

FOCUS ON

COVID-19 Vaccines for Children 5 to 11 Years of Age



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Key Messages

- Many children have been infected with Severe Acute Respiratory Coronavirus-2 (SARS-CoV-2) over the course of the pandemic. In most infections, children have no symptoms or experience mild COVID-19 disease. However, some children develop severe disease requiring hospitalization. Children are also at risk of developing multisystem inflammatory syndrome in children (MIS-C), myocarditis/pericarditis, and other post-acute COVID-19 conditions following infection.
- Health Canada has authorized the use of two pediatric COVID-19 vaccines. In November 2021, Pfizer-BioNTech Comirnaty (10 microgram (mcg) dose) was authorized for use in children 5 to 11 years of age and in March 2022, Moderna Spikevax (50 mcg dose) was authorized for use in children 6 to 11 years of age. Over 17 million doses in the United States and almost three million doses in Canada of pediatric Pfizer-BioNTech Comirnaty COVID-19 vaccine have been administered. The majority of adverse events reported to date have been mild to moderate in nature and in Canada, the rate of adverse event reports in this age group is the lowest among all age groups eligible to receive COVID-19 vaccines.
- Vaccinating children 5 to 11 years of age will help protect them from severe illness and hospitalization due to COVID-19 and is an important layer of protection to reduce the risk of SARS-CoV-2 infection.

Introduction

On November 19, 2021, Health Canada authorized for use the first pediatric COVID-19 vaccine in Canada, a pediatric formulation of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (10 mcg dose) as a two-dose primary series for children 5 to 11 years of age.¹ The National Advisory Committee on Immunization (NACI) strongly recommends that a complete series with an mRNA COVID-19 vaccine should be offered to children in the authorized age groups without contraindications to the vaccine, with a recommended dosing interval of at least 8 weeks between the first and second dose.² Children 5 to 11 years of age who are moderately to severely immunocompromised should be offered a three-dose primary series of an mRNA COVID-19 vaccine.² Ontario began offering the pediatric Pfizer-BioNTech COVID-19 vaccine to children 5 to 11 years of age the week of November 23, 2021.³ In March 2022, Moderna's submission for a COVID-19 vaccine for children aged 6 to 11 years was authorized for use by Health Canada.²

This Focus On is intended for health care providers and public health partners. It provides an overview of the epidemiology and burden of SARS-CoV-2 infection in the 5 to 11 year-old age group, benefits of COVID-19 vaccination in children, post-market vaccine safety surveillance data for the pediatric Pfizer-BioNTech Comirnaty vaccine, characteristics of the pediatric COVID-19 vaccine products, and select COVID-19 vaccine resources. It is current as of the date published and will be updated as new information becomes available.

Epidemiology and Burden of COVID-19 in Children 5 to 11 Years of Age

Many children have been infected with SARS-CoV-2 over the course of the pandemic. Using the provincial Public Health Case and Contact Management (CCM) Solution database, analyses performed by Public Health Ontario showed that from July 4, 2021 to January 8, 2022, children 5 to 11 years of age accounted for 8.6% (29,174) of total reported cases (338,740), while representing 7.3% of Ontario's population.^{4,5} As of December 31, 2021, diagnostic PCR testing was restricted to high-risk populations, limiting eligibility among most children, and therefore subsequent Ontario case counts will underestimate the burden of infection in the province.^{6,7}

In most infections, children have no symptoms or experience mild COVID-19 disease. However, some children develop severe disease requiring hospitalization.⁸ Since the beginning of the pandemic, January 15, 2020, up until April 21, 2022, there have been 228 hospitalized cases (rate of 21.1/100,000) among children 5 to 11 years of age in Ontario, the lowest rate among age groups for those under 20 years (i.e., 0 to 4 years at 121.9/100,000; 12 to 19 years at 33.6/100,000).⁹ However, with expected increases in infections in the population, including among children, associated with the highly transmissible Omicron variant sub-lineage BA.2, the numbers with severe disease are likely to increase as the number of infections increase.⁶ From the beginning of the fifth wave dominated by Omicron sub-lineages BA.1 and BA.1.1 on December 12, 2021 to April 9, 2022, during the Omicron BA.2-dominant sixth wave, there were 127 hospitalized cases among children 5 to 11 years of age in Ontario, comprising more than half the total hospitalizations over the course of the pandemic.⁸

