



Key Messages and Questions and Answers

National Advisory Committee on Immunization (NACI) Recommendations and key messages on the use of the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine in children 5-11 years of age

Key Messages:

- Health Canada approved the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine for children aged 5 to 11 on November 19, 2021. On the same day, Canada's National Advisory Committee on Immunization (NACI) recommended that children 5 to 11 years of age may be offered the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine in Canada.
- To date, while most children who've been infected with the SARS-CoV-2 virus have had no symptoms or experienced only mild COVID-19 disease, some have experienced severe disease requiring hospitalization and in rare instances, death.
- Children can also develop a rare but serious condition called multisystem inflammatory syndrome (MIS-C), occurring several weeks following their infection. Other health impacts such as post-COVID-19 syndrome, though less well understood, may also be a risk in this age group.
- Based on a review of the safety, efficacy and quality of the vaccine, Health Canada determined that the benefits of the vaccine in this age group outweigh the risks. During the clinical trial of the vaccine, children had a comparable immune response to people 16 to 25 years of age. How long the protection will last is currently unknown.
- There were no new safety signals identified during clinical trials for the vaccine in children 5 to 11 years of age. The pediatric clinical trial was well conducted.
- As with all vaccines, it is possible that rare events will be found to occur once the vaccine is in widespread use. Despite all the knowledge gained about a product pre-market, it is not possible to detect all (AEFIs) at that stage, especially if they are very rare.
- The Government of Canada will continue to monitor the safety and effectiveness of the COVID-19 vaccine in the 5-11 years age group very closely—both in Canada and internationally—and will provide updates as data continue to emerge.
- In addition to Canada's strong COVID-19 vaccine safety monitoring system, Canada also has a safety surveillance system specifically designed for monitoring pediatric vaccinations. This system, called Canadian Immunization Monitoring Programme, ACTIVE or IMPACT, has been used to monitor the efficacy and safety of childhood immunizations for more than 20 years.
- As Health Canada, NACI and PHAC closely monitor the domestic rollout of the pediatric program and continue to consider new information from international programs and research, it is very important to support children and their caregivers in making informed decisions about COVID-19 vaccination, while respecting their choices and pace of decision-making.



NACI guidance and recommendations on vaccination in those 5 to 11 years of age:

- On November 19, 2021, the Public Health Agency of Canada (PHAC) released guidance from the National Advisory Committee on Immunization (NACI) on the use of the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine in children 5-11 years of age.
- These recommendations are based on current scientific evidence and NACI's expert opinion. NACI reviewed the available evidence on the use of the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine in children 5-11 years of age, as well as ethical considerations related to COVID-19 vaccination in children.
- NACI recommends that a complete series of the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine may be offered to children 5-11 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.
- It is essential that children and their caregivers are supported and respected during the decision-making process so they are able to make an informed decision about COVID-19 vaccination.
- NACI reiterates that all adults should receive a primary series of a COVID-19 vaccine. Adults, including caregivers and youth, who interact with children should be vaccinated against COVID-19 to offer additional protection to children.
- Public health measures remain very important for preventing transmission of the COVID-19 virus in children. It is important that everyone, regardless of vaccination status, continues to follow recommended public health measures.
- NACI will continue to monitor and review evidence regarding the safety and effectiveness of COVID-19 vaccines in children and will update their recommendations as needed.

Pediatric dose formulation:

- The Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine for children aged 5 to 11 years uses a smaller dose than for adolescents and adults.
- The Pfizer-BioNTech COVID-19 vaccine used for adolescents and adults has a 30 micrograms (mcg) of mRNA dosing formulation, whereas the pediatric vaccine has a 10 micrograms (mcg) dosing formulation.
- The 10 micrograms dose in children has been found to result in a similar immune response as the 30 micrograms dose for older adolescents and young adults, and the pediatric dosing has been shown to result in fewer side effects than higher doses in this age group.

On recommended interval:

- NACI recommends an interval of at least 8 weeks between the first and second doses. Emerging evidence in adults suggests that, compared to shorter intervals, this



longer interval between the first and second doses result in a more robust immune response and higher vaccine effectiveness, which is expected to last longer.

- Moreover, it is expected that longer intervals may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.

Questions and Answers:

Q1. Why should children receive a COVID-19 vaccine if they are at lower risk of serious outcomes from COVID-19?

Although children and youth are less likely to get very ill from COVID-19 when compared to adults, if they do get infected they can still:

- develop symptomatic COVID-19, including resulting in severe illness requiring hospitalization in some instances, or rarely resulting in death;
- be infected and not have any symptoms but still be able to spread COVID-19 to others; and
- experience [longer-term effects](#).

Children are also at risk of developing multisystem inflammatory syndrome in children (MIS-C), following infection with the COVID-19 virus. MIS-C is a serious but uncommon event that can occur several weeks following infection and requires hospitalization and treatment.

