Ontario

Ministry of Health

Health Care Provider Fact Sheet: COVID-19 Vaccine

This fact sheet provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice. This document can be used as a reference for vaccine administrators to support COVID-19 immunization. Complementary resources include the vaccine product monographs, the COVID-19: Vaccine Storage and Handling Guidance and the COVID-19 Vaccine: Canadian Immunization Guide.

Ontario's COVID-19 vaccine program

Ontario's COVID-19 vaccine program aims to ensure as many Ontarians are protected against COVID-19 disease, including severe outcomes such as hospitalization and death.

At this time, the evolutionary trajectory of SARS-CoV-2 and seasonality of COVID-19 has not been established. However, based on previous years and consistent with other respiratory viruses, a surge in COVID-19 activity is expected during the fall and winter months.

Over the past several years, the National Advisory Committee on Immunization (NACI) has recommended individuals receive a recently updated COVID-19 vaccine in the fall, when increased activity of respiratory viruses is observed. Receiving an updated vaccine is expected to offer additional protection against SARS-CoV-2 infection and severe COVID-19 disease since the strain(s) in the updated vaccines are likely to be more closely related to circulating strains, and the additional dose is expected to increase the immune response that has waned over time.

Recommended high-risk and priority populations for COVID-19 immunization (as soon as vaccine becomes available)

COVID-19 vaccination is strongly recommended for previously vaccinated and unvaccinated individuals who are at increased risk of SARS-CoV-2 infection or severe illness due to COVID-19 should be prioritized to receive the COVID-19 vaccine as soon as vaccine becomes available this fall:

- Adults 65 years of age or older
- Individuals 6 months of age and older who are/have:
    - Residents of long-term care homes and other congregate living settings
    - Pregnant
    - From First Nations, Métis and Inuit communities

- Members of racialized and other equity-deserving communities
- Underlying medical conditions that places them at higher risk of severe COVID-19, including children with complex health needs

To optimize co-administration with influenza vaccine, children 6 months to 4 years of age, staff and care providers of long-term care homes and other congregate living settings, health care workers, first responders, individuals with significant exposure to birds and mammals (such as poultry, livestock, slaughterhouse and processing plant workers, wildlife officers/researchers, and veterinarians) should also be prioritized to receive COVID-19 and influenza vaccines as soon as vaccine becomes available this fall.

Recommended populations for COVID-19 immunization (starting Oct. 28, 2024)

Starting October 28, 2024, all other previously vaccinated and unvaccinated individuals (6 months of age and older) who are not at increased risk of SARS-CoV-2 infection or severe illness from COVID-19 (i.e., not listed above), are recommended to and may receive COVID-19 vaccine. Of note, people who provide essential community services are particularly recommended to receive COVID-19 vaccine.

COVID-19 vaccines available for fall 2024

NACI recommends that only vaccines containing the latest selected strain should be used in fall 2024. Ontario will have two mRNA COVID-19 vaccines for the 2024/2025 season, Moderna and Pfizer, both targeting the Omicron KP.2 variant. Moderna will be the vaccine available for children 6 months to 11 years of age.

The updated protein subunit COVID-19 vaccine, Novavax will not be available in Ontario for the 2024/2025 season. Individuals who are unable to receive an mRNA vaccine, should speak with their health care provider about treatment options, including the use of Paxlovid, to reduce the duration and severity of illness. Please see Table 1: COVID-19 Vaccine Product Characteristics Available for fall 2024 in the Appendices.

Vaccine preparation and administration

See the individual vaccine product monographs for step-by-step directions on administration and expiry dates. To ensure the correct volume is accurately drawn up, refer to Table 1 in the Publicly Funded Immunization Schedules for Ontario for assistance in selecting appropriate needle length and gauge.

For the most up to date information on vaccine storage and handling, stability and disposal refer to the COVID-19: Vaccine Storage and Handling Guidance.

