

Immunization Competencies for Nurses

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MODULE 1: ABOUT THE COVID-19 VACCINES

Module Outline

Approved COVID-19 Vaccines

mRNA Vaccines

Non-replicating viral vector vaccines

Dosing Intervals

Vaccine Development

Resources

Approved COVID-19 Vaccines in Canada

- 1) Spikevax COVID-19 Vaccine (Moderna)
- 2) Comirnaty COVID19 Vaccine (Pfizer-BioNTech-30mcg)
- 3) Comirnaty COVID-19 Vaccine (Pediatric Pfizer-BioNTech-10mcg)
- 4) AstraZeneca/COVISHIELD COVID-19 Vaccine
- 5) Janssen (Johnson & Johnson) COVID-19 Vaccine

SPIKEVAX™ (Moderna)

✓ **Indications:**

- Spikevax (mRNA-1273 SARS-CoV-2 vaccine) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 12 years of age and older.

✓ **Contraindications:**

- COVID-19 Vaccine Spikevax is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container.

✓ **Primary Series Dose:**

- Spikevax is administered intramuscularly, as two 0.5 mL doses (100mcg), 4 weeks apart.

✓ **Booster Dose:**

- >3 months (84 days). Half the dose administered in primary series is given 0.25ml (50mcg) unless immunocompromised/ >70 y/o a 0.5ml (100mcg) dose is given.

✓ **# of Doses per Multi-dose Vial:**

- 10 doses (or max 20 (0.25ml) doses).

✓ **Dilution Required:**

- No

SPIKEVAX™ (Moderna)

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	Dispersion, (0.20 mg /mL) Elasomeran (mRNA), encoding the pre fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2) Multidose vial (5 mL)	<ul style="list-style-type: none">• Acetic acid• Cholesterol• DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine)• Lipid SM-102• PEG2000-DMG (1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol)• Sodium acetate trihydrate• Sucrose• Trometamol• Trometamol hydrochloride• Water for injection

Table 1: Dosage Forms, Strengths, Composition and Packaging; Product Monograph²

PRODUCT MONOGRAPH: A factual, scientific document on a drug product

COMIRNATY (Pfizer-BioNTech)

✓ **Indications:**

- Comirnaty COVID-19 Vaccine (COVID-19 mRNA Vaccine) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older.

✓ **Contraindications:**

- Comirnaty COVID-19 Vaccine is contraindicated in individuals who are hypersensitive to the active substance or to any ingredient in the formulation.

✓ **Primary Series Dose:**

12 years of age and Older: (purple cap) two doses (0.3ml) 3 weeks apart

Age 5 years to <12 years: (orange cap) two doses (0.2ml) 8 weeks apart (recommended)

Booster Dose:

- 18 years and older eligible for booster dose at 84 days (3 months) after a second dose.

✓ **# of Doses per Multi-dose Vial:**

- 6 doses (purple cap) once diluted
- 10 doses (orange cap) once diluted

✓ **Dilution Required:**

- Yes (0.9% Normal Saline)

COMIRNATY (Pfizer-BioNTech)

- o Check out the following Comirnaty link: www.CVDvaccine.ca for extensive education and reference materials on the vaccine for Canadian Health Care Professionals.
- o [Comirnaty Product Monograph](#)

AstraZeneca and COVISHIELD®

✓ **Considerations:**

As of May 11th ,2021, Ontario paused the rollout and administration of first doses.

- Individuals who received AstraZeneca/COVISHIELD as a first dose, a mRNA vaccine is preferred for the second dose.
- Currently, in Ontario, viral vector vaccines for second doses are only available to individuals with a contraindication to the mRNA vaccines as identified by an allergist/immunologist or specialist.

✓ **Contraindications:**

- AstraZeneca and COVISHIELD® COVID-19 Vaccines are contraindicated in individuals who are hypersensitive to the active substance or to any ingredient in the formulation.
- Patients who have experienced major venous and or arterial thrombosis with thrombocytopenia following vaccination with any vaccine. Including specifically CVST (cerebral venous sinus thrombosis) and HIT (heparin induced thrombocytopenia).

✓ **Dose:**

- The AstraZeneca and COVISHIELD® COVID-19 Vaccines have a vaccination course that consists of two separate doses of 0.5 mL each. The second dose should be administered between 4 and 12 weeks after the first dose.

