

Immunization Competencies for Nurses

*MODULE 3: CONTRAINDICATIONS AND SPECIAL
CONSIDERATIONS*

Module Outline

Contraindications

Precautions

Special Populations

Obtaining Consent

Resources

Contraindications

- ✓ The authorized COVID-19 vaccine is contraindicated in individuals with a history of anaphylaxis after previous administration of the vaccine.
- ✓ The vaccine is also contraindicated in persons with proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its packaging.
- ✓ Polyethylene glycol is a potential allergen in the Moderna and Pfizer-BioNTech COVID-19 vaccines known to cause type 1 hypersensitivity reactions.
- ✓ Guidance on situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccines is mentioned further in recommendations for special populations.

Precautions

- ✓ Patients who have a bleeding problem, bruise easily or use a blood-thinning medicine should receive the vaccine; the condition should be optimally managed prior to immunization to minimize the risk of bleeding.
- ✓ Individuals receiving long-term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized through the intramuscular route as recommended, without discontinuation of their anticoagulation therapy.
- ✓ There is some evidence to suggest that intramuscular administration may be safer when given with a small gauge needle (23 gauge or smaller) and when firm pressure is applied to the injection site for 5 to 10 minutes.
- ✓ Vaccination of individuals who may be currently infected with SARSCoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, in order to avoid attributing any complications resulting from infection with SARS-CoV-2 to vaccine related AEFI and to minimize the risk of COVID-19 transmission at an immunization clinic/venue.

Precautions Cont'd

- ✓ As a precautionary measure wait until all symptoms of an acute illness are completely resolved before vaccinating with an authorized COVID-19 vaccine.
- ✓ Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g. intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.
- ✓ Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g. foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination.
- ✓ Additional information on the use of COVID-19 vaccines is available in statements and publications by the National Advisory Committee on Immunization (NACI).
- ✓ For additional general information on precautions, contraindications, concerns refer to Part 2 Vaccine Safety in the Canadian Immunization Guide

Vaccination in Special Populations

- ✓ The following section contains recommendations based on current scientific knowledge based on COVID-19 vaccination for mentioned populations.
- ✓ Check regularly for updates on the Ontario Ministry of Health and Long-Term Care website guidance document "[COVID-19 Vaccination Recommendations for Special Populations](#)" as updates on COVID-19 disease and vaccines are evolving.
- ✓ Ontario Ministry of Health Long-Term Care Immunization document "[COVID-19 Vaccine-Pre-Screening Assessment Tool for Health Care Providers](#)" is to be used to assess patients prior to immunization.
- ✓ **In the event of any conflict between mentioned guidance documents and any orders or directives issued by the Minister of Health or the Chief Medical Officer of Health (CMOH), the order or directive prevails.**

Special Populations

Pregnancy

- ✓ All pregnant individuals in the authorized age group are eligible and recommended to be vaccinated as soon as possible, at any stage in pregnancy, as COVID-19 infection during pregnancy can be severe, and the benefits of vaccination outweigh the risks. Vaccination may be considered at any gestational age, including the first trimester. While pregnant individuals were not included in Phase III trials for COVID-19 vaccines, an mRNA vaccine is preferred due to published safety data.
- ✓ Counselling for pregnant individuals can include: (1) a review of the risks and benefits of receiving the vaccine, (2) a review of the potential risks /consequences associated with a COVID-19 infection during pregnancy, (3) a review of the local epidemiology and the risk of acquiring a COVID-19 infection during pregnancy and (4) an acknowledgment of the limited evidence for the use of current COVID-19 vaccines in the pregnant population.
- ✓ Tools to support decision making can be found on the Ministry of Health's website:
 - COVID-19 Vaccination: Special Populations - Vaccination in Pregnancy & Breastfeeding Decision-Making Support Tool for Health Care Providers
 - COVID-19 Vaccination: Special Populations - Vaccination in Pregnancy & Breastfeeding Decision-Making Tool for Pregnant Individuals.

Special Populations

Breastfeeding

- ✓ COVID-19 vaccines can also be safely given to breastfeeding individuals and recent data shows that mRNA from vaccines do not transfer into breast milk. Anti-COVID-19 antibodies produced by the breastfeeding person have been shown to transfer through the milk and provide protection to the infant. The vaccines are safe for the breastfeeding person and should be offered to those eligible for vaccination.