There is limited evidence on clinical risk factors for severe COVID-19 disease in children under 12 years of age; while early evidence suggested that there was an association between the presence of any comorbidity and severe COVID-19 outcomes, approximately one-third of children aged 5-11 admitted to US hospitals in a large surveillance network did not have an underlying medical condition.^{10,11} Children are also at risk of developing multisystem inflammatory syndrome in children (MIS-C), a rare but serious

condition that can occur weeks following infection with the COVID-19 virus.¹² As of October 4, 2021, there were 5,217 reports of MIS-C in the United States (US), with 44% of cases occurring in children aged 5 to 11 years.¹³ In Canada, 269 cases of MIS-C were reported between March 11, 2020 and October 2, 2021.¹⁴ In addition to MIS-C, children may be at risk of myocarditis/pericarditis following COVID-19 and other post-acute COVID-19 conditions may occur with unknown long-term sequelae, although the risk appears to be lower compared to older age groups, though evidence is still accumulating.¹²

Benefits of COVID-19 Vaccination for Children 5 to 11 Years of Age

Evidence on the real-world effectiveness of the Pfizer-BioNTech Comirnaty COVID-19 vaccine suggests there is substantial protection against severe outcomes among children 5 to 11 years old after completing a two-dose primary series during the Omicron-dominant period. Using surveillance data from Ontario, in the 30 days preceding March 27, 2022, unvaccinated children were 2.5 times more likely to be hospitalized compared to those who had completed the primary series.¹⁵ The effectiveness of the vaccine against hospitalization among SARS-CoV-2 cases after two doses in Ontario was estimated to be 59% among children and adolescents (4 to 17 years old) combined; children 4 to 11 years old were included in the study from the time they were eligible for vaccination on November 28, 2021 to January 10, 2022.¹⁶

In a recent multicentre and multistate study from the US, vaccine effectiveness (VE) against COVID-19-associated hospitalizations among children who received their second dose on average a month earlier was 68%.¹⁷ In another US study, the effectiveness against emergency department and urgent care visits was 51% approximately two weeks to just over two months after the second dose.¹⁸ US data have also shown that the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) has a high VE (91%) against the development of MIS-C in vaccinated youth aged 12 to 18 years,¹⁷ data which provides indirect evidence for the likely prevention of MIS-C in vaccinated children aged 5 to 11 years, in whom the incidence of MIS-C is greatest among pediatric age groups.²⁰

Similar to findings in adolescent and adult populations, effectiveness of the vaccine in 5 to 11 year olds against infection with the Omicron variant appears to be lower in comparison to the Delta variant. In a large US cohort study, VE against any infection among children 5 to 11 years old, regardless of symptoms, was 31% at two weeks to just under three months after the second dose.²¹ Although protection against Omicron infection may be lower than what was seen in efficacy trials against previous strains of SARS-CoV-2, protection against severe outcomes remains high among children 5 to 11 years old during a time of uncertainty around the magnitude of the next wave of COVID-19.

Safety of Pfizer-BioNTech Comirnaty COVID-19 Vaccine for Children 5 to 11 Years of Age from Post-market Vaccine Surveillance

As of April 6, 2022, over 17 million doses of pediatric Pfizer-BioNTech Comirnaty COVID-19 vaccine have been administered to children 5 to 11 years of age in the United States (US).²² Real-world safety data from v-safe, a voluntary smartphone-based US active safety surveillance system designed to monitor adverse events after COVID-19 vaccination, found that injection site pain, fatigue, and headache were the most frequently reported reactions from 42,504 enrolled children aged 5 to 11 years after either dose one or two.²³ A small proportion of parents reported that their child was unable to perform normal daily activities on the day after vaccine receipt (5.1% following dose one and 7.4% following dose two).²³

The Vaccine Adverse Event Reporting System (VAERS), a passive surveillance system in the US, reported 4,249 adverse events following pediatric Pfizer-Comirnaty COVID-19 vaccine among this age group as of December 19, 2021; 97.6% (4,149) were non-serious, while only 2.4% (100) were serious.^{23,24} Of the serious events, fever (29%) and vomiting (21%) were the top two most commonly reported. Additionally, 12 reports of myocarditis events meeting the Centers for Disease Control and Prevention (CDC) case definition were received. Among these cases, the median age was 10 years, median time to onset was two days, more commonly after dose two, and more frequently in males.²⁴ All cases were discharged home, with eight fully recovered, and four still recovering at the time of report.^{23,24} In a subgroup analyses by sex and dose, the reporting rate of myocarditis exceeded background incidence (0.2 to 1.9 per million) for males following dose two in the 5 to 11 years age group, at 4.3 cases per million doses in days 0 through 7 after vaccination; however, this reporting rate was substantially lower than for adolescent males following the second dose (45.7 cases per million doses in 12 to 15 year olds and 70.2 cases per million doses in 16 to 17 year olds).²⁴

