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OIAC Ontario Immunization Advisory Committee
CCOI Comité consultatif ontarien de l'immunisation

Recommendations on the Use of Quadrivalent Meningococcal Conjugate Vaccines in Ontario

Published: July 2026

Key Highlights

- Currently in Ontario, children are eligible to receive the meningococcal serogroup C conjugate vaccine (Men-C-C) at 12 months of age and the quadrivalent meningococcal conjugate vaccine (Men-C-ACYW) through the grade 7 school-based immunization program (~12 years of age).
- Both Health Canada authorized Men-C-C vaccines, Menjugate (GlaxoSmithKline Inc.) and NeisVac-C (Pfizer Canada ULC), will be discontinued in 2026.
- Due to these anticipated changes to vaccine availability, Ontario will be replacing the Men-C-C dose for children 12 months of age with Men-C-ACYW starting in June 2026.
- Based on scientific and programmatic considerations, the OIAC recommends:
  - All children starting at 12 months of age should be vaccinated against invasive meningococcal disease (IMD).
  - Ontario should maintain the current routine immunization schedule for invasive meningococcal disease (IMD), with the first dose offered to children starting at 12 months of age and the second dose offered to adolescents through the grade 7 school-based immunization program.
- The OIAC does not currently recommend a one-time catch-up program for children previously immunized with Men-C-C. The Committee advises continued monitoring of the epidemiology of IMD in Ontario to inform the need for any programmatic changes to the routine meningococcal immunization program in the future.

Overview

Ontario's publicly funded meningococcal immunization program aims to protect children, adolescents and young adults from invasive meningococcal disease (IMD), a rare but serious illness caused by *Neisseria meningitidis*.[1] The current routine immunization schedule in Ontario includes a dose of meningococcal serogroup C conjugate vaccine (Men-C-C) for children at 12 months of age, and an adolescent dose of the quadrivalent meningococcal conjugate vaccine (Men-C-ACYW) for students in grade 7 (typically given around 12 years of age) through the school-based immunization program.[2,3]

Currently, there are two Health Canada authorized Men-C-C vaccines, Menjugate (GlaxoSmithKline Inc.) and NeisVac-C (Pfizer Canada ULC), which will both be discontinued from the Canadian market in 2026.[4-6] Sanofi Pasteur Limited discontinued the diphtheria toxoid conjugated quadrivalent meningococcal vaccine (Men-C-ACYW-DT), Menactra, in December 2025 and has substituted the product with the tetanus-toxoid conjugated vaccine (Men-C-ACYW-TT), MenQuadfi (Sanofi Pasteur Limited).[7] As a result of these changes in meningococcal vaccine product availability, Ontario will replace the Men-C-C dose with Men-C-ACYW at 12 months of age as of spring 2026.

At the request of the Ministry of Health, the Ontario Immunization Advisory Committee (OIAC) convened over a series of three meetings held on November 12, 2025, January 21, 2026 and February 18, 2026 to consider the optimal timing of Men-C-ACYW doses and the need for a one-time catch-up program for children previously immunized with Men-C-C. To inform their decision, OIAC members reviewed and discussed the epidemiology of IMD, Men-C-ACYW vaccine characteristics (e.g., immunogenicity, safety), as well as clinical and implementation considerations. This document summarizes the scientific evidence and considerations discussed by the OIAC and outlines the committee's recommendations.

Recommendations

The OIAC recommends that all children in Ontario without contraindications should be vaccinated with a meningococcal conjugate vaccine that protects against IMD starting at 12 months of age as part of Ontario's routine publicly funded schedule. Specifically:

1. The OIAC recommends that Ontario should maintain its routine immunization schedule for invasive meningococcal disease, which includes two doses of a meningococcal conjugate vaccine. One dose should be offered to children at 12 months of age and one dose should be offered to adolescents through the school-based grade 7 program.
2. The OIAC does not recommend a catch-up program with Men-C-ACYW for children previously immunized with Men-C-C at this time but will continue to monitor the epidemiology of IMD in Ontario, particularly the recent increase in serogroup W, to inform the potential need for a future catch-up program.

Background

Invasive Meningococcal Disease

Invasive meningococcal disease (IMD) is a rare but life-threatening disease caused by the gram-negative bacterium *Neisseria meningitidis*.[8] Between 2012 and 2022, there were 1,196 cases of IMD across Canada, with a mean incidence of 0.31 cases per 100,000 population.[9]

IMD is primarily caused by six meningococcal serogroups: A, B, C, X, W and Y, and is transmitted by mucosal contact with respiratory droplets from the nose and throat of infected individuals.[8] IMD primarily manifests as meningococcal meningitis (approximately 50% of cases), meningococcal sepsis (35–40% of cases), or both. Meningococcal meningitis is characterized by fever, intense headache, nuchal rigidity and nausea, while meningococcal sepsis is characterized by the sudden onset of fever, myalgia, vomiting and tachypnea. In addition to this classical presentation, IMD caused by serogroup W has been reported to present atypically; this can include acute gastrointestinal symptoms, bacteremic pneumonia, septic arthritis and severe upper respiratory tract infection that can sometimes lead to misdiagnoses.[10,11]

In Canada, approximately 14% of IMD occurring between 2012–2021 has resulted in death, with the highest fatality rate generally observed among infants less than 1 year of age, followed closely by that in adults 60 years and older and young adults 20 to 24 years of age.[8] In 2020–2024, approximately 90–97% of IMD cases in Ontario required hospitalization and 9–15% of cases resulted in death.[12] Long-term sequelae, including hearing loss, seizures, neurological disabilities and amputation, occur in approximately 15–20% of IMD survivors.[8]

Health Canada Authorized Men-C-ACYW Vaccines

As of February 2026, there are four Men-C-ACYW vaccines currently authorized by Health Canada.[4] All four contain meningococcal capsular carbohydrates from serogroups A, C, Y and W, but differ in their protein carrier. The diphtheria toxoid-conjugated vaccine, Men-C-ACYW-DT (Menactra), was discontinued by Sanofi Pasteur in December 2025 and will no longer be commercially available in Canada once vaccine supply is depleted in 2026.[7,13] Men-C-ACYW-CRM (Menveo) is conjugated to CRM_{197}, a genetically detoxified form of diphtheria toxin, while the Men-C-ACYW-TT vaccines (Nimenrix and MenQuadfi) are conjugated to tetanus toxoid.[13-16] To differentiate between the two authorized Men-C-ACYW-TT vaccines, trade names will be included in parentheses throughout the statement. Note that vaccine trade names are used to help differentiate meningococcal vaccines using the same carrier protein. The use of trade names is for identification only and does not indicate endorsement of any specific vaccine product.

Vaccine characteristics, age indications and dosage requirements for each Men-C-ACYW vaccine are outlined in Table 1.

Table 1: Characteristics of Authorized Men-C-ACYW Vaccines in Canada[4,13-16]

Vaccine	Description	Age Indication	Schedule
Menactra (Sanofi Pasteur, discontinued as of Dec 2025)	Meningococcal polysaccharides conjugated to diphtheria toxoid protein (Men-C-ACYW-DT)	9 months to 55 years	• 9–23 months: 2 doses* • 2–55 years: 1 dose
MENVEO (GlaxoSmithKline)	Meningococcal oligosaccharides conjugated to CRM_{197} protein (Men-C-ACYW-CRM)	2 months to 55 years	• 2–6 months: 3 doses + booster† • 7–23 months: 2 doses‡ • 2–55 years: 1 dose
NIMENRIX (Pfizer)	Meningococcal polysaccharides conjugated to tetanus toxoid protein (Men-C-ACYW-TT)	6 weeks to 55 years	• 6 weeks–5 months: 2 doses + booster¶ • 6–11 months: 1 dose + booster¶ • 1–55 years: 1 dose
MenQuadfi (Sanofi Pasteur)	Meningococcal polysaccharides conjugated to tetanus toxoid protein (Men-C-ACYW-TT)	≥ 6 weeks**	• 6 weeks–5 months: 4 doses§,‖ • 6–11 months: 2 doses#,‖ • ≥12 months: 1 dose‖

Abbreviations: CRM_{197}, cross reacting material 197 - a genetically detoxified form of diphtheria toxin; DT, diphtheria toxoid; Men-C-ACYW, quadrivalent meningococcal conjugate vaccine; TT, tetanus toxoid.