Special Populations

Autoimmune conditions/Immunocompromised patients (by disease/or treatment)

- ✓ Since all Health Canada authorized COVID-19 vaccines are not live vaccines, they are considered safe in these groups, however there is limited data on efficacy. Individuals who were immunocompromised due to disease or treatment were excluded from some of the Phase III trials for COVID-19 vaccines available at present and those with autoimmune conditions had very small representation.
- ✓ Individuals in the authorized age group with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment that are receiving stem cell therapy, CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g., rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors etc.) should be offered the vaccine. These individuals **are strongly encouraged to speak with their treating health care provider** regarding the timing of vaccination in relation to therapy for their underlying health condition and/or treatment modification in view of possible decreased vaccine effectiveness with the use of immunosuppressive therapy.
- ✓ All other individuals in the authorized age group with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment may choose to receive the vaccine. These individuals may choose to consult with their health care provider prior to vaccination (for example, to discuss immunosuppressive medication management/timing in relation to their vaccination).

Special Populations

Allergies

- ✓ Individuals who have had a severe allergic reaction or anaphylaxis to a previous dose of a COVID-19 mRNA vaccine or to any of its components should not receive the mRNA COVID-19 vaccine in a general vaccine clinic.
- ✓ **An urgent referral to an allergist/immunologist is recommended for these individuals. Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.**
- ✓ Individuals who have had an allergic reaction within 4 hours of receiving a previous dose of an mRNA COVID-19 vaccine or any of components of the mRNA COVID-19 vaccine should not receive either mRNA COVID-19 vaccine unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine. The components include polyethylene glycol and, due to potential cross-reactivity, polysorbate.

Special Populations

Allergies

- ✓ Documentation of the discussion with the allergist-immunologist must be provided to the clinic and include a vaccination care plan, confirm that appropriate counselling on the safe administration of vaccine was provided, and include the date, the clinician's name, signature and contact information as well as the individual's name and date of birth.
- ✓ Refer to Ontario Ministry of Health and Long-Term Care guidance document "COVID-19 Vaccination: Allergy Form" (March 11, 2021 or as current)
- ✓ In response to the COVID-19 vaccination roll out, the Ontario eConsult Centre or Excellence in partnership with Public Health, OMA, OntarioMD, Ontario Health and the MOH have created a COVID-19 – Allergy/Immunology BASE Managed Specialty Group. This group enables physicians and nurse practitioners to ask COVID-19 vaccine allergy related clinical questions to Allergy and Clinical Immunology specialists electronically and receive a response within days. The general COVID-19 infectious disease group continues to be available.
- ✓ If you would like to sign up for eConsult, visit: www.otnhub.ca

Special Populations

Allergies

- ✓ For individuals who have had an allergic reaction within 4 hours and/or anaphylaxis that occurred with a vaccine or injectable medication that **does not** contain a component or cross-reacting component of the mRNA COVID19 vaccines, the mRNA COVID-19 vaccine can be given with an extended observation post-vaccination of 30 minutes in the clinic.
- ✓ Individuals with a history of significant allergic reactions and/or anaphylaxis to any food, drug, venom, latex or other allergens not related to the mRNA COVID-19 vaccine can receive the COVID-19 vaccine followed by a 15-minute wait. Persons with allergy issues like allergic rhinitis, asthma and eczema can receive the vaccine followed by a 15-minute wait.

For additional information on allergies, consult the Canadian Society of Allergy and Clinical Immunology statement on COVID-19 vaccination.

Special Populations

Children and Adolescents

- ✓ The Pfizer vaccine is now licensed by Health Canada for adolescents aged 12 years and older. The Pfizer vaccine has been proven to be safe in clinical trials and provided excellent efficacy in adolescents. Side effects reported in adolescents were similar to those observed in adults and were more frequent after the second dose.
- ✓ Clinical trials of the Moderna COVID-19 vaccine, and Janssen COVID-19 vaccine are currently in progress in pediatric populations. **The Moderna, Janssen and AstraZeneca COVID-19 vaccines are not indicated for use for those under the age of 18 years.**
- ✓ For children less than 12 years of age, vaccination is not recommended at this time.

Special Populations

Children and Adolescents

✓ MOHLTC Vaccine-Relevant Information and Planning Resources

Youth Resources

Document Title	Description	Date
COVID-19 Vaccine Information Sheet: For Youth (Age 12-17)	Vaccine information for youth receiving the Pfizer BioNTech COVID-19 vaccine.	May 19, 2021
What Youth Need to Know About their Appointment	Provides information for youth on how to prepare for an upcoming COVID-19 vaccination appointment and what to do after receiving the vaccine.	May 19, 2021
COVID-19 Vaccine Youth (Age 12-17) Consent Form	A paper copy of the form used by health care providers to document consent from youth and/or their parent/legal guardian for the COVID-19 vaccination.	May 21, 2021

Special Populations

Vaccine Hesitancy

Document Title	Description	Date
CARD Summary	Summary of CARD system for HCP	June 18, 2021
CARD Improving the Vaccination Experience	Advice on using the CARD system for vaccination planning	June 18, 2021
School Vaccine Student Poster	Poster of strategies to aid vaccination	June 18, 2021
CARD Parent Pamphlet	Advice for parents to prepare children for vaccination	June 18, 2021
Needle Fears Resource	Strategies to reduce needle fear	June 18, 2021
School Vaccine Student Resource	Self-help tool used to support vaccination	June 18, 2021
Recommendations for Reducing Vaccine Pain in Adults	Infographic on reducing vaccine pain in adults	June 18, 2021

https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/covid19_vaccine.aspx

Obtaining Consent

- ✓ **General Immunization Documents for Patients** on the Ministry of Health and Long-Term Care website.

