

Recommendation for the Routine Pediatric Pneumococcal Immunization Program

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Overview

Health Canada recently authorized two new pneumococcal conjugate vaccine (PCV) products for use in children: a 15-valent PCV (PCV15, Vaxneuvance®) in July 2022 and a 20-valent PCV (PCV20, Prevnar®20) in July 2023.^{1,2} In December 2023, the National Advisory Committee on Immunization (NACI) released a statement on recommendations for use of these new products in pediatric populations stating that either PCV15 or PCV20 could be used for routine provincial/territorial immunization programs.³

At the request of the Ministry of Health (MOH), the Ontario Immunization Advisory Committee (OIAC) provided a recommendation on the provincial program implementation of PCV15 or PCV20 for routine immunization of children less than 5 years of age who are not at increased risk of invasive pneumococcal disease (IPD). The Committee met on December 13, 2023, and January 17, 2024, to review and discuss evidence on the burden of disease, vaccine characteristics (immunogenicity and safety), equity, ethics, acceptability, and feasibility (EEFA) considerations, and cost-effectiveness. This document provides a summary of OIAC's recommendation and the evidence used to inform its decision.

At this time, the OIAC has not reviewed evidence nor made any provincial program recommendations related to the high-risk pediatric pneumococcal immunization program. The OIAC previously reviewed the use of these new vaccines for adults 18 years of age or older in Ontario, recommending PCV20 for both the older adult program (age 65+ years) and high-risk program (with varying age requirements); the OIAC's statement on adult pneumococcal immunization was published in September 2023.⁴

Recommendation

The OIAC recommends PCV20 as the product choice for the routine pneumococcal immunization program for children less than 5 years of age in Ontario who are not at increased risk of IPD.

This recommendation includes immunization of children who have not been previously vaccinated with a PCV or have not completed an age-appropriate PCV series and children whose pneumococcal vaccination status is unknown.

Background

The bacterium *Streptococcus pneumoniae* is a leading cause of bacterial meningitis in young children.^{5,6} It also commonly causes non-invasive clinical presentations, such as community-acquired pneumonia (CAP), acute otitis media (AOM), and sinusitis. Children less than 2 years of age have the highest burden of pediatric pneumococcal disease in Canada, particularly children who are immunocompromised or have other medical conditions that increase their risk of IPD.^{5,7} Almost 100 distinct *S. pneumoniae* serotypes have been identified, but only a subset cause the majority of pneumococcal disease.^{5,6}

Since January 2005, Ontario has included a PCV in its publicly funded routine immunization schedule for children who are not at increased risk of IPD. The 13-valent PCV (PCV13), which was introduced in November 2010, is currently given to infants in Ontario according to a 2+1 schedule (at 2, 4, and 12 months of age) through the routine immunization program.⁸ Five pneumococcal vaccines are currently authorized for use in children in Canada ([Table 1](#)).

Table 1. Pneumococcal vaccines currently available for use in children in Canada

Vaccine (Brand Name)	Manufacturer	Date of Authorization	Type of Vaccine	Pediatric Age Indication
PCV10* (Synflorix®)	GSK	December 11, 2008	Conjugate	6 weeks–5 years
PCV13 (Prennar®13)	Pfizer	December 21, 2009	Conjugate	6 weeks–17 years
PCV15 (Vaxneuvance®)	Merck	July 8, 2022	Conjugate	6 weeks–17 years
PCV20 (Prennar®20)	Pfizer	July 21, 2023	Conjugate	6 weeks–17 years
PPV23† (Pneumovax®23)	Merck	December 23, 1983	Polysaccharide	2 years–17 years

PCV=pneumococcal conjugate vaccine; PPV=pneumococcal polysaccharide vaccine

* Currently only used in Quebec

† Currently only children ≥2 years of age who have certain high-risk medical conditions are eligible to receive PPV23 in Ontario in addition to receiving an age-appropriate PCV13 series

In July 2022, Health Canada authorized PCV15 (Vaxneuvance®) in children 6 weeks to 17 years of age for the prevention of IPD caused by 15 *S. pneumoniae* serotypes. In July 2023, Health Canada authorized PCV20 (Prennar®20) in children 6 weeks to 17 years of age for the prevention of IPD caused by 20 *S. pneumoniae* serotypes. Both PCV15 and PCV20 contain all 13 serotypes included in PCV13 (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F), plus two additional serotypes (22F, 33F), with PCV20 containing five additional unique serotypes (8, 10A, 11A, 12F, 15B) ([Table 2](#)).

Table 2. Serotype coverage of pneumococcal vaccines*

Vaccine	<i>S. pneumoniae</i> serotype																							
	1	4	6B	9V	14	18C	19F	23F	5	7F	3	6A	19A	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20
PCV10	•	•	•	•	•	•	•	•	•	•														
PCV13	•	•	•	•	•	•	•	•	•	•	•	•	•											
PCV15	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•									
PCV20	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
PPV23	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•

PCV=pneumococcal conjugate vaccine; PPV=pneumococcal polysaccharide vaccine

* Dots represent included serotypes for each pneumococcal vaccine.

In December 2023, NACI released four recommendations for public health decision making for use of the new PCV15 and PCV20 products in children (Table 3).³ All four are strong NACI recommendations. For routine immunization programs, NACI recommends that either PCV15 or PCV20 should be the current product of choice for children less than 5 years of age who are not at increased risk of IPD. For high-risk programs, NACI recommends that PCV20 should be the preferred product for children less than 18 years of age who are at increased risk of IPD due to medical or environmental/living conditions.

