

## COVID-19 Immunization Program Question and Answer Document for Health Care Professionals Updated January 22, 2021

This Q&A document includes general information about COVID-19 vaccines and questions and answers specific to the vaccines currently in use in B.C. COVID-19 vaccine information is evolving, and as such, this Q&A may be updated as new information and new COVID-19 vaccines become available in B.C.

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## COVID-19 Disease

### 1. What is the epidemiology for COVID-19?

Information on COVID-19 epidemiology is continually evolving. For the most up-to-date data on COVID-19 cases, go to:

- Global: <https://health-infobase.canada.ca/covid-19/international/>
- Canada: <https://health-infobase.canada.ca/covid-19/>
- British Columbia: <http://www.bccdc.ca/health-info/diseases-conditions/covid-19/data>

### 2. Why is COVID-19 vaccination important?

While preventive measures such as physical distancing, frequent handwashing, and wearing a mask help to reduce the risk of exposure and transmission of SARS-CoV-2, the virus that causes COVID-19 infection and disease, these measures alone are not enough. The combination of COVID-19 vaccination and following BCCDC's [prevention measures](#) offer the best protection from COVID-19. Ending this pandemic requires all the tools we have available, including, most importantly, vaccination.

COVID-19 vaccination protects not only the person being vaccinated, but also people around them, including those who are unable to get the vaccine. While the level of COVID-19 vaccination coverage required to achieve herd immunity will vary based on vaccine effectiveness, it is estimated that for an  $R_0$  of 2.5 to 3.5 (the average number of people infected by a single case of COVID-19) approximately 60-72% of the population would need to be immune to block the continued transmission of SARS-CoV-2.

## Vaccine development and safety

### 3. How do we know that the COVID-19 vaccines being developed so quickly are safe and effective?

Factors that allowed COVID-19 vaccines to progress quickly include advances in vaccine development technology, government funding and purchase commitments, international collaboration among health professionals, researchers, industry and governments to develop the vaccines, rapid recruitment of participants for clinical trials, and streamlined vaccine approval processes by the regulatory body at Health Canada. Canada's rigorous vaccine approval process has remained in place to assess COVID-19 vaccines.

As for all vaccines and treatments that are authorized in Canada, Health Canada reviews the evidence and scientific data and decides whether to authorize the COVID-19 vaccine and will only do so when the evidence shows that the vaccine:

- is safe, effective and of good quality and
- demonstrates that the benefits outweigh the known and potential risks

Health Canada's approval of the Pfizer-BioNTech vaccine on December 9, 2020 is an example of this accelerated process. Health Canada ensured that the Pfizer-BioNTech vaccine, laboratory studies and three phases of double-blind randomized clinical trials have shown safety, immunogenicity (ability to generate an immune response) and efficacy (ability to prevent COVID-19 disease) of this vaccine in animals and in adolescents and adults 16 years of age and older. Approximately 44,000 individuals randomized (1:1) to receive either the vaccine or placebo participated in phases 2 and 3 of the clinical trials. This population has been considered sufficient to approve vaccine based on safety and efficacy.

Health Canada also has processes in place to share information with other countries' regulatory bodies including the US Food and Drug Administration and the European Medicines Agency.

Once a vaccine is approved, vaccine safety and effectiveness are continuously monitored to detect rare serious or unexpected side effects.

#### 4. What is the approval process for COVID-19 vaccines in Canada?

The Biologic and Radiopharmaceutical Drugs Directorate (BRDD), which is part of Health Canada, supervises all aspects of vaccine production and quality control throughout the vaccine's lifecycle. When a manufacturer develops enough scientific and clinical evidence of a vaccine's safety, efficacy, and quality, they file a complete package of information that is submitted to BRDD for market authorization. A submission contains data from scientific studies, including laboratory and clinical studies, and information about the manufacturing process, including the manufacturing facility and manufacturing method. BRDD thoroughly reviews the submission to determine whether the benefits of a vaccine outweigh any potential risks. BRDD also reviews procedures for the manufacturer's safety monitoring and any plans to minimize any identified risks. In addition, BRDD may visit the manufacturing site to evaluate the manufacturing process' quality and make sure the manufacturer can carry out the necessary quality controls for the vaccine.

