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# COVID-19 Vaccines: mRNA Vaccines

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## Introduction

The novel coronavirus disease (COVID-19) pandemic has stimulated unprecedented efforts to develop vaccines that provide protection against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1]

This Focus On is intended for health care providers and public health partners. It provides an overview of messenger ribonucleic acid (mRNA) vaccines, including products authorized for use in Canada. This document will be updated as new information becomes available.

## The Basics: mRNA Vaccines

mRNA vaccines have emerged as a promising alternative to conventional vaccine platforms.[2,3] While efforts to develop a mRNA vaccine were initially limited by the transient nature of mRNA in human cells, major innovations over the last two decades have accelerated mRNA vaccine development.[2-4]

> **What is mRNA?**
>
> Messenger ribonucleic acid (mRNA) is a type of transcript, which is used by our cells to transfer genetic information from DNA to make proteins.[2,5-7]

Vaccines work by training our immune system to recognize and respond to infectious agents. For most vaccines, this is accomplished by delivering a weakened or inactivated virus or a component of the virus (such as a specific protein) to the body, which triggers an immune response.[2,3] In contrast, mRNA vaccines work by delivering instructions to human cells to produce a viral protein, which is then recognized by the body as foreign.[2-8] These proteins, known as antigens, use the body's normal processes to safely produce an immune response. There are two main types of RNA vaccines:

- **Non-replicating (or non-amplifying) RNA vaccines** are the simplest type and consist of mRNA coding for the viral antigen. Our cell machinery is used to make a specific viral antigen and once this is accomplished, the mRNA is cleared.[9,10] COVID-19 mRNA vaccines are non-replicating RNA vaccines.[3,10]
- **Self-replicating (or self-amplifying) RNA vaccines** consist of an RNA coding for the viral antigen and the virus' replication machinery, allowing for abundant production of viral antigen.[9,10]

**Key messages: COVID-19 mRNA vaccines**

**1. You cannot get COVID-19 from an mRNA vaccine.**

mRNA COVID-19 vaccines are non-infectious (they do not contain whole or live SARS-CoV-2); therefore there is no risk of an mRNA vaccine causing COVID-19.[3-7]

**2. mRNA vaccines are a new vaccine platform, but not a new technology.**

While mRNA therapeutics have been studied for over two decades, recent scientific advancements have improved mRNA stability and delivery which has been important for bringing mRNA vaccines and cancer mRNA therapeutics into clinical use.[2,4,6,7]

**3. mRNA vaccines do not affect or interact with our DNA.**

Human cells break down and get rid of mRNA as soon as they finish using its instructions. mRNA does not enter the nucleus of human cells, where our DNA is located, eliminating any risk of mRNA interacting with our DNA.[2-7,11]

**4. Both mRNA COVID-19 vaccines used in Canada are safe and highly effective**

The mRNA COVID-19 vaccines used in Canada (Pfizer-BioNTech Comirnaty and Moderna Spikevax) are both safe and highly effective against severe outcomes, such as hospitalization and death.[12-18] Both vaccines work in the same way to produce an immune response in our body.

# Mechanism of Action and Immune Response

COVID-19 mRNA vaccines use our normal cell processes to safely produce the SARS-CoV-2 spike (S) glycoprotein antigen, which activates both **antibody** and **cell-mediated** immune responses.[7,10,11]

- mRNA vaccines are encapsulated in a lipid coat, commonly referred to as a lipid nanoparticle (LNP), which allows them to easily cross cell membranes into our cells.[2-7]
- Once inside our cells, mRNA is released into the cytoplasm where the body's cell machinery makes copies of the SARS-CoV-2 spike glycoprotein antigen. The mRNA instructions are then rapidly broken down and disposed of by our cells.[3-7,10,11]
- Next, the SARS-CoV-2 spike glycoprotein antigen is temporarily displayed on the surface of our cells, where it is recognized as foreign and activates B (antibody-mediated) and T (cell-mediated) cells of the immune system.[3,10,11]
- Activation of **cell-mediated** immune responses are expected to play a central role in providing us with longer-term protection.[10] **Antibody-mediated** responses directed against the SARS-CoV-2 spike glycoprotein are believed to be important for blocking the virus from entering our cells.[10]

