • Chronic cerebrospinal fluid (CSF) leak 	<ul style="list-style-type: none"> • Immunocompromising therapy, including: <ul style="list-style-type: none"> • Use of long-term corticosteroids • Chemotherapy • Radiation therapy • Post-organ transplant therapy • Hematopoietic stem cell transplant (recipient) • Solid organ or islet transplant (candidate or recipient) • Splenectomy • Immunocompromised due to acquired disease or dysfunction, including: <ul style="list-style-type: none"> • Asplenia or splenic dysfunction • HIV infection • Nephrotic syndrome • Cancer • Immunocompromised due to inherited or congenital disease, including: <ul style="list-style-type: none"> • Congenital immunodeficiencies • HIV infection • Congenital asplenia • Sickle cell disease 	<ul style="list-style-type: none"> • Individuals: <ul style="list-style-type: none"> • who smoke • who use unregulated drugs* (sometimes/previously known as ‘illicit drugs’) • with alcohol use disorder* • who are unhoused or underhoused* • who live in communities or settings experiencing sustained high IPD rates

*Language adapted based on consultation with Public Health Ontario’s Health Equity group to ensure inclusive and non-stigmatizing communication.

Adapted from: Public Health Agency of Canada; National Advisory Committee on Immunization. [Public health level recommendations on the use of pneumococcal vaccines in adults, including the use of 15-valent and 20-valent conjugate vaccines](#). Ottawa, ON: His Majesty the King in Right of Canada, as represented by the Minister of Health; 2023. Table 1. Medical conditions and other biological and/or social risk factors resulting in high risk of IPD; p. 6. Used with permission.

The pneumococcal polysaccharide vaccine (PPV23) was first authorized for use in Canada in 1983. In the early 2000s, the first pneumococcal conjugate vaccines (PCV7, PCV10) were authorized for use in Canada, and in 2009, PCV13 received approval and replaced earlier conjugate vaccines in publicly-funded immunization programs starting in 2010. PCV13 protects against 13 distinct serotypes whereas PPV23 protects against 11 additional serotypes but does not provide protection against serotype 6A. Currently, PPV23 is offered to adults who meet eligibility criteria for the Ontario publicly-funded pneumococcal vaccination program (i.e., ≥65 years and adults that meet certain high-risk criteria).¹

PCV13 is only publicly-funded for immunocompromised adults aged ≥50 years in Ontario, although NACI recommends it for all immunocompromised adults. The current Ontario pneumococcal vaccination program eligibility, including the vaccine type and number of doses, is outlined in Table 2 below. Currently PPV23 is not publicly-funded for individuals living with any social IPD risk factors (Table 1, Group 3).

Table 2. Ontario’s current pneumococcal vaccination program for adults

Population	Type of vaccine and doses
Adults aged ≥18 years with an immunocompromising condition (Table 1, Group 2)	PPV23 (1 dose)
Immunocompetent adults aged 18-64 years at high risk of invasive pneumococcal disease due to an underlying medical condition (Table 1, Group 1) [†] and who are residents of long-term care facilities	PPV23 (1 dose)
Adults aged ≥50 years with an immunocompromising condition (Table 1, Group 2 except haematopoietic stem cell transplantation [HSCT])	PCV13 (1 dose) + PPV23 (1 dose)
Adult HSCT recipients aged ≥50 years	PCV13 (3 doses) + PPV23 (1 dose)
Adults aged ≥65 years, regardless of risk factors or previous pneumococcal vaccination	PPV23 (1 dose)

[†]Asthma is included as a high risk medical condition only if treated with high-dose corticosteroid therapy.

Although, PPV23 is effective in reducing IPD risk among adults, conjugate vaccines, such as PCV13, have been shown to elicit a stronger immunologic response and provide a longer duration of protection against pneumococcal disease compared to polysaccharide vaccines.² Though conjugate vaccines offer distinct benefits, in its 2018 statement on the use of PCV13 for older adults, NACI did not make a public health level recommendation for its routine use in older adults as it concluded it would not significantly decrease the disease burden in a cost-effective manner, mainly due to the indirect benefits adults receive from routine pediatric PCV13 vaccination programs.^{4,5}