* Doses at least 3 months apart; † Doses at least 2 months apart with a booster dose at 12 – 16 months of age; ‡ 2nd dose should be administered in the 2nd year of life, at least 2 months after first dose; ¶ Booster at 12 months, at least 2 months after the last dose; § Given at least 2 months apart, with fourth dose administered in the second year of life (12 to 18 months of age; # Second dose administered in the second year of life (at 12 to 18 months of age); ‖Single booster dose may be give to adolescents/adults at continued risk for IMD if at least 4 years have elapsed since the last Men-C-ACYW dose. There are no data available on the optimal timing of a booster dose for those primed with MenQuadfi; ** Age indication expanded as of March 26, 2026.

NACI Recommendations on the Use of Men-C-ACYW

In light of changes in Men-C-C vaccine supply and Men-C-ACYW vaccine product availability and indications,[4-6] the National Advisory Committee on Immunization (NACI) recently updated their recommendations on the use of Men-C-ACYW vaccines for children <2 years of age.[17] In their rapid response, NACI recommends that all children 12–23 months of age should receive one dose of Men-C-ACYW vaccine, regardless of the number of doses given during the first year of life. Further, children 6 weeks–23 months of age who are at high risk of IMD caused by serogroups A, C, W or Y are strongly recommended to be immunized using a Men-C-ACYW vaccine without a preferential recommendation for any specific Men-C-ACYW vaccine product.

NACI also recommends that all jurisdictions maintain the adolescent Men-C-ACYW program to sustain herd immunity and support individual protection during adolescence and young adulthood.[17] In the Canadian Immunization Guide, NACI currently recommends either Men-C-C or Men-C-ACYW for healthy adolescents and young adults aged 12–24 years regardless of Men-C-C vaccination in infancy or childhood.[4] Timing of administration may vary depending on local epidemiology and programmatic considerations. NACI is currently undertaking a more comprehensive review of its meningococcal immunization recommendations.[18]

Meningococcal vaccines are also recommended for individuals at high risk of IMD, including those with underlying medical conditions (i.e., some congenital immunodeficiencies, acquired complement deficiency, functional or anatomic asplenia, sickle cell disease or human immunodeficiency virus (HIV)) and those at increased risk of exposure (i.e., travellers to areas with high rates of endemic diseases or transmission, military personnel, laboratory workers).[4] A review of Ontario's high-risk IMD programs was considered out of scope for this statement.[3]

Ontario's Meningococcal Immunization Program

Ontario's publicly funded meningococcal program was introduced in September 2004 and was initially limited to providing the Men-C-C vaccine to children 12 months of age. In January 2005, the publicly funded program was expanded to include a catch-up program for children aged 12 years (grade 7) and adolescents 15–19 years of age. A routine, school-based meningococcal immunization program was subsequently initiated in September 2005 for students in Grade 7 (~12 years of age) until September 2009 when Men-C-C vaccine was replaced with Men-C-ACYW. All students in grades 7–12 are currently eligible for the Men-C-ACYW vaccine, if not previously vaccinated, along with individuals born in or after 1997. Those born between 1986 and 1996, and those born on or after September 1, 2003 and are ≥1 year of age remain eligible for the Men-C-C vaccine until it is discontinued in 2026.[2] During the 2024–25 school year, the estimated immunization coverage for Men-C-C among 7-year-olds was 83.6%, while the coverage for Men-C-ACYW among 12- and 17-year-olds were 78.4% and 88.1%, respectively.[19]

Jurisdictional Scan of Meningococcal Immunization Programs

As of February 2026, the majority of provinces and territories (PTs) across Canada offered a childhood dose of Men-C-C at 12 months, with the exception of Quebec, which offered the vaccine at 18 months (Table 2).[2,20-31] Yukon also offered Men-C-C to infants 2 months of age.[20] As of March 1, 2024, Manitoba became the first Canadian PT to switch from Men-C-C to Men-C-ACYW for the 12-month dose, driven by a substantial increase in IMD cases caused by serogroup W. From 2023–2025, there were a total of 60 IMD cases in Manitoba resulting in 6 deaths, with annualized incidence rates reaching as high as 1.7 per 100,000 population observed in 2024.[28] Most cases were observed in children <5 years and adults ≥60 years. The Northwest Territories followed suit in early 2026, offering Men-C-ACYW to infants and children aged 2 and 12 months.[20]

It is anticipated that all PTs will be transitioning their publicly funded routine programs to the Men-C-ACYW vaccine for the early childhood dose in response to the recent changes to product availability in Canada.

Most PTs offer the adolescent Men-C-ACYW dose as part of their school-based programs to students in grades 6–9 (11–14 years old), with some variability in timing across the country (Table 2).[2,20-31] Newfoundland offers the adolescent dose as early as 9 years of age, while Northwest Territories offers it as late as 17 years of age. In the majority of PTs, Men-C-ACYW is publicly funded for all adolescents, except in the Northwest Territories where the cost is only covered for individuals attending post-secondary education or military recruits who will be living in congregate settings.[22]

Table 2: Meningococcal Immunization Programs in Canada as of February 2026.[2,20-31]

Province/ Territory	Early Childhood (age in months)									Adolescence (age in years)								
	2	4	6	8	10	12	18	24	9	10	11	12	13	14	15	16	17	18
Ontario						x						y						
Nova Scotia						x						y						
Newfoundland						x			y									
Prince Edward Island						x								y				
New Brunswick						x								y				
Quebec							x							y				
Manitoba						y					y							
Saskatchewan						x							y					
Alberta						x								y				
British Columbia						x								y				
Yukon	x					x								y				
Northwest Territories	y					y											y*	
Nunavut						x								y				

Legend x Men-C-C y Men-C-ACYW

*Vaccine offered to grade 12 students attending post-secondary education or military recruits who will be living in a congregate setting. Men-C-ACYW, quadrivalent meningococcal conjugate vaccine; Men-C-C, meningococcal serogroup C conjugate vaccine

Many jurisdictions around the world also offer infant, childhood and/or adolescent doses of meningococcal vaccines, with variation in targeted age groups and vaccines offered (Table 3).[32-42] As of February 2026, Italy and Spain offered infant/child Men-C-C doses and an adolescent Men-C-ACYW dose (current program in most Canadian PTs), whereas in Australia, Belgium, France, the Netherlands and Switzerland, Men-C-ACYW is offered to both children and adolescents (anticipated future program in most PTs).

Table 3: Jurisdictional Scan of Routine Meningococcal Immunization Programs[32-42]

Example Countries	Infant	Child	Adolescent	
Germany		Men-C-C (1 dose) 12 months		
Italy		Men-C-C (1 dose) 13 – 15 months	Men-C-ACYW (1 dose) 12–18 years	
Spain	Men-C-C (Primary: 1st dose) 4 months	Men-C-C (Primary: 2nd dose) 12 months	Men-C-ACYW (1 dose) 12–18 years	
Austria, United Kingdom			Men-C-ACYW (1 dose) 10–14 years	
United States			Men-C-ACYW (Primary) 11 years	Men-C-ACYW (Booster) 16 years
Australia, Belgium, The Netherlands, Switzerland		Men-C-ACYW (Primary) 12–24 months	Men-C-ACYW (Booster) 14–16 years	
France*	Men-C-ACYW (Primary) 6 months	Men-C-ACYW (Booster) 12 months	Men-C-ACYW (Booster) 11 – 14 years	

Legend Men-C-C Men-C-ACYW

*Men-C-ACYW-TT (Nimenrix) doses at 6 and 12 months of age. Men-C-ACYW, quadrivalent meningococcal conjugate vaccine; Men-C-C, meningococcal serogroup C conjugate vaccine

Evidence Summary and Considerations

To inform its recommendations regarding the optimal timing of Men-C-ACYW doses and the need for a one-time catch-up program with Men-C-ACYW for children previously vaccinated with Men-C-C, the OIAC reviewed and discussed evidence on scientific (e.g.., burden of disease, vaccine characteristics) and programmatic (e.g., Ethics, equity, feasibility and accessibility [EEFA] considerations, cost-effectiveness) factors.