Document Title	Description	Date
COVID-19 Vaccine- Pre-Screening Assessment Tool for Health Care Providers	A pre-screening tool for health care providers administering any COVID-19 vaccine.	March 11, 2021
COVID-19 Vaccine Information for Individuals that received a first dose of the AstraZeneca COVID-19 vaccine/COVISHIELD vaccine	A supplemental document for patients who received a first dose of the AstraZeneca COVID-19 vaccine, to be reviewed before they receive a second dose of vaccine.	June 14, 2021
COVID-19 Vaccine Consent Form	Used by health care providers to obtain consent from patients for the COVID-19 vaccination. Documents in other languages	March 11, 2021
Consent for Collection of Sociodemographic Data	Used by health care providers to obtain consent from patients to support data collection on the vaccine roll-out. Documents in other languages	June 2, 2021

- ✓ Use the [Consent for Collection of Sociodemographic Data](#) form to collect data for the purposes of supporting the efficient, equitable and effective roll-out of the COVID-19 vaccine for communities that are at-risk and disproportionately impacted by the pandemic.

Resources

- ✓ COVID-19 Vaccine – [Pre-Screening Assessment Tool for Health Care Providers](#)
- ✓ Tool - *Pre-Screening Questions and Guidance: COVID-19 Vaccine Clinics*
- ✓ [COVID-19 Vaccination Recommendations for Special Populations](#)
- ✓ [COVID-19 Vaccination: Allergy Form](#)
- ✓ [Vaccination in Pregnancy & Breastfeeding Decision-Making Support Tool](#)
- ✓ [COVID-19 Vaccination in Pregnancy & Breastfeeding Patient Decision-Making Tool](#)

References

1. NACI recommendations
2. Moderna Product Monograph (June 9, 2021)
3. Pfizer-BioNTech Product Monograph (May 19, 2021)

Quiz

1. Polyethylene glycol is a potential allergen in the Moderna and Pfizer-BioNTech COVID-19 vaccines known to cause type 1 hypersensitivity reactions.

- A) True
- B) False

Quiz

2. The authorized COVID-19 vaccine is contraindicated in individuals with:

A) a history of anaphylaxis after previous administration of the vaccine.

B) proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its packaging.

C) a history of fainting after previous administration of the vaccine.

D) A and B

Quiz

3. Individuals who are pregnant or breastfeeding are not able to receive the COVID-19 vaccine.

- A) True
- B) False

Quiz

4. An urgent referral to an allergist/immunologist is recommended for individuals who have had a severe allergic reaction or anaphylaxis to a previous dose of a COVID-19 mRNA vaccine or to any of its components. Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.

- A) True
- B) False

Quiz

5. Children under the age of 12 are able to receive the Pfizer-BioNTech vaccine, as long as they have parental consent.

- A) True
- B) False

Quiz

6. Verbal confirmation of counselling received is required prior to vaccination of COVID-19 vaccines for:

- A) individuals who are pregnant
- B) autoimmune/immunocompromised persons
- C) individuals who are over the age of 65
- D) individuals who are breastfeeding
- E) no longer required but may be strongly encouraged for individuals on immunosuppressive therapies.

Quiz

7. Individuals who are on a blood thinner or have a blood clotting disorder, will need to be monitored following their vaccine for:

- A) 30 minutes
- B) 15 minutes
- C) 1 hour
- D) 45 minutes

Quiz

8. If an individual shows up to a COVID-19 vaccination clinic and screens positive for having symptoms, you should:

- A) go ahead and administer the vaccine but monitor for a longer period of time after vaccination.
- B) tell them they are no longer eligible to receive the COVID-19 vaccine, as they have already developed natural antibodies from having symptoms.
- C) not allow them entry to the clinic that day and advise them to book another appointment when their symptoms have resolved.
- D) None of the above.

Quiz

9. Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines should be monitored following vaccination for:

- A) 1 hour
- B) 30 minutes
- C) 15 minutes
- D) These individuals are not eligible to receive the vaccine at a community clinic.

Quiz

10. Informed consent is required for each individual receiving a COVID-19 vaccine.

- A) True
- B) False