The Vaccine Safety Datalink (VSD) is an active surveillance system in the US that uses a rapid cycle analysis (RCA), to examine the observed number of adverse events compared with the expected number of events. Klein et al. assessed the safety of the pediatric Pfizer-BioNTech Comirnaty COVID-19 vaccine administered to 5 to 11 year olds from one to 21 days after dose one or two. As of December 11, 2021, 431,485 doses were administered to this age group at nine study sites and no safety signals were found.²⁵

In Canada, vaccines are highly regulated.^{26,27} They are thoroughly reviewed for efficacy and safety prior to being authorized for use, and are continually monitored through post-marketing surveillance to ensure their safety. As of April 8, 2022, there were 508 AEFIs reported in the 5 to 11 age group out of a total 2,941,306 pediatric Pfizer-BioNTech Comirnaty COVID-19 vaccine doses administered to this age group in Canada, for a reporting rate of 17.20 per 100,000 doses administered.²⁸ This rate is the lowest among adverse event reports for all age groups eligible to receive COVID-19 vaccine.

Public Health Ontario carries out passive vaccine safety surveillance in Ontario, in collaboration with Ontario Public Health Units and the Ontario Ministry of Health.²⁷ In Ontario, as of April 10, 2022, 1,054,415 doses of pediatric Pfizer-BioNTech Comirnaty COVID-19 vaccine have been administered. Of the 217 confirmed AEFIs reported (representing 0.02% of all doses administered), five were considered serious events (i.e. resulting in hospitalization).²⁹

Due to the recent authorization of pediatric Moderna Spikevax COVID-19 vaccine in Canada and other jurisdictions, post-market safety data is not currently available to summarize, but will accrue over time.

COVID-19 mRNA Vaccines for Children

In Canada, the Pfizer-BioNTech Comirnaty COVID-19 vaccine was authorized by Health Canada on November 9, 2021 for pediatric indication (age 5 to 11 years) under the Food and Drug Regulations as the first COVID-19 vaccine available for children.³⁰ On March 17, 2022, Moderna's submission for a COVID-19 vaccine for children age 6 to 11 years was authorized for use by Health Canada.³⁰ NACI's recommendations are that Moderna Spikevax (50 mcg) may be offered as an alternative to Pfizer-BioNTech Comirnaty (10 mcg); however, the use of Pfizer-BioNTech Comirnaty is preferred to Moderna Spikevax to start or continue the primary vaccine series due to the abundant clinical experience and safety data available for the pediatric Pfizer-BioNTech Comirnaty vaccine.²

Indirect data from adult populations (≥ 18 years of age) suggests Moderna (100 mcg) may result in higher VE after a two-dose primary series compared to Pfizer-BioNTech Comirnaty (30 mcg) and is associated

with a higher seroconversion rate among adult immunocompromised patients. Given this potential benefit, as per NACI, administration of the Moderna (50 mcg) vaccine as a three-dose primary series may be considered for some immunocompromised individuals 6 to 11 years of age, as outlined in the product monograph.²

Detailed characteristics of the pediatric COVID-19 vaccines are outlined in Table 1.

Table 1. Characteristics of the Pediatric COVID-mRNA Vaccines Authorized for Use in Canada

Trade Name	Pfizer-BioNTech Comirnaty COVID-19 Vaccine (pediatric formulation)	Moderna Spikevax COVID-19 Vaccine
Manufacturer	Pfizer Inc., BioNTech Manufacturing GmbH	ModernaTX Inc.
Generic Name	BNT162b, tozinameran	mRNA-1273, elasomeran
Vaccine Platform	LNP-encapsulated, non-replicating, nucleoside-modified mRNA vaccine ^{31,32}	LNP-encapsulated, non-replicating, nucleoside-modified mRNA vaccine ³³
Antigenic Target	Pre-fusion SARS-CoV-2 spike (S) glycoprotein ^{31,32}	Pre-fusion SARS-CoV-2 spike (S) glycoprotein ³³
Clinical trial data		
Estimated vaccine efficacy against symptomatic, lab-confirmed COVID-19	90.7%, 7 or more days after the second dose in those without evidence of prior SARS-CoV-2 infection ³¹	88.0%, 14 or more days after the first dose in those without prior SARS-CoV-2 infection ^{2,a}
Safety	Mild to moderate side effects with no serious adverse events ^{31,a}	Mild to moderate side effects with no serious adverse events ^{2,b}
Authorized Ages for Use	5 years to 11 years of age ^{30,32}	6 years to 11 years of age ^{30,33}
No. of Doses Administered	2 doses (primary series) ³² 3 doses (primary series for moderately to severely immunocompromised) ^{12,32,34}	2 doses (primary series) ³² 3 doses (primary series for moderately to severely immunocompromised) ^{2,34}
Dosage	10 mcg of mRNA per 0.2 mL dose ³²	50 mcg of mRNA per 0.25 mL dose ³³
Adjuvant	No ³²	No ³³

^a There were too few cases identified beginning 14 days after dose two to generate estimates of vaccine efficacy for dose two.

