COVID-19 Vaccines Information Sheet: Children ages six months to under five years

Key Information

Considerations for vaccination for children ages six months to under five years

How to book an appointment

General Questions

- 1. Why should my child get the COVID-19 vaccine? Aren't COVID-19 symptoms milder for children?
- 2. Will the COVID-19 vaccine interfere with getting other vaccines?

 Additional information for healthcare providers

Dosages and Intervals

- 3. How long should I wait between my child's first and second doses of the COVID-19 vaccine?
- 4. My child had COVID-19. Should they still get vaccinated? How long should they wait to get the vaccine?
- 5. Will children aged six months to under five years receive the same dose of the vaccine as children aged five to 11 years?
- 6. My child is four years old and received Moderna for their first dose. They have turned five and are due for their second dose. Should they receive Pfizer or Moderna?
- 7. My child is four years old and received Pfizer 10mcg and is still four years old. Can they have Pfizer 10mcg for their second dose?

Vaccine Effectiveness and Recommendations

- 8. <u>Is vaccination for children aged six months to under five years being strongly recommended?</u>
- How effective is the Moderna vaccine for children aged six months to under five? Should I wait for Pfizer for my children?
 Additional information for healthcare providers
- 10. For parents and caregivers that have recently received their booster and have children that are currently breastfeeding, is there any concern about interference with the child's vaccine effectiveness?

Vaccine Safety

- 11. Will my child experience side effects or reactions?
- 12. <u>Have the long-term side effects of the COVID-19 vaccine for children been</u> determined?
- 13. Are vaccines safe for children who are immunocompromised or have medical conditions?
- 14. <u>Has the COVID-19 vaccine been thoroughly tested for children? How do I</u> know it is safe?
- 15. What is the risk of myocarditis and/or pericarditis in children aged six months to under five years?

Additional information for healthcare providers

<u>Additional Resources</u>

- 16. I'm seeing a lot of vaccine hesitancy in my patient population. Where can I go for resources to support these conversations?
- 17. My patient's vaccine hesitancy is persistent. Where can I refer them for additional support?

COVID-19 vaccination and your practice

Billing

- 18. How do I bill for a COVID-19 vaccine given in my office?
- 19. Can I bill for counselling patients about the COVID-19 vaccine?

COVaxon

- 20. How do I access COVAX_{ON} (the provincial vaccine database)?
- 21. I've heard COVaxon is difficult to use are there resources that I can go to for help?

Supply and Wastage

- 22. How do I order vaccine supply?
- 23. How does the vaccine need to be stored?
- 24. What should I do if I must waste doses of the vaccine?

Key Information

As of July 28, children aged six months to under five years are eligible to receive the Moderna COVID-19 vaccine.

The Moderna COVID-19 vaccine is a two-dose primary series administered at a recommended interval of eight weeks, or at a minimum interval of 28 days between the first and second doses.

Considerations for vaccination for children ages six months to under five years:

While most children who get infected with COVID-19 typically experience mild symptoms or are asymptomatic, some children can get very sick and require hospitalization. Clinical trial data showed that the Moderna COVID-19 vaccine was well tolerated in children six months to five years of age. Additionally, vaccination in this age group will be important to protect them, their families and their communities against severe outcomes from COVID-19, this fall as children go back to school and we enter respiratory virus season.

Children with underlying medical conditions are strongly encouraged to complete the two dose primary series. If the child is immunocompromised, they should complete a three dose primary series.

Additionally, the following factors may be taken into consideration when discussing vaccination with parents or caregivers:

Personal circumstances, such as high-risk exposure or upcoming travel
 Some known health conditions/syndromes that may put one at greater risk for severe disease or outcomes from COVID-19 including:

 being moderately to severely immunocompromised

 having a high-risk medical condition: e.g. those with cardiac or pulmonary disorders, diabetes mellitus and other metabolic diseases, cancer, immune compromising conditions (due to underlying disease, therapy, or both, such as solid organ transplant or hematopoietic stem cell transplant recipients), renal disease, anemia or hemoglobinopathy, neurologic or neurodevelopmental conditions, Class 3 obesity (BMI of 40 and over)
 living with someone at higher risk

□ routine immunization schedules.

