

Recommendations: Pfizer-BioNTech COVID-19 Vaccine for Children 5 to 11 Years of Age

November 30, 2021

Overview

A pediatric formulation (10 mcg per dose) of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (hereafter referred to as Pfizer-BioNTech vaccine) was authorized for use in children 5 to 11 years of age by Health Canada on November 19, 2021.¹ Canada's National Advisory Committee on Immunization (NACI) issued recommendations on its use on November 19, 2021.²

In anticipation of Health Canada authorization and NACI guidance, the Ontario Immunization Advisory Committee (OIAAC) met on October 15 and November 5, 2021, to review and discuss evidence for a pediatric COVID-19 vaccine program in Ontario, including Ontario data and several operational questions relating to pediatric and adult formulations of the Pfizer-BioNTech vaccines. Since August 18, 2021, Ontario has offered the adult/adolescent formulation of the Pfizer-BioNTech vaccine authorized for use in those 12 years of age and older (30 mcg per dose) to all 11 year old children born in 2009 (turning 12 years in 2021).³

This document provides a summary of the evidence and the OIAAC's recommendations on Ontario's pediatric COVID-19 vaccine program for children 5 to 11 years of age.

Recommendations

1. All children 5 to 11 years of age should be offered a complete series of the pediatric formulation of the Pfizer-BioNTech vaccine (10 mcg per dose) using an interval of at least 8 weeks between the first and second dose as recommended by NACI.²
2. Children and adolescents should receive an age-appropriate vaccine dose and formulation of the Pfizer-BioNTech vaccine, based on their age on the day of vaccination.
 - Children 5 to 11 years of age should receive the 10 mcg dose of the Pfizer-BioNTech vaccine, whereas adolescents 12 years of age and older should continue to receive the 30 mcg dose of the Pfizer-BioNTech vaccine.
 - Children who are 5 to 11 years of age should be offered the pediatric formulation of the Pfizer-BioNTech vaccine once eligible, instead of waiting to become eligible for the vaccine product that is authorized for use in those 12 years of age and older.
 - Children who receive the 10 mcg dose of the Pfizer-BioNTech vaccine for their first dose and who have turned 12 years of age by the time the second dose is due are recommended to receive the 30 mcg dose of the Pfizer-BioNTech vaccine to complete their primary series. If a second dose of 10 mcg dose is given inadvertently, the dose should be considered valid and the series complete.

- Children who are 11 years of age and received the 30 mcg dose of the Pfizer-BioNTech vaccine as their first dose under Ontario's extended eligibility (2009 birth year) are recommended to complete the vaccine series with the product authorized for their age at the time of the second dose (i.e. 10 mcg if 11 years, 30 mcg if 12 years). If an 11 and 12 year old child is inadvertently given a second dose that is not authorized for their age, the dose should be considered valid and the series complete.
3. Currently there are no immunogenicity or safety data available for OIAC to recommend the routine use of the pediatric 10 mcg dose of the Pfizer-BioNTech vaccine in individuals who are outside of the authorized age indication of the vaccine product (5 to 11 years of age). OIAC will continue to monitor the evidence on this topic and update its recommendations as needed.

Background

Children have borne numerous direct and indirect impacts of the COVID-19 pandemic. Using the provincial Public Health Case and Contact Management Solution database, analyses performed by Public Health Ontario demonstrated a downward shift in the age distribution of COVID-19 cases in Ontario during the period of August 1 to November 2, 2021, corresponding to age groups of children not eligible for vaccination.⁴ Children 5 to 11 years of age accounted for 12.3% of the total cases, despite comprising only 7.3% of Ontario's population. Over this period, weekly infection rates in the 5-11 year old age group surpassed rates in all other age groups by 60 to 80%, with a cumulative infection rate of 572 cases per 100,000 population. Since the beginning of the pandemic, there have been 84 hospitalizations and 1 death associated with COVID-19 in children 5 to 11 years of age in Ontario. While the frequency of severe outcomes among children who become infected with Severe Acute Respiratory Coronavirus 2 (SARS-CoV-2) is lower compared to older age groups, serious but rare complications such as Multisystem Inflammatory Syndrome in Children (MIS-C), myocarditis, and other post-acute COVID-19 conditions can occur and long-term sequelae remain unknown.^{2, 5-10} In a 2020 study from the United States (US), MIS-C rates were highest in the 5-9 year old age group, and myocarditis was a complication in 1 in 6 children with MIS-C.⁹ A US review of pediatric COVID-19-associated hospitalizations found that the risk of severe COVID-19 among hospitalized children was higher among children with at least one underlying medical condition; however, one-third with severe disease had no underlying conditions.¹¹ In addition, the disproportionate burden of COVID-19 in low-income, Indigenous, racialized and marginalized communities and widespread school disruptions have widened existing inequalities and impacted children's physical, developmental and mental health.^{2, 12-14, 16-17}

Evidence Summary

The following summary provides a brief description of data and evidence reviewed by the OIAC.