# Advantages and Limitations of mRNA Vaccines

Recent advances in mRNA vaccine technology offer several advantages over classical vaccine platforms. Rapid and scalable manufacturing as compared to conventional vaccines, allows for quicker vaccine

production in response to novel pathogens, such as SARS-CoV-2, or novel SARS-CoV-2 variants of concern (VOC).[3,4,11,18] Studies about the duration of protection provided by COVID-19 vaccination are ongoing; however, waning vaccine effectiveness against infection over time has been noted to potentially occur less quickly with mRNA vaccine than viral vector vaccines. Additionally, the National Advisory Committee on Immunization (NACI) has made a preferential recommendation for the use of mRNA COVID-19 vaccines in all authorized age groups due to their better effectiveness and the rare risk of certain serious adverse events following viral vector COVID-19 vaccines. Clinical trial data have demonstrated that COVID-19 mRNA vaccines are highly efficacious against confirmed symptomatic and severe COVID-19 disease. In real-world studies, mRNA vaccines provide protection against SARS-CoV-2 transmission and severe COVID-19 disease (i.e., hospitalizations, deaths) against VOC.[19,20] Finally, mRNA vaccines are non-infectious so there is no risk of infection from the vaccine.[3-7,11]

Limitations of mRNA vaccines include issues related to vaccine storage and handling requirements, including the need for freezing temperatures (due to mRNA being highly labile), and increased reactogenicity (i.e., side effects such as fever, muscle aches and fatigue), relative to some other vaccine platforms.[3-5,12,13,17]

# COVID-19 mRNA Vaccines

In September 2021, Health Canada under the *Food and Drug Regulations* granted full authorization to two COVID-19 mRNA vaccines: Pfizer-BioNTech Comirnaty COVID-19 vaccine and Moderna Spikevax COVID-19 vaccine.[21,22] In November 2021, Health Canada authorized for use a pediatric Pfizer-BioNTech Comirnaty COVID-19 vaccine for children 5 – 11 years of age.[22]

Detailed characteritisics of each vaccine are outlined in Table 1.

**Table 1: Characteristics of COVID-19 mRNA vaccines authorized for use in Canada**

| Trade Name | Pfizer-BioNTech Comirnaty COVID-19 Vaccine | Pfizer-BioNTech Comirnaty COVID-19 Vaccine (pediatric formulation) | Moderna Spikevax COVID-19 Vaccine |
|---|---|---|---|
| Manufacturer | Pfizer Inc., BioNTech Manufacturing GmbH | Pfizer Inc., BioNTech Manufacturing GmbH | ModernaTX Inc. |
| Generic Name | BNT162b, tozinameran | BNT162b, tozinameran | mRNA-1273, elasomeran |
| Vaccine Platform | LNP-encapsulated, non-replicating, nucleoside-modified mRNA vaccine[12,13] | LNP-encapsulated, non-replicating, nucleoside-modified mRNA vaccine[13,14] | LNP-encapsulated, non-replicating, nucleoside-modified mRNA vaccine[15-17] |
| Antigenic Target | Pre-fusion SARS-CoV-2 spike (S) glycoprotein[12,13] | Pre-fusion SARS-CoV-2 spike (S) glycoprotein[13,14] | Pre-fusion SARS-CoV-2 spike (S) glycoprotein[15,17] |
| Authorized Ages for Use | 12 years of age and older[13,18,21] | 5 years to 11 years of age[13,21] | 12 years of age and older[17,21] |