How to book an appointment:

First and second dose appointments can be booked <u>through all vaccine channels</u>, including:

- at <u>participating pharmacies</u>
- through the provincial COVID-19 vaccination portal (Ontario.ca/bookvaccine)
- by calling the Provincial Vaccine Contact Centre at <u>1-833-943-3900</u> (TTY for people who are deaf, hearing-impaired or speech-impaired: 1-866-797-0007)
- directly through <u>public health units</u>
- through Indigenous-led vaccination clinics
- at select primary care settings
- at hospital clinics (visit your local hospital or public health unit for booking details, if available in your region)
- through mobile or pop-up clinics (visit your local public health unit website for details, if available in your region)

Public health units may also offer additional options for vaccination of children aged six months to under five years old, such as walk-in clinics, which will not be on the provincial COVID-19 vaccination portal. For information on local options, please visit your local public health unit website.

General Questions

1. Why should my child get the COVID-19 vaccine? Aren't COVID-19 symptoms milder for children?

Vaccination remains one of the most effective ways children, including those aged six months to under five years can protect themselves, their families and their communities against severe outcomes from COVID-19.

While children who get infected with COVID-19 typically experience mild symptoms, some can get very sick, resulting in hospitalization, ICU admission or even death. Others can experience serious and longer-lasting symptoms (i.e. multi-inflammatory syndrome/MIS-C, long COVID-19, post-acute COVID-19 syndrome). This is especially true for children who are immunocompromised or have underlying health conditions.

The COVID-19 vaccine will help your child fight off the virus more easily if they are infected and may help make their symptoms milder. It also provides further protection to their family members, especially if they have family members who are at risk for more severe illness.

2. Will the COVID-19 vaccine interfere with getting other vaccines?

Children between six months and under five years should book 14 days before or after the administration of another vaccine before getting their COVID-19 vaccine. It is important to discuss the best timing and approach for COVID-19 vaccination while also ensuring that routine immunizations are up to date.

Additional information for healthcare providers:

Routine vaccination is an essential preventive care service for children, that **should not be delayed**. As a result of the COVID-19 pandemic, many children in Canada have missed routine immunizations. It is important to assess the vaccination status of children at each patient visit to avoid missed opportunities for vaccinations and ensure timely vaccine catch-up. All vaccines due or overdue should be administered according to the Publicly Funded Immunization Schedule for Ontario.

Routine immunizations should be prioritized and not be delayed in lieu of a COVID-19 vaccine. The National Advisory Committee on Immunization (NACI) recommends that children who are six months to five years should wait 14 days between (before or after) their routine immunizations to receive their COVID-19 vaccine. This is a precautionary recommendation in order to enable more accurate vaccine safety surveillance of this new product and to help prevent erroneous attribution of an adverse event to one particular vaccine or the other.

NACI has acknowledged that it can be challenging for health care providers (HCPs) and parents when multiple immunization visits are required and that concurrent vaccine administration or a shortened interval between vaccines may be warranted on an individual basis, in some circumstances, at the clinical discretion of the HCP.

Dosages and Intervals

3. How long should I wait between my child's first and second doses of the COVID-19 vaccine?

Children aged six months to under five years may receive a Moderna COVID-19 vaccine in a two-dose primary series at a recommended interval of eight weeks, or at a minimum interval of 28 days between the first and second doses.

To provide the strongest possible protection, the National Advisory Committee on Immunization (NACI) recommends waiting eight weeks (56 days) between the first and second dose. This is based on evidence that suggests longer intervals between doses results in a stronger immune response and higher vaccine effectiveness that is expected to last longer. It is possible to book the second dose sooner, by providing

informed consent and calling the Provincial Vaccine Contact Centre at 1-833-943-3900.

Children who are moderately to severely immunocompromised are recommended to get a third dose of the COVID-19 vaccine eight weeks (56 days), or at a minimum of 28 days, after their second dose as part of an extended primary series. Parents of children who are taking immunosuppressive medications should consult with their child's treating provider around optimal timing of vaccination.