✓ **# of Doses per Multi-dose Vial:**

- 8 or 10

✓ **Dilution Required:**

- No

Janssen (Johnson & Johnson)

Every effort should be made to immunize with an mRNA vaccine. The Janssen vaccine should only be used when an mRNA vaccine is declined and after informed consent.

Indications:

- Janssen COVID-19 Vaccine is indicated for active immunization for the prevention of coronavirus disease-2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years of age and older.

Contraindications:

- Janssen COVID-19 Vaccine is contraindicated in individuals who are hypersensitive to the active ingredient, any other adenovirus-based vaccines, or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Janssen COVID-19 Vaccine is contraindicated in individuals with a history of Capillary Leak Syndrome (CLS).

Janssen (Johnson & Johnson)

Dose:

- Janssen COVID-19 Vaccine should be administered intramuscularly, as a single dose of 0.5 mL.
- Individuals with moderate to severe immunosuppression are recommended to receive a mRNA vaccine at least 2 months (56 days) later.

of Doses per Multi-dose vial:

- 5 doses

Dilution:

- none

MOH Information Sheets

- [COVID-19 Vaccine Information Sheet \(age 12+\)](#)
 - [COVID-19 Vaccine Information Sheet: For Children \(age 5-11\)](#)
 - [Janssen COVID-19 Vaccine Information Sheet](#)
- Provides basic information for individuals to read, be informed, and have their questions answered by a HCP prior to receiving the vaccine.

What is a mRNA COVID-19 vaccine?

- Comirnaty and Spikevax are mRNA vaccines.
- mRNA is like a code that tells the cells in your body how to make a piece of the outer lining of the virus, for a short time. This piece of the virus cannot hurt you, but it is enough for your immune system to learn how to recognize and be ready to fight off the virus.
- The genetic instructions in molecules (mRNA) generate a coronavirus protein that initiates the body's natural production of antibodies and cellular immune response. mRNA vaccines are not live vaccines and cannot cause infection in the host. mRNA vaccines also cannot alter a person's DNA.

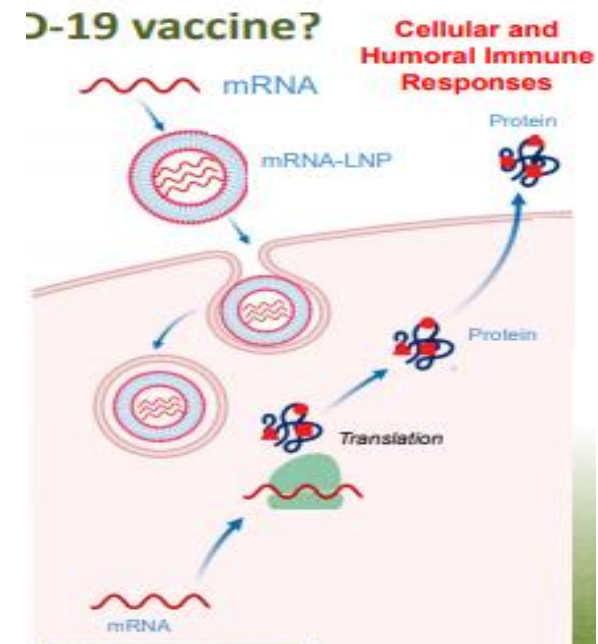


Image from NACI recommendations on use of Moderna COVID-19 vaccines presentation

How does mRNA vaccines work?

- mRNA lipid nanoparticles are made of two parts: mRNA and lipids.
- The lipids allow the mRNA to enter into the cell and the spike gene to be translated into protein.
- Lipids do not mix well with water so the mRNA lipid nanoparticle vaccines have special storage and handling requirements (i.e. no shaking).

[Mechanism of Action Video](#)