COVID-19 immunization schedules

For detailed schedules please refer to Table 2: Immunization schedule for unvaccinated individuals and Table 3: Immunization schedule for previously vaccinated individuals in the Appendices.

Primary series schedule for children 6 months to 4 years of age

Two (2) doses of Moderna or 3 doses of Pfizer are recommended, with an 8-week interval between doses for those who are not immunocompromised. An additional dose is recommended for individuals who are moderately to severely immunocompromised, with an interval of 4 to 8 weeks between each dose. If both Pfizer and Moderna were used in the same primary series, the total number of doses in the series should follow the Pfizer schedule.

Children who started the primary series at less than 5 years of age and turn 5 years of age before completing the series, should complete the series as follows:

- Non-immunocompromised: 1 dose of KP.2 vaccine
- Moderately to severely immunocompromised: so that the total number of COVID-19 doses received is 3 doses for Moderna, or 4 doses for Pfizer (or a mixed schedule which includes Pfizer).

Primary series schedule for individuals 5 years of age and over

One (1) dose of COVID-19 vaccine is recommended for those not previously vaccinated who are not immunocompromised. For individuals who are moderately to severely immunocompromised, 2 doses of COVID-19 vaccine are recommended for the primary series and a third dose may also be offered, with an interval of 4 to 8 weeks between the doses. Healthcare providers can use clinical discretion to determine the potential benefit of a third dose.

New hematopoietic stem cell transplantation (HSCT) recipients and chimeric antigen receptor (CAR) T cell therapy are considered immunologically naïve and should be vaccinated with 3 doses beginning at 3 to 6 months post-HSCT/CAR T-cell therapy, regardless of previous vaccination history, with 4 to 8 weeks between doses.

If a person 5 years of age and over started the primary series with a non-XBB/non-KP.2 vaccine (i.e., original monovalent, BA.1 bivalent or BA.4/5 bivalent) but did not complete the series, they should complete the primary series as follows:

- Not immunocompromised: 1 dose of KP.2 vaccine
- Moderately to severely immunocompromised: such that the total number of COVID-19 vaccine doses in the primary series are 3 doses.

Moderately to severely immunocompromised individuals

As indicated by NACI, the following individuals are considered to be moderately to severely immunocompromised and are recommended to receive additional dose(s) as detailed in the immunization schedules section above:

- Solid tumour or hematologic malignancies or treatments for these conditions.
- Solid-organ transplant and taking immunosuppressive therapy.
- Hematopoietic stem cell transplant (HSCT) (within 2 years of transplantation or taking immunosuppression therapy).
- Immunocompromise due to chimeric antigen receptor (CAR) T cell therapy targeting lymphocytes.
- Moderate to severe primary immunodeficiency with associated humoral and/or cell-mediated immunodeficiency or immune dysregulation.
- HIV with AIDS-defining illness or TB diagnosis in last 12 months before starting vaccine series, or severe immune compromise with CD4 < 200 cells/μL or CD4 <15%, or without HIV viral suppression.
- Recent treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids, alkylating agents, antimetabolites, or tumor-

necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive.

- Chronic kidney disease on dialysis.

Interchangeability of vaccines

The Moderna and Pfizer vaccines can be used interchangeably, provided that the vaccine is authorized for their age, to:

1. complete a primary series started with another product, and
2. as a subsequent dose in previously vaccinated individuals

When a KP.2 vaccine formulation is used to complete a primary series started with another COVID-19 vaccine formulation (either XBB or non-XBB), the previous dose should be counted, and the series does not need to be restarted.

Co-administration

The COVID-19 vaccines may be given at the same time with other vaccines, or at any time before or after other non-COVID-19 vaccines (live or non-live vaccines), including influenza vaccine, respiratory syncytial virus (RSV) vaccine and/or the RSV monoclonal antibody, Beyfortus.

If multiple injections are to be given at the same visit, separate limbs should be used if possible. Alternatively, the injections may be administered into the same muscle separated by at least 2.5 cm (1”). Different immunization equipment (needle and syringe) must be used for each vaccine.