The fourth wave is having a greater impact on children, as they are unvaccinated and many children less than 12 years of age have returned to in-person school and activities. As of mid- November, children aged 5 to 11 years of age have the highest COVID-19 case incidence rate across all age groups.

The Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine can be offered to children aged 5 to 11 years to give them protection against COVID-19. The vaccine gives very good protection against symptomatic infection based on the results of the clinical trial in this age group. How long this protection will last is currently unknown, but is the subject of ongoing post-marketing surveillance of pediatric immunization programs underway worldwide. As additional data accumulate on vaccine effectiveness of the pediatric formulation in Canada and worldwide, we will update advice as needed to ensure the best protection possible for children in Canada.

Q2. In Canada, how many children have died from COVID-19 to date? How many children have been hospitalized to date?

As of November 12, 2021, among the twelve jurisdictions currently reporting detailed age data to the Public Health Agency of Canada (PHAC), severe outcomes from COVID-19 including hospitalization, ICU admissions and death are very infrequent in children, occurring in 0.2% (=299/123,652), 0.04% (=48/123,652) and 0.002%(=2/123,652) of confirmed SARS-CoV-2 infections in children aged 5–11 years respectively.

Q3. Why does the NACI recommendation for children ages 5 to 11 indicate that a vaccine “may be offered” instead of “should be offered?” Is there a difference?

The National Advisory Committee on Immunization (NACI) provides technical advice to PHAC, for use by provinces and territories and health care providers. NACI makes two types of



recommendations in their technical advice—strong recommendations and discretionary recommendations. A strong recommendation uses the words “should/should not be offered” while a discretionary recommendation uses the words “may/may not be offered.”

A strong recommendation is one that applies to most individuals in a population unless a compelling alternative is available. A discretionary recommendation means that the vaccine may be considered for individuals in a population, but that the decision should be made considering factors such as individual benefits and risks, or local epidemiology. NACI will continue to monitor the information related to the Pfizer-BioNTech vaccine for children, including how well it works and its safety profile, and will update its recommendations as required.

Q4. Is the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine safe for children 5 to 11 years of age? What are the side effects?

Parents or guardians who would like to vaccinate their child(ren) aged 5 to 11 years can feel confident that Health Canada found no safety signals in the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine clinical trials in their review of the data.

The pediatric clinical trial was not large enough to determine rare to very rare adverse events following immunization, such as rare reports of myocarditis and pericarditis after vaccination, in this specific age group. An adverse event occurring at a frequency less often than 1 in 1,000 would not be detected by the clinical trial, in which approximately 3,100 children received the active vaccine.

Rare adverse events are sometimes detected after approval when a vaccine is used in large populations. Pediatric vaccine programs are currently rolling out in multiple countries. Public health agencies and regulators—both internationally and in Canada—are actively monitoring the rare side effects, including rare cases of myocarditis and pericarditis in vaccinated people 5 to 11 years of age. Reports of adverse events from Canada and other countries will be monitored closely and any safety signals that are detected will be communicated to the public.

As these additional data accumulate on use of the pediatric formulation in Canada and worldwide, we will update advice as needed to ensure the best protection possible for children in Canada.

Q5. Why were clinical trials for ages 5 to 11 years a size that would be unable to detect adverse events occurring at a frequency greater than 1 in 1,000 (e.g., myocarditis and pericarditis)? When will there be more data?

The clinical trial in children 5 to 11 years of age was an extension of the large Phase 3 trial conducted in adults and adolescents. The sample size for ages 5 to 11 was not as large as the initial clinical trial because the efficacy and safety of the vaccine had already been tested. Despite all the knowledge gained about a product pre-market, it is not possible to detect all Adverse Events Following Immunization (AEFIs) at the clinical trial stage, especially if they are very rare. However, there is now a large and accumulating amount of safety data from real world use of the vaccine in Canada and internationally in adolescents and adults.

Q6. Why is COVID-19 vaccine mandatory for adults in many settings but not children? What about vaccination requirements for school or travel?

Provinces, territories and other organizations are responsible for vaccine requirements, including which settings have mandatory vaccine policies and for which populations. Please



consult with your local, provincial, territorial government and/or the relevant organization in question for guidance on vaccination mandates.

It is outside of NACI's mandate to provide guidance on whether to mandate a vaccine to any jurisdictions, including the provinces, territories, or federal government. NACI notes in their statement that it is essential that children aged 5-11 years and their parents or guardians are supported and respected in their decisions regarding COVID-19 vaccinations for their children, whatever decisions they make, and are not stigmatized for accepting, or not accepting, the vaccination offer.

Vaccination requirements for the [Mandatory COVID-19 vaccination requirements for federally regulated transportation employees and travellers](#) apply to travellers 12 years of age and older.

Q7. What consent is required for someone aged 5 to 11 years to receive a COVID-19 vaccine?

Provinces and territories are responsible for determining their vaccination policies, including consent. For more information on COVID-19 vaccination in your area, please visit your [provincial or territorial website](#).

