



# SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF OCTOBER 21, 2022

Recommendations on the use of Pfizer-BioNTech  
Comirnaty (3 mcg) COVID-19 vaccine in children  
6 months to 4 years of age



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PARTNERSHIP, INNOVATION AND ACTION IN PUBLIC HEALTH.**

— Public Health Agency of Canada

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Résumé de la déclaration du Comité consultatif national de l'immunisation (CCNI) du 21 octobre 2022 : Recommandations sur l'utilisation du vaccin Comirnaty de Pfizer-BioNTech (3 mcg) contre la COVID-19 chez les enfants de 6 mois à 4 ans

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## OVERVIEW

- On October 21, 2022, the Public Health Agency of Canada (PHAC) released recommendations from the National Advisory Committee on Immunization (NACI) on the use of the Pfizer-BioNTech Comirnaty COVID-19 (3 mcg) vaccine for children 6 months to 4 years of age. This guidance is based on current evidence and NACI expert opinion.
- Health Canada has authorized two COVID-19 vaccines for children under 5 years of age:
  - The Moderna Spikevax mRNA (25 mcg) vaccine was authorized on July 14, 2022 for use as a 2-dose primary series in children 6 months to 5 years of age. NACI released guidance on the use of this vaccine on July 14, 2022.
  - The Pfizer-BioNTech Comirnaty mRNA (3 mcg) vaccine was authorized on September 9, 2022 for use as a 3-dose primary series in children 6 months to 4 years of age.
- **NACI recommends that:**
  - **A primary series with an mRNA COVID-19 vaccine may be offered to children 6 months to 4 years of age who are not moderately to severely immunocompromised, with an interval of at least 8 weeks between doses. (*Discretionary NACI recommendation*)**
    - The same mRNA vaccine is recommended for all doses of a primary series, if possible. If two different mRNA vaccines are given, please refer to [PHAC's Quick reference guide on the use of COVID-19 vaccines: Managing vaccine administration errors or deviations](#).
  - **A primary series plus an additional dose of an mRNA COVID-19 vaccine may be offered to children 6 months to 4 years of age who are moderately to severely immunocompromised. (*Discretionary NACI recommendation*)**
    - **NACI preferentially recommends a 3-dose primary series of the Moderna Spikevax (25 mcg) vaccine for children who are moderately to severely immunocompromised, with an interval of 4 to 8 weeks between each dose. (*Strong NACI Recommendation*)**
    - **If the Moderna Spikevax (25 mcg) vaccine is not readily available, a 4-dose primary series with the Pfizer-BioNTech Comirnaty (3mcg) vaccine may be offered, with an interval of 4 to 8 weeks between each dose. (*Discretionary NACI Recommendation*)**
  - **For children 6 months to 5 years of age, COVID-19 vaccines should not routinely be given on the same day as other vaccines. (*Strong NACI recommendation*)**
    - For this age group, NACI recommends that a COVID-19 vaccine should be given 14 days before or after a different vaccine. This is a

precautionary measure to help determine if a potential side effect is due to a COVID-19 vaccine or a different vaccine. There may be situations 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.

For the full statement, including supporting evidence and rationale, please see [NACI Recommendations on the use of the Pfizer-BioNTech Comirnaty \(3 mcg\) COVID-19 vaccine in children 6 months to 4 years of age](#).

For more information on recommendations on the use of the Moderna Spikevax (25 mcg) COVID-19 vaccine and guidance on COVID-19 vaccines for children 5 years of age, please see [NACI Recommendations on the use of the Moderna Spikevax COVID-19 \(25 mcg\) vaccine in children 6 months to 5 years of age](#).

For more information on NACI's recommendations on the use of COVID-19 vaccines, please refer to the [COVID-19 vaccine chapter](#) in the [Canadian Immunization Guide \(CIG\)](#), as well as additional statements on the [NACI web page](#).

## WHAT YOU NEED TO KNOW

- The COVID-19 virus continues to circulate in Canada. Most children who get COVID-19 have mild or no symptoms but some children can get very sick and need to be hospitalized.
- Recent data suggest children under 5 years of age may be more likely to be hospitalized from COVID-19 than older children.
- Children who get COVID-19 are at risk of experiencing multisystem inflammatory syndrome in children (MIS-C), a rare but serious complication that usually requires hospitalization.
- Children who have underlying medical conditions may be at higher risk of getting really sick and experiencing complications, but hospitalization and MIS-C can occur in any child.
- COVID-19 vaccination can help protect children from experiencing serious illness and complications from COVID-19.
- Health Canada has authorized two COVID-19 vaccines for children under 5 years of age. For most children, there is no preference between the two vaccines; however, the number of doses required per product differs.
  - The Moderna Spikevax mRNA (25 mcg) vaccine was authorized on July 14, 2022 for use as a 2-dose primary series in children 6 months to 5 years of age.
  - The Pfizer-BioNTech Comirnaty mRNA (3 mcg) vaccine was authorized on September 9, 2022 for use as a 3-dose primary series in children 6 months to 4 years of age.

