



# SUMMARY OF THE NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF NOVEMBER 19, 2021

Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) in children 5-11 years of age



## OVERVIEW

- On November 19, 2021, the Public Health Agency of Canada (PHAC) released guidance from the National Advisory Committee on Immunization (NACI) on the use of the pediatric formulation of the Pfizer-BioNTech COVID-19 vaccine in children 5-11 years of age. These recommendations are based on current scientific evidence and NACI's expert opinion.
- The new pediatric formulation of the Pfizer-BioNTech COVID-19 vaccine is 10 micrograms (mcg) compared to the 30 mcg formulation authorized for adolescents and adults 12 years of age and older.
- NACI reviewed the available evidence on the use of the Pfizer-BioNTech COVID-19 mRNA vaccine (10 mcg) in children 5-11 years of age, as well as ethical considerations related to COVID-19 vaccination in children.

### **NACI recommends that:**

- A complete series of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) may be offered to children 5-11 years of age who do not have contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose.

To see the full guidance, including the evidence and rationale behind these recommendations, please visit [NACI Recommendations on the use of the Pfizer-BioNTech COVID-19 vaccine \(10 mcg\) in children 5-11 years of age.](#)

## WHAT YOU NEED TO KNOW

- The new pediatric formulation of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) is the first COVID-19 vaccine authorized in Canada for children under 12 years of age. Health Canada approved the Pfizer-BioNTech pediatric formulation of the mRNA COVID-19 vaccine for use in children 5-11 years of age on November 19, 2021.
- Over the course of the pandemic, many children have been infected with the COVID-19 virus. In most cases, children have no symptoms or experience mild COVID-19 disease. Although less frequent than in older age groups, some children may rarely develop severe COVID-19 disease and require hospitalization. Children are also at risk of developing multisystem inflammatory syndrome in children (MIS-C), following infection with the COVID-19 virus. MIS-C is a serious but rare event that can occur several weeks following infection.

- While evidence is limited in pediatric populations, children may also be at risk of a post-COVID-19 condition (i.e., long COVID or post-acute COVID-19 syndrome), although current evidence suggests the risk is lower in children compared to older age groups.
- Due to its increased transmissibility, the Delta variant may pose a higher risk of infection for children, although the risk of severe disease does not appear to be increased with this variant.
- Children have experienced collateral harms from the pandemic. School disruptions, social isolation, and reduced access to academic and extra-curricular resources have had impacts on the mental and physical well-being of children and their families. These harms can disproportionately affect some children and families and may further exacerbate social inequities among some groups, including racialized and Indigenous communities, refugees and other newcomers to Canada, persons living in low-income settings, as well as children with disabilities.
- Clinical trial data suggest the pediatric formulation of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) produces a good immune response in children 5-11 years of age, similar to the response seen in young adults 16-25 years of age who receive the adolescent/adult formulation (30 mcg).
  - Preliminary efficacy of the 10 mcg dose vaccine against symptomatic COVID-19 in children 5-11 years of age is estimated to be 90.7%. Interim clinical findings did not indicate any serious safety concerns and no cases of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the heart lining) 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.

***NACI recommends:***

- **A complete series with the Pfizer-BioNTech COVID-19 vaccine (10 mcg) may be offered to children 5-11 year of age who do not have contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose.**
- When authorizing a vaccine, Health Canada reviews clinical trial data submitted by the manufacturer. Health Canada has authorized the Pfizer-BioNTech COVID-19 mRNA vaccine for children 5-11 years of age as a primary series of two 10 mcg doses given 21 days apart.

- When developing recommendations, NACI reviews clinical trial data, as well as data from real-world use of the vaccine. NACI recommends an interval of at least 8 weeks between the first and second dose since emerging evidence in adults suggests that compared to shorter intervals, longer intervals between the first and second doses result in a stronger immune response, higher vaccine effectiveness that is expected to last longer, and may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.
- 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. If a child who has turned 12 by the time of their second dose receives the pediatric formulation (10 mcg), their series should still be considered valid and complete.
- Children with previous COVID-19 infection may be offered two doses of the vaccine once symptoms of acute illness have resolved and the child is no longer considered infectious, based on current criteria. Children with a history of MIS-C may be vaccinated once they have recovered or once it has been more than 90 days since diagnosis, whichever is longer.
- As a precaution, children who experience myocarditis and/or pericarditis after a first dose of the vaccine should wait to get a second dose until more information is available. Children who have a history of myocarditis unrelated to COVID-19 vaccination should consult their clinical care team for individual considerations and recommendations. If they are no longer under active care for myocarditis, they may receive the vaccine. Caregivers should be advised to seek medical attention for children if they develop symptoms including chest pain, shortness of breath, or palpitations following receipt of a COVID-19 vaccine.
- At this time, NACI recommends that children receive the Pfizer-BioNTech COVID-19 vaccine (10 mcg) at least 14 days before or after another vaccine. This is a precaution to help to determine if a side effect that may arise is due to the COVID-19 vaccine or another vaccine. There may be circumstances when a dose of a COVID-19 vaccine and another vaccine need to be given at the same time – a healthcare provider can help with this decision.
- It is essential that children and their caregivers are supported and respected during the decision-making process so they are able to make an informed decision about COVID-19 vaccination.
- Pediatric COVID-19 immunization programs should aim to minimize inequities by ensuring all children have equitable access to trustworthy, accurate, culturally sensitive COVID-19 vaccination information and services.