4. My child had COVID-19. Should they still get vaccinated? How long should they wait to get the vaccine?

If a child has already had COVID-19, they should still be vaccinated for protection against severe outcomes.

While a previous COVID-19 infection provides some immunity, it is unclear how long that immunity lasts, and individuals may be reinfected. Evidence shows that vaccination combined with infection provides stronger and longer-lasting protection from COVID-19 than infection alone. With the spread of new and transmissible variants, it is important that everyone gets vaccinated to protect themselves and those around them from serious illness, hospitalization and death.

Children and youth who have had COVID-19 are recommended to wait eight weeks after symptom onset or positive test (if they had no symptoms) before beginning or continuing their vaccine series. This interval may be shortened to four weeks for children who are moderately to severely immunocompromised. Although they are able receive a COVID-19 vaccine as soon as they are asymptomatic, longer intervals between infection and vaccination may result in a better immune response.

5. Will children aged six months to under five years receive the same dose of the vaccine as children aged five to 11 years?

The dose volume varies depending on age and product.

- For the Moderna COVID-19 vaccine:
 - Children aged six months to five years: 25 mcg
 - Children aged six to 11 years: 50 mcg
 - Youth aged 12 years and over: 100 mcg.
- For the Pfizer COVID-19 vaccine:
 - Children aged five to 11 years: 10 mcg
 - Youth aged 12 years and older: 30 mcg.

Our immune systems weaken with age, so younger children are able to develop the same protection from COVID-19 from a smaller dose than older children and adults.

6. My child is four years old and received Moderna for their first dose. They have turned five and are due for their second dose. Should they receive Pfizer or Moderna?

The same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a primary series started with a specific mRNA COVID-19 vaccine. Children who have received a Moderna (25 mcg) dose and turn five years old prior to completing their primary series are recommended to receive Moderna (25 mcg) to complete their primary series. With informed consent from parents or caregivers, children who turn five prior to completing their primary series can receive the Pfizer vaccine.

7. My child is four years old and received Pfizer 10mcg and is still four years old. Can they have Pfizer 10mcg for their second dose?

No. Pfizer is not currently authorized by Health Canada for four-year-olds. No child under the age of five may receive Pfizer until it is authorized by Health Canada for use in this age group. Pfizer is only authorized for use in children aged five and older.

Vaccine Effectiveness and Recommendations

8. Is vaccination for children aged six months to under five years being strongly recommended?

Vaccination remains one of the most effective ways children, including those aged six months to under five years can protect themselves, their families and their communities against severe outcomes from COVID-19.

Given that this age group is also recommended to receive other vaccines to protect against diseases such as diphtheria, tetanus, pertussis, polio, measles, mumps, rubella and varicella, it is recommended to discuss optimal timing and approach for COVID-19 vaccination for children aged six months to under five years with parents and caregivers.

Children who are immunocompromised or have other significant underlying medical conditions are strongly recommended to complete the primary series.

If parents and caregivers have more questions about vaccine safety and the benefits of vaccination, they can contact the SickKids COVID-19 Vaccine Consult Service to book a confidential phone appointment with a SickKids paediatric Registered Nurse through sickkids.ca/vaccineconsult, or call 1-888-304-6558. This service is available in multiple languages using over-the-phone language interpretation.

9. How effective is the Moderna vaccine for children aged six months to under five? Should I wait for Pfizer for my children?

Vaccination remains one of the most effective ways children, including those aged six months to under five years can protect themselves, their families and their communities against severe outcomes from COVID-19. Although the majority of children who get infected with COVID-19 have mild symptoms or are asymptomatic; some children can get very sick and require hospitalization. For parents and caregivers who want to vaccinate their child now, the Moderna COVID-19 vaccine is currently available for children aged six months to under five years old.

The authorization of the Pfizer COVID-19 vaccine for children aged six months to under five years old is under review by Health Canada pending safety and efficacy trials, and there is currently no set date for when the Pfizer vaccine will be authorized. The Pfizer COVID-19 vaccine is currently authorized for use in the United States and requires three doses to complete the primary series.