Vaccine Efficacy and Safety

A phase III randomized placebo-controlled clinical trial evaluated immune response, efficacy and safety following administration of two doses of 10 mcg of the Pfizer-BioNTech vaccine, administered 21 days apart, in over 3,000 healthy children 5 to 11 years of age.¹⁸⁻¹⁹ The median age was 8 years and baseline SARS-CoV-2 status was 8.8% in the vaccine group and 8.7% in the placebo group. Immune responses elicited in children 5 to 11 years of age were found to be non-inferior when compared with young adults 16 to 25 years. While a primary vaccine efficacy analysis was not performed due to the low number of events, a descriptive analysis found a vaccine efficacy of 90.7% (95% Confidence Interval (CI): 67.7-98.3)

against symptomatic COVID-19 seven or more days after the second dose in those without evidence of prior infection. No cases of severe disease were observed. The most commonly reported side effects were mild to moderate in nature and included injection site pain (sore arm), redness and swelling, fatigue, headache, muscle and/or joint pain, chills, fever, swollen lymph nodes, nausea and decreased appetite. Compared with participants 12 to 25 years of age in a previous study,²⁰ children 5 to 11 years reported more local reactions (i.e. redness and swelling) but fewer systemic events such as fever and chills.¹⁸⁻¹⁹ No serious adverse events following the vaccine were reported in the clinical trial, including no events of anaphylaxis, myocarditis or pericarditis. While vaccine clinical trials are typically not large enough to detect rare or very rare adverse events following immunization, as of November 25, 2021 over 3.6 million doses of the pediatric formulation of the Pfizer-BioNTech vaccine have been administered to children 5 to 11 years of age in the United States.²¹ Robust post-marketing active and passive vaccine safety surveillance systems in Canada and the United States are in place to monitor the program and the OIAC will continue to closely monitor vaccine safety data for this age group.²²⁻²³

Clinical Considerations for Immunization

NACI has provided a recommended dosing interval of at least 8 weeks between the first and second dose for children 5 to 11 years of age.² This recommendation takes into consideration NACI's guidance on optimal intervals (i.e. an interval of 8 weeks between the first and second dose), which is based on immunogenicity data suggesting a stronger immune response and evidence from observational studies of increased vaccine effectiveness at extended dose intervals.^{2,15,24} In addition, an extended dose interval is supported by emerging data from Ontario and national passive vaccine safety surveillance systems, suggesting an association between a longer dose interval and a lower incidence of very rare events of myocarditis/pericarditis following the second dose of COVID-19 mRNA vaccines authorized for adolescents/adults.²

The risk of myocarditis/pericarditis following COVID-19 mRNA vaccines is also strongly associated with age. While still rare, higher reporting rates of myocarditis/pericarditis in older adolescents (16 to 17 years) as compared to younger adolescents (12 to 15 years), have been observed in data from Ontario's passive vaccine safety surveillance system. This is consistent with trends in other jurisdictions.^{19, 25} While the risk of myocarditis/pericarditis following the 10 mcg Pfizer-BioNTech vaccine among children 5 to 11 years of age is currently unknown (no events reported in clinical trial), these insights from passive safety surveillance data, in addition to the lower dose of the pediatric formulation suggest that children 5 to 11 years of age may be at a lower risk of myocarditis/pericarditis than other age-eligible groups in Ontario, such as adolescents and young adults.^{2,18-19}

Pediatric vaccines (and dosage) are generally recommended for use based on chronological age, rather than size or weight.²⁶⁻²⁹ Immune system maturity and functionality are largely age-dependent, with the lowest optimal dose of antigen selected to maximize immunogenicity and minimize potential side effects.²⁶ The pediatric formulation of the Pfizer-BioNTech vaccine (10 mcg dose) has not been studied in individuals 12 years of age and older.¹⁸⁻¹⁹ At present there are no data to support the routine administration of 10 mcg dose of the Pfizer-BioNTech vaccine to individuals outside the age indication of 5 to 11 years.

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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 visit [PHO's website](#).

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