In November 2021 and May 2022, PCV15 and PCV20, respectively, two new pneumococcal conjugate vaccines, were authorized by Health Canada for adults aged ≥ 18 years based on evidence comparing the immunogenicity and safety of these vaccines compared to PCV13 and PPV23. Both new conjugate vaccines provide protection against additional serotypes not included in PCV13 (Table 3). On February 24, 2023, NACI published its recommendations on the use of PCV15 and PCV20, which included a strong recommendation for PCV20 for several adult populations. Tables 4a and 4b provide a summary of NACI's recommendations for PCV20, specific to adult populations.²

Table 3. Serotypes covered by existing and newly authorized pneumococcal vaccines

Vaccine	Type of vaccine	Serotypes included
PCV13	Conjugate	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F
PCV15	Conjugate	PCV13 serotypes + 22F and 33F
PCV20	Conjugate	PCV15 serotypes + 8, 10A, 11A, 12F, and 15B
PPV23	Polysaccharide	PCV20 serotypes + 2, 9N, 17F, and 20 (does not include 6A)

Table 4a. Summary of NACI recommendations on the use of PCV20* for adults, No previous pneumococcal vaccine or immunization status unknown

Population	Age	Recommendation Strength	Included conditions or intervals
Immunocompromised adults	≥ 18 years	Strong	Table 1, Group 2
Immunocompetent adults living with risk factors placing them at higher risk of PD	18-49 years	N/A	No PCV20 NACI recommendation
Immunocompetent adults living with risk factors placing them at higher risk of PD	50-64 years	Strong	Table 1, Group 1 and Group 3
Older adults	≥ 65 years	Strong	N/A

*NACI has provided a discretionary recommendation for the use of PCV15 followed by PPV23 as an alternative to PCV20 for adults who have not previously received a pneumococcal vaccine or whose immunization status is unknown, ≥ 65 years, 50-64 years living with risk factors placing them at higher risk of IPD and immunocompromised ≥ 18 years.²

Table 4b. Summary of NACI recommendations on the use of PCV20 for adults, Previously immunized

Population	Age	Recommendation Strength	Included conditions or intervals
Immunized with PPV23 alone	≥65 years	Strong	After interval of ≥5 years since last dose
Immunized with PCV13 and PPV23 in series	≥65 years	Strong	After interval of ≥5 years since last dose
Immunized with PCV13 alone	≥65 years	Discretionary	After interval of ≥1 year since last dose

Health Canada authorization of these new products, which offer the benefits of conjugate vaccines while also protecting against additional serotypes, and the release of NACI recommendations for their use led the MOH to seek advice from OIAC on their potential implementation into Ontario’s publicly-funded pneumococcal vaccination program for adults.