| Trade Name | Pfizer-BioNTech Comirnaty COVID-19 Vaccine | Pfizer-BioNTech Comirnaty COVID-19 Vaccine (pediatric formulation) | Moderna Spikevax COVID-19 Vaccine |
|---|---|---|---|
| | 18 years of age and older[13,21,a] (booster) | | 18 years of age and older[17,21] (booster) |
| No. of Doses Administered | 2 or 3 doses[13,18] (primary series)<br>1 booster dose[13] | 2 or 3 doses[13] (primary series) | 2 or 3 doses[15,17,18] (primary series)<br>1 booster dose[17] |
| Dosage | 30 mcg of mRNA per 0.3 mL dose[13] | 10 mcg of mRNA per 0.2 mL dose[13] | 100 mcg of mRNA per 0.5 mL dose[17]<br>50 mcg of mRNA per 0.25 mL dose[17] (booster dose) |
| Adjuvant | No[12,13] | No[13,14] | No[15,17] |
| Diluent | Yes[12,13] | Yes[13,14] | No[15,17] |
| Schedule[a]<br>(Two-dose primary series)[b] | Authorized interval: 21 days (3 weeks)[13,18]<br>Optimal interval: 8 weeks[18]<br>Minimum interval: 19 days[18] | Authorized interval: 21 days (3 weeks)[17,18]<br>Optimal interval: 8 weeks[18]<br>Minimum interval: 19 days[18] | Authorized interval: 28 days (4 weeks)[17,18]<br>Optimal interval: 8 weeks[18]<br>Minimum interval: 21 days[18] |
| Schedule (Booster dose)[c] | Authorized interval: 6 months after completion of the primary series[13,c] | N/A | Authorized interval: 6 months after completion of the primary series[17,e] |
| Route of Administration | Intramuscular (IM) [12,13] | Intramuscular (IM) [13,14] | Intramuscular (IM)[17] |
| Storage Conditions | Vials have purple caps[13]<br>- 90°C to - 60°C until expiry date[13]<br>- 25°C to -15°C for up to 2 weeks[13,c]<br>Once thawed, unpunctured vials should be stored for up to 31 days at 2°C to 8°C OR at room temperature (up to 25°C) | Vials have orange caps[13]<br>-90°C to -60°C until expiry date[13]<br>Do not store vials at -25°C to -15°C<br>- 25°C to -15°C until expiry date[13]<br>Once thawed, unpunctured vials should be stored at 2°C to 8°C for up to 10 weeks OR at | -25°C to -15°C until expiry date[17]<br>Once thawed, unpunctured vials should be stored at 2°C to 8°C for up to 30 days OR at 8°C to 25°C for up to 24 hours[16]<br>Once thawed, store at 2°C to 25°C and use |

| Trade Name | Pfizer-BioNTech Comirnaty COVID-19 Vaccine | Pfizer-BioNTech Comirnaty COVID-19 Vaccine (pediatric formulation) | Moderna Spikevax COVID-19 Vaccine |
|---|---|---|---|
| | for no more than 2 hours.[13]<br>Once thawed, after dilution, store at 2°C to 25°C and use within 6 hours from first puncture.<br>Do not refreeze<br>Keep vials in original packaging to protect from light | room temperature (up to 25°C) for no more than 24 hours.<br>Once thawed, after dilution, store at 2°C to 25°C and use within 24 hours from first puncture.<br>Do not refreeze<br>Keep vials in original packaging to protect from light | within 24 hours from first puncture.<br>Do not refreeze<br>Keep vials in original packaging to protect from light |

[a] The authorized interval is the dosing schedule approved by Health Canada, based on evidence from clinical trials. The recommended interval is determined by NACI and is included in their recommendations following review of available data and based on expert opinion. The minimum interval is the interval between doses in which an adequate immune response will be achieved.

[b] As per NACI and the MOH, moderately to severely immunocompromised groups are recommended to receive a three-dose primary series, with a minimum interval[24] of 28 days between the 2nd and 3rd dose; optimal interval ≥2 months (56 days)[25] Exact timing should be decided with the treating provider.

[c] Health Canada has approved booster doses of Pfizer-BioNTech Comirnaty and Moderna Spikevax COVID-19 vaccines for those 18 years and older only.[21]

[d] NACI and the MOH have issued a preferential recommendation for the use of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg dose) as a booster dose in individuals 12 to 29 years of age due to an increased risk of myocarditis/pericarditis in this age cohort. In Ontario, the recommended schedule for a booster dose is ≥6 months (168 days) after completion of the primary series in 12-17 year olds. With informed consent, individuals 12-17 years of age may receive a booster dose at a minimum of 3 months (84 days) after completion of a primary COVID-19 vaccine series. Individuals ≥18 years old are eligible to receive booster doses of an mRNA vaccine ≥3 months (84 days) after the completion of a primary COVID-19 vaccine series.[18]

[e] Vials stored at -25◦C to -15◦C for up to 2 weeks may be returned one time to the recommended storage conditions of -90◦C to -60◦C.