Table 3. Summary of NACI recommendations (December 2023)³

Program	Population	Recommended Product	Recommended Schedule
Routine	Children <5 years of age who are not at increased of IPD	PCV15 or PCV20	2+1 or 3+1
High-risk	Children 2 months to <18 years of age who are at increased risk of IPD	PCV20	3+1 (series initiation and completion)
High-risk	Children <18 years of age who are at increased risk of IPD due to medical or environmental/living conditions and completed their series with PCV13/PCV15	PCV20	1 dose (catch-up)
High-risk	Children <18 years of age who received a hematopoietic stem cell transplant (HSCT) after consultation with a transplant specialist	PCV20	3+1

IPD=invasive pneumococcal disease; PCV=pneumococcal conjugate vaccine

Evidence Summary

To inform its recommendation on product choice for the routine pediatric pneumococcal immunization program in Ontario, the OIAC considered evidence on scientific (i.e., burden of disease, immunogenicity, safety) and programmatic (i.e., EEFA considerations, cost-effectiveness) factors.

The following factors were influential in its decision to recommend PCV20 over PCV15 for the routine immunization of children less than 5 years of age who are not at increased risk of IPD:

- **Burden of disease:** PCV20 offers greater serotype coverage than PCV15. The seven additional serotypes contained in PCV20 could potentially prevent an additional 37% of pediatric IPD cases than the existing PCV13 program based on average historical proportions of serotype-specific IPD cases reported in children less than 18 years of age in Ontario from 2011 to 2022 ([Figure 3](#)). By comparison, the two additional serotypes contained in PCV15 could potentially prevent an additional 13% of pediatric IPD cases ([Figure 3](#)).
- **Immunogenicity:** PCV15 and PCV20 are both immunogenic in children. Both vaccines met non-inferiority criteria for shared serotypes with PCV13 and superiority criteria for unique serotypes in clinical trials that compared these new vaccines to PCV13. However, both vaccines had statistically lower immune responses against most PCV13-shared serotypes, with the exception of serotype 3, for which PCV15 recipients had a relatively higher immune response. The clinical significance of these immunogenicity findings is unknown at this time.
- **Safety:** PCV15 and PCV20 had similar safety profiles relative to PCV13 in clinical trials, with no safety signals of concern identified.
- **EEFA considerations:** PCV20 has a greater potential to reduce disease burden in pediatric populations, particularly for groups at increased risk of IPD, and likely offers greater indirect benefit via herd immunity to those ineligible for vaccination. Using a single PCV20 product for both routine and high-risk pediatric immunization programs would simplify program delivery and communications, while minimizing immunization administration errors. The use of a single product for the pediatric program would also eliminate the potential need to re-immunize children whose high-risk status changes over time.
- **Cost-effectiveness:** Published economic evaluations of PCV15 or PCV20 favoured the new, higher-valent vaccines. NACI's systematic review included two cost-utility analyses of PCV15 (one industry-sponsored), which found PCV15 to be the dominant strategy over PCV13 (i.e., intervention was cost-saving and more effective). Four additional cost-utility analyses (one for PCV15 and three for PCV20, all of which were industry-sponsored) were published after the completion date for NACI's review, including one conducted in Canada. All four studies found the intervention (PCV15 or PCV20) to be the dominant strategy over its comparator.

In NACI's *de novo* cost-utility analysis, PCV15 was more cost-effective than PCV20 at commonly used thresholds in Canada under both a health system and societal perspective. However, these models were sensitive to assumptions around vaccine price and vaccine effectiveness for PCV15 and PCV20, which are currently unknown, along with indirect effects of vaccinating children on the incidence of pneumococcal disease in unvaccinated populations. At lower incremental prices and when indirect effects were included, PCV20 was a cost-effective option in NACI's models.

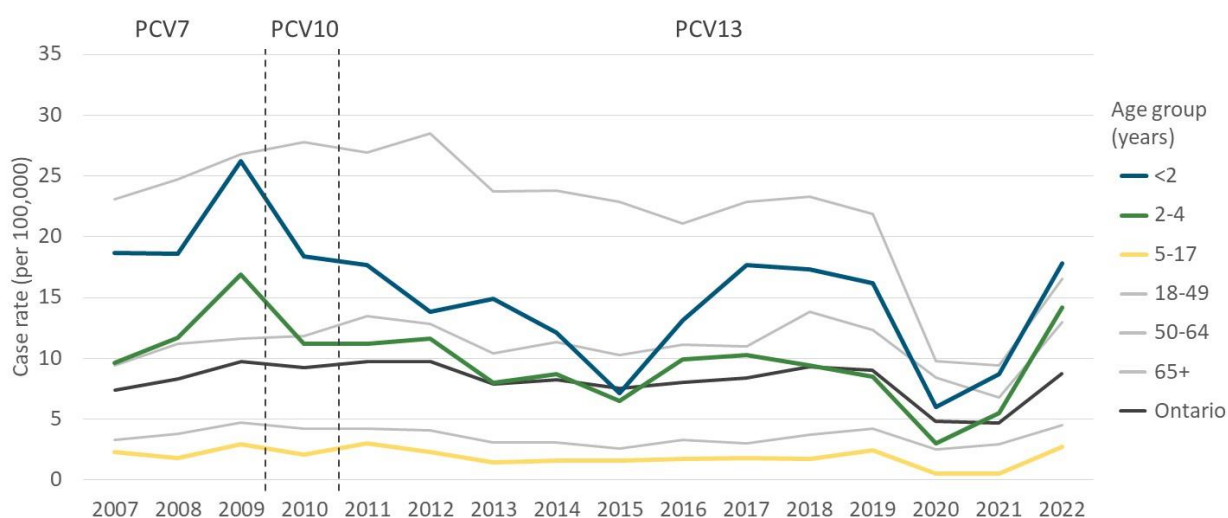
A more detailed description of these scientific and programmatic considerations is provided below.