- Clinical trial findings show that a 3-dose primary series of the Pfizer-BioNTech Comirnaty (3 mcg) vaccine produces an immune response in children 6 months to 4 years of age that is comparable to the immune response seen in young adults 16 to 25 years of age who receive a 2-dose primary series of the Pfizer-BioNTech Comirnaty (30 mcg) vaccine.
- Clinical trial findings show that the Pfizer-BioNTech Comirnaty (3 mcg) vaccine has a good safety profile in children 6 months to 4 years of age.
- Real-world data on the use of mRNA COVID-19 vaccines in children show that these vaccines continue to be safe. No safety signals, including myocarditis, have been reported after administration of about 1.5 million doses in this age group. NACI, Health Canada and PHAC will continue to closely monitor real-world data on the use of this vaccine in children.
- Evidence in older groups continues to show that mRNA COVID-19 vaccines provide good protection against severe COVID-19 outcomes and can prevent hospitalization due to MIS-C in adolescents.
- For children who have had COVID-19, NACI suggests waiting 8 weeks after a positive COVID-19 test or the start of symptoms before beginning or continuing the primary series. This interval may be shortened to 4 weeks for children who are moderately to severely immunocompromised.
- Children receiving the Pfizer-BioNTech Comirnaty (3 mcg) vaccine who turn 5 before completing the primary series are recommended to receive the Pfizer-BioNTech Comirnaty (10 mcg) vaccine, which is authorized for children 5 to 11 years of age, to complete the primary series.
- NACI will continue to monitor the evolving evidence on COVID-19 vaccination in children under 5 and will update guidance as needed.

For the full statement, including supporting evidence and rationale, please see [NACI Recommendations on the use of the Pfizer-BioNTech Comirnaty \(3 mcg\) COVID-19 vaccine in children 6 months to 4 years of age](#).

For more information on risk factors associated with severe disease in children, please refer to the NACI [Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 months to 5 years of age](#).

For more information on recommendations for the use of the Moderna Spikevax (25 mcg) COVID-19 vaccine in children under 5, please see [NACI Recommendations on the use of the Moderna Spikevax COVID-19 \(25 mcg\) vaccine in children 6 months to 5 years of age](#).

For more information on NACI's recommendations on the use of COVID-19 vaccines, please refer to the [COVID-19 vaccine chapter](#) in the [Canadian Immunization Guide](#) (CIG), as well as additional statements on the [NACI web page](#).

## QUOTES

“The Pfizer-BioNTech Comirnaty 3-microgram COVID-19 vaccine includes 3 doses for primary series and is now an option for infants and children 6 months to 4 years of age. This product is different from the Moderna Spikevax 25 mcg vaccine for young children because it includes one additional dose, but both products were shown to provide very good protection once the series was completed.

NACI continues to recommend spacing the doses of a primary series 8 weeks apart for most children, consistent with evidence for the other COVID-19 vaccines. There have been over a million of first and second vaccine doses given to young children aged 6 months to 5 years worldwide, and so far there has been no concern for the safety of these products.”

- Dr. Shelley Deeks, NACI Chair

“Data continue to show that children under 5 years of age may be more likely to be hospitalized from COVID-19 than older children. Canada now has two pediatric COVID-19 vaccine options for children aged 6 months to 4 years. Lower dose paediatric formulations of both the Moderna Spikevax (25 mcg) and Pfizer-BioNTech Comirnaty (3 mcg) COVID-19 vaccines provide good protection against serious COVID-19 illness, hospitalization and complications. Likewise, following administration of more than 1.5 million first and second vaccine doses in children under 5 years, both vaccines have a good safety profile, including no cases of myocarditis reported.

Parents and caregivers are encouraged to seek information from credible sources to help with making informed and confident decisions about COVID-19 vaccinations for children in their care. As well, parents and caregivers should be supported and respected as they make their decisions.

As always, the Public Health Agency of Canada will continue to support provinces and territories as they roll out their COVID-19 immunization programs for children.”

- Dr. Theresa Tam, Chief Public Health Officer