

Immunization Competencies for Nurses

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) Moderna – Currently being used in Renfrew County & District (RCD)
- 2) Pfizer-BioNTech – Currently being used in RCD
- 3) AstraZeneca and COVISHIELD® – AstraZeneca Currently being used in RCD
- 4) Janssen – Currently **not** being used in RCD

Moderna

✓ **Indications:**

- COVID-19 Vaccine Moderna (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 18 years of age and older.

✓ **Contraindications:**

- COVID-19 Vaccine Moderna 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.

✓ **Dose:**

- COVID-19 Vaccine Moderna should be administered intramuscularly, as two 0.5 mL doses, 4 weeks apart.

✓ **# of Doses per Multi-dose Vial:**

- 10

✓ **Dilution Required:**

- No

Moderna

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	Dispersion, (0.20 mg /mL), mRNA, encoding the pre fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2) Multidose vial (5 mL, containing 10 doses of 0.5 mL)	<ul style="list-style-type: none">• 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)• Acetic acid• Cholesterol• 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

Pfizer-BioNTech

✓ **Indications:**

- Pfizer-BioNTech 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 **12 years** of age and older.

✓ **Contraindications:**

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

✓ **Dose:**

- Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection which must be diluted prior to administration. After preparation, a single dose is 0.3 mL. Pfizer-BioNTech COVID-19 Vaccine is administered as a series of two doses (0.3 mL each) 21 days apart.

✓ **# of Doses per Multi-dose Vial:**

- 6

✓ **Dilution Required:**

- **Yes**

Pfizer-BioNTech

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	<p>Suspension (to be diluted)</p> <p>Multiple dose vial (after dilution, each vial contains 6†* doses of 0.3 mL)</p>	<ul style="list-style-type: none"> • ALC-0315 = ((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) • ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide • 1,2-distearoyl-sn-glycero-3-phosphocholine • cholesterol • dibasic sodium phosphate dihydrate • monobasic potassium phosphate • potassium chloride • sodium chloride • sucrose • water for injection

Table 1: Dosage Forms, Strengths, Composition and Packaging; Product Monograph³

AstraZeneca and COVISHIELD®

✓ **Indications:**

- AstraZeneca and COVISHIELD® COVID-19 Vaccines (COVID-19 Vaccine (ChAdOx1-S [recombinant])) are indicated for active immunization of individuals 18 years of age and over for the prevention of coronavirus disease 2019 (COVID-19).
- **NACI now recommends that for individuals who received AstraZeneca/COVISHIELD as a first dose, an mRNA vaccine is preferred for the second dose based on emerging evidence; however, AstraZeneca may still be offered for the second dose if the individual requests this vaccine and is informed of the rare risk of Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)**

✓ **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

AstraZeneca and COVISHIELD®

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	Solution Multidose vial (8 dose and 10 dose vial presentations)	<ul style="list-style-type: none">• Disodium edetate dihydrate (EDTA)• Ethanol• L-Histidine• L-Histidine hydrochloride monohydrate• Magnesium chloride hexahydrate• Polysorbate 80• Sodium chloride• Sucrose• Water for injection

Table 1: Dosage Forms, Strengths, Composition and Packaging; Product Monograph⁴

What is a mRNA COVID-19 vaccine?

- Pfizer-BioNTech and Moderna are mRNA vaccines.
- Both vaccines use a method called messenger RNA (mRNA). The 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.
- Fast manufacturing timeline is why they are the first available vaccines.

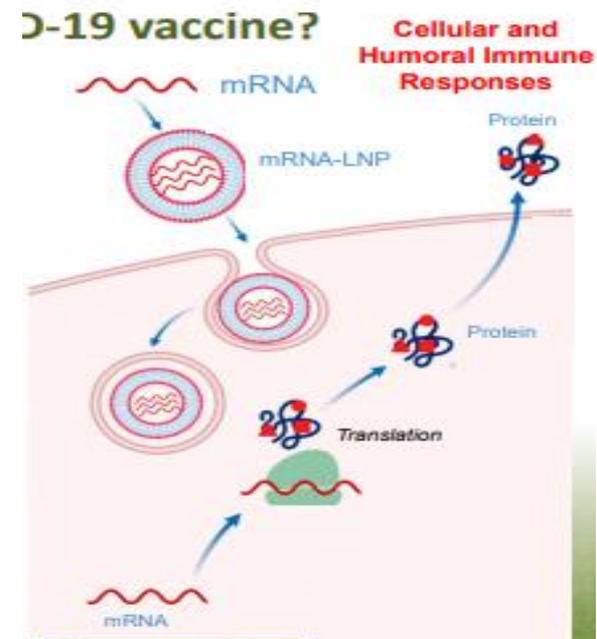


Image from NACI recommendations on use of Moderna COVID-19 vaccines presentation

How does mRNA vaccines work?

- Use genetic instructions in molecules called mRNA to 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.
- 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).