Burden of Pneumococcal Disease in Ontario

The OIAC reviewed the epidemiology of reported IPD cases in Ontario from 2007 to 2022 using provincial surveillance data from the Integrated Public Health Information System (iPHIS).

Following implementation of the PCV7/PCV10/PCV13 program in Ontario, incidence of pediatric IPD has declined in Ontario,⁹ as elsewhere in Canada.^{7,10,11} Children under 2 years of age have the highest IPD burden among pediatric age groups in Ontario, followed by children 2-4 years of age (Figure 1). In children less than 2 years of age, IPD incidence decreased by more than 70% from 26.2 cases per 100,000 population in 2009 to 7.1 cases per 100,000 population in 2015 following the implementation of PCV10/PCV13. Incidence in this youngest age group increased to about 17 cases per 100,000 population from 2017 to 2019 (likely as a result of serotype replacement), then decreased during the COVID-19 pandemic in 2020 and 2021, followed by a rebound to pre-pandemic levels in 2022.

Figure 1. Confirmed IPD case rates by age group in Ontario, 2007–2022*

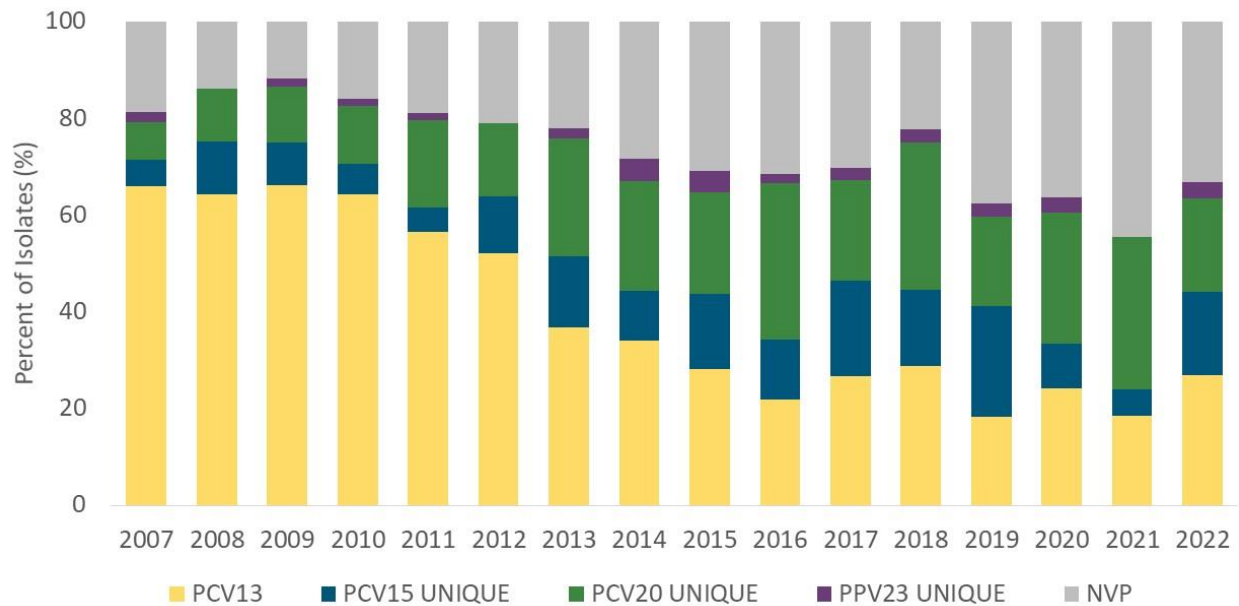


IPD=invasive pneumococcal disease; PCV=pneumococcal conjugate vaccine

* PCV10 (October 2009) and PCV13 (November 2010) implementation periods are indicated with dashed vertical lines
Source: Ontario. Ministry of Health. Integrated Public Health Information System (iPHIS) [database]. Toronto, ON: Queen's Printer for Ontario; 2020 [cited 2024 Jan 22]

The proportion of IPD isolates attributable to *S. pneumoniae* serotypes included in the PCV13 vaccine in children less than 18 years of age decreased from around 65% in 2007 to 2010 (prior to PCV13 implementation) to 22% in 2016 (five years after PCV13 implementation) then remained stable between 18% and 29% thereafter (Figure 2). The relative proportion of IPD isolates attributable to PCV15-unique serotypes (22F, 33F) or PCV20-unique serotypes (8, 10A, 11A, 12F, 15B) increased over the same time period. In 2022, about half of the pediatric IPD burden in Ontario was due to only five serotypes: 3, 19A, and 19F (included in PCV13, PCV15, and PCV20), 22F (included in PCV15 and PCV20), and 15B (unique to PCV20). These proportions are based on pediatric cases of IPD and may not reflect the serotype distribution of non-invasive pneumococcal disease, for which data are limited in the Canadian context.³ The serotype distribution of IPD in adults 18 years of age and older in Ontario is available in the OIAC's statement on adult PCV recommendations.⁴

