

Updated July 29, 2022

## Alberta COVID-19 Immunization Program Update Summary

Dear colleagues,

Beginning August 2, 2022, Moderna Spikevax (6 months – 5 years) COVID-19 vaccine will be available to children in Alberta who have not previously been eligible for a vaccine – those from 6 months of age to less than 5 years.

- A complete **two-dose** series of the vaccine (25 mcg) may be offered to **immunocompetent** children 6 months of age to 4 years who do not have contraindications.

For a two-dose series, it is recommended that the second dose be given at least 8 weeks after the first dose.

- A complete **three-dose** series of the vaccine (25mcg) may be offered to moderately to severely **immunocompromised** children 6 months of age to 4 years who do not have contraindications.

For a three-dose series, it is recommended that the second dose be given 28 days after the first, and the third dose 8 weeks after the second.

This update is based on the recommendations from the Alberta Advisory Committee on Immunizations (AACI), in alignment with the National Advisory Council on Immunization (NACI).

More information is included below.

### COVID-19 Immunization Update

## Overview:

- The following are considerations to take into account when advising parents on vaccine choices.
- COVID-19 transmission remains high within the general population. There is evidence that community transmission of COVID-19 is once again increasing based on [wastewater data](#) and an increasing [test-positivity rate](#). It is also likely that we will have a larger wave in the late fall, due to seasonal variation.
- While many children have no symptoms from a SARS-CoV-2 infection, severe cases can occur, and some require hospitalization.

Since the beginning of the pandemic to July 13, 2022, 370 children under 1 year and 357 aged 1-4 years have been hospitalized with COVID-19 in Alberta. Of those, 71 children under 1 year and 37 aged 1-4 years required an ICU stay.

Due to the high number of cases in the community during the Omicron wave, the number of hospitalizations due to COVID-19 in children aged 6 months to less than 5 years has also increased. Per [data](#) from the Public Health Agency of Canada (PHAC), the average monthly rate of hospitalization due to COVID-19 for children 6 months to under 5 years in Canada from March 1, 2020 to December 31, 2021 was 1.4 per 100,000 children. Monthly hospitalizations were 15.9 per 100,000 children during January 1, 2022 to March 31, 2022, corresponding with the Omicron wave.

COVID-19 can cause a condition called multi-system inflammatory syndrome (MIS-C) in children which although rare, can be severe. Symptoms can include hemodynamic shock and cardiac abnormalities, including myocarditis. One [study](#) from the United States estimated that the incidence of MIS-C is 316 per 1,000,000 SARS-CoV-2 infections in children and adolescents under the age of 21.

While prevalence in children is still unknown, COVID-19 may also cause post-COVID syndrome (sometimes called “long COVID”). It is possible that this may occur even if children have a mild course of illness. [Data](#) suggest that vaccination may decrease the risk of post-COVID syndrome in the general population to some extent.

- Although many children have already had a COVID-19 infection, a prior infection may not provide robust protection against re-infection, especially against Omicron or new variants. A recent [study](#) found children and adolescents with a prior SARS-CoV-2 infection (pre-Omicron) showed some loss of cross-neutralization against all variants, particularly Omicron, compared to against ancestral WA-1 strain.

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- [Preliminary data](#) suggest that immunity from both infection and previous COVID-19 vaccines wanes over time. There is a growing body of evidence that suggests that hybrid immunity (protection from both infection and vaccination) provides more robust protection than infection or vaccination alone.
- Moderna Spikevax (6 months – 5 years) COVID-19 vaccine will be available mainly to children 6 months of age to under 5 years of age in Alberta.
- Children who are starting their primary series at 5 years of age will be offered the Pfizer BioNTech pediatric formulation licensed for children 5 to 11 years of age. There is a limited supply of the SpikeVax (6 months – 5 years) vaccine and the National Advisory Committee on Immunization (NACI) recommends that for children beginning their COVID-19 vaccine primary series at 5 years of age, Pfizer-BioNTech pediatric vaccine is preferred to SpikeVax (6 months - 5 years) vaccine.
- SpikeVax (6months -5 years) vaccine may be offered to 5 year olds in one of the following scenarios:

If a child receives a Moderna Spikevax (6 months – 5 years) vaccine and turns 5 before completion of the primary series.