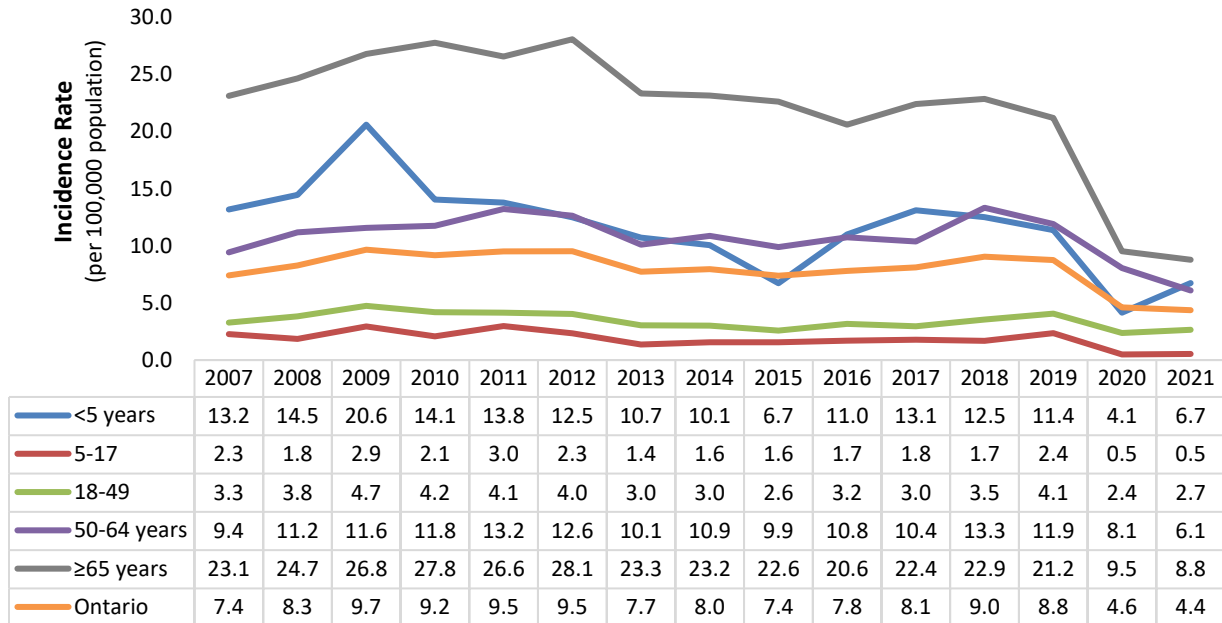
Evidence Summary and Considerations

The following summary provides an overview of the evidence reviewed and considerations discussed by the OIAC.

Epidemiology

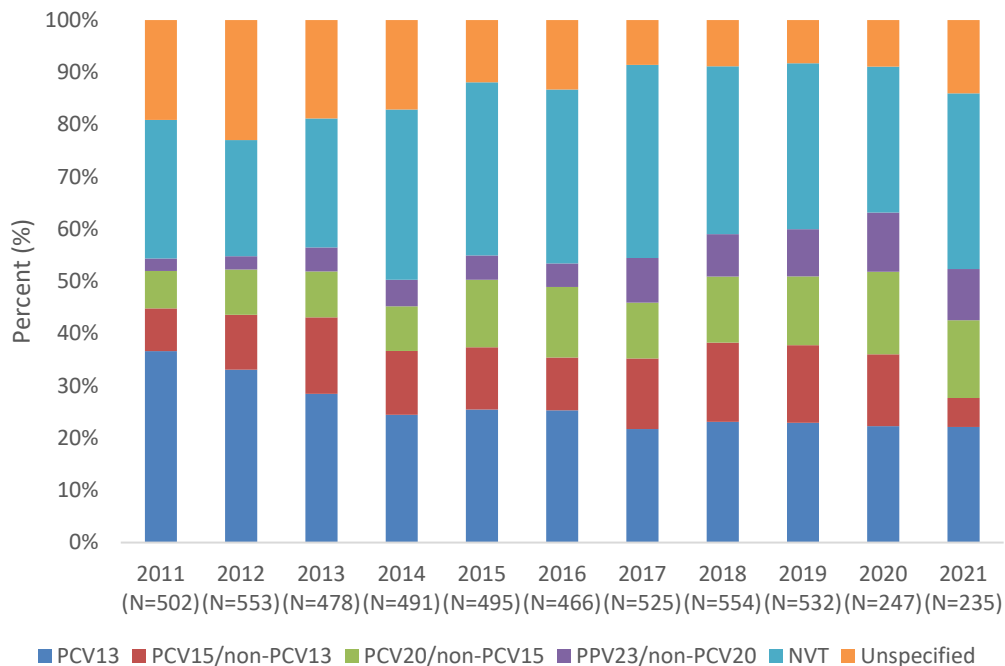
- The burden of IPD in Ontario is highest among older adults; 70% of IPD cases in 2019 were among adults aged ≥50 years.⁶
- 42% of IPD cases in 2019 were among adults aged ≥65 years and 87% of these cases were hospitalized.
- The burden of IPD decreased among adults aged ≥65 years after the introduction of PCV13 in Ontario’s pediatric publicly-funded immunization program (as of 2010). Incidence in adults aged ≥65 years also decreased dramatically during the COVID-19 pandemic years of 2020 and 2021 ([Figure 1](#)). Rates were more stable in other age groups but all saw cases decline in 2020 and 2021.
- The proportion of IPD attributable to PCV13 has declined in Ontario, particularly among adults aged ≥65 years, whereas the proportion attributable to other vaccine serotypes (PCV15/PCV20/PPV23) and non-vaccine preventable serotypes has been increasing over time ([Figure 2](#)).

Figure 1. IPD incidence rate in Ontario by age and year



Adapted from: Hillier K, Yeung A, Wijayasri S, Harris T, Wilson S, Buchan S. EV006 / #158. Changes in invasive pneumococcal epidemiology following the introduction of the 13-valent pneumococcal conjugate vaccine in Ontario, Canada, 2007-2019. Poster presented at: 12th International Symposium on Pneumococci and Pneumococcal Diseases; 2022 Jun 19-23; Toronto, ON. Adapted with permission.