The following factors were influential in their recommendations regarding the **timing of vaccine doses**:

- **Epidemiology:** During the post-COVID-19 pandemic period (2023 to present) in Ontario, there has been an increase in IMD caused by serogroups contained within the Men-C-ACYW vaccine, driven primarily by an increase in IMD caused by serogroup W. In 2024 and 2025, the incidence of IMD was highest among infants <1 year of age and children 1–4 years of age followed by adults 65 years of age and older. During these years, 77% and 68% of reported IMD cases were caused by serogroups C, Y and W.
- **Vaccine characteristics:** Seroprotection following a primary or booster dose of Men-C-ACYW starts to wane at 4–5 years post vaccination in children aged 1–3 years but may persist for some serogroups for at least 10 years. Booster vaccination with Men-C-ACYW was well tolerated and resulted in a strong anamnestic immune response persisting for at least 6 years among children primed with either Men-C-C or any Men-C-ACYW vaccine product. Co-administration of Men-C-ACYW with routine pediatric vaccines was well tolerated but may result in lower antibody titres against some antigens; however, in most instances, seroprotective levels were still achieved.
- **EEFA considerations:** OIAC members considered maintaining the adolescent dose in the grade 7 school-based program to be a more equitable, acceptable and feasible approach, especially for individuals without a regular care provider or who experience barriers to accessing primary care. Additionally, the timing of the 12-month dose currently aligns with established well-child visits and other routine childhood vaccines according to the Ontario publicly funded schedule.

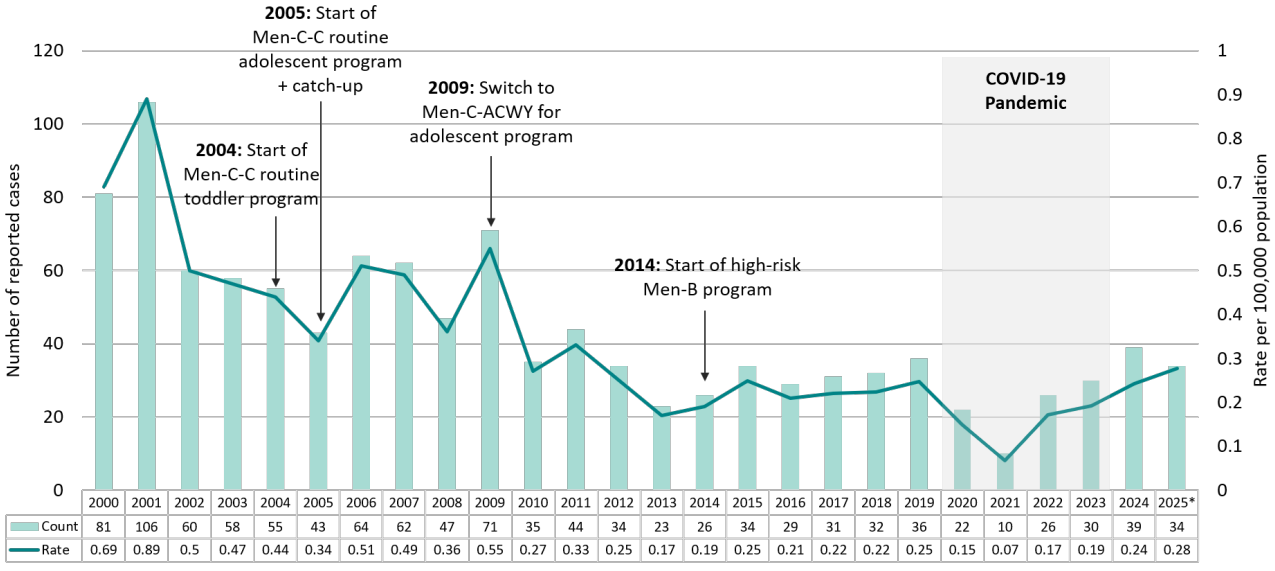
The following factors were influential in their recommendations regarding the need for a **one-time catch-up program**:

- **Epidemiology:** Despite the increase in serogroup W in Ontario, reported IMD cases remain rare in children (incidence 0.83 per 100,000 population in infants <1 year of age and 0.44 per 100,000 population in children 1–4 years of age). Ontario's current epidemiology is distinct from that of Manitoba, where an outbreak of serogroup W predominately affecting children <5 years of age and older adults is ongoing.
- **Vaccine characteristics:** Men-C-ACYW elicits a strong immune response when administered to individuals who have previously received Men-C-C as infants or children.
- **EEFA considerations:** A comprehensive communication strategy about the catch-up campaign would be required to ensure awareness among healthcare providers, parents and guardians. Parental decisions around vaccination and healthcare provider recommendations should incorporate the perceived risk of IMD as well as the benefits of Men-C-ACYW vaccination for children who have already received Men-C-C.
- **Cost-effectiveness:** Due to the low number of IMD cases among children 12 months of age and older, a one-time catch-up vaccination campaign would be expected to have limited incremental benefit in terms of the number of cases prevented.

Epidemiology and Burden of IMD in Ontario

Rates of reported IMD cases declined in Ontario from 2000–2013 (Figure 1). This decline was largely due to reductions in serogroup C IMD incidence due to direct and indirect vaccine program impacts following the introduction of the routine meningococcal Men-C-C vaccine programs for children and adolescents in 2004 and 2005, respectively, and the switch to Men-C-ACWY for the adolescent program in 2009.[43,44] Rates remained stable around 0.20–0.25 cases per 100,000 population from 2014–2019 but declined during the COVID-19 pandemic-impacted years (2020–2023). Since then, rates have returned to pre-pandemic levels. The annualized rate for 2025 (interim data to September 30, 2025) was 0.28 cases per 100,000 population.

Figure 1: Annual Count and Rate of Reported Invasive Meningococcal Disease Cases in Ontario, 2000-2025*

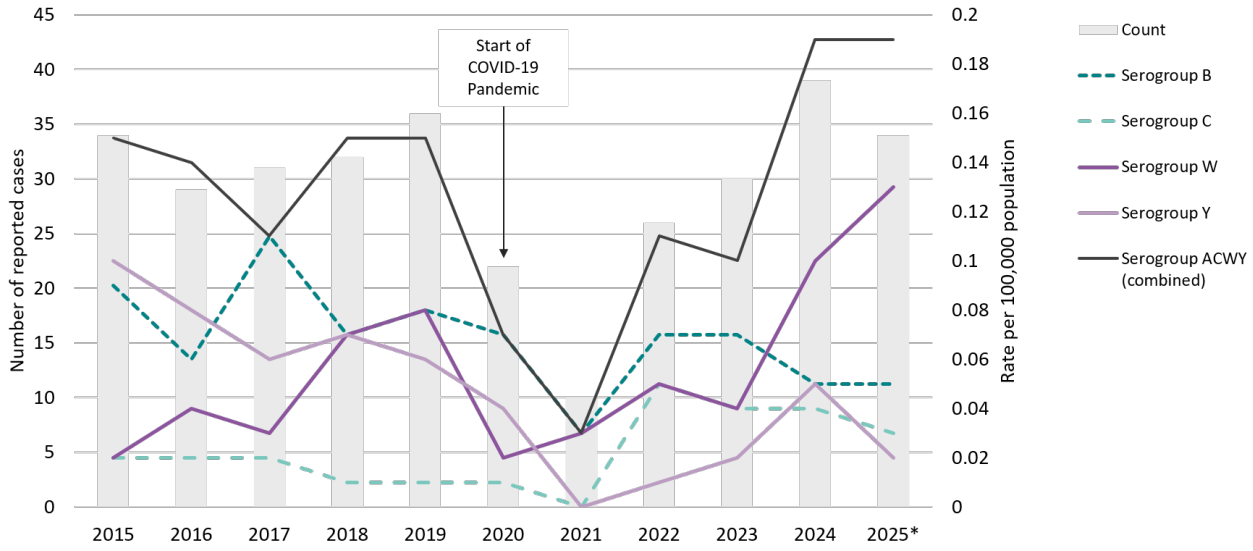


	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025*
Count	81	106	60	58	55	43	64	62	47	71	35	44	34	23	26	34	29	31	32	36	22	10	26	30	39	34
Rate	0.69	0.89	0.5	0.47	0.44	0.34	0.51	0.49	0.36	0.55	0.27	0.33	0.25	0.17	0.19	0.25	0.21	0.22	0.22	0.25	0.15	0.07	0.17	0.19	0.24	0.28

* Interim data to September 30, 2025; annualized rate adjusted for partial year (population denominator multiplied by 9/12 months). Data source: iPHIS.