# Vaccine Effectiveness and Safety

Both mRNA COVID-19 vaccines authorized for use in Canada have been shown to be safe and highly effective against symptomatic COVID-19 disease and severe outcomes, such as hospitalization and death.[12-18] Clinical trials and real-world studies demonstrates very high vaccine efficacy (91%-94%) and vaccine effectiveness (VE) following a complete primary series.[18,20] Both vaccines offer strong protection against infection with the variants of concern (VOC) B.1.1.7 (Alpha) and B.1.617.2 (Delta), albeit a small reduction in VE is observed for Delta and a more substantial decline in VE is observed for B.1.1.529 (Omicron).[12-18,26,27] Real-world evidence suggests that a primary series of both mRNA vaccines are highly effective (>90%) in preventing severe disease, and hospitalizations and death against Alpha and Delta.[19] Given evidence of waning immunity ≥ 6 months after dose 2 of mRNA vaccines, preliminary VE and immunogenicity data in adults (≥ 18 years old) suggests that protection against infection,

hospitalizations, and death is improved with a third (booster) dose of a mRNA COVID-19 vaccine.[19,28] Multiple studies from the UK, Scotland and the US show that VE against Omicron infection and symptomatic disease after a two doses of a primary homologous series of mRNA vaccines) is low, and progressively decreases with time after the second dose.[29] For those who had received two doses of Pfizer-BioNTech Comirnaty, VE against symptomatic confirmed SAR-CoV-2 (Omicron variant) was 65.5% (95% CI, 63.9-67.0) 2 to 4 weeks after the second dose, dropping to 15.4% (95% CI, 14.2-16.6) after 15 to 19 weeks and 8.8% (95% CI, 7.0 to 10.5) after 25 or more weeks. VE of two doses of Moderna Spikevax vaccine similarly demonstrated a reduction over time from 75.1% (95% CI, 70.8-78.7) after 2 to 4 weeks to 14.9% (95% CI, 3.9-4.7) after 25 or more weeks against symptomatic COVID-19 caused by Omicron.[30] Data from Ontario found VE against symptomatic infection after the second mRNA dose was 36% from 1 week to <2 months, 15% or less from 2 months to <6 months and approximately 1% from 6 months onward.[31] However, VE against severe disease (hospitalization or death) after the second dose of mRNA vaccine was higher even after dose 2 in Ontario (82 to 86% ≥6 months post-vaccination)[31] which was similar to findings from the UK.[29] After a third dose of an mRNA vaccine, VE against Omicron severe disease increased to > 90% and remained highly effective at two-three months post booster dose, in Ontario and UK studies.[31,32]

In clinical trials, the most common side effects following vaccination with mRNA vaccines included pain at the injection site, headache and fatigue, with systemic symptoms (e.g., fatigue, headache, muscle pain, joint pain, chills and fever) reported more frequently after the second dose.[12-17] These side effects are typically mild and resolve within a few days. Reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following COVID-19 mRNA vaccines have been identified through post-marketing safety surveillance in Ontario, and internationally.[13,16,17,33,34] These events are most frequently reported in adolescents and younger adults 12 to 30 years of age, more frequently in males as compared to females, more frequently after the second dose, and more frequently following the Moderna Spikevax COVID-19 vaccine as compared to the Pfizer-BioNTech COVID-19 vaccine.[33] The majority of cases have been relatively mild and resolved quickly with conservative therapy and rest. Canada's National Advisory Committee on Immunization (NACI),[18] continue to recommend a complete series of mRNA vaccine be offered to all eligible individuals as the benefits of COVID-19 vaccination outweigh the very rare risk of myocarditis/pericarditis. Health Canada has updated the Pfizer-BioNTech Comirnaty and Moderna Spikevax product monographs to include information on these conditions.[13,17] In order to further minimize the rare risk of adolescents and young adults experiencing myocarditis and/or pericarditis after receiving a COVID-19 mRNA vaccine, NACI recommends that Pfizer-BioNTech Comirnaty mRNA vaccine (30 mcg) is preferred in adolescents and young adults 12 to 29 years of age for both their primary vaccine series or booster dose[34,35] For more information on myocarditis and pericarditis following mRNA vaccines see Public Health Ontario's Focus On: Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines,[36] the Enhanced Epidemiological Summary: Mycocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to November 21, 2021[33] and the COVID-19 vaccine: Canadian Immunization Guide.[18]

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