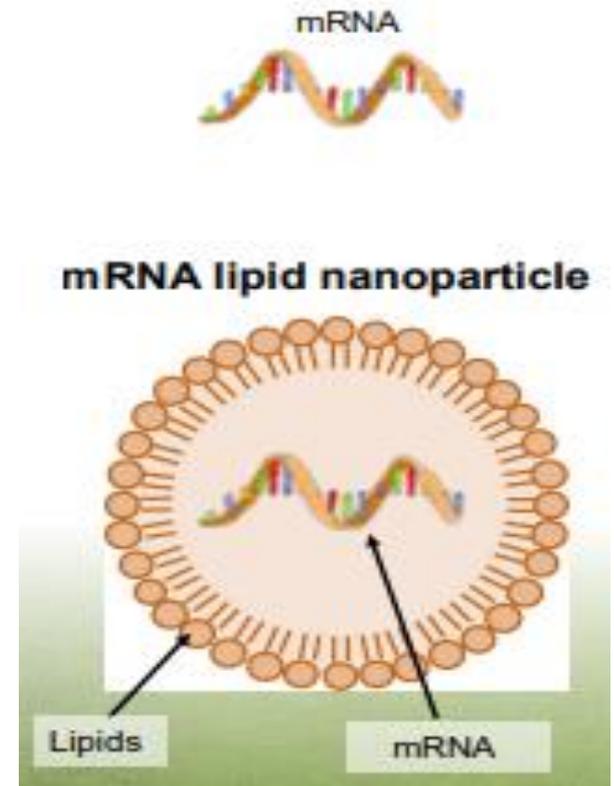


Image from NACI recommendations on use of Moderna COVID-19 vaccines presentation

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

- ✓ AstraZeneca, COVISHIELD, and Janssen 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.
- ✓ COVID-19 viral vector-based vaccines authorized for use in Canada are non-replicating vaccines.

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).

Dosing Intervals

Vaccine product (manufacturer)	Immunization schedule	Minimum interval	Authorized interval	Extended interval ^a
Pfizer-BioNTech COVID-19 (Pfizer-BioNTech)	2-dose schedule	19 days ^b	21 days ^c	16 weeks
Moderna COVID-19 (Moderna)	2-dose schedule	21 days ^d	28 days	16 weeks
AztraZeneca COVID-19 (AstraZeneca)	2-dose schedule	28 days	4 to 12 weeks ^e	16 weeks ^e

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

Dose Intervals

- ✓ While studies have not yet collected four months of data on vaccine effectiveness after the first dose, the first two months of real world effectiveness are showing sustained high levels of protection.
- ✓ Short term sustained protection is consistent with immunological principles and vaccine science where it is not expected to see rapid waning of a highly effective vaccine in adults over a relatively short period of time. Extending the interval between doses was shown to be a good strategy through modelling, even in scenarios considering a six month interval and in theoretical scenarios where waning protection was considered.
- ✓ Residents of long-term care homes, retirement homes, elder care lodges, assisted living facilities; individuals who are recipients of targeted treatments/therapies, all first Nation, Inuit and Metis and high risk health care workers are eligible to receive a second dose at the intervals described in the product monographs. Refer to ministry guidance COVID-19 Vaccine Series Second dose Eligibility Quick Reference frequently for updates on shortened intervals throughout vaccine roll-out. https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_series_quick_ref_chart.pdf
- ✓ This guidance on dosing interval is aligned with the updated National Advisory Committee on Immunization's recommendations on the use of COVID-19 mRNA vaccines. It is also consistent with the recommendations from the World Health Organization and the Centre for Disease Control.

Summary

	Moderna	Pfizer- BioNTech	AstraZeneca & COVISHIELD®
Type	mRNA	mRNA	Non-replicating viral vector
Dose	0.5 mL	0.3 mL	0.5 mL
# of Doses per Multidose Vial	10	6	8 and 10 dose presentations
Dilution Required	No	Yes	No

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.
- ✓ The authorized COVID-19 vaccines that are recommended for use by NACI have been shown to be safe, as well as efficacious against symptomatic laboratory-confirmed COVID-19 disease.
- ✓ 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 is progressing 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. Moderna Product Monograph (June 9, 2021)
3. Pfizer-BioNTech Product Monograph (May 19, 2021)
4. AstraZeneca and COVISHIELD® Product Monograph (April 23, 2021)
5. Public Health Ontario. *FOCUS ON: COVID-19 Vaccines: Viral Vector-based Vaccines*. March 16, 2021.

Quiz

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

- A) 2
- B) 4
- 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. The following COVID-19 vaccines require 2 doses:

- A) Pfizer-BioNTech
- B) Moderna
- C) AstraZeneca
- D) All of the above

Quiz

5. Extending the interval between doses was shown to be an ineffective strategy through modelling, even in scenarios considering a six month interval and in theoretical scenarios where waning protection was considered.

- A) True
- B) False

Quiz

6. 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

7. Authorized COVID-19 vaccines that are recommended for use by NACI have been shown to be safe, as well as efficacious against symptomatic laboratory-confirmed COVID-19 disease.

- A) True
- B) False

Quiz

8. Potential barriers to immunization include:

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

Quiz

9. 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

10. 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