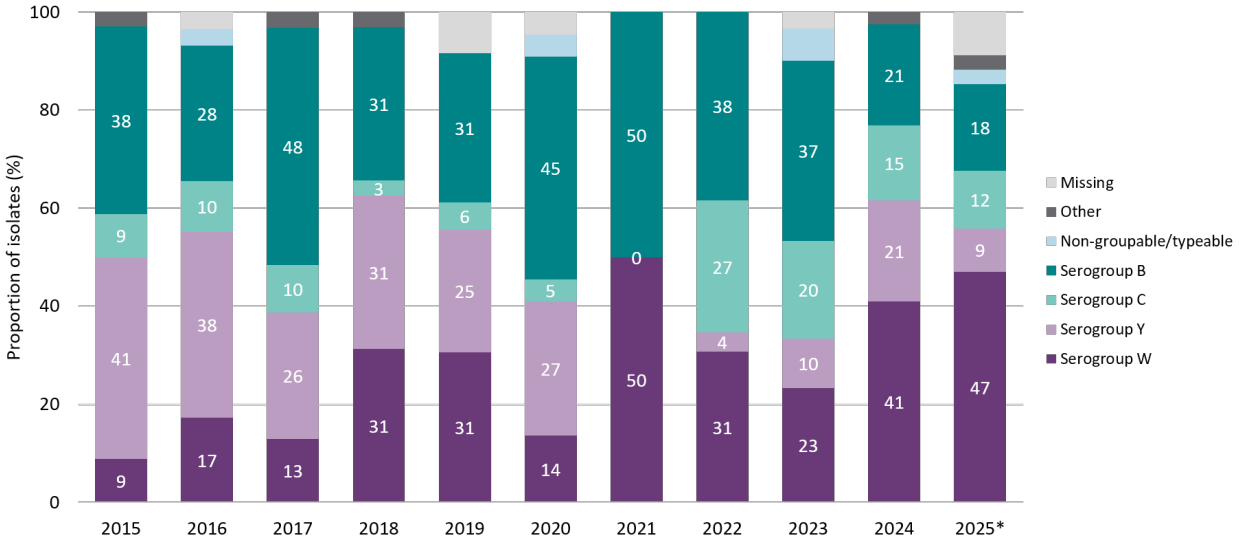
The rate of reported IMD cases due to serogroups contained within the Men-C-ACWY vaccine has increased during the post-COVID-19 pandemic period, driven primarily by an increase in IMD cases caused by serogroup W (Figure 2). The proportion of serogroup W cases among all IMD isolates increased from less than 20% in 2015–2017 to around 30% in 2018 and 2019 (Figure 3). Since the COVID-19 pandemic, the proportion of serogroup W cases continued to increase from around 30% in 2022 and 2023 to more than 40% in 2024 and almost 50% in 2025. As of September 30, 2025, the annualized rate for serogroup W cases was 0.13 cases per 100,000 population.

Figure 2: Annual Count and Rate of Reported Invasive Meningococcal Disease Cases by Serogroup in Ontario, 2015-2025*



* Interim data to September 30, 2025; annualized rate adjusted for partial year (population denominator multiplied by 9/12 months). Data source: iPHIS.

Figure 3: Proportion of Invasive Meningococcal Disease Isolates by Serogroup in Ontario, 2015-2025*



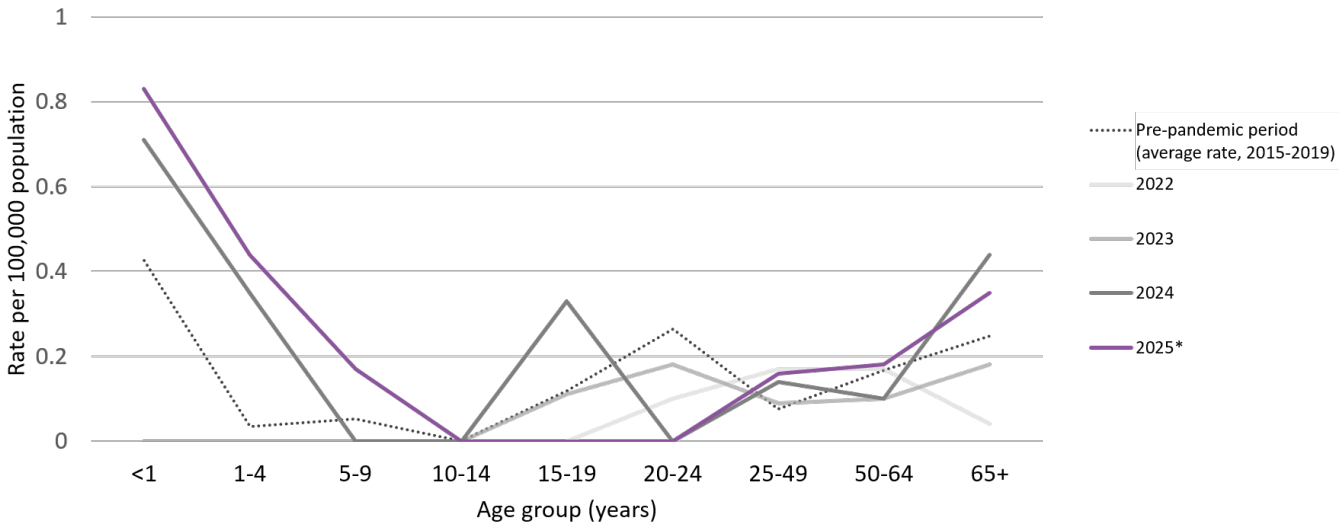
* Interim data to September 30, 2025. Data source: iPHIS.

The increase in serogroup W in Ontario corresponds to the emergence of the hypervirulent serogroup W sequence type-11 clonal complex (ST-11 CC), which first emerged in Ontario in 2014.[45-47] Since 2016, all serogroup W isolates in Ontario have belonged to ST-11 CC, including two recent clusters in 2024 and 2025 that resulted from introduction of different serogroup W strains and subsequent local transmission.[48]

The majority of IMD cases in Ontario occur in adults, with sporadic detections in children. In 2025 (interim data to September 30, 2025), the highest incidence due to serogroups contained in the Men-C-ACWY vaccine occurred in infants less than 1 year of age (0.83 per 100,000 population) who are ineligible for meningococcal vaccination, followed by children 1 to 4 years of age (0.44 per 100,000 population) (Figure 4). Incidence is generally low in children over 5 years of age and adolescents, but increases again starting in early adulthood, with the highest age-specific incidence for adults occurring in those 65 years of age and older.

Of note, pediatric incidence rates are based on a small number of reported cases, given the rarity of IMD. From 2022–2025, only two IMD cases due to serogroups W and Y were reported in infants <1 year of age, four cases in children 1–4 years of age, one case in children 5–9 years of age, and four cases in adolescents 15–19 years of age; no cases were reported in children 10–14 years of age who were eligible to receive the Men-C-ACWY vaccine through the school-based grade 7 program. There have been no reported cases of serogroup C in birth cohorts eligible for the Men-C-C program since the COVID-19 pandemic, and no reported cases of serogroup A in any cohort since 2013.

Figure 4: Age-specific Rate of Reported Invasive Meningococcal Disease Cases Due to Serogroup ACWY in Ontario, 2015–2019 and 2022–2025*



* Interim data to September 30, 2025; annualized rate adjusted for partial year (population denominator multiplied by 9/12 months). Pre-pandemic period represents 5-year weighted average rate from 2015 to 2019. Data source: iPHIS.

Systematic Literature Review

To inform the synthesis and appraisal of Men-C-ACYW vaccine characteristics, the OIAC secretariat conducted a systematic literature review on antibody persistence and co-administration of Men-C-ACYW vaccines in consultation with Public Health Ontario's Library Services team. Details regarding the methodology may be found in the associated Appendix.

Of the 96 relevant articles identified by the systematic literature review, 50 were on antibody persistence following immunization with Men-C-ACYW, 22 articles examined the immunogenicity and safety of a Men-C-ACYW booster dose, and 41 were on co-administration of Men-C-ACYW with routine vaccines (refer to Tables 2–4 of the Appendix). The following sections summarize the key findings and general trends identified.

Antibody Persistence Following a Primary Vaccination with Men-C-ACYW

Surrogate Measures of Vaccine Efficacy: Serum Bactericidal Antibody Assay

Due to the rarity of IMD and associated challenges of assessing vaccine efficacy in clinical trials, immunogenicity markers based on serum bactericidal antibody (SBA) assays have been widely used as a surrogate method to evaluate meningococcal vaccine efficacy. Accordingly, persistence of seroprotective levels of antibodies against vaccine serotypes, as measured by SBA, is a surrogate measure of duration of protection following immunization with meningococcal vaccines.