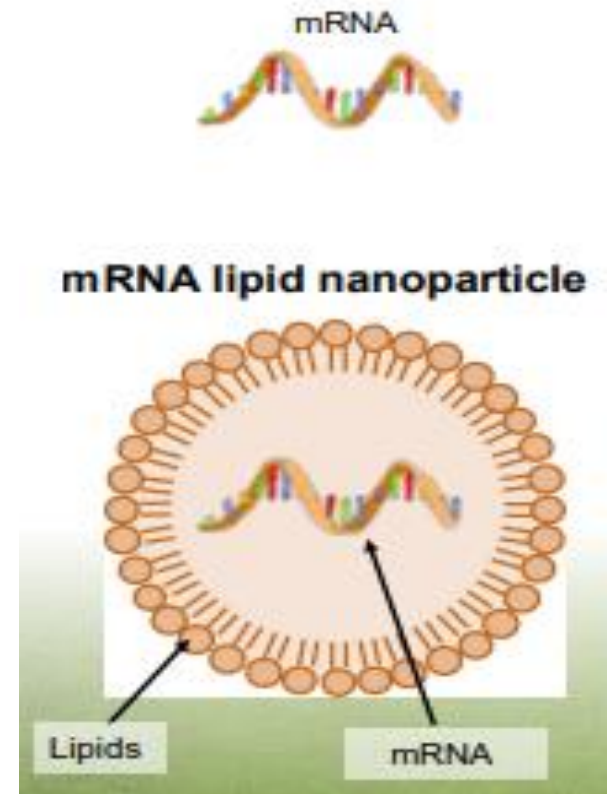


Image from NACI recommendations on use of Moderna COVID-19 vaccines presentation

What is a non-replicating viral vector COVID-19 vaccine?

- ✓ AstraZeneca/COVISHIELD, and Janssen (Johnson/Johnson) are non-replicating viral vector COVID-19 vaccines.
- ✓ A viral vector is a harmless, attenuated (weakened) virus that has been modified to act as a delivery system for transferring genetic instructions to our cells.
- ✓ Non-replicating (or replication-incompetent or replication-deficient) viral vector-based vaccines are genetically modified so that they are unable to produce new viral particles. The viral vector enters our cells where our cell machinery is used to produce viral antigen; once this is accomplished, the viral vector is cleared.

How does a non-replicating viral vector vaccine work?

- ✓ COVID-19 vaccines based on viral vector platforms use a modified virus to carry genes that encode SARS-CoV-2 spike proteins into the host cells.
- ✓ The vector virus is a type of adenovirus that has been modified to carry COVID-19 genes and to prevent replication. These modifications are intended to prevent the viral vector from causing disease. (i.e., they are non-replicating).
- ✓ Once inside the cell, the SARS-CoV-2 spike protein genes are transcribed into mRNA in the nucleus and translated into proteins in the cytosol of the cell.
- ✓ The AstraZeneca vaccine uses a modified chimpanzee adenovirus vector (ChAd).

[Video: What are viral vector vaccines and how do they work?](#)

Dosing Intervals

Vaccine product	Immunization schedule ^a	Minimum interval	Authorized interval	Optimal interval ^b
Pfizer-BioNTech Comirnaty	2-dose schedule	19 days ^c	21 days	8 weeks
Moderna Spikevax	2-dose schedule	21 days ^d	28 days	8 weeks
AstraZeneca Vaxzevria	2-dose schedule	28 days	4 to 12 weeks	At least 8 weeks
Janssen COVID-19 vaccine	1-dose schedule	N/A	N/A	N/A

Table 2: Recommended immunization schedule, by COVID-19 vaccine; NACI Recommendations on the use of COVID-19 vaccines¹

Booster Doses

- ✓ Evidence is emerging that vaccine effectiveness against infection and COVID-19 disease decreases with time, and the effectiveness of currently authorized COVID-19 vaccines against the Omicron variant is uncertain. Therefore, for certain populations, an additional dose may be needed to obtain more durable protection.
- ✓ The Comirnaty and Spikevax COVID-19 vaccines have been authorized for use by Health Canada as a booster dose after completion of the primary series in individuals 18 years of age and older.
- ✓ Three dose primary series vs. booster doses- information is evolving.
- ✓ A third dose for moderate to severely immunocompromised individuals is considered completing a primary series. To receive a full dose of a mRNA vaccine (Spikevax or Pfizer).
- ✓ NACI minimum interval for a third dose is 28 days. Ontario, had first recommended an interval of 2 months for this population, although when an additional dose is to be given it should be discussed with their treating provider.
- ✓ General population (18 +) have been eligible for a booster dose 84 days (3 months) after the second dose. Half doses of Moderna (50mcg) or a full Pfizer dose (30mcg).
- ✓ Those >70 receive a full doses a third dose.(Spikevax or Pfizer)

4th Doses

- Residents of long-term care homes and retirement homes, and older adults living in other congregate settings are at increased risk for both COVID-19 infection and severe disease, such as hospitalization and death. Many of these individuals are now up to five months from their third dose and are likely becoming increasingly susceptible to COVID-19 infection due to waning immunity. A fourth dose of an mRNA vaccine is recommended for residents of long-term care homes (LTCH), retirement homes (RH), Elder Care Lodges and older adults living in other congregate settings providing assisted-living and health services* who received their third dose at least three months (84 days) prior.
- Moderately to severely immunocompromised individuals who are eligible for a three-dose primary series are recommended to receive a booster dose (i.e. 4th dose) ≥3 months (84 days) after completion of the extended primary series. See section on booster doses in the [MOH guidance for third doses](#) for more information.