Figure 2. Serotype distribution of IPD isolates among children <18 years of age in Ontario, 2007–2022



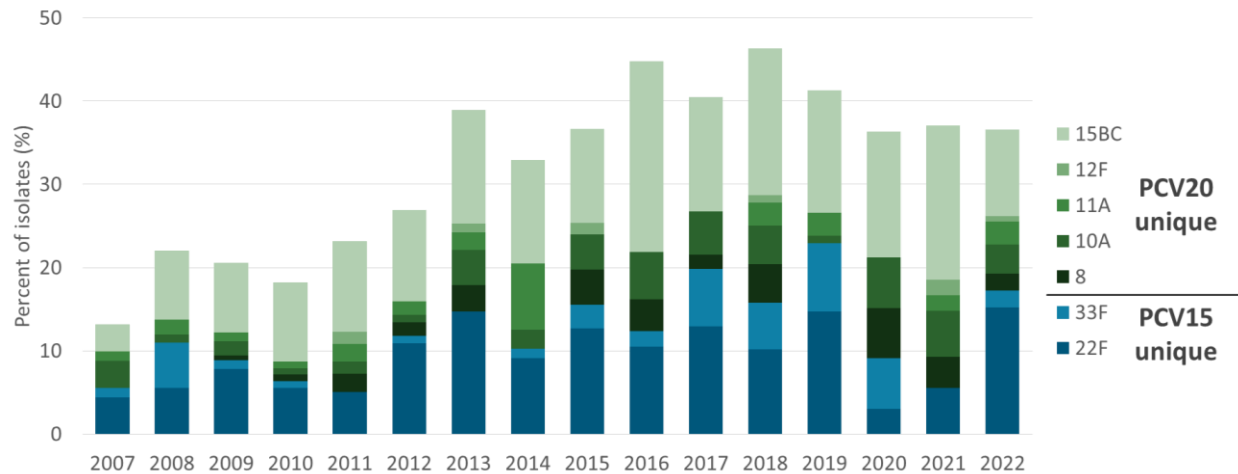
IPD=invasive pneumococcal disease; PCV=pneumococcal conjugate vaccine; PPV=pneumococcal polysaccharide vaccine; NVP=not vaccine preventable

Source: iPHIS (data current as of 24 October 2023)

On average during the PCV13 period (2011 to 2022), 44% of pediatric IPD cases in Ontario were due to one of the 15 serotypes contained in PCV15, while 68% of pediatric IPD cases were due to one of the 20 serotypes contained in PCV20. The two unique serotypes contained in PCV15 and PCV20 but not in PCV13 (22F, 33F) caused 13% of pediatric IPD cases, while the five unique serotypes contained in PCV20 but not in PCV15 nor PCV13 (8, 10A, 11A, 12F, 15B) caused 24% of pediatric IPD cases. Together, these seven PCV20-unique serotypes not contained in PCV13 (8, 10A, 11A, 12F, 15B, 22F, 33F) caused 37% of pediatric IPD cases on average from 2011 to 2022 following the implementation of PCV13 (Figure 3). These proportions are based on historical trends in reported IPD cases and do not capture potential serotype replacement over time.

In summary, PCV20 is expected to prevent more pediatric IPD cases than PCV15 based on its expanded serotype coverage. Compared with the existing PCV13 program, switching to a new program with PCV15 could potentially prevent an additional 13% of pediatric IPD cases, while switching to a new program with PCV20 could potentially prevent an additional 37% pediatric IPD cases (or 24% more than PCV15) based on historical provincial surveillance data.

Figure 3. Distribution of PCV15/PCV20-unique serotypes in IPD isolates among children <18 years of age in Ontario, 2007–2022



IPD=invasive pneumococcal disease; PCV=pneumococcal conjugate vaccine

Source: iPHIS (data current as of 24 October 2023)

Immunogenicity

No vaccine efficacy or effectiveness studies of PCV15 or PCV20 in children are currently available. Instead, Health Canada based its authorization of these new vaccines on immunogenicity and safety evidence.^{1,2} In its recent statement,³ NACI systematically reviewed immunogenicity data from seven phase 2/3 clinical trials that compared PCV15 to PCV13 and five phase 2/3 clinical trials that compared PCV20 to PCV13.¹²⁻¹⁹ Most of these trials were conducted in healthy infants who are not at increased risk of IPD. Head-to-head studies of PCV15 and PCV20 have not been conducted.

Both PCV15 and PCV20 met non-inferiority criteria for serotypes shared with PCV13 and superiority criteria for serotypes unique to PCV15/PCV20 that were required for Health Canada authorization.^{1,2} However, both vaccines had statistically lower immune responses (as measured by total and functional IgG antibody levels) for most PCV13-shared serotypes using either a 2+1 or 3+1 schedule. Immunogenicity for both PCV15 and PCV20 was more comparable to PCV13 when defined as seroresponse proportions (i.e., the proportion of participants meeting a pre-defined antibody threshold or ratio) instead of absolute antibody levels.