The assay involves serial dilution of serum samples from vaccinated individuals, which are subsequently incubated with the meningococcal test strain and human or baby rabbit complement to assess bactericidal responses to meningococcal vaccines. SBA titers are then defined as the highest dilution of sera at which ≥50% bactericidal activity occurred. SBA titers ≥1:4 using human complement (hSBA) or SBA titers ≥1:8 using rabbit complement (rSBA) have generally become accepted correlates of protection for Men-C-C vaccines.[49,50] Similarly, Men-C-ACYW vaccines been licensed based on rSBA data, hSBA data or both.[50]

Antibody Persistence Following Primary Vaccination of Infants and Children

Of the 50 articles identified, 17 assessed the duration of protection in individuals who were primed with Men-C-ACYW as children 1–3 years of age. Key findings are summarized in the following sections, and detailed data may be found in the Appendix (Appendix Table 5).

Men-C-ACYW-TT (Nimenrix)

Men-C-ACYW-TT (Nimenrix) had the largest body of evidence, with 11 studies examining antibody persistence up to 10 years post priming (Table 4).[51-61] Waning of the humoral response over time was clearly demonstrated in a series of three articles by Vesikari et al., which reported on antibody persistence outcomes at 3, 5 and 10 years post priming among children immunized with a single dose of Men-C-ACYW-TT (Nimenrix) at 12–23 months of age.[56-58] While seroprotection (defined as rSBA titer ≥1:8) proportions >90% were maintained within the first 3 years following immunization, waning began to be observed at 4–5 years post vaccination for some serogroups, with seroprotection dropping to 74%, 77%, 43% and 35% for serogroups A, C, Y and W, respectively. Seroprotection plateaued at later years, with proportions of 66%, 83%, 44% and 31% for serogroups A, C, Y and W, respectively, at 10 years post priming.

Men-C-ACYW-TT (MenQuadfi)

Among individuals immunized with Men-C-ACYW-TT (MenQuadfi) at 12–23 months of age, there is evidence to suggest waning of the immune response within 5 years of priming, as with Nimenrix (Table 4). One study reporting antibody persistence outcomes at 3 years post priming showed seroprotection (defined as rSBA titer ≥1:8) was maintained at ≥85% for serogroups C, Y and W and 74% for serogroup A.[53] In contrast, another study reporting on the persistence of the immune response 5 years post immunization reported lower seroprotection ranging from 58–66% for the four meningococcal serogroups contained within the vaccine.[62]

Men-C-ACYW-DT

For individuals primed with Men-C-ACYW-DT at 2–3 years of age, there is evidence to suggest waning within 3 years post immunization (Table 4), with one study noting seroprotection ranging from 52–90% across meningococcal serogroups using a more conservative threshold of rSBA titer ≥1:128.[63-65] No data on antibody persistence for Men-C-ACYW-DT were available more than 3 years post priming.

Men-C-ACYW-CRM

Consistent with studies in other Men-C-ACYW vaccine platforms, antibody waning for some meningococcal serogroups was also observed within 4 years among children immunized with 1 or 2 doses of Men-C-ACYW-CRM at 15–18 months of age (Table 4).[66] At 42–45 months post immunization, seroprotection (defined as rSBA titer ≥1:8) was 30% and 47% for serogroups C and W, but was maintained at 95% and 80% for serogroups A and Y.

Table 4: Antibody Persistence Following Primary Vaccination of Infants and Children

Vaccine	Studies	Age at Primary	Max Duration Examined (years)	Antibody Persistence at Max. Duration (%)*			
				A	C	Y	W
Men-C-ACYW-TT (Nimenrix)[51-61]	Bona 2016	12 – 15 mo	0.5	93	71	82	87
	Knuf 2012	12 – 14 mo	1.25	98	92	98	98
	Piazza 2022	12 – 23 mo	3	82	43	86	84
	Vesikari 2014, 2015	12 – 23 mo	4	74	40	58	49
	Klein 2013, 2016†	9 – 13 mo	5	32 – 38‡	75‡	64 – 78‡	66 – 86‡
	Cutland 2023†	12 – 24 mo	5	59 – 66	21 – 28	47 – 58	44 – 50
	Vesikari 2012, 2016, 2020	12 – 23 mo	10	66	83	44	31
Men-C-ACYW-TT (MenQuadfi)[53]	Piazza 2022	12 – 23 mo	3	74	90	92	85
	Martinon-Torres 2025	12 – 23 mo	5	66	59	62	58
Men-C-ACYW-CRM[66]	Bona 2016	12 – 15 mo	0.5	100	64	80	71
	Klein 2019¶	12 – 18 mo	4	95 – 96	27 – 30	71 – 80	31 – 47
Men-C-ACYW-DT[63-65]	Granoff 2004, 2005	2 – 3 yrs	3	-	15§	-	-
	Pichichero 2006	2 – 3 yrs	3	75Δ	52Δ	90Δ	61Δ

*rSBA titer ≥1:8 unless otherwise noted; †Tested 1- or 2-dose primary series. Range shows % with seroprotective titer; ‡hSBA titers ≥1:8; ¶ Tested 1-, 2- or 4-dose primary series. Range shows % with an rSBA titer ≥1:8; §hSBA titers ≥1:4; ΔrSBA titer ≥1:128
CRM, cross reacting material 197; DT, diphtheria toxoid; hSBA, serum bactericidal antibody using human complement; Men-C-ACYW, quadrivalent meningococcal conjugate vaccine; mo, months; rSBA, serum bactericidal antibody using baby rabbit complement; TT, tetanus toxoid

Antibody Persistence Following Primary Vaccination of Children, Adolescents and Adults

A total of 33 studies examined antibody persistence among other age groups including children, adolescents and adults. Key findings are summarized in the following sections, and detailed data may be found in the Appendix (Appendix Table 6).

Men-C-ACYW-TT (Nimenrix)

Antibody persistence following a single priming dose of Men-C-ACYW-TT (Nimenrix) among children ranging in age from 2–10 years showed evidence of waning within 5 years for some meningococcal serogroups (Table 5);[67-69] however, studies following children up to 10 years post priming showed the potential for long-term persistence of antibodies against certain serogroups with seroprotective levels (defined as rSBA titer ≥1:8) maintained in ≥84% of participants for serogroups A and C, and 66–67% for serogroups Y and W.[57,58,70]

Studies on individuals primed with Men-C-ACYW-TT (Nimenrix) as adolescents or young adults (10–25 years old) generally showed persistence of antibody responses for at least 10 years post priming (Table 6).[71-78]

Men-C-ACYW-TT (MenQuadfi)

Among individuals immunized with a single priming dose of Men-C-ACYW-TT (MenQuadfi) at 10–55 years of age, seroprotection, as defined as hSBA titers ≥1:8, was 73%, 86%, 82% and 89% for serogroups A, C, Y and W, respectively, at 3–6 years post priming (Table 6).[79] Seroprotection was similar for the subset of individuals primed at 10–12 years of age.[80]

Men-C-ACYW-DT

A total of 6 studies examined antibody persistence among individuals immunized as adolescents to young adults 11–25 years of age (Table 6).[75,81-85] While data is inconsistent across studies, there is some evidence to suggest waning of the immune response within 3–5 years following vaccination.

Men-C-ACYW-CRM

For individuals vaccinated with a single dose of Men-C-ACYW-CRM at 2–10 years of age, waning of the humoral response for some meningococcal serogroups begins to be evident within 1 year (Table 5).[86-88] Two studies reported seroprotection (defined as hSBA titers ≥1:8) one year post immunization ranging from 11–28%, 41–68%, and 57–86% for serogroups A, C, and Y, respectively.[86,87] Seroprotection levels ≥90% were maintained for serogroup W.