Figure 2. Proportion of IPD cases by vaccine-specific serotypes, by age and year among Ontario adults aged ≥65 years. NVT = non-vaccine preventable.



Vaccine Product Considerations

- NACI² provided a strong recommendation for the use of PCV20 in adults due to the following benefits, which were also noted by OIAC:
 - Serotype coverage is 15-20% greater than that of PCV15 and covers more than 90% of the serotypes in PPV23, while also providing the immunological benefits of a conjugate vaccine.
 - Unlike PCV15, PCV20 does not require subsequent administration of PPV23 to optimize protection against a larger number of serotypes, thus reducing the number of healthcare visits and injections.
 - Increased feasibility and acceptability with the above considerations in mind.
- In immunocompetent adults aged ≥ 60 years who have not previously received a pneumococcal vaccine, PCV20 was shown to have a comparable immune response to PCV13. PCV20 elicited superior or comparable immune responses as PPV23 for most serotypes.^{7,8} PCV20 also produced a robust immune response among adults aged ≥ 65 years previously vaccinated with PPV23, PCV13, or both.⁹
- In studies among adults aged ≥ 60 years who have not previously received a pneumococcal vaccine and adults previously vaccinated with PPV23 (one to five years prior), the safety profile of PCV20 was shown to be comparable to receiving a dose of PCV13.⁷⁻⁹
- Based on the current burden of IPD and assumptions regarding pricing and effectiveness of the new pneumococcal vaccines, a single dose of PCV20 is expected to be the most cost-effective strategy according to Canadian¹⁰ and US^{11,12} studies.² Cost-effectiveness estimates are expected to be influenced by indirect effects if PCV20 is also implemented in the pediatric immunization schedule in the future; however, not all models included assumptions regarding indirect effects.

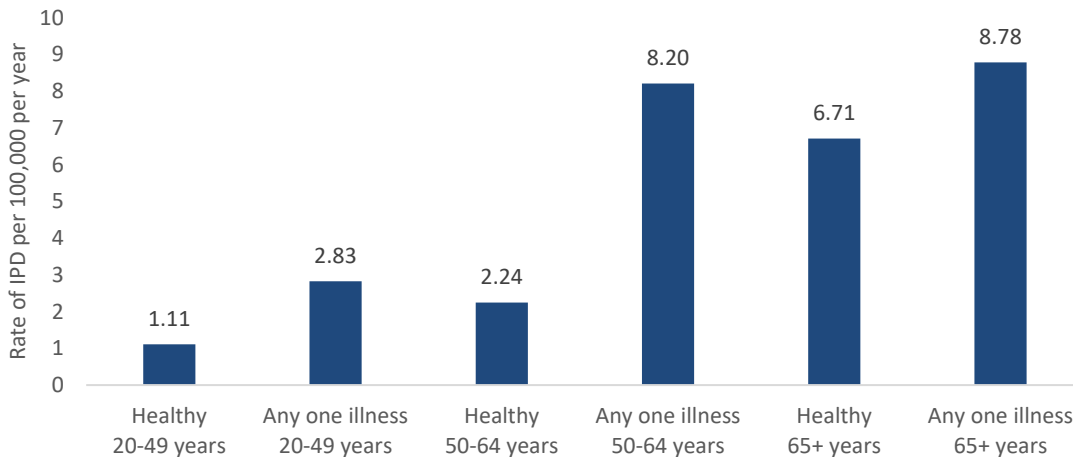
Groups at Higher Risk of IPD

Age/Medical Risk Factors

- Regardless of age, individuals living with immunocompromising conditions are at high risk of IPD. Older adults and/or individuals living with non-immunocompromising conditions (see Table 1) are also at higher risk of IPD than the general population.
- Adults aged ≥ 65 years have the highest incidence rate of IPD compared to other adult age groups, followed by those aged 50-64 years.
- Data from the Toronto Invasive Bacterial Diseases Network (TIBDN) suggest incidence of IPD is much higher among adults aged 50-64 years with a chronic medical condition compared to healthy adults in this age group. The same observation is not as apparent among younger adults (aged 20-49 years) (Figure 3).
- In contrast, among those aged 20-49 years, the incidence of IPD due to PCV20 serotypes from the TIBDN among adults living with renal failure requiring dialysis was high at 167 per 100,000 per year from 2014-21.¹³

- Individuals with cochlear implants and chronic CSF leaks have an increased risk of IPD. Given the rarity of these conditions, yet the high risk of disease development, a PCV20 recommendation among adults aged 18-49 years for this group would have a small impact on the cost and delivery of the program.¹⁴