If a child is immunocompromised and their clinician recommends or their parents or guardians request Moderna Spikevax.

If the parents or guardians refuse the Pfizer BioNTech pediatric formulation and requests Moderna Spikevax (6 months – 5 years) vaccine.

- Moderna has an ongoing clinical trial of children 6 months to 5 years receiving the Moderna Spikevax 25mcg dose.

Data from the trial, with a February 21, 2022 cutoff, showed that the vaccine efficacy against symptomatic infection was 50.6% (95% CI 21.4-68.6%) for children aged 6 to 23 months and 36.8% (95% CI 12.5-54.0%) for children aged 2-5 years, irrespective of prior infection. The clinical trial took place while Omicron was the dominant variant, and these numbers are consistent with the vaccine effectiveness reported for Pfizer-BioNTech Comirnaty (10mcg) vaccine among children aged 5 to 11 during the Omicron wave.

No participants in the intervention nor the placebo group met the criteria for severe case of COVID-19 and therefore, there is no estimate of vaccine efficacy against severe outcomes such as hospitalization or death.

In a measurement of immune response, the neutralizing antibody titre to 2 doses of vaccine in children 6 months to 5 years without evidence of prior infection was similar to the response found in young adults aged 18-25.

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- Moderna’s clinical trial for the 25mcg COVID-19 vaccine dose did not identify safety concerns for use in young children, nor did they find any cases of myocarditis or pericarditis, although the sample size of the study may have been too small to find any uncommon adverse events. Within Moderna’s trial, there were two serious adverse events (a high fever 6 hours after the first dose followed by a febrile convulsion) in the same study participant that was attributed to the vaccine.

Per the United States’ [Centers for Disease Prevention and Control \(CDC\)](#), as of July 25, 2022 over 500,000 doses of COVID-19 vaccines (including both Moderna and Pfizer vaccines) have been given to children under the age of 5 in the United States. No safety signal has been identified through the CDC’s [ongoing vaccine safety monitoring](#) to-date.

- The risk of myocarditis and/or pericarditis following immunization with the 25mcg dose of Moderna Spikevax in children 6 months to 5 years of age is currently unknown. [Current data](#) suggest that the risk of myocarditis and/or pericarditis following an mRNA vaccine is lower in children 5 to 11 years of age than adolescents and young adults.
- [Common side effects](#) of the vaccine include localized redness, swelling, or pain, fever, irritability, sleepiness, loss or loss of appetite. Side effects are more common following the second dose. Symptoms generally resolve hours to days after the injection. No safety signals were identified during the Moderna trial.
- Adverse events following immunizations (AEFI) and adverse events of special interest (AESI) will continue to be monitored closely by Alberta through an enhanced surveillance system. Healthcare providers play an important role and mandated responsibility to report any AEFI or AESI. More information on this can be found [here](#).

## Pediatric doses of COVID-19 vaccine to children 6 months to under 5 years of age:

- A complete **two-dose** series of the Moderna Spikevax COVID-19 vaccine (25 mcg) may be offered to children 6 months of age to under 5 years who do not have contraindications to the vaccine.
- A complete **three-dose** series of the vaccine (25 mcg) may be offered to **moderately to severely immunocompromised** children 6 months of age to 4 years who do not have contraindications to the vaccine.

Some populations have suboptimal immune response to vaccines, putting them at increased risk for severe outcomes from COVID-19.

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- Alberta will be offering a three-dose series to those with the following conditions:
  - Recipients of chimeric antigen receptor (CAR)-T-cell therapy
  - Individuals with moderate to severe primary immunodeficiency (for example, DiGeorge syndrome, Wiskott-Aldrich syndrome)
  - HIV-infected individuals without viral suppression, or those with acquired immunodeficiency syndrome (AIDS)
  - Recipients of immunosuppressive therapies (for example, anti-B cell therapies, high-dose systemic corticosteroids, alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents)
  - Transplant recipients, including solid organ and hematopoietic stem cell transplants
  - Individuals with chronic kidney disease receiving regular dialysis
  - Recipients of active cancer treatment (chemotherapy, immunotherapy or targeted therapies), excluding those receiving only hormonal therapy, radiation therapy or surgery
  - Individuals taking certain medications for autoimmune diseases including rituximab, ocrelizumab, ofatumumab and methotrexate.

