



SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF JANUARY 25, 2022

Updated recommendations on the use of COVID-19
vaccines in children 5 to 11 years of age



OVERVIEW

- On January 25, 2022, the Public Health Agency of Canada (PHAC) released updated advice from the National Advisory Committee on Immunization (NACI) regarding the use of COVID-19 vaccines in children 5 to 11 years of age. These recommendations are based on current scientific evidence and NACI's expert opinion.
- Canada is currently facing a fifth wave of the pandemic, largely driven by the highly transmissible Omicron variant. Children 5 to 11 years of age continue to remain at low risk of severe COVID-19 outcomes, including from the Omicron variant; however, the number of children experiencing severe disease or requiring hospitalization is increasing due to large number of children becoming infected with SARS-CoV-2 during this wave of the pandemic.
- When updating these recommendations, NACI reviewed the available evidence on the Omicron variant, new and reassuring real-world safety data on the use of the Pfizer-BioNTech Comirnaty vaccine (10 mcg) in children, and current evidence on the use of mRNA vaccines in those who are immunocompromised.
- It is essential that children and their caregivers continue to be supported and respected in their decisions regarding COVID-19 vaccination.

NACI has strengthened their recommendation on the use of COVID-19 vaccines in children 5 to 11 years of age. NACI now recommends:

- **A complete series with the Pfizer-BioNTech Comirnaty vaccine (10 mcg) *should* be offered to children 5 to 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 doses.**

NACI now also recommends that:

- **Children 5 to 11 years of age who are moderately to severely immunocompromised should be offered a three dose primary series of the Pfizer-BioNTech Comirnaty vaccine (10 mcg), using an interval of 4 to 8 weeks between each dose.**
- **Children 5 to 11 years of age who are moderately to severely immunocompromised who have previously received two doses of the Pfizer-BioNTech Comirnaty vaccine (10 mcg), should be offered a third dose of the Pfizer-BioNTech Comirnaty vaccine (10 mcg) 4 to 8 weeks after the second dose.**

To see the full update, please visit [NACI rapid response: Updated recommendations on the use of COVID-19 vaccines in children 5 to 11 years of age.](#)

WHAT YOU NEED TO KNOW

- Canada is currently facing a fifth wave of the pandemic, largely driven by the highly transmissible Omicron variant.
- Children 5 to 11 years of age continue to remain at low risk of severe COVID-19 outcomes, including from the Omicron variant; however, the number of children experiencing severe disease or requiring hospitalization is increasing due to the large number of children becoming infected with SARS-CoV-2.
- The Pfizer-BioNTech Comirnaty vaccine (10 mcg) is the only COVID-19 vaccine authorized for use in children 5 to 11 years of age at this time. The pediatric formulation of Pfizer-BioNTech Comirnaty is 10 mcg compared to the 30 mcg formulation authorized for adolescents and adults 12 years of age and older.
- Clinical trial data showed that in children 5 to 11 years of age, the Pfizer-BioNTech Comirnaty vaccine (10 mcg dose) has a good safety profile and produces a good immune response similar to the response seen in individuals 16 to 25 years of age who receive the adolescent/adult formulation of the vaccine (30 mcg dose).
- Additional real-world safety data from the United States suggest the Pfizer-BioNTech Comirnaty vaccine (10 mcg) is well tolerated in children 5 to 11 years of age.
 - Very rare cases of myocarditis (inflammation of the heart muscle) have been reported in children 5 to 11 years of age following COVID-19 vaccination in the United States.
 - Data from the United States suggest the risk of myocarditis may be lower in children 5 to 11 years of age following vaccination with the 10 mcg vaccine compared to adolescents and young adults who receive the 30 mcg vaccine.
 - Similar to what has been seen in older age groups, data currently suggest myocarditis in children 5 to 11 years of age usually occurs within a week of vaccination, more commonly in males and more commonly after a second vaccine dose. Most cases of myocarditis in both older age groups and children 5 to 11 years of age following mRNA vaccination have been mild and resolved quickly.
 - Myocarditis can also occur as a complication in people who are infected with the COVID-19 virus.
- It is essential that children and their caregivers continue to be supported and respected in their decisions regarding COVID-19 vaccination.

Recommendations on the use of the Pfizer-BioNTech Comirnaty vaccine (10 mcg) in children 5 to 11 years of age

- In November 2021, NACI issued a discretionary recommendation that a complete series of Pfizer-BioNTech Comirnaty (10 mcg) may be offered to children 5 to 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 doses.

- NACI has strengthened its recommendation after careful consideration of the reassuring additional safety data from real-world use and evidence in older age groups that a primary series of an mRNA COVID-19 vaccine continues to offer good protection against hospitalization, including from the Omicron variant.
- NACI now recommends that a complete series of Pfizer-BioNTech Comirnaty vaccine (10 mcg) *should* be offered to children 5 to 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 doses.
- NACI continues to recommend a dosing interval of at least 8 weeks between first and second doses. An interval of at least 8 weeks gives children the opportunity to develop better and longer-lasting immunity, which will be important in future waves of the pandemic, and further minimizes the very rare risk of myocarditis following vaccination. In making this recommendation, NACI considered the current Omicron variant wave, the likelihood of future waves of the pandemic, evidence in adults that suggests longer intervals result in a stronger immune response that is expected to be longer lasting, as well as evidence that longer intervals may be associated with a lower risk of myocarditis in adolescents and young adults.