Why Immunize?

- ✓ The goal of Canada's pandemic response is to minimize serious illness and death while minimizing societal disruption as a result of the COVID-19 pandemic. Safe and effective COVID-19 vaccines could help achieve this goal.
- ✓ Efforts should be made to improve knowledge about the benefits of vaccines in general and of COVID-19 vaccines specifically once available, address misinformation, and communicate transparently about COVID-19 vaccine allocation decisions.

Potential Barriers to Immunization



Vaccine Development & Evaluation

- ✓ Health Canada only approves a vaccine if it is supported by very robust scientific data and evidence.
- ✓ After approval, Health Canada and the Public Health Agency of Canada continue to monitor the ongoing safety and effectiveness of all approved vaccines in Canada.
- ✓ Canadians have easy access to detailed information on the vaccine and the evidence behind the vaccine approval process through the [Government of Canada Website](#).

How can a vaccine be developed so quickly, when it usually takes years?

The development of vaccines for COVID-19 progressed quickly for many reasons, including:

- ✓ Reduced time delays in the vaccine approval process.
- ✓ Quick adaptation of existing research programs such as those focusing on mRNA- and viral-vector based technology.
- ✓ International collaboration among scientists, health professionals, researchers, industry and governments.
- ✓ Increased dedicated funding.
- ✓ Quick recruitment of participants for clinical trials.
- ✓ Rapid set-up of clinical trials to demonstrate effectiveness of the vaccine.

Where to Find the Information

- ✓ **National Advisory Committee on Immunization (NACI)**
 - NACI makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable disease for whom vaccine programs should be targeted. All NACI recommendations on vaccine use in Canada are published every four years in the [Canadian Immunization Guide](#).
- ✓ **Product monograph of vaccine**
- ✓ **Health Canada**
- ✓ **Ministry of Health**
 - [COVID-19 Vaccine-Relevant Information and Planning Resources](#)

References

1. NACI recommendations
2. Spikevax Product Monograph
3. Comirnaty Product Monograph
4. Pfizer-BioNTech www.cvdvaccine.ca
5. AstraZeneca/COVISHIELD® Product Monograph
6. Janssen Product Monograph
7. Public Health Ontario. *FOCUS ON: COVID-19 Vaccines: Viral Vector-based Vaccines*.
8. Ministry of Health COVID-19 Vaccine-Relevant Information and Planning Resources.

Quiz

1. How many vaccines are currently approved for use in Canada?

- A) 2
- B) 5
- C) 6
- D) None

Quiz

2. AstraZeneca is a mRNA COVID-19 vaccine.

A) True

B) False

Quiz

3. A non-replicating viral vector COVID-19 vaccine:
- A) uses a modified virus to carry genes that encode SARS-CoV-2 spike proteins into the host cells.
 - B) uses a vector virus, which is a type of adenovirus that has been modified to carry COVID-19 genes and to prevent replication.
 - C) uses modifications that are intended to prevent the viral vector from causing disease.
 - D) All of the above.

Quiz

4. Which of the following vaccines requires reconstitution using 1.8 mL of sterile 0.9% Sodium Chloride?

- A) Pfizer-BioNTech
- B) Moderna
- C) AstraZeneca
- D) None of the above

Quiz

5. Potential barriers to immunization include:

- A) Education
- B) Culture
- C) Income
- D) All of the above

Quiz

6. After approval, Health Canada and the Public Health Agency of Canada no longer monitor the ongoing safety and effectiveness of a vaccine in Canada.

- A) True
- B) False

Quiz

7. Where can you go to find reputable and accurate information about vaccines? Select all that apply.

- A) Google
- B) Your friends and family
- C) the National Advisory Committee on Immunization (NACI)
- D) Health Canada
- E) Product monograph of the vaccine
- F) Ministry of Health website