Health Canada has one of the most rigorous scientific review systems in the world and only approves a vaccine if it is safe, works and meets the highest manufacturing and quality standards. After a thorough and independent scientific review of the evidence, Health Canada determined that the authorized Moderna COVID-19 vaccine is safe and effective at providing a strong immune response against COVID-19 in children.

We are expecting the efficacy of the Pfizer and Moderna vaccines to be similar, based on previous evidence for how effective the vaccines were in adults.

Additional information for healthcare providers:

On clinical trial data:

Based on Phase 2/3 clinical trial data, the humoral (antibody) immune responses generated by the vaccine met non-inferiority criteria in children aged six months to five years compared to young adults, suggesting it worked at least as well in children as in young adults. The vaccine was well tolerated with no safety signals reported. Reactogenicity was consistent with other recommended vaccines in this age group.

Although the clinical trial is still ongoing, early results have shown that efficacy against confirmed symptomatic SARS-CoV-2 infection starting 14 days post second dose was estimated at 50.6% among study participants aged six – 23 months and 36.8% among participants aged two to five years old. Efficacy against asymptomatic SARS-CoV-2 infection at 14 days post second dose, was estimated at 3.8% among those six-23 months and 22.9% among those two to five years old. Real world evidence suggests

mRNA vaccines in older age groups have high vaccine effectiveness at preventing severe outcomes of COVID-19 including hospitalization and death.

On risks for unvaccinated children:

Population level estimates of hospitalization and ICU admission in pediatric populations have increased since Omicron became the predominant variant. For children six months to four years of age, the average monthly rate of hospitalization due to COVID-19 increased from 1.4 to 15.9 per 100,000, comparing March 1, 2020 - December 31, 2021, to January 1, 2022 – March 31, 2022 (Public Health Agency of Canada, 2022).

Children who have had COVID-19 are at risk of multisystem inflammatory syndrome in children (MIS-C), a rare but serious post-infection complication that generally requires acute care hospital admission.

While evidence is limited in children five years of age and younger, a COVID-19 infection may lead to post-COVID condition/post-acute COVID syndrome.

10. For parents and caregivers that have recently received their booster and have children that are currently breastfeeding, is there any concern about interference with the child's vaccine effectiveness?

Children aged six months and older are eligible for vaccination whether or not they are breastfed. Vaccinated individuals who are breastfeeding pass along antibodies in their breast milk. These antibodies from breast milk do not interfere with the immunity acquired from the vaccine, which will provide additional protection. There is no need to delay or time vaccination differently for either the breastfeeding parent or children 6 months or older.

Vaccine Safety

11. Will my child experience side effects or reactions?

Like any medication or vaccinations, the COVID-19 vaccine may cause side effects. However, these side effects are typically mild to moderate and on average do not last longer than three days. The most frequently reported short-term side effects for children following the COVID-19 vaccine include soreness, swelling or colour changes (for example red or purple) at the injection site, fatigue, headache, chills, muscle aches and loss of appetite. These side effects are part of their body's efforts to build immunity to COVID-19 following vaccination. Mild side effects and reactions will typically subside anywhere from a few hours to a few days after vaccination.

12. Have the long-term side effects of the COVID-19 vaccine for children been determined?

According to the clinical trials that supported Health Canada's authorization of the Moderna COVID-19 vaccine for children aged six months to under five years, children were monitored up to 103 days after receiving their first dose of vaccine and no safety signals were identified.

The benefits of getting vaccinated and being protected against COVID-19 far outweigh the risks of any side effects from the vaccine. COVID-19 infection may cause longer-lasting symptoms and health problems for some people, including children, which is why it is important that children get vaccinated as soon as possible.

13. Are vaccines safe for children who are immunocompromised or have medical conditions?

Health Canada has one of the most rigorous scientific review systems in the world and only approves a vaccine if it is safe, works and meets the highest manufacturing and quality standards. After a thorough and independent scientific review of the evidence, Health Canada determined that the authorized COVID-19 vaccine is safe and effective at providing a strong immune response against COVID-19 in children.