## Dose interval

### Recommendation:

For a two-dose series, it is recommended that the second dose be given 8 weeks after the first dose.

For a three-dose series, it is recommended that the second dose be given 28 days after the first, and the third dose 8 weeks after the second.

### Evidence and rationale for dose interval:

- There is no direct evidence for an optimal dosing interval for pediatric vaccines; however, evidence from older populations suggests that extending the dosing interval may lead to greater and longer-lasting protection.
- In alignment with NACI, Alberta recommends a dosing interval of at least 8 weeks between first and second doses to optimize immune response.

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There is a need to balance risk based on local transmission patterns of COVID-19, the degree of individual exposure, and the need of a second dose for earlier protection. A shortened interval may be considered in certain situations. For example: upcoming travel, increased levels of local transmission or high risk of exposure.

- The optimal dosing interval for immunocompromised children is unknown. As recommended by the AACI, a dose interval of 28 days between the first and second dose, and 8 weeks between the second and third dose is recommended. However, it is also recommended to discuss with the child's clinician regarding the timing of immunization based on the unique circumstances of each child.

### Clinical considerations for administering a pediatric vaccine in eligible populations

- Although not required, parents or guardians of eligible children may wish to consult with their healthcare provider about any advantages or disadvantages of receiving a vaccine.
- Children aged 6 months to less than 5 years with a history of previous COVID-19 infection (confirmed by PCR or antigen testing from a respiratory specimen) may be immunized according to the NACI's guidance on intervals between infection and COVID-19 immunization.

A period of 8 weeks between infection and initiation or completion of a COVID-19 primary series is recommended for immunocompetent children.

The recommended period between infection and a vaccine dose in the primary series is 4-8 weeks for immunocompromised children.

If a child has not received an initial dose of a COVID-19 vaccine, and have developed an infection, the parents or guardians may choose to vaccinate their child earlier than the above recommended period as long as the child is no longer considered to be infectious and 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 it has been  $\geq 90$  days since diagnosis, whichever is longer.
- As a precautionary measure, Alberta Health recommends that the parents or guardians of children who experienced myocarditis after any dose of an mRNA vaccine should discuss subsequent dose with their clinician. In general, they are advised to defer receiving an additional dose until more data is available.

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- Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of an mRNA COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.
- In general, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis that is unrelated to COVID-19 mRNA vaccines.
- The pediatric dosing of mRNA COVID-19 vaccines is based on the age of the children at presentation, and not on weight.
- Serologic testing or cellular immunity testing to assess immune response and guide clinical care are not recommended at this time.
- Consistent with NACI guidelines, Alberta recommends that the Moderna Spikevax vaccine for children not be routinely co-administered with other vaccines at this time (either live, inactivated, adjuvant, or unadjuvanted). In the absence of evidence, it is prudent to wait for a period of 14 days before or after the administration of another vaccine, if it does not create a barrier to receipt of vaccines. This is to prevent misattribution of an AEFI or AESI to one vaccine or another.

Co-administration or a shortened interval between COVID-19 vaccines and others may occur in some circumstances at the clinical discretion of a healthcare provider.

## Booking a pediatric appointment for children 6 months to under 5 years of age:

### All eligible populations

- Vaccines for children aged 6 months to under 5 years will be available only at AHS sites and not at pharmacy locations.
- Parents or guardians of eligible individuals can now book appointments to receive a booster dose of vaccine by calling 811 or [booking online](#).
- Parents or guardians of First Nations children book a dose of the vaccine at an on-reserve public health clinic or by calling 811 or [booking online](#).
- Parental or guardian consent is required for children to get the vaccine. This can be done in-person at the vaccine appointment or by a signed consent form.

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