Individuals with symptoms of COVID-19 or other infectious agents

In accordance with provincial guidance, individuals who have symptoms of COVID-19 or other infectious agents should self-isolate, including attending COVID-19 vaccine clinics, until the following criteria are met:

- Symptoms have been improving for at least 24 hours (or 48 hours if nausea, vomiting and/or diarrhea were present)
- No fever
- There has not been development of additional symptoms

These suggested waiting times are intended to minimize the risk of transmission of COVID-19 and other respiratory or gastrointestinal pathogens at an immunization venue and to enable monitoring for COVID-19 vaccine adverse events following immunization (AEFI) without potential confounding from symptoms of COVID-19 or other illnesses.

Contraindications, precautions & population-specific considerations

See the COVID-19 Vaccine: Canadian Immunization Guide’s section on Contraindications and Precautions for recommendations for individuals with several conditions including allergies, bleeding disorders, myocarditis and/or pericarditis following vaccination, Guillain-Barré syndrome (GBS), multisystem inflammatory syndrome in children or adults (MIS-C or MIS-A), and Bell’s palsy.

Pregnant or breastfeeding

Pregnant or breastfeeding women should receive a COVID-19 dose this fall to provide protection during pregnancy and to lower the risk of hospitalization for their newborn. COVID-19 vaccine may be offered at any stage of the pregnancy (i.e., in any trimester) and while breastfeeding. There have been no safety concerns with receiving a COVID-19 dose during pregnancy or lactation. Compared to non-pregnant women, SARS-CoV-2 infection in pregnancy is associated with increased risk of hospitalization. SARS-CoV-2 infection during pregnancy is also associated with an increased risk in the neonate of preterm birth and low birth weight.

In addition to protecting the pregnant women, the benefits of immunization during pregnancy for the fetus and infants have also been well-documented. Protective antibodies are transferred to the fetus transplacentally, resulting in increased protection for the infant during the early postnatal period when they are not yet eligible for vaccination.

Additional information for women who are pregnant and/or breastfeeding can be accessed at the Provincial Council for Maternal and Child Health's decision making tool, the Society of Obstetricians and Gynaecologists of Canada Statement on COVID-19 Vaccination in Pregnancy, and Canadian Immunization Guide.

Vaccine safety

COVID-19 vaccines authorized for use in Canada are safe and well tolerated. As with other vaccines, they must be authorized for use by the Canadian regulator, Health Canada, following review of a products safety and how well it works (e.g., clinical trial and other evidence).

Once a vaccine is authorized for use in Canada, provincial surveillance in Ontario and national surveillance coordinated by Health Canada and the Public Health Agency of Canada ensures ongoing monitoring of vaccine safety.

Adverse events

Many people who receive COVID-19 vaccine have no side effects or adverse events. For those that do, side effects are usual mild and last a few days.

The most common side effects from the COVID-19 vaccine are:

- Redness, swelling, and soreness at the injection site
- Headache
- Mild fever
- Chills
- Fatigue
- Joint pain
- Muscle aches

Life-threatening allergic (anaphylactic) reactions are very rare. If they do occur, it is typically within a few minutes to a few hours after receiving the vaccine. Please refer to the safety and adverse events section of the Canadian Immunization Guide (CIG) for

more information on rare and very rare adverse events following immunization (e.g., myocarditis/pericarditis, GBS).

Guidance on reporting adverse events following immunization (AEFI)

To ensure the ongoing safety of vaccines in Ontario, reporting AEFIs by physicians, nurses, pharmacists or other persons authorized to administer an immunizing agent is mandatory under the *Health Protection and Promotion Act.* Vaccine providers are asked to report AEFIs through local public health units using the Ontario AEFI Reporting Form.

Those administering vaccines should advise vaccine recipients or their parents/guardians to contact their health care provider if they experience an adverse event after vaccination.

