



SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF AUGUST 19, 2022

Recommendations on the use of a first booster
dose of Pfizer-BioNTech Comirnaty COVID-19
vaccine in children 5 to 11 years of age



**TO PROMOTE AND PROTECT THE HEALTH OF CANADIANS THROUGH LEADERSHIP,
PARTNERSHIP, INNOVATION AND ACTION IN PUBLIC HEALTH.**

— Public Health Agency of Canada

Également disponible en français sous le titre :

Résumé de la déclaration du Comité consultatif national de l'immunisation (CCNI) du 19 août 2022 : Recommandations sur l'utilisation d'une première dose de rappel du vaccin Comirnaty de Pfizer-BioNTech contre la COVID-19 chez les enfants de 5 à 11 ans

To obtain additional information, please contact:

Public Health Agency of Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications-publications@hc-sc.gc.ca

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, 2022

Publication date: August 2022

This publication may be reproduced for personal or internal use only without permission provided the source is fully acknowledged.

Cat.: HP5-141/2-2022E-PDF

ISBN: 978-0-660-45069-8

Pub.: 220376

OVERVIEW

- On August 19, 2022, the Public Health Agency of Canada (PHAC) released recommendations from the National Advisory Committee on Immunization (NACI) on the use of a first booster dose of the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine in children 5 to 11 years of age. This guidance is based on current evidence and NACI's expert opinion.
- On August 19, 2022, Health Canada authorized the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine for use as a booster dose in children 5 to 11 years of age. This is the first COVID-19 vaccine authorized as a booster dose in this age group.
- NACI reviewed clinical trial data on the safety, efficacy and immune response generated by a booster dose of the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine in children 5 to 11 years of age, as well as the spread and severity of COVID-19 in children 5 to 11 years of age in Canada.
- NACI continues to recommend that a two-dose primary series of an mRNA COVID-19 vaccine 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 dose. For children who are moderately to severely immunocompromised, NACI recommends a primary series of three doses of an mRNA vaccine, using an interval of 4 to 8 weeks between each dose.
- **NACI makes the following recommendations on the use of a first booster dose of the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine in children 5 to 11 years of age:**
 - **For children 5 to 11 years of age who have an underlying medical condition that places them at high risk of severe illness due to COVID-19, including children who are immunocompromised, NACI recommends that a first booster dose of the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine should be offered at least 6 months after completion of a primary series. (*Strong NACI recommendation*)**
 - **For all other children 5 to 11 years of age, NACI recommends that a first booster dose of the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine may be offered at least 6 months after completion of a primary series in the context of heightened epidemiological risk. (*Discretionary NACI recommendation*)**

For the full statement, including supporting evidence and rationale, please see [NACI Statement: Recommendations on the use of a first booster dose of Pfizer-BioNTech Comirnaty COVID-19 vaccine in children 5 to 11 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

- On August 19, 2022, Health Canada authorized the Pfizer-BioNTech Comirnaty (10 mcg) mRNA COVID-19 vaccine for use as a booster dose in children 5 to 11 years of age. This is the first COVID-19 vaccine authorized as a booster dose in this age group in Canada.
- When developing these recommendations, NACI reviewed the spread and severity of COVID-19 in children 5 to 11 years of age; level and duration of protection due to vaccination, infection, or hybrid immunity (i.e., protection due to a combination of both infection and appropriate vaccination) in this age group; clinical trial data on the safety, efficacy and immune response of a booster dose of the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine in children 5 to 11 years of age; and ethical considerations related to COVID-19 vaccination in this population.
- During the summer of 2022, Canada has been experiencing an increase in COVID-19 activity driven by the BA.5 and BA.4 Omicron sub-variants.
- Most children who get COVID-19 have mild or no symptoms; however, some children experience severe disease and require hospitalization. Severe COVID-19 outcomes, including hospitalization, are lower in children who are vaccinated against COVID-19.
- Children who have an underlying medical condition may be at higher risk of severe outcomes from COVID-19. Children at increased risk for severe outcomes may include children with obesity; children who are medically fragile or have medical complexities; children with more than one comorbidity; children with neurological disorders; children with Down syndrome; and children with immunocompromising conditions.
- Studies show that a primary series of an mRNA COVID-19 vaccine offers good protection against severe COVID-19 disease and hospitalization in children 5 to 11 years of age. Vaccine effectiveness of a primary series against severe disease, including hospitalization, due to Omicron infection ranged from 41% to 68% in this age group. In studies looking at adolescents, mRNA vaccines were highly effective at preventing hospitalization due to multisystem inflammatory syndrome in children (MIS-C).
- Preliminary evidence in adults suggests protection acquired from both infection and vaccination wanes over time. Studies assessing vaccine effectiveness of a first booster dose in adults show that protection increases after receiving a booster dose, including protection against severe disease due to Omicron infection.
- Clinical trial findings show that a booster dose of the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine was well tolerated in children 5 to 11 years of age. Side effects were typically mild or moderate and resolved themselves within a few days.
- NACI recommends that a booster dose be offered at least 6 months after completion of a primary series or SARS-CoV-2 infection. A shorter interval of at least 3 months may be warranted in the context of increased COVID-19 activity and risk. However, a longer interval between vaccine doses may result in a stronger and more durable immune

response after the booster dose, which may be an important consideration for long-term immunity in children.

- Informed consent should include discussion regarding what is known and unknown about the benefits and risks of providing a booster dose to children 5 to 11 years of age.
- Vaccine manufacturers are working on new COVID-19 vaccines, including multivalent vaccines. Multivalent vaccines are designed to provide protection against two or more strains of the COVID-19 virus. Pending regulatory approval, it is anticipated that these vaccines will be available for adults in the coming months; however, it is unclear if and/or when a multivalent vaccine will be available for children.
- NACI continues to monitor the spread and severity of COVID-19 and the safety, effectiveness and duration of protection of a Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine booster dose in children 5 to 11 years of age and will update guidance as needed.

For the full statement, including supporting evidence and rationale, please see [NACI Statement: Recommendations on the use of a first booster dose of Pfizer-BioNTech Comirnaty COVID-19 vaccine in children 5 to 11 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

“NACI has been closely monitoring the evidence on the benefit and need for booster doses in Canada, and is now providing advice on the use of a first booster dose for children 5 to 11 years of age. Similar to the booster guidance for adolescents, these recommendations will help to continue to protect children at higher risk of severe illness due to COVID-19 across Canada, while also providing an option to add to protection in other children 5 to 11 years of age. The Committee continues to monitor the evolving and emerging evidence related to the use of COVID-19 vaccines in all populations, and guidance will be updated as needed.”

- Dr. Robyn Harrison, NACI Vice-Chair

“A primary series of mRNA COVID-19 vaccines provides very good protection against severe COVID-19 disease and reduces the risk of hospitalization, but we know that COVID-19 vaccine protection wanes over time. As we have seen in adults, booster doses can restore this protection. The availability of the Pfizer-BioNTech Comirnaty COVID-19 vaccine for use as a first booster dose in children 5 to 11 years of age provides a great option to restore protection in this age group, especially for children who have an underlying medical condition that places them at high risk of severe illness due to COVID-19. As always, I am grateful to NACI for their timely advice on the use of COVID-19 vaccines.”

- Dr. Theresa Tam, Chief Public Health Officer