The expedited review performed for COVID-19 vaccines has been possible because of a number of administrative changes to the process. These have included allowance of submission of data when available rather than the sponsor needing to wait until the entire data package is complete prior to submission. As well, for approval of these vaccines in Canada and many countries, there has been allowance for a shorter period of follow-up of people enrolled into the phase 3 clinical trials, whereas for non-pandemic vaccines, that follow-up period is typically upwards of one year. As a result, the clinical trials will continue to accrue cases and safety information for up to two years following immunization. Results from these studies will be reported in the future and will provide additional information about issues such as duration of protection from the vaccine(s).

Additional Health Canada information is available at: [Vaccines and Treatments for COVID-19: Progress](#) and [Interim order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#).

## 5. How do we reassure the public that COVID-19 vaccines are safe and effective?

For an effective conversation about COVID-19 vaccines, we can start from a place of compassion and understanding. Patients consistently rank healthcare providers as their most trusted source for vaccine information. Be transparent about the latest vaccine(s) information, reassure that we have a robust vaccine safety system in Canada, and emphasize vaccines' role to protect recipients and the people around them. Your willingness to listen to the patients' concerns will play a significant role in building trust in you and your recommendation. If a patient has concerns or questions, this doesn't necessarily mean they won't accept a COVID-19 vaccine. Sometimes patients simply want your answers to their questions. Once you've answered their questions, let them know that you are open to continuing the conversation. Encourage your patients to schedule another appointment or go to the [BCCDC](#) or [ImmunizeBC](#) websites for more information about COVID-19 vaccination. Continue the conversation about COVID-19 vaccination during future visits.

## 6. How will the safety of the COVID-19 vaccines continue to be monitored in Canada?

Canada has a system of local, provincial, and national surveillance to carefully monitor adverse events following immunization and detect any vaccine safety concerns. Once a vaccine is approved, its safety is continuously being monitored as long as it is used. In most provinces and territories, including BC, health care providers are legally obliged to report all serious and unexpected adverse events following immunization to the medical health officer. Every serious or concerning event is reported to the BC Centre for Disease Control (BCCDC). These reports are reviewed at BCCDC and also sent to the Public Health Agency of Canada system called the Canadian Adverse Events Following Immunization System (CAEFISS), as are reports from all provinces and territories. Additional monitoring for adverse events is being done through a system called [CANVAS](#) (Canadian National Vaccine Safety Network) through which recipients of the vaccine can enroll to self-report adverse events following receipt of the vaccine, with serious events being reported on to the regional health authority.

Vaccine safety is also monitored at the international level. The World Health Organization's International Drug Monitoring Program collects reports from over 75 countries and uses these global data to monitor for any vaccine safety concerns. In addition, all vaccine manufacturers must report serious adverse events of which they become aware, in Canada or internationally, to Health Canada. For COVID-19 vaccines, manufacturers are expected to implement enhanced monitoring activities.

More information about the Canadian vaccine safety surveillance system is contained in the [Canadian Immunization Guide, Part 2 – Vaccine Safety, Vaccine safety and pharmacovigilance](#).

## 7. How do health care providers report an adverse event following COVID-19 immunization in BC?

Vaccine providers should refer to the BC Immunization Manual, [Part 5 – Adverse Events Following Immunization](#) for criteria on reporting adverse events following immunization (AEFI), and report AEFIs to the regional health authority. Information on reporting can be found on the BCCDC's [Surveillance Forms](#) page under Adverse Events Following Immunization.

For more information and details on how to report an AEFI in B.C. go to the BCCDC [Reporting Adverse Events Following Immunization: For BC Community Vaccine Providers](#).