Health care providers should report any event which may be related to receipt of a vaccine, as outlined in Public Health Ontario's AEFI Reporting fact sheet. Of particular importance are events which require medical consultation, or unusual or unexpected events. Submitting a report does not mean that the vaccine caused the event.

Some common or mild events do not need to be reported. These include:

- fever that is not accompanied by any other symptoms
- injection site reactions that last less than 4 days
- sudden drop in blood pressure and/or heart rate (without injury)
- events that are clearly attributed to other causes

Vaccine recipients should be advised to go to the nearest emergency department if severe reactions develop, including the following:

- Signs and symptoms of severe allergic reaction, including:
    - Hives
    - Swelling of the mouth or throat
    - Trouble breathing, hoarseness or wheezing.
- High fever (over 40°C or 104°F)
- Convulsions (seizures)
- Other serious reactions

COVID-19 vaccine errors and deviations

For guidance on managing COVID-19 vaccine administration errors and deviations, please see the Government of Canada's Planning guidance for immunization clinics for COVID-19 vaccines: Managing vaccine administration errors or deviations. For inadvertent immunization errors and deviations that are not addressed in the document linked above and/or that involve multiple errors or have additional complexity, health care providers are encouraged to contact their local public health unit or Public Health Ontario (at ivpd@oahpp.ca) for further advice.

The local public health unit should be notified, and vaccine administration errors or deviations should be handled and reported in accordance with both the site (if non-public health unit) and public health unit procedures.

If an inadvertent vaccine administration error or deviation results in an AEFI, complete Ontario's AEFI reporting form, including details of the error or deviation. See the guidance on reporting AEFI section above for additional information.

Observation period following vaccination

NACI recommends a 15-minute post-vaccination observation period, as specified in the CIG. If there is a specific concern about possible vaccine allergy, 30 minutes is a safer interval.

Record of immunization

All immunizations must be documented into COVaxON. Each vaccine recipient should be provided with an electronic immunization record. Vaccine recipients, or their parents or guardians, should be instructed to keep the record in a safe place.

Persons with inadequate immunization records

Individuals with incomplete or no immunization records, should be considered unimmunized and should receive COVID-19 vaccines on a schedule that is appropriate for their age and risk factors, regardless of possible previous immunization.

Additional information

Please visit the following websites or call your local public health unit:

a) Ontario Ministry of Health: COVID-19 vaccine program

b) National Advisory Committee on Immunization (NACI) Statement: Guidance on the use of COVID-19 vaccines during the fall of 2024

c) Canadian Immunization Guide: COVID-19 vaccine

d) Public Health Ontario: COVID-19 Health Care Resources

e) List of public health units: www.ontario.ca/page/public-health-unit-locations

Version française disponible en communiquant avec le 1-866-532-3161 ATS: 1-800 387-5559 (web site: www.ontario.ca/page/covid-19-vaccine-program)

Appendices

Table 1: COVID-19 Vaccine Product Characteristics Available for fall 2024

	COVID-19 Vaccines		
Vaccine name	Moderna		Pfizer
Brand name	Spikevax		Comirnaty
Protection against	Omicron KP.2 variant		Omicron KP.2 variant
Manufacturer	Moderna Biopharma Canada Corporation		BioNTech Manufacturing GmbH
Vaccine type	Monovalent COVID-19 mRNA*		Monovalent COVID-19 mRNA*
Age indication	6 months to 11 years	12 years and older	12 years of age and older
Dosage	0.25 mL/25 ug	0.5 mL/50 ug	0.3 mL/30 mcg
Route	Intramuscular (IM)		Intramuscular (IM)
Format	Multidose vial (MDV)		Multidose vial (MDV)
Vial volume	2.5 mL		1.8 mL
# of doses per vial	10 (0.25mL) doses 5 (0.5 mL) doses		6 doses
Unpunctured self life (thawed vials)	50 days at +2˚C to +8˚C 12 hours at +8˚C to +25˚C Do not refreeze thawed vials		10 weeks at +2˚C to +8˚C 12 hours at +8˚C to +25˚C Do not refreeze thawed vials
Post-puncture shelf life	24 hours at +2˚C to +8˚C 12 hours at +8˚C to +25˚C		12 hours at +2°C to +25°C
Package dimension	5.4 x 13.8 x 6.1 cm		3.7 x 4.7 x 8.9 cm
DIN	02541270		02541823
Product monograph	https://pdf.hres.ca/dpd_pm/00077065.PDF		https://pdf.hres.ca/dpd_pm/00077149.PDF

