

Dr. Charles Gardner, Medical Officer of Health  
Dr. Colin Lee, Associate Medical Officer of Health  
Dr. Lisa Simon, Associate Medical Officer of Health

## COVID-19 Vaccine: Update #44

### COVID-19 Vaccine Approved for Use in Children 5 to 11 Years of Age

**Attention:** Physicians, Emergency Departments, Hospital CEOs, Hospital Laboratories, Infection Control Practitioners, Occupational Health Practitioners, Walk-In Clinics/Urgent Care Clinics, Nurse and Nurse Practitioners, EMS, Designated Officers, Midwives, Family Health Teams, Pharmacies, Central LHIN, NSM LHIN, Beausoleil First Nation, Moose Deer Point First Nation, Rama First Nation, Wahta First Nation, Long-term Care Homes, Retirement Homes, Hospices, Coroners, Funeral Directors, Dentists, Group Homes, Homes for Special Care, Optometrists, Corrections, Municipalities, Licensed Child Care Providers

**Date:** November 22, 2021

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Health Canada has announced the authorization of the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine for children 5 to 11 years of age. Based on Health Canada's review of the safety, efficacy, and quality of the vaccine, they determined that the benefits of the vaccine in this age group outweigh the risks. The National Advisory Committee on Immunization (NACI) recommends that a complete series of the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine may be offered to children 5 to 11 years of age who do not have contraindications to the vaccine.

Although children 5 to 11 years of age generally present with mild or asymptomatic COVID-19 disease, those who get infected can still:

- develop symptomatic COVID-19.
- rarely, develop severe COVID-19 disease and require hospitalization.
- rarely, develop multisystem inflammatory syndrome in children (MIS-C), a serious condition that can follow several weeks after infection with the COVID-19 virus.
- potentially be at risk for a post-COVID-19 condition (i.e., long COVID-19 or post-acute COVID-19 syndrome), although current evidence is limited in pediatric populations and suggests the risk is lower in children compared to older age groups.
- be asymptotically infected but still able to spread COVID-19 to others.

The fourth wave has had a greater impact on children, as they are unvaccinated and many children less than 12 years of age have returned to in-person school and activities. As of mid-November, children aged 5 to 11 years of age have the highest COVID-19 case incidence rate across all age groups in Simcoe

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Muskoka. Vaccinating children allows them to get back - and stay back - to doing things they love and miss and contributes to herd immunity and community protection, which is the way out of this pandemic.

### Key Messages for Families

We recognize that parents and guardians will have questions about vaccinating children for COVID-19. The following [Fact Sheet](#) provides parents and guardians with key messages about why they should consider vaccinating their children for COVID-19, and information about COVID-19 vaccine and kids. The health unit also has a [dedicated webpage](#) specifically to support families of children 5 to 11.

### Accessing the Pediatric COVID-19 Vaccine via Health Care Providers (HCPs), Community Clinics and Pharmacies

Health care providers who are currently providing COVID-19 vaccine, can order pediatric COVID-19 vaccine using our updated [COVID-19 Vaccine Order Form](#). Provided there are no delays in our initial vaccine delivery, vaccine orders placed by 3:00 p.m. Thursday, November 25<sup>th</sup> will be available in each local health unit office for HCPs to pick up the morning of Tuesday, November 30<sup>th</sup>.

It is expected that we will start vaccinating children in SMDHU Community Clinics on Friday November 26<sup>th</sup>. All clinics will be by appointment. There will be enough vaccine supply and clinic capacity to get all children 5 to 11 years of age their first dose in the next three to four weeks. It is expected that parents will be able to start booking appointments using the Provincial Vaccine Appointment Booking system [online](#) or by calling the Provincial Vaccine Contact Centre at 1-833-943-3900 starting the morning of Tuesday, November 23<sup>rd</sup>. There are also over 70 pharmacies in Simcoe Muskoka that will be offering the pediatric COVID-19 vaccine. Parents can locate a pharmacy near them on the Ministry website using the [COVID-19 Vaccine Pharmacy locator](#).

### Key Vaccine Information

The pediatric formulation approved for 5 to 11 year-olds is different than the adult formulation.

	<b>Adult/Adolescent Formulation</b>	<b>Pediatric Formulation</b>
Age	12 years of age and over	5 to 11 years
Vial Cap Colour	Purple	Orange
Diluent (only use diluent provided)	1.8 mL	1.3 mL
Dose	0.3 mL (30 mcg)	0.2 mL (10 mcg)
Doses per vial	6	10
Unpunctured vials can be stored in the fridge at 2°C – 8°C	Up to 1 month	Up to 10 weeks
Post Dilution Expiry (time post first puncture)	6 hours	12 hours

The 10 microgram dose for children has been found to result in a similar immune response as the 30 microgram dose for older adolescents and young adults, and the pediatric dosing has been shown to result in fewer side effects than higher doses in this age group.