^b This study was not adequately powered to detect potential very rare and rare side effects of the vaccine.

Trade Name	Pfizer-BioNTech Comirnaty COVID-19 Vaccine (pediatric formulation)	Moderna Spikevax COVID-19 Vaccine
Diluent	Yes ³²	No ³³
Schedule	<p>Authorized interval: 21 days (3 weeks)^{12,b}</p> <p>Optimal Interval: 8 weeks^{12,35,36,c}</p> <p>Minimum Interval: 19 days¹²</p> <p>Three dose primary series (immunocompromised): ≥2 months (56 days) between 2nd and 3rd dose³⁴</p>	<p>Authorized interval: 28 days^{2,12}</p> <p>Optimal Interval: 8 weeks^{2,12}</p> <p>Minimum Interval: 21 days^{2,12}</p> <p>Three dose primary series (immunocompromised): ≥2 months (56 days) between 2nd and 3rd dose³⁴</p>
Co-administration with other vaccines	Current NACI recommendations advise against routine co-administration (i.e. same day) with other vaccines. As a precautionary measure, it is recommended to wait for a period of at least 14 days before or after the administration of another vaccine before administering COVID-19 vaccine to prevent erroneous attribution of an AEFI to one particular vaccine or the other. ¹²	Current NACI recommendations advise against routine co-administration (i.e. same day) with other vaccines. As a precautionary measure, it is recommended to wait for a period of at least 14 days before or after the administration of another vaccine before administering COVID-19 vaccine to prevent erroneous attribution of an AEFI to one particular vaccine or the other. ²
Route of Administration	Intramuscular (IM) ³²	Intramuscular (IM) ³³
Storage Conditions	<p>-90°C to -60°C until expiry date³²</p> <p>Frozen vials may be thawed in the fridge at 2°C to 8°C and stored for up to 10 weeks. After dilution (post-puncture), store at 2°C to 25°C for up to 12 hours.</p> <p>Do not refreeze</p> <p>Keep vials in original packaging to protect from light</p>	<p>-25°C to -15°C until expiry date³³</p> <p>Frozen vials may be thawed in the fridge at 2°C to 8°C and stored for up to 30 days. Post-puncture, store at 2°C to 25°C for up to 24 hours.</p> <p>Do not refreeze</p> <p>Keep vials in original packaging to protect from light</p>

^b The authorized interval is the dosing schedule approved by Health Canada based on evidence from clinical trials.

^c The recommended interval between doses is provided by NACI and following review of available data and based on expert advice. Emerging evidence in adult populations that longer intervals between first and second doses result in more robust strength and breadth of immune responses, which may be important to establish durable protection against new or future COVID-19 variants. Canadian vaccine safety surveillance data also suggests an extended interval between first and second doses may reduce the risk of myocarditis/pericarditis following the second dose of an mRNA COVID-19 vaccine.

Resources Supporting Pediatric COVID-19 Vaccination

The following is a select list of resources intended to support parents and guardians in their pediatric COVID-19 vaccine decision-making for their children.

- [About Kids Health CARD System](#): The CARD (Comfort, Ask, Relax, Distract) system provides strategies, in the form of videos and handouts, that can be used to help children cope before and during vaccination.³⁷
- [Canadian Paediatric Society](#): Caring for Kids - a guide for parents to reduce vaccination pain including information regarding topical anaesthetics, proper positioning, and distraction techniques.³⁸
- [Vaccines for children - what to expect at the vaccination appointment](#): Information for parents/caregivers about the vaccination appointment for children.³⁹
- [Sick Kids COVID-19 Vaccine Consult Service](#): A by-appointment phone service with paediatric Registered Nurses, supporting residents of Ontario 5 years or older and their parents, caregivers, or legal guardians who have questions or concerns related to the COVID-19 vaccine for youth/children, or who require additional support to receive the COVID-19 vaccine due to medical complexity, developmental disorder or mobility, communication, behavioural or other specialized needs, including significant needle phobia.⁴⁰
- [COVID-19 vaccines for children and youth in Ontario](#): A government of Ontario website with information about COVID-19 vaccines for children and youth, including vaccine safety and efficacy, where to get vaccinated in Ontario, and what to expect at the appointment.⁴¹

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