* Messenger ribonucleic acid (mRNA)

Table 2: Immunization schedule for unvaccinated individuals

Age at 1st dose	**Health status**	**# of doses recommended**	**Interval between doses**
6 months to 4 years	Not IC	2 doses	8 weeks
	IC	3 doses	4-8 weeks
≥5 years	Not IC	1 dose	N/A
	IC	2 doses^	4-8 weeks
	IC: HSCT recipient or CAR T cell therapyð	3 doses	4-8 weeks

IC - Immunocompromised

^ A third dose may also be offered. Healthcare providers can use clinical discretion to determine the potential benefit of a third dose.

ð 3 doses, regardless of previous vaccination history prior to transplant/treatment.

Table 3: Immunization schedule for previously vaccinated individuals

Current Age	Health status	Vaccination history	# of additional doses recommended	Interval between doses
6 months to 4 years	Not IC	1 dose Moderna**	1 dose	8 weeks
		1 dose Pfizer**	2 doses	8 weeks
		2 doses with ≥1 doses Pfizer**	1 dose	8 weeks
		2 doses both Moderna**	1 dose	6 months°
		≥3 doses, any product	1 dose	6 months°
	IC	1 dose Moderna**	2 doses	4-8 weeks
		1 dose Pfizer**	3 doses	4-8 weeks
		2 doses both Moderna**	1 dose	4-8 weeks
		2 doses with ≥1 doses Pfizer**	2 doses	4-8 weeks
		3 doses with ≥1 doses Pfizer**	1 dose	4-8 weeks
		3 doses all Moderna**	1 dose	6 months°
		≥4 doses, any product	1 dose	6 months°
≥5 years^	Not IC	≥1 dose, any product	1 dose	6 months°
	IC	1 dose XBB or KP.2	1 dose¥	4-8 weeks
		1 dose non-XBB/non-KP.2	2 doses¥	4-8 weeks
		2 doses with ≥1 doses non-XBB/non-KP.2	1 dose¥	4-8 weeks
		2 doses, XBB	1 dose	6 months°
		≥3 doses, any product	1 dose	6 months°
	IC: HSCT recipient or CAR T cell therapy	1 dose XBB or KP.2	2 doses	4-8 weeks
		2 doses XBB and/or KP.2	1 dose	4-8 weeks
		≥3 doses XBB	1 dose	6 months°

** KP.2, XBB and/or non-XBB/non-KP.2

¥ An additional dose may also be offered. Healthcare providers can use clinical discretion to determine the potential benefit of an additional dose.

^ Children who started the primary series at less than 5 years of age and turn 5 years of age before completing the series, should complete the primary series as follows:

- Not IC: 1 additional dose, 8-week interval between doses.
- IC: continue the primary series schedule that was initiated (i.e., continue schedule as if child is under 5 years of age).

° For previously vaccinated individuals the recommended interval is 6 months from the last COVID-19 vaccine dose, and a minimum of 3 months from the last dose may be used. This minimum interval of 3 months will ensure that those who received a spring 2024 dose (which includes those who are most at risk for severe disease) will be eligible for an updated fall 2024 dose. Individuals/immunizers may consider delaying COVID-19 immunization by 3 to 6 months in circumstances where recent test-confirmed SARS-CoV-2 infection is known for previously vaccinated individuals.