While Health Canada approved a two-dose series of the 10 mcg formulation for children 5 to 11 years of age at a 21 day interval, NACI has recommended an **interval of at least 8 weeks between the first and second doses** based on emerging evidence that longer intervals between the first and second doses result in a more robust immune response and higher vaccine effectiveness, which is expected to last longer. Longer intervals may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.

Dose	Immunization Schedule	Minimum Interval	Health Canada Authorized Interval	NACI Recommended Interval
0.2 mL of the pediatric formulation	2-doses	19 days	21 days	At least 8 weeks (56 days)

Children who are turning 5 in 2021 (2016 birth year) are eligible to receive the vaccine even if they have not yet had their 5<sup>th</sup> birthday. For 2022, provincial decision making is underway regarding eligibility of children turning 5 that year (2017 birth year).

Children should receive the dose approved for their age at time of vaccination. Children who are 11 years old and received the 30 mcg dose as their first dose under Ontario’s extended eligibility for the 2009 birth cohort are recommended to complete the series with the product authorized for their age at time of the second dose (i.e. 10 mcg if 11 years, 30 mcg if 12 years). Children who receive the pediatric formulation of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) for their first dose who turn 12 by the time of their second dose may receive the adolescent/adult formulation of the Pfizer-BioNTech COVID-19 vaccine (30 mcg) to complete their primary series.

**Safety and Efficacy Profile**

Parents/guardians who would like to vaccinate their child(ren) aged 5 to 11 years can feel confident that Health Canada found no safety signals in the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine clinical trials in their review of the data.

Based on data from the clinical trial which is outlined in the [Summary of NACI Statement](#) and the [full NACI statement](#):

- the pediatric formulation of the vaccine produces a good immune response in children 5 to 11 years of age, similar to the response seen in young adults 16 to 25 years of age who receive the adolescent/adult formulation.
- preliminary efficacy of the 10 mcg dose vaccine against symptomatic COVID-19 in children 5 to 11 years of age is estimated to be 90.7%.
- the vaccine was well tolerated in children 5 to 11 years of age. Local reactions were very common and mostly mild to moderate in severity. Reactions resolved after a median of 1 to 2 days.
- interim clinical findings did not indicate any serious safety concerns and no cases of myocarditis and/or pericarditis related to the vaccine were reported.

- the size of the clinical trial would not detect rare or very rare adverse events that may occur at a frequency less often than 1 in 1,000 people. Health Canada, PHAC and NACI will continue to monitor the safety and effectiveness of the vaccine.

## **Educational Events for Health Care Providers to Prepare for Vaccinating 5 to 11 Year-Olds**

### ***Getting Kids Back to Being Kids: COVID-19 Vaccinations for Children 5 to 11***

*Information session for immunizers and other healthcare workers*

**Friday, November 26, 2021 | 8:00 to 9:15 a.m. ET**

As Ontario prepares to vaccinate children ages 5 to 11, we know those working in health care want more information and parents of young children have many questions too. Addressing those questions and concerns will be crucial to a successful vaccine rollout.

In an upcoming session, **Dr. Kieran Moore, Chief Medical Officer of Health**, and **Dr. Daniel Warshafsky, Associate Chief Medical Officer of Health**, will share current information regarding the safety and efficacy of the vaccine in children ages 5 to 11, and the provincial roll-out plans, followed by a panel of professionals providing an overview of implementation through a variety of lenses. A moderated Q&A will follow the discussion.

Register to attend: [https://us02web.zoom.us/webinar/register/WN\\_jBYfteAZRAi2UyqgweKFDQ](https://us02web.zoom.us/webinar/register/WN_jBYfteAZRAi2UyqgweKFDQ)

### ***Learning to Play Your Cards: The Childhood Vaccination Experience***

*Information session for immunizers and other healthcare workers with Dr. Anna Taddio hosted by PHO*

**Tuesday, November 23<sup>rd</sup> at 10:00am-11:00am**

Learn about the vaccination delivery framework called the Comfort, Ask, Relax, Distract (CARD) system to reduce immunization stress-related responses and promote more positive vaccination experiences.

Register to attend: <https://www.eventbrite.ca/e/webinar-learning-to-play-your-cards-the-childhood-vaccination-experience-tickets-212645025997>

## **Additional COVID-19 Vaccine Information**

For more information about the rollout of COVID-19 vaccine in our area, please refer to the SMDHU [COVID-19 Vaccine and Immunization](#) webpages.

For more information on the province's three-phased vaccine distribution implementation plan, please [visit COVID-19 vaccines for Ontario](#).

There are a number of COVID-19 resources and documents available through our Health Professional Portal at [www.smdhu.org/hpportal](http://www.smdhu.org/hpportal) as well as through [Public Health Ontario](#) and the [Government of Ontario](#).