Antibody persistence trends for individuals primed as adolescents to young adults aged 11–18 years were consistent with studies for other Men-C-ACYW vaccines (Table 6). Within 3 years of priming, seroprotection was 28%, 64%, 65% and 82%, as defined as hSBA titers ≥1:8, for meningococcal serogroups A, C, Y and W, respectively, and was maintained at similar levels at 5 years post priming.[84,85]

Table 5: Antibody Persistence Among Individuals Vaccinated with Men-C-ACYW as Young Children

Vaccine	Studies	Age at Primary (years)	Max Duration Examined (years)	Antibody Persistence at Max. Duration (%)*			
				A	C	Y	W
Men-C-ACYW-TT (Nimenrix) [57,58,67-70]	Knuf 2012	3 – 5	1.25	100	100	100	100
	Nolan 2019	7	2	64 – 72	-	88 – 95	91 – 96
	Knuf 2018	2 – 10	5	87	40	71	53
	Vesikari 2012, 2016, 2020	2 – 10	10	89	84	66	67
Men-C-ACYW-CRM [86-88]	Black 2010	2 – 10	1	28†	68†	86†	94†
	Johnston 2016‡	2 – 10	1	11 – 20†	41 – 55†	57 – 65†	90 – 91†
	Block 2015	2 – 10	5	14†	32†	48†	74†

*Defined as rSBA titers ≥1:8 unless otherwise noted; †hSBA titers ≥1:8 unless otherwise noted; ‡Range shows values across age ranges examined

CRM, cross reacting material 197; DT, diphtheria toxoid; hSBA, serum bactericidal antibody using human complement; Men-C-ACYW, quadrivalent meningococcal conjugate vaccine; rSBA, serum bactericidal antibody using baby rabbit complement; TT, tetanus toxoid

Table 6: Antibody Persistence Among Individuals Vaccinated with Men-C-ACYW as Adolescents and Young Adults

Vaccine	Studies	Age at primary (years)	Max duration examined (years)	Antibody Persistence at Max. Duration (%)*			
				A	C	Y	W
Men-C-ACYW-TT (MenQuadfi) [79,80]	Peterson 2025	10 – 12	3 – 6	71†	87†	82†	88†
	Zambrano 2023	10 – 55	3 – 6	73†	86†	82†	89†
Men-C-ACYW-TT (Nimenrix) [71-78]	Ostergaard 2012	11 – 17	0.6	99	98	100	100
	Van Ravenhorst 2017	10 – 15	1	95 – 99	-	97 – 99	96 – 100
	Ostergaard 2009, 2013	15 – 25	3.5	100	100	100	100
	Baxter 2015	10 – 25	5	49†	93†	94†	87†
	Quiambao 2016, 2017, 2020	11 – 17	10	85‡	90‡	90‡	71‡
Men-C-ACYW-DT [75,81-85]	Gill 2010	11 – 18	1.8	95	60	74	84
	Vu 2006	14	3	-	38†‡	60†‡	44†‡
	Keyserling 2005	11 – 18	3	97‡	81‡	95‡	98‡
	Baxter 2014a, 2014b	11 – 18	5	34†	60†	54†	73†
	Baxter 2015	10 – 25	5	44†	80†	91†	84†
Men-C-ACYW-CRM [84,85,89,90]	Jackson 2009	11 - 17	1	29†	77†	82†	93†
	Gill 2010, Baxter 2014a, 2014b	11 – 18	5	32†	59†	64†	82†
	Jacobson 2013	11 – 18	5	30†	72 – 76†		

*rSBA titers ≥1:8 unless otherwise noted; †hSBA titers ≥1:8. Highlighted cells are values <50%; ‡Value approximated from the graph presented in the article. CRM, cross reacting material 197; DT, diphtheria toxoid; hSBA, serum bactericidal antibody using human complement; Men-C-ACYW, quadrivalent meningococcal conjugate vaccine; TT, tetanus toxoid

Immunogenicity, Antibody Persistence and Safety of a Booster Dose of Men-C-ACYW

The comprehensive literature review identified a total of 22 articles that examined the immunogenicity and safety of Men-C-ACYW as a booster dose (refer to Table 3 of the Appendix). Of these, there were nine on Men-C-ACYW-TT (Nimenrix),[54,58,61,68,75,77,91-93] six on Men-C-ACYW-TT (MenQuadfi),[53,62,79,94-96] five on Men-C-ACYW-CRM,[84,88,90,97,98] and three on Men-C-ACYW-DT.[83,95,99] One study on Men-C-ACYW-CRM was excluded from the analysis as it only reported hSBA results for a limited number of hypervirulent meningococcal serogroup C strains.[98] Detailed immunogenicity and safety outcomes may be found in the Appendix (Appendix Table 7).

Studies on the duration of protection following a booster dose of Men-C-ACYW were limited, with a total of 8 articles identified on the subject: five on Men-C-ACYW-TT (Nimenrix),[54,68,92,100,101] three on Men-C-ACYW-CRM,[85,100,102] and one reporting outcomes on Men-C-ACYW-DT (Table 7).[103] There were no studies examining antibody persistence following a booster dose of Men-C-ACYW-TT (MenQuadfi) since this vaccine was authorized more recently. Key findings are summarized in the following sections, and detailed data may be found in the Appendix (Appendix Tables 5 and 6).

Immunogenicity

Overall, these studies showed that all Men-C-ACYW vaccines were able to elicit a strong anamnestic immune response when used as a booster in children to young adults who were primed between 1–12 years prior using the same or different Men-C-ACYW vaccine or Men-C-C (booster response to serogroup C). Across studies, seroprotection (defined as rSBA or hSBA titers ≥1:8 one month after booster vaccination) was 92 – 100% regardless of age group, primary Men-C-C or Men-C-ACYW vaccine or booster Men-C-ACYW used. However, some studies on Men-C-ACYW-TT (Nimenrix) reported poorer seroresponse (defined as rSBA titers ≥1:32 if seronegative before booster or ≥ 4-fold increase if seropositive) to some meningococcal serogroups when the meningococcal polysaccharide vaccine (MPSV4), Mencevax, which is no longer authorized for use in Canada, was used as a primary vaccine.[77,91,93]

Antibody Persistence Following a Men-C-ACYW Booster Dose

Men-C-ACYW-TT (Nimenrix)

Three studies examined individuals primed with a meningococcal serogroup C-containing vaccine (e.g., Men-C-C or Hib-MenC-TT) in early childhood between 1–6 years of age who were boosted with Men-C-ACYW-TT (Nimenrix) ≥5 years later (Table 7). Overall, these studies showed persistence of seroprotective levels of antibodies against serogroup C for at least 2 years following a booster dose with Men-C-CAYW-TT at 7–19 years of age. The 2 remaining articles reported on the same trial, which evaluated antibody persistence up to 6 years in individuals primed with Men-C-ACYW-TT (Nimenrix) as children aged 12–23 months and boosted with the same vaccine at 5 years of age. These studies showed maintenance of seroprotection (defined as an rSBA titer ≥1:8) in >90% of participants for serogroups A, Y and W, and 72% for serogroup C.

Men-C-ACYW-DT

Robertson et al. reported on antibody persistence following a booster dose of Men-C-ACYW-DT in adolescents to adults (Table 7).[103] In this study, individuals aged 15–55 years received a booster dose of Men-C-ACYW-DT after being primed with the same vaccine 4 years prior. Results suggest that immunity was maintained for at least 1 year, with seroprotection (defined as an hSBA titer ≥1:8) ranging from 82% to 95% across all meningococcal serogroups.

Men-C-ACYW-CRM

Of the three studies identified for Men-C-ACYW-CRM, two examined antibody persistence among individuals primed with Men-C-ACYW (Table 7). One study demonstrated that antibodies against meningococcal serogroups may persist at least 2 years among individuals primed with either Men-ACYW-CRM or Men-C-ACYW-DT as adolescents (11–18 years of age) and boosted with Men-C-ACYW-CRM three years later, with seroprotection (defined as hSBA titers ≥1:8) ranging from 77–100% across meningococcal serogroups.[85] For individuals primed with an infant series (2 and 4 months of age) and boosted as a child (12 months of age) significant waning of immunity may be observed for some serogroups within 4 years, with levels as low as 3–4%, 27–45% and 42–57% for serogroups A, C and Y, respectively.[102]

Table 7: Antibody Persistence Following a Booster Dose of Men-C-ACYW

Vaccine	Studies	Primary Vaccine	Age at Primary (booster)	Max Follow-up Duration (years)	Antibody Persistence (%)*			
					A	C	Y	W
Men-C-ACYW-TT (Nimenrix) 54,68,92,100, 101	Ishola 2015	Men-C-TT or Men-C-CRM	3 – 6 years (16 – 19 years)	0.75	-	96	-	-
	Van Ravenhorst 2017†	Men-C-TT	1 – 3 years (10 – 15 years)	1	-	97 – 100	-	-
	Nolan 2019	Hib-Men-C-T or Men-C-CRM	1 – 1.5 years (7 years)	2	-	94 – 100	-	-
	Vesikari 2015, 2020	Men-C-ACYW-TT (Nimenrix)	12 – 23 mo (5 years)	6	93	72	94	86
Men-C-ACYW-CRM 85,100,102	Ishola 2015	Men-C-TT or Men-C-CRM	3 – 6 years (16 – 19 years)	0.75	-	100	-	-
	Baxter 2014	Men-C-ACYW-CRM (Menveo) or Men-C-ACYW-DT (Menactra)	11 – 18 years (14 – 21 years)	2	77 – 79‡	87 – 95‡	93 – 95‡	97 – 100‡
	Khatami 2012	Men-C-ACYW-CRM (Menveo)	2 – 6 mo (12 mo)	4	3 – 4‡	27 – 45‡	42 – 57‡	81 – 84‡
Men-C-ACYW-DT 103	Robertson 2019	Men-C-ACYW-DT (Menactra)	≥11 years (15 – 55 years)	1	95‡	82‡	97‡	95‡