Generally, children with medical conditions should be vaccinated as soon as possible, since they are often at higher risk of becoming more ill if they are infected with COVID-19. Children who are moderately to severely immunocompromised require an extended three-dose primary series to provide sufficient protection based on a suboptimal or waning immune response to vaccines and increased risk of COVID-19 infection. These individuals are recommended to get a third dose of a COVID-19 vaccine eight weeks after their second dose to strengthen the protection against COVID-19 and its variants. We continue to monitor new data and follow the advice of the Chief Medical Officer of Health and the National Advisory Committee on Immunization (NACI).

14. Has the COVID-19 vaccine been thoroughly tested for children? How do I know it is safe?

Health Canada has one of the most rigorous scientific review systems in the world and only approves a vaccine if it is safe, works and meets the highest manufacturing and quality standards. After a thorough and independent scientific review of the evidence, Health Canada determined that the authorized COVID-19 vaccine is safe and effective at providing a strong immune response against COVID-19 in children.

According to the clinical trials that supported Health Canada's authorization of the Moderna vaccine for children aged six months to under five years, children were

monitored up to 103 days after receiving their first dose of vaccine and no safety signals were identified. This means that no serious side-effects developed as a result of being vaccinated.

15. What is the risk of myocarditis and/or pericarditis in children aged six months to under five years?

Myocarditis/pericarditis following COVID-19 mRNA vaccines remains a rare adverse event following immunization (AEFI), which is defined by the Canadian Immunization Guide as occurring at frequency of 0.01 per cent to less than 0.1 per cent. Myocarditis and pericarditis are more likely to occur after a COVID-19 infection than after COVID-19 vaccines.

Although the trial size was limited, there have been **no cases** of myocarditis and/or pericarditis reported in any participant during the Phase 2/3 clinical trial that included children six months through five years of age. Post-market vaccine safety in pediatric populations is closely monitored and signals of adverse events (AE) will be reviewed on an ongoing basis.

The National Advisory Committee on Immunization (NACI) continues to recommend vaccination with mRNA COVID-19 vaccines for all individuals aged six months and older since the vaccines are highly effective at preventing severe outcomes (i.e., hospitalization, death) from COVID-19. NACI also recommends that children and youth wait eight weeks between the first and second doses of the COVID-19 vaccine. This interval may be associated with a lower risk of myocarditis and/or pericarditis.

For more information on the risk of myocarditis and/or pericarditis parents and caregivers can go to COVID-19 vaccination for ages under five (aboutkidshealth.ca).

Additional information for healthcare providers:

As real-world evidence on the use of this vaccine is not available yet, and the clinical trial size was limited, the risk of any rare or very rare adverse event (AE), such as myocarditis and/or pericarditis is unknown at this time.

Canadian and international post-market safety surveillance data for other mRNA COVID-19 vaccines in older populations have reported the rare risk of myocarditis and/or pericarditis with mRNA vaccines, which varies by sex, age, interval between doses, vaccine dose, and vaccine product. Current data suggests the risk of myocarditis and/or pericarditis in younger children is lower than that of adolescents or young adults.

Additional Resources

16. I'm seeing a lot of vaccine hesitancy in my patient population. Where can I go for resources to support these conversations?

The Ministry of Health has a dedicated webpage Ontario.ca/covidvaccinekids with resources related to vaccinating children and youth.

The Public Health Agency of Canada also prepared a <u>Vaccine Confidence Info Bulletin</u>, which includes information on the Moderna COVID-19 vaccine in children six months to under five years of age, practical vaccine administration information, key reminders prior to and for vaccination, managing pain for a positive vaccination experience, anxiety-related adverse events and anaphylaxis following vaccination.

The Centre for Effective Practice also developed the <u>PrOTCT Framework</u> to use when discussing COVID-19 with parents and caregivers.

Another resource is the <u>COVID-19 vaccine for children aged 6 months to under 5 years</u> developed by the Ontario College of Family Physicians.

SickKids has also developed the <u>COVID-19 vaccination for ages under five</u> (<u>aboutkidshealth.ca</u>) document, which helps to answer questions that parents and caregivers may have regarding vaccination.