## COVID-19 Vaccines in Canada

### 8. Which COVID-19 vaccines are currently authorized for use in Canada?

At this time, there are two COVID-19 mRNA vaccines approved for use in Canada:

- Pfizer-BioNTech COVID-19 vaccine was authorized on December 9, 2020. Pfizer information including the product monograph is available from: <https://www.cvdvaccine.ca/>.
- Moderna COVID-19 vaccine was authorized on December 23, 2020. Moderna information including product monograph is available from: <https://www.modernacovid19global.com/ca/>.

### 9. What are COVID-19 mRNA vaccines?

Messenger RNA (mRNA) is the 'blueprint' that cells use to synthesize proteins required for our physiology. The two newly approved COVID-19 vaccines use mRNA contained inside a lipid nanoparticle (LNP) that contains the synthetic nucleotide sequences that codes for the SARS-CoV-2 spike protein. After injection, the LNP is taken up by immune system cells, and once inside a cell, the mRNA provides the instructions that allow the cell to manufacture the spike protein. Once manufactured, the spike protein exits the cell, and becomes anchored onto the cell's surface. The immune system is activated to recognize the spike protein as foreign and initiates an immune response. The mRNA is then cleared by the cell's natural mRNA degradation process. The estimated half-life for mRNA after injection is about 8-10 hours before degradation by native RNases (enzymes that break up the mRNA) in the body; the expressed spike protein persists in the body for several days and during this time continues to stimulate the immune response. mRNA vaccines are not live vaccines and cannot cause infection in the host. The delivered mRNA does not replicate, and does not enter the cell nucleus or interact with or alter the recipient's DNA.

Several mRNA vaccines are under development for other infections including cytomegalovirus, human metapneumovirus, parainfluenza virus type 3, Zika and influenza viruses.

Manufacturing of mRNA vaccines has been under development for a decade. The process is cell-free (does not use human or other animal cells) and does not use vectors (like other viruses) or animal products, preservatives or adjuvants.

## General Questions

### 10. Will there need to be additional booster doses or a need for a yearly dose as given for influenza?

There is currently no evidence on the need for booster doses of COVID-19 vaccine after the vaccine series is complete. As the first participants in clinical trials were vaccinated at the end of July 2020, and the first vaccines being approved in December 2020, only short-term clinical trial data are available. Clinical trial participants will continue to be monitored for a total of at least two years to understand how long immunity lasts after vaccination.

There are also several research and surveillance priorities that are occurring with respect to the efficacy, effectiveness, immunogenicity and safety of the COVID-19 vaccines, which include population effectiveness and medium and long-term duration of protection of a complete series of COVID-19 vaccine. The degree to which these vaccines protect against COVID-19 one, two or more years after vaccination will be determined with ongoing vaccine effectiveness surveillance.

### 11. Once an individual is vaccinated will they need to continue practicing the recommended public health measures?

Yes, individuals should continue to practice recommended public health measures for the prevention and control of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine. At this time, there is insufficient evidence on the duration of protection of COVID-19 vaccines in preventing infection and reducing transmission of SARS-CoV-2 to recommend discontinuation of public health measures. It is expected, however, that over time with more information about the impact of vaccination on COVID-19 transmission that there will be changes to the current prevention and control measures.

## Eligibility

### 12. Who is eligible and how are priority populations chosen to receive initial doses COVID-19 vaccine?

Vaccination will happen in phases. The first groups to get vaccinated include individuals who are at increased risk of exposure to the virus and those most at risk of serious complications.

NACI's [Preliminary guidance on key populations for early COVID-19 immunization](#) informs planning for the equitable allocation of COVID-19 vaccine(s) once authorized for use in Canada in the context of a limited initial vaccine supply to prioritize some populations earlier than others. NACI noted that a sequential approach cannot be determined until vaccine characteristics, results of clinical trials, and the number of available doses is known. As such, NACI has provided urgent guidance on the efficient and equitable prioritization of initial doses (further sequencing key populations), to assist with the planning for allocation of the first COVID-19 immunization programs. This guidance is outlined in NACI's [Guidance on the prioritization of initial doses of COVID-19 vaccine\(s\)](#).