An exception to these findings was that PCV15 (but not PCV20) recipients had a relatively higher immune response against serotype 3. In Ontario, serotype 3 caused 8% of pediatric IPD cases in 2022. PCV13 vaccine effectiveness is known to be lower for serotype 3 than for other serotypes, particularly with a 2+1 schedule, which may explain the ongoing contribution of this serotype to the IPD burden in Ontario despite being vaccine-preventable with PCV13.²⁰⁻²²

All of the clinical trials included concomitant administration of PCV15 or PCV20 with other recommended pediatric vaccines, with no evidence of reduced protection against these other antigens that were concomitantly administered.

In summary, PCV15 and PCV20 were considered equivalent products with respect to immunogenicity, with the exception of serotype 3, which showed a better immune response for PCV15. Both vaccines had lower immune responses against most shared serotypes with PCV13, but higher immune responses for PCV15/PCV20-unique serotypes. The impact of these immunogenicity findings on clinical outcomes is currently unknown in the absence of efficacy/effectiveness data.

Safety

In its recent statement,³ NACI systematically reviewed safety data from eight phase 2/3 clinical trials for PCV15 and five phase 2/3 clinical trials for PCV20.^{12-19,23}

PCV15 and PCV20 were well-tolerated and had comparable safety profiles to PCV13 (i.e., the current standard of care) using either a 2+1 or 3+1 schedule. Most adverse events recorded in the clinical trials were mild to moderate with a duration of three days or less. The most frequently reported adverse events were irritability, somnolence, pain and other injection-site reactions, and decreased appetite.

Most serious adverse events (SAEs) were deemed to be not related to vaccination. Seven SAEs were considered vaccine-related in the PCV15 trials, which included more than 5,600 children across four studies.²⁴ Four SAEs (all pyrexia) were reported in participants who received PCV15, while three (two pyrexia and one febrile convulsion) were reported in participants who received PCV13.²⁴ Four deaths occurred (two after PCV15 and two after PCV13), but none were considered vaccine-related. One SAE due to inflammation was reported in a participant who received PCV20 based on an integrated analysis of safety data across four studies that included more than 5,100 children.

In summary, no safety signals of concern were identified for either PCV15 or PCV20; both vaccines had a similar safety profile to PCV13. However, ongoing safety surveillance for rare or very rare adverse events that were not detectable in clinical trials is required, as with any newly licenced vaccine product.

Ethics, Equity, Acceptability, and Feasibility (EEFA) Considerations

The OIAC considered EEFA factors related to either a single-product program with PCV20 or a mixed-product program with PCV15 for the routine pediatric program and PCV20 for the high-risk pediatric program.

Because PCV20 offers protection against five more serotypes than PCV15 (representing approximately one-quarter of pediatric IPD cases in Ontario), it has a greater potential to reduce disease burden in pediatric populations, particularly for groups at increased risk of IPD due to medical or environmental/living conditions. It also likely offers greater indirect benefit to older age groups and unvaccinated pediatric populations via herd immunity. Under a mixed-product program, some high-risk children will need to be re-immunized with PCV20 if they were initially vaccinated with PCV15 as part of routine programs but later develop a medical condition that makes them eligible for the high-risk program. A mixed-product program could also possibly worsen inequities if parents of children in higher-income households decide to pay for PCV20 out-of-pocket.

In terms of feasibility, using a single PCV20 product for both routine and high-risk immunization programs would simplify program delivery and communications to healthcare providers and the general public, potentially improving vaccine uptake, while reducing the risk of immunization administration errors. With a mixed-product program, some PCV20 product might be diverted to healthy children, resulting in higher vaccine wastage of PCV15. Acceptability among both healthcare providers and parents is anticipated to be greater for the higher-valent PCV20 product. The OIAC also commented on the public perception of recommending different vaccine products for different age and risk groups and harmonization across programs given OIAC's recommendation for use of PCV20 in adult programs,⁴ as well as NACI's preferential recommendation for PCV20 in high-risk children.³

Together, these EEFA considerations favoured a single product with PCV20 for both the routine and high-risk pediatric pneumococcal immunization programs.

Cost Effectiveness

The OIAC reviewed cost-effectiveness evidence from two sources: a systematic review of published and unpublished cost-utility analyses of PCV15 and PCV20 in pediatric populations and a *de novo* cost-utility analysis of PCV15 and PCV20 in the Canadian pediatric population conducted by NACI.²⁵

SYSTEMATIC REVIEW OF PCV15/PCV20 COST EFFECTIVENESS IN PEDIATRIC POPULATIONS

NACI's systematic review identified two peer-reviewed cost-utility analyses for PCV15 in children less than 18 years of age published between January 1, 2018, and March 7, 2023 (Table 4).^{26,27} Both studies were conducted in the United States, which currently uses a 3+1 schedule; one was industry-sponsored. In both studies, PCV15 was the dominant strategy over PCV13 (i.e., the intervention was both cost-saving and more effective), assuming price parity between the two vaccines.