*rSBA titer ≥1:8 unless otherwise noted; †Data shows range across age groups examined (10, 12 or 15 years old); ‡hSBA titer ≥1:8. CRM, cross reacting material 197; DT, diphtheria toxoid; hSBA, serum bactericidal antibody using human complement; Men-C, meningococcal C conjugate vaccine; Men-C-ACYW, quadrivalent meningococcal conjugate vaccine; mo, months; rSBA, serum bactericidal antibody using baby rabbit complement; TT, tetanus toxoid

Safety and Reactogenicity

The majority of articles (19/22, 86%), representing over 5,000 individuals, reported on the safety and reactogenicity of a booster dose of Men-C-ACYW (refer to Table 7 of the Appendix). Overall, the reactogenicity profiles of Men-C-ACYW vaccines were similar when given as a primary or a booster, with adverse events generally being transient and mild-to-moderate in severity. The most common solicited local adverse events were injection site pain and erythema, and the most common solicited systemic adverse events included headache, myalgia, fatigue and malaise. No serious adverse events were deemed related to the study vaccines.

Co-administration with Routine Infant and Childhood Vaccines

The OIAC focused on data from 22 studies investigating the concomitant administration of Men-C-ACYW with routine infant and childhood vaccines (refer to Table 4 of the Appendix),[104-125] noting that, in Ontario, the Men-C-ACYW vaccine is already routinely co-administered with HPV and HBV vaccines given through the adolescent school-based grade 7 program.

Immunogenicity

In general, concomitant administration of Men-C-ACYW with routine childhood immunizations did not interfere with the immune response to meningococcal or other vaccine antigens; however, some exceptions of poorer immune response with co-administration were noted (e.g., some pertussis and pneumococcal antigens), although the clinical significance of these findings are unknown. The following sections describe notable immunogenicity outcomes for each Men-C-ACYW and co-administered vaccine and summarize available safety data. More detailed information on meningococcal vaccine seroprotection outcomes, and notable safety and immunogenicity outcomes for co-administered vaccines may be found in the Appendix (Appendix Table 8).

Men-C-ACYW-TT (Nimenrix)

Concomitant administration of Men-C-ACYW-TT (Nimenrix) with the diphtheria, tetanus, pertussis vaccine (DTaP) or the 10-valent pneumococcal non-typeable *Haemophilus influenzae* protein D-conjugate vaccine (PHiD-CV), which is no longer used in Ontario, resulted in lower geometric mean concentrations (GMC) of antibodies against some vaccine antigens including pertussis toxoid (PT) and pertactin (PRN), and pneumococcal serotype 18C, respectively.[108,112] Similarly, co-administration with the measles, mumps, rubella and varicella vaccine (MMRV) resulted in a lower geometric mean titer (GMT) of anti-rubella antibodies compared to when MMRV was administered alone.[114] However, the clinical relevance of these findings were uncertain as antibody concentrations still met established protective levels in ≥95% of participants.

The order of vaccine administration may also impact the immune response to vaccine antigens.[107] For example, compared to the co-administration group, a lower proportion of individuals who received the hexavalent diphtheria, tetanus, pertussis, hepatitis B, polio and *Haemophilus influenzae* type b vaccine (DTaP-HBV-IPV-Hib) one month after receiving Men-C-ACYW-TT (Nimenrix) achieved seroprotective titers (rSBA titers ≥1:8) to serogroups C and Y. The difference was observed for all meningococcal serogroups when a more conservative threshold (rSBA titers ≥1:128) was used. Additionally, sequential administration of DTaP-HBV-IPV-Hib and Men-C-ACYW-TT (Nimenrix) one month apart resulted in lower anti-tetanus antibody GMC and proportion of participants with a vaccine response to pertussis filamentous hemagglutinin (FHA) compared to vaccine co-administration.

Men-C-ACYW-TT (MenQuadfi)

A significantly lower GMT was observed for meningococcal serogroup A when Men-C-ACYW-TT (MenQuadfi) was co-administered with the 13-valent pneumococcal conjugate vaccine (PCV13) compared to when it was administered alone.[118] Despite the lower antibody titers observed for serogroup A, no differences in seroresponse and seroprotection rates for any of the other meningococcal serogroups were identified between the Men-C-ACYW-TT (MenQuadfi) and co-administration groups. No data were available for concomitant administration of Men-C-ACYW with higher valent pneumococcal vaccines (i.e., PCV15, PCV20), which are currently offered in Ontario.

Men-C-ACYW-DT

Levels of antibodies for specific serotypes contained within the 7-valent pneumococcal conjugate vaccine (PCV7), which is no longer used in Ontario, were decreased with co-administration with Men-C-ACYW-DT and did not meet pre-specified non-inferiority criteria.[119] Despite this, 98–100% of study participants achieved established pneumococcal protective thresholds.

Men-C-ACYW-CRM

There is evidence to suggest that co-administration of Men-C-ACYW-CRM with PCV7 or PCV13 negatively affects the immune response to some pneumococcal antigens. In one study, seroresponse rates for pneumococcal antigens were lower and failed to reach non-inferiority when the first three doses of PCV7 were co-administered with the 3-dose infant series of Men-C-ACYW-CRM and routine vaccines versus routine vaccines alone.[123] In another study, seroresponse to pneumococcal serotypes 3, 5 and 19A were diminished after the first 3 PCV13 doses when they were concomitantly administered with Men-C-ACYW-CRM versus other routine vaccines.[122] In both studies, the differences resolved following the administration of the fourth dose of PCV7 or PCV13.[122,123]

The immune response to some pertussis antigens may also be negatively impacted by co-administering the pentavalent diphtheria, tetanus, pertussis, hepatitis B and polio vaccine (DTaP-HBV-IPV) or DTaP with Men-C-ACYW-CRM. Two studies described lower seroresponse rates or GMC ratios for the pertussis pertactin (PT) antigen following co-administration of these routine vaccines with a primary infant series of Men-C-ACYW-CRM.[116,123] Additionally, a lower GMC ratio for pertussis filamentous hemagglutinin (FHA) was also observed when DTaP and Hib were co-administered with Men-C-ACYW-CRM compared to DTaP and Hib alone.[116]

Safety and Reactogenicity

Overall, co-administration of Men-C-ACYW vaccines with other licenced vaccines used for routine immunization of infants and children was well tolerated, based on data across 22 studies representing over 30,000 individuals. Overall, the most common solicited local reactions following co-administration included redness, tenderness and induration at the injection site, while the most common solicited systemic reactions included irritability, crying, pyrexia and somnolence. Reactogenicity profiles of Men-C-ACYW vaccines were generally similar when given alone or with other routine vaccines for infants and children; however, some exceptions were noted and outlined in Table 8. The incidence of serious adverse events was similar whether Men-C-ACYW was given alone or co-administered with routine vaccines.

Table 8: Differences in Reactogenicity Profile with Co-administration Compared with Men-C-ACYW Administration Alone

Men-C-ACYW vaccine	Co-administered vaccine	Safety Outcome
Men-C-ACYW-TT (Nimenrix)	DTaP-IPV-HBV-PRP-T[126]	• Higher frequency of systemic reactions with co-administration including crying (50% vs. 30%), irritability (77% vs. 49%), pyrexia (30% vs 11%), somnolence (52% vs. 32%) compared to Men-C-ACYW alone • Higher frequency of grade 3 intensity local reactions with co-administration (11% vs. 1%) and injection site pain (47% vs. 18%) compared to Men-C-ACYW alone
	DTaP-HBV-IPV/Hib[107]	• Statistically significant higher frequency of injection site pain (p=0.02) and mild solicited systemic reactions (p≤0.01)

Men-C-ACYW vaccine	Co-administered vaccine	Safety Outcome
Men-C-ACYW-TT (MenQuadfi)	PCV13[118]	• Overall higher rates of solicited reactions (37% Co-admin vs. 28% Men-C-ACYW vs. 17% PCV13)
Men-C-ACYW-DT	PCV7, MMRV, HAV[119]	• Higher incidence of injection site tenderness when co-administered with PCV7 (49%) or MMRV + PCV7 + HAV (49%) vs. Men-C-ACYW alone (35%) • Higher incidence of solicited systemic reactions when co-administered with MMRV, PCV7, or MMRV + PCV7 + HAV (71%, 68%, 73.2%, respectively vs. 61% for Men-C-ACYW alone)
Men-C-ACYW-CRM	MMRV[124]	• Higher rate of solicited systemic reactions with co-administration, but lower than when MMRV was given alone (e.g., fever observed in 22% of subjects receiving Men-C-ACYW alone, 42% receiving MMRV alone, and 35% in the co-administration group)

DT, diphtheria toxoid; DTaP, diphtheria, tetanus, acellular pertussis vaccine; HAV, hepatitis A virus vaccine; Hib, *Haemophilus influenzae* type b; IPV, inactivated polio virus; Men-C-ACYW, quadrivalent meningococcal conjugate vaccine; MMRV, measles, mumps, rubella, varicella vaccine; PCV, pneumococcal conjugate vaccine.