Recommendations on the use of the Pfizer-BioNTech Comirnaty vaccine (10 mcg) in children who are moderately to severely immunocompromised

- Evidence shows that some people who are moderately to severely immunocompromised may have a reduced immune response to COVID-19 vaccines.
- In September 2021, NACI recommended that individuals 12 years of age and over who are moderately to severely immunocompromised should receive a 3-dose primary series of an authorized mRNA COVID-19 vaccine.
- While there are currently no data on the safety, immunogenicity, or efficacy of an additional dose of a COVID-19 vaccine in children who are immunocompromised, studies have shown that a third dose of an mRNA vaccine leads to increased immune response in some adults who are immunocompromised. An additional dose provides another opportunity for those who are immunocompromised to develop a better immune response and in turn better protection against COVID-19.
- NACI now recommends that children 5 to 11 years of age who are moderately or severely immunocompromised:
 - should receive three doses of the Pfizer-BioNTech Comirnaty vaccine (10 mcg) if they have not yet been immunized; or
 - should receive a third dose of the Pfizer-BioNTech Comirnaty vaccine (10 mcg) if they have already received 2 doses of the vaccine.

- For this recommendation, moderately to severely immunocompromised includes children with the following conditions:
 - Active treatment for solid tumour or hematologic malignancies
 - Receipt of solid-organ transplant and taking immunosuppressive therapy
 - Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
 - Moderate to severe primary immunodeficiency with associated humoral and/or cell-mediated immunodeficiency or immune dysregulation
 - HIV with prior AIDS defining illness OR prior CD4 count \leq 200/mm³ OR prior CD4 fraction \leq 15% OR perinatally acquired HIV infection
 - Active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the Canadian Immunization Guide for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive
- The interval between each dose in the primary series should be 4 to 8 weeks. However, a longer interval will likely result in a better immune response and a longer duration of protection. If a longer interval is being considered, risk factors for exposure to the virus, including local epidemiology, and the risk of severe outcomes should be taken into account.
- Children who are immunocompromised may still have reduced protection against COVID-19 even after an additional dose. Children should continue to follow recommended personal public health measures. It is also recommended that close contacts, including household members and healthcare workers providing care, be vaccinated against COVID-19 in order to help protect the child who is immunocompromised.
- NACI will continue to monitor the evidence on the use of COVID-19 vaccines in children 5 to 11 years of age and will update guidance as needed.

For the full update, please see [NACI rapid response: Updated recommendations on the use of COVID-19 vaccines in children 5 to 11 years of age.](#)

For more information on the use of COVID-19 vaccines in children, please see [Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine \(10 mcg\) in children 5-11 years of age](#) published on November 19, 2021.

For more information on additional doses of COVID-19 dose in people who are moderately to severely immunocompromised, please see the [COVID-19 chapter](#) of the Canadian Immunization Guide.

QUOTES

“We know that compared to older age groups, school-aged children continue to be at lower risk of experiencing severe outcomes from COVID-19; however, due to the sheer number of children infected with the Omicron variant as it continues to spread through Canada, hospitalizations are increasing in children.

Throughout the pandemic, NACI continuously reviews the latest evidence to ensure COVID-19 vaccine recommendations are up to date and informed by the best available evidence. As the Committee has done before, NACI first made a discretionary recommendation for COVID-19 vaccination in children 5 to 11 years of age. Since this time, additional data have become available as the vaccine is rolled out through public vaccination programs in Canada and around the world. NACI carefully reviewed data from the United States where millions of children have received the Pfizer-BioNTech vaccine. After reviewing the latest real-world use data, NACI has strengthened its advice and now strongly recommends that children 5 to 11 years of age receive two doses of the pediatric Pfizer-BioNTech vaccine with a dosing interval of at least 8 weeks between the first and second dose. NACI now also recommends a third dose of mRNA COVID-19 vaccine for children 5 to 11 years of age who are moderately to severely immunocompromised.

NACI continues to emphasize that children and their caregivers should be respected and supported during their vaccination decision-making. As always, the Committee continues to review the evolving data around COVID-19 and COVID-19 vaccines and we will update our guidance as required.”

- Dr. Shelley Deeks, NACI Chair

“With the unprecedented number of infections associated with the Omicron surge continuing, infection rates remain high across all age groups, including among children aged 5 to 11 years of age. Despite evidence indicating that children remain at low risk of severe outcomes compared to older individuals, substantially higher infection rates mean greater numbers of children are experiencing severe illness requiring hospitalization than previously. Children can also develop a rare but serious multisystem inflammatory syndrome in children (MIS-C) occurring several weeks after COVID-19 infection. In its continuing commitment to provide Canadians with the best possible protection from COVID-19 vaccines, NACI has considered the latest vaccine safety monitoring data. Based on data from millions of doses of the pediatric Pfizer-BioNTech Comirnaty mRNA COVID-19 vaccine administered in Canada and worldwide, NACI has strengthened its advice to now strongly recommend that children aged 5 to 11 years receive two doses of the pediatric vaccine, with a dosing interval of at least 8 weeks between the first and second dose. In addition, NACI now also recommends a third dose of mRNA COVID-19 vaccine for children aged 5 to 11 years who are moderately to severely immunocompromised.”

- Dr. Theresa Tam, Chief Public Health Officer