NACI's statement also summarized unpublished economic evaluations of PCV15 and PCV20 in children that became available after completion of their systematic review,³ including three cost-utility analyses presented to the U.S. Advisory Committee on Immunization Practices.²⁸ In a scenario where PCV13 is replaced with PCV20 using a 3+1 schedule in the United States, PCV20 was cost-saving in two industry-sponsored models, while it had an incremental cost-effectiveness ratio (ICER) of USD \$57,000/quality-adjusted life year (QALY) in the Tulane-CDC model. In a scenario where PCV15 is replaced with PCV20 using a 3+1 schedule, PCV20 was cost-saving in the Pfizer-sponsored study but was associated with an ICER of USD \$105,000/QALY and USD \$125,000/QALY in the Merck-sponsored and Tulane-CDC models, respectively. All three models assumed an incremental price of PCV20 that was 11–16% higher than PCV13 or PCV15, which were about equally priced. In a Quebec-based analysis, neither a 2+1 schedule with PCV15 nor PCV20 was found to be cost effective under a health system perspective when compared to the current standard of care in that province (i.e., 2 doses of PCV10 and 1 dose of PCV13). Conversely, PCV20 was cost-effective under the health system perspective and dominant under the societal perspective, which takes into account the broader economic impacts of a vaccination program outside of the healthcare sector, in a scenario comparing PCV20 to PCV15 using a 2+1 schedule.

In addition to NACI's review, the OIAC reviewed four additional cost-utility analyses of PCV15 and PCV20 in pediatric populations, including one in Canada, that were all published after the completion date (March 7, 2023) of NACI's review (Table 4).²⁹⁻³² A Merck-sponsored study in Japan compared PCV15 to PCV13 using a 3+1 schedule.²⁹ Similar to the two PCV15 studies included in NACI's review, this study found that PCV15 was the dominant strategy over PCV13 assuming price parity between the two vaccines. A Pfizer-sponsored study in the United Kingdom (UK) compared PCV20 or PCV15 using a 2+1 or 1+1 schedule to PCV13 using a 1+1 schedule (i.e., the current standard of care in the UK).³⁰ That study found PCV20 to be dominant over both PCV15 and PCV13, with a PCV20 2+1 schedule being more cost effective than a PCV20 1+1 schedule. A Pfizer-sponsored study in Greece examined switching to PCV15 in 2023 or PCV20 in 2024 from the current PCV13 program using a 3+1 schedule.³¹ That study found that PCV20 was the dominant strategy, with higher prices assumed for PCV15 and PCV20 over PCV13.

In a Pfizer-sponsored study conducted in a Canadian pediatric population, Lytle et al. compared PCV20 to the current standard of care with PCV13 or a potential program with PCV15 using a 2+1 schedule.³² Both models considered a publicly funded health system and societal perspective over a 10-year time horizon using a 1.5% discount rate in accordance with NACI guidelines.³³ The incremental price of PCV20 was assumed to be 10% higher than PCV13 or PCV15, which were priced at parity. The model considered the direct impact of vaccinating infants less than 2 years of age on IPD, all-cause pneumonia, and AOM, along with indirect effects against these disease outcomes due to PCV15/PCV20-unique serotypes in unvaccinated populations. Under both the health system and societal perspectives, their model found PCV20 to be dominant over PCV13 and PCV15. PCV20 remained the dominant strategy in all sensitivity and scenario analyses, including with a 20% reduction in the incremental price of PCV15.

Table 4. Systematic review of published PCV15 and PCV20 cost-utility analyses in pediatric populations*

Study	Prasad et al. (2023) ²⁶	Huang et al. (2023) ²⁷	Tajima et al. (2023) ²⁹	Wilson et al. (2023) ³⁰	Warren et al. (2023) ³¹	Lytle et al. (2023) ³²
Included in NACI review	Yes	Yes	No	No	No	No
Industry-sponsored	No (CDC-Tulane)	Yes (Merck)	Yes (Merck)	Yes (Pfizer)	Yes (Pfizer)	Yes (Pfizer)
Vaccine vs. comparator	PCV15 vs. PCV13	PCV15 vs. PCV13	PCV15 vs. PCV13	PCV20 or PCV15 vs. PCV13	PCV15 in 2023 or PCV20 in 2024 vs. PCV13	PCV20 vs. PCV13 or PCV15
Schedule	3+1	3+1	3+1	2+1 or 1+1	3+1	2+1
Country	United States	United States	Japan	United Kingdom	Greece	Canada
Perspective*	Societal	Societal	Societal	Health system	Health system	Health system + societal
Model (cohort)	Static Markov model (single cohort)	Monte Carlo simulation (multi-cohort)	Static Markov model (single cohort)	Dynamic model	Not specified	Static Markov model (multi-cohort)
Time horizon	15 years	100 years (lifetime)	10 years	5 years	10 years	10 years
Outcomes	IPD, pneumococcal pneumonia, AOM	IPD, all-cause pneumonia, pneumococcal AOM	IPD, non-bacteremic pneumococcal pneumonia, pneumococcal AOM	IPD, pneumococcal CAP, AOM	IPD, pneumococcal pneumonia, AOM	IPD, all-cause pneumonia, AOM
Direct effects	PCV15 = PCV13	PCV15 = PCV13 (except CAP)	PCV15 = PCV13	PCV20 = PCV15 = PCV13, 2+1 > 1+1	Not specified	PCV20 = PCV15 = PCV13