Figure 3. Incidence of IPD from the Toronto Invasive Bacterial Diseases Network (TIBDN) for PCV20 serotypes, by age with or without underlying chronic illness, 2014-2021



Data Source: Zhong Z, Shigayeva A, Kwong JC, Demczuk W, Martin I, Almohri H, et al. Incidence of vaccine-preventable invasive pneumococcal disease in younger adults with co-morbidity in the post-PCV13 era. Presented at: 2023 AMMI Canada-CACMID Annual Conference. 2023 Mar 28-31. Toronto, ON. Used with permission.

Social Risk Factors

- Social risk factors of IPD are provided in [Table 1](#), Group 3. Ontario’s current adult publicly-funded pneumococcal vaccination program does not include individuals living with these risk factors.
- In 2008, NACI released a statement recommending pneumococcal vaccination (PPV23) among individuals who use unregulated drugs (previously/sometimes known as ‘illicit drugs’) and unhoused individuals.¹⁵ NACI’s recommendation for pneumococcal vaccination among individuals who smoke and with alcohol use disorder existed prior to the 2008 NACI statement. NACI now recommends PCV20 for these groups in addition to communities experiencing sustained high rates of IPD.²
- Among those aged 20-49 years, the incidence of IPD due to PCV20 serotypes from the TIBDN among unhoused/underhoused adults was 68 per 100,000 per year from 2014-21.¹³ This was much higher than those of any age with any one illness (as seen in Figure 3).

- A report comparing the epidemiology of invasive bacterial diseases in northern Canada, using data from the International Circumpolar Surveillance (ICS) program, with the incidence rates in the rest of Canada, using data from the Canadian Notifiable Diseases Surveillance System (CNDSS), found the age standardized incidence rate of IPD in northern Canada was 25.7 cases per 100,000 from 2001-18 whereas the age standardized incidence rate of IPD in the rest of Canada was only 9.1 cases per 100,000.¹⁶ Within northern Canada, the IPD incidence rate per year was 31.3 cases per 100,000 among Indigenous Canadians compared to 7.0 cases per 100,000 among non-Indigenous Canadians. NACI emphasizes the importance of autonomous decision-making by Indigenous Peoples with the support of healthcare and public health partners in accordance with the United Nations Declaration on the Rights of Indigenous Peoples.² OIAC members also discussed the importance of autonomous decision-making in their discussions of PCV20 vaccine.

