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

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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