Study	Prasad et al. (2023) ²⁶	Huang et al. (2023) ²⁷	Tajima et al. (2023) ²⁹	Wilson et al. (2023) ³⁰	Warren et al. (2023) ³¹	Lytle et al. (2023) ³²
Duration of effects	15 years (waning after 5 years)	15 years (waning after 5 years)	10 years (waning after 5 years)	Median = 1.4 years	Not specified	10 years (waning after 5 years)
Indirect effects	Included	Included	Included	Included	Included	Included
Discount rate	3%	3%	2%	3.5%	3.5%	1.5%
Vaccine coverage	92% primary, 82% booster	92% primary, 82% booster	100% primary + booster	97% primary, 91% booster	84.5% primary + booster	84% primary + booster
Vaccine price	PCV15 ≈ PCV13	PCV15 = PCV13	PCV15 = PCV13	PCV20 > PCV15 ≈ PCV13	PCV15 > PCV20 > PCV13	PCV20 > PCV15 = PCV13
Main finding	PCV15 dominant	PCV15 dominant	PCV15 dominant	PCV20 dominant, PCV20 2+1 > PCV20 1+1	PCV20 dominant	PCV20 dominant

AOM=acute otitis media; CAP=community-acquired pneumonia; IPD=invasive pneumococcal disease; PCV=pneumococcal conjugate vaccine

* Model parameters are shown for the base-case models.

† The health system perspective includes only direct healthcare and program implementation costs, while the societal perspective includes non-healthcare costs (e.g., productivity loss, caregiving, out-of-pocket medical expenses) in addition to health system costs.

NACI'S COST-UTILITY ANALYSIS OF PCV15/PCV20 IN THE CANADIAN PEDIATRIC POPULATION

The OIAC also reviewed the results of NACI's cost-utility analysis of PCV15 and PCV20 in the Canadian pediatric population, along with a discussion of its limitations and main conclusions.²⁵

The NACI cost-utility model followed a multi-age cohort over 10 years. They used a sequential ICER analysis to directly compare PCV13, PCV15, and PCV20. Previously unvaccinated infants who were eligible for routine pneumococcal immunization were vaccinated according to a 2+1 schedule (at 2, 4, and 12 months of age), consistent with current NACI guidelines.³⁴ Their analysis considered both the health system and societal perspectives with a 1.5% discount rate. Outcomes included IPD, pneumococcal CAP, and AOM. The incremental prices of PCV20 and PCV15 over PCV13 were assumed to be 26% and 9% higher, respectively. Indirect effects (i.e., herd immunity) were excluded from the base-case model but were considered in a sensitivity analysis.

NACI's sensitivity analysis used a cost-effectiveness (i.e., willingness-to-pay) threshold of \$30,000/QALY or \$60,000/QALY. Although Canada does not have an explicit cost-effectiveness threshold, an ICER threshold for Canada has been estimated at 2019 USD \$45,000/QALY (range: 2019 USD \$38,000-\$56,000/QALY).³⁵ The Canadian Agency for Drugs and Technologies in Health (CADTH) uses an implicit threshold of CAD \$50,000/QALY.³⁶

In NACI's analysis, PCV20 was projected to avert about twice as many pediatric cases of pneumococcal disease as PCV15 over a 10-year period, given its greater serotype coverage. In their base-case model, PCV15 was found to be more cost-effective (i.e., lower ICERs) than PCV20 at commonly used thresholds. Under the health system perspective, the sequential ICER for PCV15 (vs. PCV13) was \$58,823/QALY, while the sequential ICER for PCV20 (vs. PCV15) was \$135,289/QALY. Under the societal perspective, the corresponding values were \$18,272/QALY and \$93,416/QALY, respectively. PCV20 was more cost-effective (i.e., lower ICER compared to the sequential ICER approach) when compared directly to PCV13.

In one-way sensitivity analyses, PCV13 was the most cost-effective option for most parameters at the \$30,000/QALY threshold under the health system perspective, except at lower incremental prices for PCV15 and PCV20. Conversely, at the \$60,000/QALY threshold, PCV15 was more frequently identified as a cost-effective option, especially at higher parameter values for vaccine effectiveness for IPD or AOM, case-fatality rate for patients with IPD or pneumococcal CAP, or the probability of a patient with pneumococcal CAP requiring hospitalization and at lower incremental prices. PCV20 was the most cost-effective option at this threshold when its incremental price was less than 20% higher than PCV13.

In two-way sensitivity analyses that varied the price per dose of PCV15 and PCV20 simultaneously, PCV15 was the optimal strategy at the \$30,000/QALY threshold if its price per dose was up to 5% higher than PCV13 and PCV20 was priced at 10–15% higher. Whereas, PCV20 was the optimal strategy at this threshold if its price per dose was up to 10% higher than PCV13 and PCV15 was priced at least 5% higher or at lower prices when priced equivalently to PCV15. Findings were similar at the \$60,000/QALY threshold, except PCV20 was the optimal strategy at slightly higher incremental prices. In another two-way sensitivity analysis that considered the indirect effects of vaccinating infants on the incidence of pneumococcal disease due PCV15/PCV20-unique serotypes in unvaccinated populations, PCV20 was more frequently found to be cost-effective. At both thresholds, PCV20 was the optimal strategy if serotype-attributable disease was reduced by at least 5–10% due to indirect effects.