- NACI reiterates that all adults should receive a primary series of a COVID-19 vaccine. Adults, including caregivers and youth who interact with children, should be vaccinated against COVID-19 to offer additional protection to children.
- Public health measures remain very important for preventing transmission of the COVID-19 virus in children. It is important that everyone, regardless of vaccination status, continue to follow recommended public health measures.
- NACI will continue to monitor and review evidence regarding the safety and effectiveness of COVID-19 vaccines in children and will update their recommendations as needed.

To see the full guidance, including the evidence and rationale behind these recommendations, please visit [NACI Recommendations on the use of the Pfizer-BioNTech COVID-19 vaccine \(10 mcg\) in children 5-11 years of age](#).

## QUOTES

“With the authorisation of the Pfizer-BioNTech vaccine for children age 5-11 years, Canada is entering into a new phase of this pandemic vaccine program. Over the past two years, we have seen children face many social disruptions, as well as harms associated with pandemic restrictions, and though they are at lower risk of severe disease than adults, COVID-19 can result in serious outcomes in children, including hospitalization and in rare instances death. After carefully reviewing all of the clinical trial data for this new lower dose formulation of the Pfizer BioNTech COVID-19 vaccine for children, NACI is recommending that this COVID-19 vaccine may be offered to children aged 5-11 years as part of the immunization strategy in Canada. NACI is recommending at least 8 weeks between doses, as we have seen that this approach generates good sustained protection in adults and emerging Canadian data suggest that longer intervals could be associated with even lower rates of myocarditis in adults and adolescents. This vaccine had a good safety profile in clinical trials, and worked very well to prevent symptomatic disease in children.”

“We will be watching this new program very closely in Canada and abroad where it is already rolling out for children in the US, and new information will accumulate over time in greater numbers to complement the clinical trials data that have already been released. In this early phase of the vaccine program roll-out, it is essential that children and their caregivers are supported and respected in making their decisions regarding COVID-19 vaccination and are not stigmatized based on whichever choice they make. We hope that the availability of this vaccine will bring comfort to many families who have been working to protect their children throughout the pandemic.”

- Dr. Shelley Deeks, NACI Chair

“I welcome this advice from NACI on the use of the pediatric dose formulation of the Pfizer-BioNTech COVID-19 vaccine in children 5 to 11 years of age. NACI’s review takes into account the available evidence on the use of the pediatric dose formulation as well as ethical considerations related to COVID-19 vaccination in children. To date, while most children who have been infected with the SARS-CoV-2 virus have had no symptoms or experienced only mild COVID-19 disease, some have experienced severe disease requiring hospitalization. Children can also develop a rare but serious condition called multisystem inflammatory syndrome (MIS-C), occurring several weeks following their infection. Other health impacts such as post-COVID syndrome (i.e., long COVID or post-acute COVID-19 syndrome), though less well understood, may also be a risk in this age group. As well, throughout the pandemic, children have experienced social isolation and disruption to schooling and extra-curricular activities, which have had impacts on their mental and physical well-being as well as that of their families. As such, it is hoped that the availability of this vaccine in Canada will provide families with an additional means to consider in protecting their children from the health and collateral harms of this pandemic. As we closely monitor the domestic rollout of the pediatric program and continue to consider new information from international programs and research, it is very important that we all support children and their caregivers in making informed decisions about COVID-19 vaccination, while respecting their choices and pace of decision-making.”

- Dr. Theresa Tam, Chief Public Health Officer

## NACI FORWARD AGENDA

NACI continues to actively review emerging evidence on COVID-19 vaccines. Upcoming recommendation may include new advice on:

- Additional advice on booster COVID-19 vaccine doses
- Recommendations on the use of the Moderna COVID-19 vaccine in children, pending a regulatory decision by Health Canada
- Recommendations on the use of the Novavax COVID-19 vaccine, pending a regulatory decision by Health Canada
- Recommendations on the use of the Medicargo COVID-19 vaccine, pending a regulatory decision by Health Canada