

November 23, 2021

## Alberta COVID-19 Immunization Program Update

Dear colleagues,

I would like to update you with some important information about COVID-19 immunization.

Starting this week, pediatric doses of Pfizer-BioNTech (Comirnaty) COVID-19 vaccine will be available to children 5 to 11 years of age in Alberta.

- A complete series (two doses) of the Pfizer-BioNTech (Comirnaty) COVID-19 vaccine (10 mcg pediatric formulation) may be offered to children 5-11 years of age who do not have contraindications to the vaccine.

In addition, Alberta has adopted the recommendations of the National Advisory Committee on Immunization (NACI) and Alberta Advisory Committee on Immunization (AACI) on optimal intervals between the first and second dose of a two-dose primary COVID-19 vaccine series.

- For children 5 to 11 years of age, the dose interval should be at least 8 weeks between dose 1 and dose 2 of the Pfizer-BioNTech (Comirnaty) COVID-19 vaccine.
- For Albertans aged 12 years and older, the recommended interval between dose 1 and dose 2 is now 8 weeks for an mRNA COVID-19 vaccine, i.e., Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax); and at least 8 weeks for the AstraZeneca (Vaxzevria) COVID-19 vaccine, noting that mRNA vaccines are recommended over viral vector vaccines.

More information on these changes is included below.

Thank you for your ongoing support for the COVID-19 Immunization Program.

Yours sincerely,

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Chief Medical Officer of Health

## Overview

- As recommended by the Alberta Advisory Committee on Immunization (AACI) and the [National Advisory Committee on Immunization \(NACI\)](#), a pediatric formulation (10 mcg) of the Pfizer-BioNTech (Comirnaty) COVID-19 vaccine may be offered to children ages 5 to 11 years of age who do not have contraindications to the vaccine.
- A clinical trial with over 3,000 young children receiving the Pfizer-BioNTech (Comirnaty) COVID-19 vaccine (10 mcg pediatric formulation) found that vaccine efficacy against symptomatic COVID-19 was 90.7%. None of the identified cases in the vaccine group or the placebo group met the pre-defined criteria for a severe case of COVID-19; therefore, the data did not include estimates of vaccine efficacy against severe outcomes such as hospitalization, MIS-C or death.
- While children 5-11 years of age who are infected with COVID-19 generally have mild symptoms or no symptoms and serious outcomes are rare, some require hospitalization.
  - COVID-19 infection is associated with a rare but severe condition in children called MIS-C (multisystem inflammatory syndrome in children). As of October 16, 2021, 272 cases of MIS-C in individuals 0-19 years of age have been reported in Canada, with 40% of reported cases in children aged 5-11 years. The majority of MIS-C cases in Canada have fully recovered with medical intervention, with no associated deaths.
  - It is not clear how common post-COVID syndrome, or “long COVID” is in children, but it is an important preventable outcome that should be considered when counselling parents about vaccine.
- The clinical trial of the Pfizer-BioNTech (Comirnaty) COVID-19 vaccine in young children did not indicate any safety concerns and found no cases of myocarditis/pericarditis or any other severe adverse events; however, the sample size was too small to identify any uncommon, rare or very rare adverse events. It should also be noted that no safety signals have been identified in the United States, where this vaccine has been administered to over 3 million children aged 5 to 11 years since early November.
- Currently, the risk of myocarditis/pericarditis in young children following immunization with the 10 mcg dose of the Pfizer-BioNTech (Comirnaty) COVID-19 vaccine is unknown. However, safety surveillance data from individuals aged 12 and older indicate the risk of myocarditis/pericarditis following mRNA COVID-19 vaccination is rare. Given that classic myocarditis related to other infections is more common in older age groups, the risk of myocarditis/pericarditis following COVID-19 immunization would not be expected to be greater in children aged 5-11 years compared to older populations. Additionally, the impact of a reduced vaccine dose (10 mcg vs 30 mcg) is also unknown.
- In Alberta, there have been 23 confirmed cases of myocarditis after COVID-19 vaccination in youths aged 12 to 17 years, which works out to 9 cases per 100,000 vaccinated youths in that age group.
- Real-world evidence in large pediatric populations is required to provide risk estimates of myocarditis/pericarditis and any other adverse event that may occur in children aged 5-11 years. See the Clinical Considerations section below for more information.

## Pediatric doses of COVID-19 vaccine to children 5 to 11 years of age:

### Recommendation:

A complete series (two doses) of the Pfizer-BioNTech (Comirnaty) COVID-19 vaccine (10 mcg pediatric formulation) may be offered to children 5-11 years of age who do not have contraindications to the vaccine.

### Current evidence and rationale

- During the fourth wave of the pandemic in Alberta, the rate of COVID-19 cases has been highest among those aged 5 to 11 years compared to other age groups although hospitalization rates in this age group have remained low.
- While severe outcomes from COVID-19 infection in children in this age group is rare, from the beginning of the pandemic to November 19, 2021, there have been 78 cases hospitalized and 20 cases admitted to ICU among children age 5 to 11 years in Alberta.
- Children and adolescents are also at risk of MIS-C following infection with COVID-19. In Alberta, there have been 29 cases of MIS-C in children age 5 to 11 years.
- Children are also at risk of broader harms of the COVID-19 pandemic. Prolonged schooling disruptions, social isolation, and reduced access to academic and extra-curricular resources have had profound impact on the mental and physical well-being of children and their families.
- [The clinical trial for](#) Pfizer-BioNTech (Comirnaty) COVID-19 vaccine (10 mcg pediatric formulation) indicates that the vaccine was 90.7% effective against symptomatic infections and local reactions were very common and mostly mild to moderate in severity. Side effects reported after vaccination include pain, redness and swelling at the injection site, as well as mild fever, chills, tiredness, muscle pain and nausea that typically improved or went away within hours or days. Systemic events occurred more frequently after the second dose. No cases of myocarditis/pericarditis, MIS-C, anaphylaxis or anaphylactoid reactions or deaths were reported.
- Alberta will continue enhanced surveillance of adverse events following immunization (AEFI) and adverse events of special interest (AESI). Health care professionals are reminded of their critical role and mandated responsibility to report adverse events following immunization that meet Alberta's definition of an AEFI or AESI. For information on what needs to be reported and when, go to: <https://www.albertahealthservices.ca/info/Page16187.aspx>.