Finally, in a scenario analysis, PCV20 was the dominant strategy under a scenario of higher pneumococcal disease incidence and higher direct costs, for example in Northern communities. Other scenarios, including lower incidence of CAP or AOM, alternative serotype distributions for AOM, and more rapid waning of vaccine effectiveness, resulted in higher ICERs (indicating lower cost effectiveness) compared with the base-case model.

Limitations and considerations for the interpretation of NACI's *de novo* cost-utility analysis are listed below. For the most part, these limitations would also apply to the systematically reviewed published and unpublished studies, with the exception of limitation #3 as these other models included indirect effects in their base-case analysis.

1. The models only examined immunization of unvaccinated infants through routine immunization programs; high-risk programs for children at increased risk of IPD were not included.
2. The models did not consider mixed or catch-up schedules or re-immunization of children previously immunized with lower-valent PCVs.
3. The models did not consider serotype replacement or herd immunity in their base-case analysis; indirect effects were included only in a sensitivity analysis.
4. Finally, the models were sensitive to assumptions around incremental vaccine prices for PCV15 and PCV20, which were unknown at the time of their analysis.

NACI's findings of better cost-effectiveness with PCV15 than PCV20 are in contrast to the Pfizer-sponsored study of PCV20 in the Canadian pediatric population, which found PCV20 to be the dominant strategy.³² [Table 5](#) summarizes the key similarities and differences between the NACI and Pfizer models.

SUMMARY OF ECONOMIC EVIDENCE

In summary, economic models favoured the new, higher-valent vaccines. In three peer-reviewed studies that compared PCV15 to PCV13 (2/3 included in NACI's systematic review and 2/3 industry sponsored), PCV15 dominated over PCV13 (i.e., cost-saving and more effective). In three peer-reviewed studies that compared PCV20 to PCV15 or PCV13 (none included in NACI's systematic review and 3/3 industry sponsored), including one study conducted in Canada, PCV20 dominated over its comparator. Unpublished economic evaluations from the United States and Quebec showed mixed results for replacing the current standard of care with PCV15 or PCV20.

In NACI's *de novo* cost-utility analysis, PCV20 had the greatest impact on pediatric pneumococcal disease burden, while PCV15 was a cost-effective strategy at commonly used thresholds. However, NACI's models were highly sensitivity to the incremental price of PCV15 and PCV20 relative to PCV13, assumptions around vaccine effectiveness, and inclusion of indirect effects. In particular, OIAC members noted that indirect effects were excluded from NACI's base-case model, which may impact their conclusions, as reductions in pneumococcal disease incidence in non-pediatric age groups have been observed following the implementation of PCV13.^{9,11,37} When indirect effects were included in sensitivity analyses, PCV20 was the optimal strategy even with relatively conservative assumptions of indirect effects (i.e., 5–10% reductions in serotype-attributable disease).

Together, these findings suggest that PCV15 is a cost-effective option in the Canadian context, with PCV20 likely being cost-effective under certain conditions, such as at lower incremental prices (up to 10–20% higher than PCV13) or when indirect effects are taken into account.

Table 5. Comparison of NACI and Pfizer cost-utility analyses of PCV20 in the Canadian pediatric population*

Study	NACI (2023) ²⁵	Lytle et al. (2023) ³²
Industry-sponsored	No (PHAC)	Yes (Pfizer)
Vaccine vs. comparator	PCV20 vs. PCV15 vs. PCV13 (sequential ICER)	PCV20 vs. PCV13 or PCV15
Schedule	2+1 (2, 4, 12 months of age)	2+1 (2, 4, 16 months of age)
Country	Canada	Canada
Perspective [†]	Health system + societal	Health system + societal
Model (cohort)	Static Markov model (multi-cohort)	Static Markov model (multi-cohort)
Time horizon	10 years	10 years
Outcomes	IPD, pneumococcal CAP, AOM	IPD, all-cause pneumonia, AOM
Direct effects	PCV20 = PCV15 = PCV13	PCV20 = PCV15 = PCV13
Duration of effects	15 years (waning after 5 years)	10 years (waning after 5 years)
Indirect effects [‡]	No (sensitivity analysis only)	Included
Discount rate	1.5%	1.5%
Vaccine coverage	87% primary, 84.5% booster	84% primary + booster
Vaccine price [§]	PCV20 >> PCV15 > PCV13	PCV20 > PCV15 = PCV13
Main finding	PCV15 > PCV20	PCV20 dominant

AOM=acute otitis media; CAP=community-acquired pneumonia; ICER=incremental cost-effectiveness ratio; IPD=invasive pneumococcal disease; PCV=pneumococcal conjugate vaccine; PHAC=Public Health Agency of Canada
 * Model parameters are shown for the base-case models.

† The health system perspective includes only direct healthcare and program implementation costs, while the societal perspective includes non-healthcare costs (e.g., productivity loss, caregiving, out-of-pocket medical expenses) in addition to health system costs.

‡ Both models incorporated indirect effects in unvaccinated individuals as a relative reduction in pneumococcal disease incidence due to PCV15/20-unique serotypes; for the NACI model, indirect effects were excluded from the base model but considered in sensitivity analyses, while for the Pfizer model, they were included in the base model.

§ The NACI model assumed PCV20 was priced at 26% higher than PCV13 and PCV15 was priced at 9% higher than PCV13 in the base case; the Pfizer model assumed PCV20 was priced at 10% higher than PCV13, with PCV15 priced equivalent to PCV13.

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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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