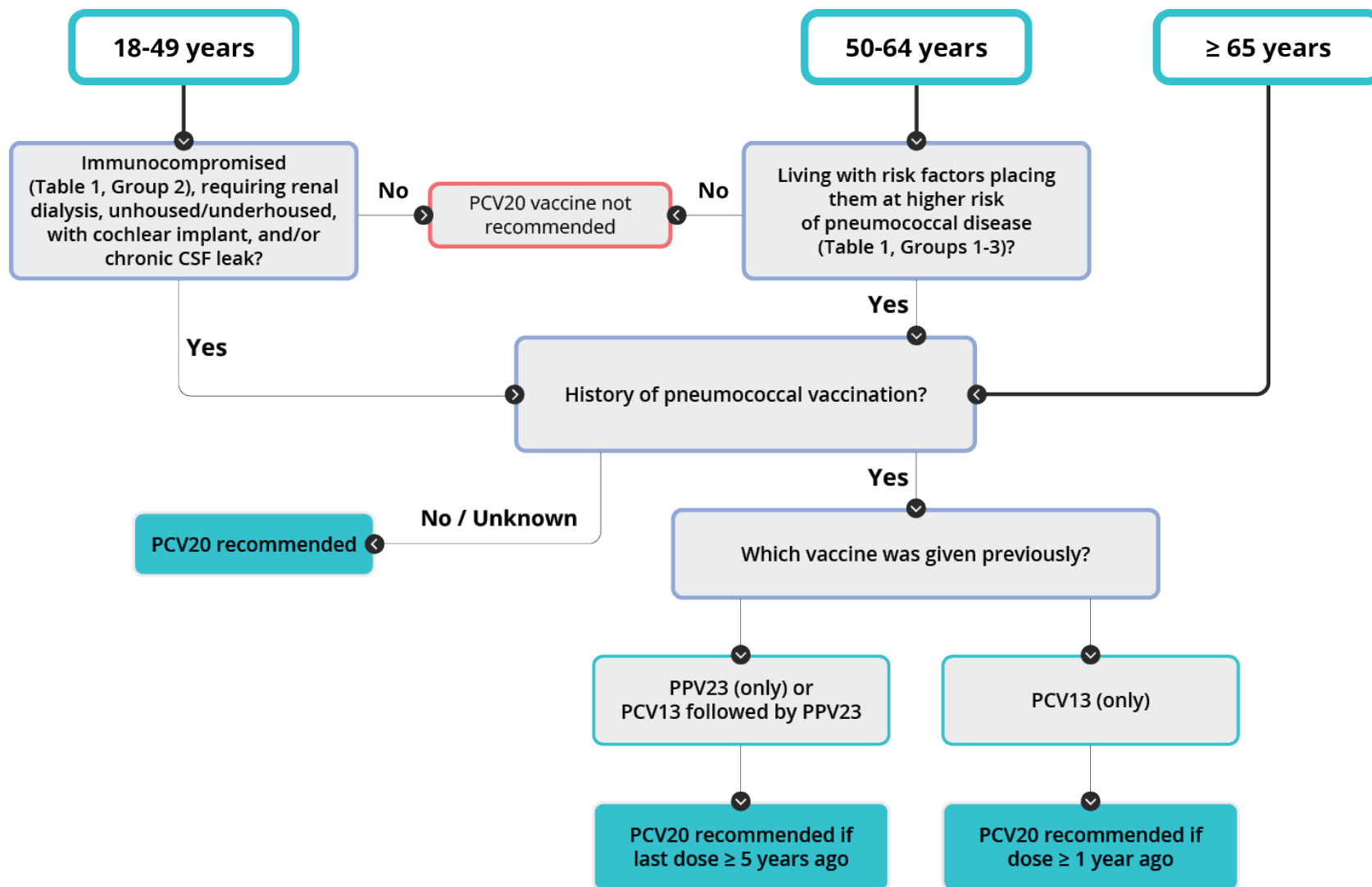
Previously Vaccinated Adults

- NACI recommendations for previously vaccinated adults aged ≥ 65 years can be found in Table 4b.
- The OIAC has expanded on these recommendations for those previously vaccinated with pneumococcal vaccines to include also adults aged 18-64 years at high risk of IPD recommended to receive PCV20 (see Recommendations).
- Consistent with the intervals recommended by NACI, an interval of 5 years between PPV23 (alone or in combination with PCV13) and PCV20 is expected to maximize the benefits of the duration of protection provided by PPV23 and the boosting anticipated by PCV20, maximizing the total duration of protection against IPD.²
- An interval of 1 year between PCV13 and PCV20 will expand serotype coverage by PCV13 alone in a timely manner.² Although there is no adult pneumococcal vaccine coverage data from Ontario available for review due to the limitations described below, based on the publicly-funded immunization schedule and NACI recommendations, receipt of PCV13 vaccine alone is not expected to be common among adults at high risk of IPD in Ontario.

Additional Considerations

Provincial surveillance of pneumococcal vaccine coverage is fundamental to program planning, implementation, evaluation and evidenced-based decision-making. However, a mechanism for monitoring coverage among adults is currently unavailable in Ontario. An immunization registry offers many benefits including facilitating improved vaccine coverage estimates, monitoring of vaccine safety and efficacy, program evaluation, efficient record-keeping, and comprehensive data collection to inform evidence-based decisions at a population health level. If PCV20 receives public funding, it will be important to have a robust tracking system in place to support future immunization program evaluation and monitoring.

Figure 4. OIAC PCV20 Recommendations



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About the Ontario Immunization Advisory Committee

The OIAC is a multidisciplinary scientific advisory body that provides evidence-based advice to Public Health Ontario (PHO) on vaccines and immunization matters including vaccine program implementation in Ontario, priority populations and clinical guidance. The focus of the OIAC's work is on publicly-funded vaccines and immunization programs in Ontario, including COVID-19 and those under consideration for new programming. For more information about the OIAC and its members contact secretariat@oahpp.ca

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Ontario Agency for Health Protection and Promotion (Public Health Ontario), Ontario Immunization Advisory Committee. Recommendations: new Health Canada authorized pneumococcal conjugate vaccine for adults aged ≥ 18 years. Toronto, ON: King's Printer for Ontario; 2023.

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