### Booking an immunization appointment for children 5 to 11 years of age:

- If parents/guardians choose to get their child immunized against COVID-19, they can now book appointments by calling 811 or [booking online](#).
- First Nations children on reserve can be vaccinated at on-reserve public health clinics or facilities or at an Alberta Health Services clinic.
- Parent or guardian consent is required for children to get their vaccine, either provided in-person at the vaccine appointment or by a signed consent form.

### Clinical considerations for administering pediatric doses in all eligible populations

- Before receiving a pediatric Pfizer-BioNTech (Comirnaty) COVID-19 vaccine, while it is not required to do so, parents may consult with you to discuss any advantages or disadvantages of receiving vaccine.
- Children aged 5-11 years with a history of previous COVID-19 infection (confirmed by PCR or antigen testing from a respiratory specimen) who are no longer be considered infectious can be immunized as long as they are well enough to be immunized.
- For children with a previous history of MIS-C, vaccination should be postponed until clinical recovery has been achieved or until at least 90 days since diagnosis, whichever is longer.
- As a precautionary measure, Alberta Health recommends that individuals who experienced myocarditis and/or pericarditis after any preceding dose of an mRNA vaccine should discuss decisions around a subsequent dose, including timing, with their clinician. In general, they are advised to defer receiving an additional dose until more data is available. Additional information for clinical considerations is available [here](#).
- It is important for health care professionals to support and encourage patients/clients to continue to maintain COVID-19 disease prevention measures, such as masking and physical distancing. Household members and close relatives of these individuals should be encouraged to receive the primary series of COVID-19 vaccine, if they have not already.
- COVID-19 vaccines for children 5-11 years of age should not routinely be given concomitantly with other vaccines (live or non-live) at this time. While available evidence for those 12 and over does not indicate any safety or efficacy concerns with co-administration, it would be prudent if possible to wait for a period of at least 14 days before and after the administration of a dose of COVID-19 vaccine and the administration of another vaccine, if it does not create a barrier to receipt of other vaccines, in order to prevent erroneous attribution of an AEFI to one particular vaccine or other. Concomitant administration or a shortened interval between COVID-19 vaccine and other vaccines may be warranted on an individual basis in some circumstances at the clinical discretion of the healthcare provider.
- A complete COVID-19 vaccine series provides strong protection against COVID-19 infection and severe outcomes, [including against the Delta variant](#), in most of the general population.

## Dose intervals for a two-dose series of COVID-19 vaccine:

### Recommendation:

For children 5 to 11 years of age, the dose interval should be **at least** 8 weeks between dose 1 and dose 2 of the Pfizer-BioNTech (Comirnaty) COVID-19 vaccine.

For Albertans aged 12 years and older, the **recommended** dose interval is 8 weeks between dose 1 and dose 2 of an mRNA COVID-19 vaccine, i.e., Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax).

For Albertans aged 12 years and older, the **recommended** dose interval is at least 8 weeks between dose 1 and dose 2 for the AstraZeneca (Vaxzevria) COVID-19 vaccine, but mRNA vaccines are recommended over viral vector vaccines.

- A shortened interval between dose 1 and dose 2 (no less than the product monograph interval for the specific COVID-19 vaccine) **may be considered** in certain situations: required for travel, work requirement, increased risk for infection based on local transmission, and the degree of individual risk of exposure.
- The optimal interval between the first dose and the second dose for the immunocompromised population is currently unknown. A dose interval of 28 days will continue to be used generally. Physician consultation is recommended regarding the timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances.

### Current evidence and rationale for interval timing

- Since the initial authorization of COVID-19 vaccines, Canadian and international studies have been evaluating the impact longer intervals have on protection against COVID-19 disease compared to the shorter interval used in clinical trials and stated in product monographs.
- Current data shows that extending the interval between the first and second doses by several weeks leads to higher immune responses and greater protection.
- Real-world data suggests that shorter intervals between doses of COVID-19 mRNA vaccines result in lower antibody titres, which may wane to below protective levels more quickly over time.
- Emerging data from older age groups (12 years and older) suggests an extended dose interval may be associated with a reduced risk of myocarditis/pericarditis following a second dose of an mRNA COVID-19 vaccine.
- [NACI](#) reviewed clinical trial data, as well as data from real-world use of the vaccine, and recommends these longer intervals.

- Currently, there is no direct evidence to establish an optimal interval between doses in pediatric populations, but evidence from older age groups listed above suggests a longer dose interval can improve the immune response, provide greater protection that may last longer and reduce potential adverse events.
- People who completed their primary vaccine series using manufacturer-authorized intervals also have very good protection against severe COVID-19 disease and do not need to restart their vaccine series.
- When choosing to use a longer dose interval, local transmission of the SARS-CoV-2 virus, the degree of individual risk of exposure to the virus, and the need of a second dose for earlier protection should be considered.