Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine in adolescents 12 to 18 years of age

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Recommendation

NACI recommends that a complete series with a Pfizer-BioNTech COVID-19 vaccine should be offered to individuals 12 to 18 years of age without contraindications to the vaccine. **(Strong NACI Recommendation)**

Background

The Pfizer-BioNTech COVID-19 vaccine (Tozinameran or BNT162b2) is an mRNA vaccine that was authorized by Health Canada for use in individuals 16 years of age and older on December 9, 2020. Since December 12, 2020, NACI has recommended the use of Pfizer-BioNTech in individuals 16 years and older. On May 5, 2021, Health Canada expanded the Interim Order authorization for the Pfizer-BioNTech COVID-19 vaccine from use in those 16 years and older to also include adolescents 12 to 15 years of age. Further information on the regulatory approval of the Pfizer-BioNTech COVID-19 vaccine can be found on Health Canada's COVID-19 vaccines and treatment portal.

Prior to this authorization, NACI had made a discretionary recommendation on the use of this vaccine in adolescents 12 to 15 years of age for select high-risk groups, as they were included in limited numbers in the original clinical trial.

For further information, please refer to NACI's Recommendations on the use of COVID-19 vaccines.

Methods

Ethical considerations related to COVID-19 vaccination in adolescents were discussed with the Public Health Ethics Consultative Group (PHECG) on May 3, 2021. The Canadian Immunization Committee (CIC) provided feedback on key policy questions to ensure alignment with program needs on May 6, 2021. NACI reviewed available evidence on the burden of illness in this population and vaccine acceptability of parents and guardians. NACI reviewed the available evidence on the use of the Pfizer-BioNTech COVID-19 vaccine in adolescents 12 to 15 years of age on May 9, 2021 (Pfizer manufacturer submission to Health Canada) and approved the recommendation on May 11, 2021.

Details of NACI's evidence-informed recommendation development process can be found elsewhere [1] [2].

Summary of evidence and rationale for the recommendation

Trial description: The Pfizer-BioNTech COVID-19 vaccine was evaluated in 2,260 adolescents 12 to 15 years of age as an amendment to study C4591001, an ongoing randomized, observer-blind, placebo-controlled Phase 3 trial. Participants were randomized to receive either two doses of the vaccine (n=1,131) or placebo (n=1,129), 21 days apart. All adolescent study participants were recruited from the United States (US). Almost half (49.0%) of participants were female and the median age of adolescent participants at vaccination was 14.0 years (range: 12 to 15 years).

Safety: Consistent with clinical findings in individuals 16 to 25 years of age [3], the Pfizer-BioNTech COVID-19 vaccine was well tolerated in adolescents 12 to 15 years of age. Local reactions were mostly mild to moderate in severity and occurred predominantly following the first dose. Systemic events were predominantly fatigue, headaches, chills, muscle pain, fever, and joint pain (in order of descending frequency) and occurred more frequently after the second dose. Compared to individuals 18 to 55 years of age, adolescents 12 to 15 years of age demonstrated increased frequency of headache, chills, and fever. Up to 64.5% of adolescent participants had headaches, up to 41.5% had chills, and up to 19.6% had fever [4]. Vaccination-related lymphadenopathy in adolescents occurred in 0.6% of vaccine recipients, and no serious adverse events related to the vaccine and no deaths were reported. Duration of safety follow-up was limited. After the second dose, 98.3% of all participants had ≥ 1 month of follow-up while

57.9% had ≥ 2 months of follow-up. Follow up will continue in trial participants for at least 2 years following the second dose for ongoing safety reporting to Health Canada.

Efficacy: In study participants 12 to 15 years of age without prior evidence of SARS-CoV-2 infection, the estimate of vaccine efficacy against the first occurrence of confirmed SARS-CoV-2 infection from 7 days after Dose 2 was 100% (95% CI: 75.3 to 100.0%; 16 cases in the placebo group, 0 cases in the vaccine group). The estimate of vaccine efficacy in all participants 12 to 15 years of age (including those with prior evidence of SARS-CoV-2 infection) was also 100% (95% CI: 78.1 to 100.0%; 18 cases in the placebo group, and 0 cases in the vaccine group). After Dose 1, there were 3 cases of confirmed COVID-19 identified in the vaccine group and 35 cases identified in the placebo group. All cases in the vaccine group occurred less than 11 days after Dose 1, before a full immune response to the vaccine would be expected. No cases meeting the severe COVID-19 case definition (hospitalization, admission to the ICU, intubation or mechanical ventilation, or death) were reported in any participant 12 to 15 years of age as of the data cut-off date for efficacy analysis of March 13, 2021.

Immunogenicity : The humoral immune response to the Pfizer-BioNTech COVID-19 vaccine was non-inferior in adolescents 12 to 15 years of age compared to individuals 16 to 25 year of age. This non-inferiority analysis comparing the immune response between adolescents 12 to 15 years of age (n=209) and young adults 16 to 25 years of age (n=186) was performed using SARS-CoV-2 50% neutralizing titers (NT50). One month following dose 2, the estimated ratio of antibody levels in adolescents relative to young adults was 1.76 (95% CI: 1.47 to 2.10), which exceeded the 1.5-fold pre-established non-inferiority criterion (lower bound of the 2-sided 95% CI for the geometric mean ratio [GMR] >0.67). Note: no correlate of protection

has been determined for SARS-CoV-2 at this time, therefore higher or lower immune responses cannot be correlated to a level of protection against SARS-COV-2 infection.

Considerations

- Approximately 1.63 million adolescents 12 to 15 years of age reside in Canada [5].
- Canada is anticipating large supplies of mRNA vaccines in June and the summer months to complete second doses in adults who have already received their first dose of vaccine, and to also vaccinate adolescents 12 years of age and older.
- There is limited evidence on the risk factors for severe COVID-19 disease in both adolescent and pediatric populations [6] however, risk of severe outcomes associated with COVID-19 (hospitalization, admittance to ICU, death) are infrequent in this age group [7].
- Public health measures remain the foundation of the pandemic response while vaccines continue to roll out across the country. It is important that everyone, regardless of vaccination status, continue to follow recommended public health measures.
- NACI will continue to monitor the evidence and update its recommendations as needed.

NACI research priorities

- NACI recommends continuous monitoring of data on the safety, efficacy and effectiveness of the Pfizer COVID-19 vaccine in adolescents through clinical trials and studies in real-world settings.
- Additional research priorities are listed in NACI's statement on Recommendations for the use of COVID-19 vaccines.

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