17. My patient's vaccine hesitancy is persistent. Where can I refer them for additional support?

Visit Ontario.ca/covidvaccinekids to learn more about COVID-19 vaccines for children and youth.

You can refer your patients to the Provincial Vaccine Contact Centre to speak to an experienced agent or health specialist at 1-833-943-3900 (TTY for people who are deaf, hearing-impaired or speech-impaired: 1-866-797-0007), available in more than 300 languages, seven days a week from 8:00 a.m. to 8:00 p.m.

In addition, patients can book a confidential phone appointment with the SickKids COVID-19 Vaccine Consult Service. No referral is necessary, and the service is available to all residents of Ontario. The consult service provides expert guidance for children, youth and those who are pregnant, breastfeeding, or planning to conceive. Patients can book an appointment with a SickKids Registered Nurse online at sickkids.ca/vaccineconsult, or by calling toll-free 1-888-304-6558. This service is available in multiple languages using over-the-phone language interpretation.

COVID-19 vaccination and your practice

Billing

18. How do I bill for a COVID-19 vaccine given in my office?

Physicians administering COVID-19 vaccines in settings that are **not** designated by the ministry as COVID-19 Assessment Centres are eligible to claim G593A as described in OHIP INFOBulletin 211201.

G593A is eligible for payment to the billing physician if they have personally rendered the COVID-19 immunization service, OR, if they have delegated the service in accordance with the payment rules and conditions described at pages GP62 and GP63 of the Schedule of Benefits for Physician Services.

In scenarios where the patient's sole reason for the visit is to obtain the COVID-19 vaccine, G700 (or Q593 in blended models) is also eligible for payment.

In scenarios where the patient has attended the visit to obtain an insured service in addition to the vaccine, G593 is payable for the vaccination service in addition to the other applicable fee codes (assuming all Schedule of Benefits requirements have been met).

19. Can I bill for counselling patients about the COVID-19 vaccine?

When a medically necessary counselling service is rendered that meets the payment requirements described within Schedule of Benefits, the applicable fee code may be claimed (e.g. K013).

The provision of routine information about the COVID-19 vaccine does not constitute a separately payable counselling service and is included in the vaccination service.

COVaxon

20. How do I access to COVAXoN (the provincial vaccine database)?

OntarioMD has been retained by the Ministry of Health to train, onboard and help set up primary care providers and teams on COVaxoN. Any primary care provider that requests COVaxoN help can contact the OntarioMD support email at covaxon.support@ontariomd.com.

21. I've heard COVaxON is difficult to use – are there resources that I can go to for help?

Any primary care provider that requests COVax_{ON} help can contact the Ontario_{MD} support email at covaxon.support@ontariomd.com. Ontario_{MD} will provide support as required.

Supply and Wastage

22. How do I order vaccine supply?

Each local public health unit has a supply of royal blue cap Moderna for their region's eligible population. If you are interested in receiving and administering to this age group, please reach out to your local public health unit.

23. How does the vaccine need to be stored?

Thawed, unpunctured vials may be stored in the refrigerator between +2°C to +8°C for up to 30 days prior to first use. Vials may be stored between +8°C to +25°C for up to 24 hours. During storage, protect vials from light. Do not refreeze thawed vials.

After the first dose has been withdrawn from, a thawed vial should be held between +2°C to 25°C for a maximum of 24 hours. Vaccine may be stored in a syringe or vial for a maximum of 24 hours.

For more information please see the <u>General COVID-19</u>: <u>Vaccine Storage and Handling Guidance</u> document.

24. What should I do if I must waste doses of the vaccine?

It remains important to limit expiry of closed vials through proper inventory management and storage and handling, including fridge monitoring (e.g., temperature logs), stock rotation based on expiry and "must use by" dating, and recommended packing and transport per product specifications.

Royal Blue cap Moderna should be reserved for children six months to four years old. However, if a punctured vial contains remaining doses that would otherwise be wasted, one or more adult booster doses can be drawn from the vial to avoid or reduce wastage.