Ethics, Equity, Feasibility and Acceptability Considerations

In addition to IMD disease burden and vaccine characteristics, the following implementation considerations, including ethics, equity, feasibility and acceptability (EEFA), were also examined to inform programmatic decisions on the timing of Men-C-ACYW vaccine doses and the need for a one-time catch-up program in Ontario. Expert opinions (unless otherwise noted) are outlined below.

Optimal Timing of Men-C-ACYW Doses

Ethics and Equity

- Two dose program ensures optimal protection of children and adolescents/young adults prior to post-secondary school
- Access to primary care providers can vary according to geography and other social/economic/structural determinants of health[127]
- School-based immunization programs are considered more equitable, with uptake of meningococcal vaccine through school-based programs generally around 80% among 12-year-olds and exceeding 90% among 17-year-olds[19]

Feasibility

- Timing of 12-month dose aligns with established well-child visits and other routine childhood vaccines according to the Ontario publicly funded schedule[3,128]
- Maintaining booster dose in school-based program is feasible/acceptable given barriers to accessing primary care[19]
- Maintaining the current schedule and using a single product (Men-C-ACYW) for children and adolescents would simplify communications to parents/guardians and health care providers

Acceptability

- Parental decisions around vaccination and healthcare provider recommendations must weigh the perceived risk of IMD against the benefits of vaccination
- Other acceptability factors included: confidence in the effectiveness and safety of vaccination and in the health system more broadly and the convenience of accessing immunizations through primary care providers and/or school-based programs

Potential Need for a One-time Catch-up Program

Ethics and Equity

- Variation in IMD burden by age group leading to inequity in disease outcomes[9]
- Access to primary care providers can vary according to geography and other social/economic/structural determinants of health[127]

Feasibility

- Need to ensure all children eligible for the one-time catch up have access to primary care or public health clinics[127]
- Aligning a catch-up program with well-child visits at 12 months, 18 months, and annually from 2 – 5 years of age could improve uptake[128]
- Feasibility of program implementation (e.g., communication to healthcare providers and parents/guardians of eligible children)
- Availability of Men-C-ACYW vaccine supply to ensure sufficient doses for all eligible children

Acceptability

- Parental decisions around vaccination and healthcare provider recommendations must weigh the perceived risk of IMD due to serogroups Y and W against the benefits of Men-C-ACYW vaccination for infants who have already received Men-C-C
- Convenience of scheduling catch-up vaccination (e.g., outside of well-child visits or through public health clinics)

Cost-effectiveness

The cost-effectiveness of routine meningococcal immunization programs for children and adolescents are affected by several factors, including the incidence of IMD caused by meningococcal serogroups A, C, Y and W, vaccine cost, vaccine effectiveness and length of protection, and anticipated herd effects.[129,130] There are currently no available Canadian data on the cost-effectiveness of catch-up meningococcal immunization programs or published studies comparing the cost-utility of meningococcal immunization programs according to target age groups to help inform the optimal time for meningococcal vaccine doses. However, a recent study from Germany comparing the cost-effectiveness of different meningococcal immunization strategies for children and/or adolescents showed marginal improvement in cost-effectiveness and comparable numbers of IMD cases averted over a 30-year time horizon when Men-C-ACYW is given at 13 versus 16 years of age.[131]

Caveats and Limitations

A quality appraisal of the body of evidence was performed using GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) domains (e.g., study design, risk of bias, inconsistency, indirectness, imprecision, publication bias) as a guide;[132] an in-depth analysis of the quality of evidence for individual studies was not conducted.

Risk of Bias

The majority of studies on antibody persistence (96%), immunogenicity, and safety of a booster dose of Men-C-ACYW (100%) and co-administration (100%) were industry-sponsored. Further, the majority (82–86%) of studies had an open-label design. Randomized controlled trials comprised 60% of studies on antibody persistence, 41% of studies on Men-C-ACYW booster dose and 95% of studies on co-administration.

Inconsistency

The studies reporting Men-C-ACYW immunogenicity outcomes reported in this statement use different SBA assay methodologies and seroprotection/seroresponse thresholds. Although both rSBA and hSBA assays are widely used to assess meningococcal vaccine immunogenicity, it is important to note some caveats and limitations of these quantitative methods when assessing and interpreting data on meningococcal vaccine immunogenicity outcomes.[50] Results of rSBA and hSBA are not always correlated, with higher titers often measured by rSBA compared with hSBA, suggesting that hSBA may underestimate the immune response to vaccine antigens. Further, it has been noted that while rSBA and hSBA reasonably correlate for protection against serogroup C, significant variation in protection against serogroups A and Y may be observed. Finally, inter-laboratory variability has also been shown to exceed intra-laboratory variability despite efforts at standardization of SBA protocols and materials (e.g., rabbit complement).

Indirectness

Results of SBA assays assess existing humoral response to vaccine antigens and do not evaluate any existing immunological memory or cellular immunity. Seroprotection/seroresponse as measured by SBA assays is not a direct measure of vaccine efficacy or duration of protection.

Imprecision

Some studies examining co-administration of Men-C-ACYW had low sample sizes or were not sufficiently powered to identify non-inferiority of co-administered vaccines. Additionally, some did not define the routine vaccines that were co-administered or vaccine schedule used, nor assess the effect of co-administration on the immunogenicity of all vaccine antigens.

Relevance

Most studies identified do not align with the age eligibility and dose interval of Ontario's routine meningococcal immunization program. Additionally, the clinical relevance of immunogenicity outcomes for other vaccine antigens (e.g., protective but lower antibody titres) are unclear.

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About the Ontario Immunization Advisory Committee

The Ontario Immunization Advisory Committee (OIAC) was established in August 2021 at the request of the Chief Medical Officer of Health. The Committee provides scientific and technical advice to Public Health Ontario on vaccines and immunization matters, including program implementation in Ontario, priority populations, clinical guidance, and vaccine safety and effectiveness.

OIAC's work focuses 'on publicly funded vaccines and immunization programs in Ontario, and those under consideration for new programming. The OIAC provides advice by applying scientific knowledge and the best available evidence, in addition to feasibility, acceptability and other implementation considerations.

For more information about the OIAC and its members contact secretariat@oahpp.ca.

About Public Health Ontario

Public Health Ontario is an agency of the Government of Ontario dedicated to protecting and promoting the health of all Ontarians and reducing inequities in health. Public Health Ontario links public health practitioners, front-line health workers and researchers to the best scientific intelligence and knowledge from around the world. For more information about PHO, visit publichealthontario.ca.

Acknowledgements

This document was prepared by the OIAC Secretariat on behalf of the OIAC: Janice Sarmiento (lead), Catharine Chambers, Elizabeth Brown, Tara Harris, Reed Morrison, and Christine Navarro. Review of the articles identified in the systematic literature review were conducted by Catharine Chambers and Janice Sarmiento, and data extraction was performed by Janice Sarmiento and Elizabeth Brown.

The OIAC would like to acknowledge Allison McArthur with the Library Services team at PHO for their help with the systematic literature review. In addition, the OIAC would like to thank PHO staff within Library Services, Stakeholder Relations, and Product Development, and Publishing for their assistance in preparing this document.

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Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario), Ontario Immunization Advisory Committee. Recommendations on the use of quadrivalent meningococcal conjugate vaccines in Ontario. Toronto, ON: King's Printer for Ontario; 2026.

ISBN: 978-1-4868-9946-3

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This document was prepared by the Ontario Immunization Advisory Committee (OIAC) for Public Health Ontario (PHO). The OIAC provides evidence-based advice to Public Health Ontario on vaccines and immunization matters. OIAC work is guided by the evidence available at the time this document was prepared. The application and use of this document is the responsibility of the user. PHO assumes no liability resulting from any such application or use.

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