Q8. If a child 5 to 11 years of age had a previous COVID-19 infection, can they still get the COVID-19 vaccine?

Children with previous COVID-19 infection may be offered two doses of the vaccine once symptoms of acute illness have resolved and the child is no longer considered infectious, based on current criteria. Vaccination in children who develop the rare complication of multisystem inflammatory syndrome in children (MIS-C) following COVID-19 infection should be postponed until they have recovered or 90 days have passed since diagnosis, in consultation with their health care provider.

Q9. Should children who previously experienced myocarditis and/or pericarditis after a first dose of the vaccine receive a second dose?

As a precaution, children who experience myocarditis and/or pericarditis after a first dose of the vaccine should wait to get a second dose until more information is available.

Children who have a history of myocarditis unrelated to COVID-19 vaccination should have a consult by their clinical care team for individual considerations and recommendations. If they are no longer under active care for myocarditis, they may receive the vaccine. Caregivers should be advised to seek medical attention for children if they develop symptoms including chest pain, shortness of breath, or palpitations after they receive the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine.

Q10. According to NACI, if someone is 11 years old at the time of their first dose, but will turn 12 years old before their second dose, which formula/dosage should they receive?

Children who receive the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine for their first dose, who turn 12 by the time of their second dose, may receive the adolescent/adult formulation of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) to complete their primary series. If a child who has turned 12 by the time of their second dose inadvertently receives the pediatric formulation (10 mcg), their series should still be considered valid and complete.



Q.11. Can my child get their COVID-19 vaccine at the same time as other vaccines, such as the flu shot?

At this time, it is not generally recommended that children aged 5 to 11 years of age receive the COVID-19 vaccine at the same time as the flu shot. The current NACI recommendation is that children wait at least 14 days between COVID-19 vaccines and non-COVID-19 vaccines. This is a precaution to help to determine if a side effect that may arise is due to the COVID-19 vaccine or another vaccine. There may be circumstances when a dose of a COVID-19 vaccine and another vaccine need to be given at the same time—a health care provider can help with this decision.

Q12. Where should I go for advice on COVID-19 vaccines for children?

Parents or guardians should speak with a trusted health care provider if they have questions about their child's health, including on COVID-19 and vaccination. Provinces and territories decide how, who, and when to vaccinate populations living in their region. Parents and guardians are encouraged to follow the advice of their [local public health authority](#) on COVID-19 vaccinations, as well as trusted websites such as Canada.ca.

Q13. My child is anxious about needles. How can I help them?

Preparing children for vaccination can help ease their worries and make it a positive experience for families. Health Canada and PHAC encourage parents or guardians to start talking to younger children about the [importance of vaccination](#) and [how vaccines work](#).

Visit Canada.ca/coronavirus to learn more about how you can support children in your care in having a positive vaccination experience, including how to talk to children in your care about vaccination and coping strategies to reduce needle anxiety at the appointment.

Q14. NACI recommends dose 2 may be offered at least 8 weeks later, will it be possible to get dose 2 earlier if parents or guardians want to?

NACI's role is to provide expert technical advice to PHAC, which can then be used to inform jurisdictional policies. Provinces and territories will determine how to implement NACI's advice based on their own jurisdictional considerations.

The dosing schedule for the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine, authorized by Health Canada based on the clinical trials, is to give the 2 doses 21 days apart. The minimum interval is 19 days.

Based on available evidence, NACI recommends an interval of at least 8 weeks between the first and second doses. Emerging evidence in adults suggests that, compared to shorter intervals, longer intervals between the first and second doses result in a more robust immune response and higher vaccine effectiveness that is expected to last longer, and may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.

If a parent or guardian wishes to vaccinate someone 5-11 years old with a second dose of the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine as soon as 21 days after their first dose, their jurisdiction and health care provider would have to determine whether they will accommodate this request. The child's health care provider can assess the risk of the child to SARS-CoV-2 exposure (e.g., living in a congregate setting) or the risk of the



child to severe outcomes of COVID-19 if infected (due to underlying comorbidities) to provide an informed clinical decision.

Q15. If a parent or guardian wants to give this low-dose version to their teen instead of the regular dose, will they be able to?

Current NACI guidance states that children who receive the Pfizer-BioNTech Comirnaty (10 mcg) pediatric formulation COVID-19 vaccine for their first dose, and who have turned 12 years of age by the time the second dose is due may receive the 30 mcg Pfizer-BioNTech COVID-19 Comirnaty vaccine that is authorized for individuals aged 12 years and older to complete their primary series. However, if the second dose of 10 mcg pediatric formulation is given, the dose should still be considered valid and the series complete.

If an individual aged 12 or older were to receive a two-dose series of the 10 mcg Pfizer-BioNTech COVID-19 vaccine, it would not necessarily be considered by jurisdictions to be a complete primary series of the vaccine.