In B.C., a list of the current eligible populations can be found on the BCCDC website at:  
<http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/eligibility>

## COVID-19 mRNA Vaccines

Additional information specific to the mRNA vaccines currently authorized for use in Canada can be found in the NACI Statement [Recommendations on the use of COVID-19 Vaccines](#), Appendices A&B.

### Efficacy

#### 13. How effective are the mRNA vaccines against COVID-19 disease?

##### **Pfizer-BioNTech COVID-19 vaccine**

The estimated vaccine efficacy at least 7 days after Dose 2 was 94.6% (95% CI: 89.9 to 97.3%), with 9 laboratory confirmed symptomatic COVID-19 cases identified among vaccine recipients (N=19,965) compared to 169 cases among placebo recipients (N=20,172). The vaccine efficacy at least 14 days after Dose 2 in this population was comparable (94.4%, 95% CI: 89.1 to 97.3%).

When stratified by age, vaccine efficacy against COVID-19 from 7 days after Dose 2 was between 93.7% (>55 years) and 95.6% (16 to 55 years). In individuals  $\geq 65$  years of age, vaccine efficacy was 94.7% (95% CI: 66.7 to 99.9%). In participants  $\geq 75$  years of age, the observed vaccine efficacy was 100% compared to placebo (95% CI: -13.1 to 100.0%), however this must be interpreted with caution as there were few cases identified in this age group, accounting for the wide confidence intervals. The estimated vaccine efficacy against confirmed COVID-19 from 7 days after Dose 2 was greater than 91% (between 91.7% and 100.0%) in all subgroups stratified by "at risk" status (e.g., presence of 1 or more comorbidities). The estimated vaccine efficacy against confirmed COVID-19 illness from 7 days after Dose 2 was greater than 89% for all races (89.3 to 100%) and 94% for all ethnicities included in the sub-analysis (94.4 to 95.4%).

##### **Moderna COVID-19 vaccine**

The estimated vaccine efficacy at least 14 days after Dose 2 was 94.1% (95% CI: 89.3 to 96.8%), with 11 confirmed COVID-19 cases identified among vaccine recipients (n= 14,134) compared to 185 confirmed COVID-19 cases among placebo recipients (n= 14,073).

When stratified by age, vaccine efficacy against COVID-19 from 14 days after Dose 2 for those 18 to < 65 years of age was 95.6% (95% CI: 90.6 to 97.9%). For those > 65 years of age, vaccine efficacy was 86.4% (95% CI: 61.4 to 95.2%). For those > 75 years of age, vaccine efficacy was 100%, however this must be interpreted with caution as there were few cases identified in this age group.



## 14. How long does it take for immunity to develop following vaccination?

For both mRNA vaccines, SARS-CoV-2 binding and neutralizing antibodies were both induced by one dose of the vaccine and boosted by the second dose of the vaccine. Maximal immune response was seen 7 days after the second dose for each vaccine.

## 15. How long does immunity after vaccination last?

The median period of follow up of vaccine and placebo recipients from the two vaccine phase 3 clinical trials was 2 months. Protection beyond this period is expected, and additional information about the duration of protection will continue to accrue in the clinical trials which will gather data for at least two years. Vaccine effectiveness information will also be obtained from post-marketing surveillance evaluations including studies using the test-negative design in populations being targeted for early vaccination such as health care workers, and eventually through the long-standing Sentinel Physician Surveillance Network (SPSN) in Canada, which uses the test-negative study design to assess seasonal influenza vaccine effectiveness and has been running in four provinces contributing data, led by BCCDC.

## Dosing, Scheduling and Administration

Refer to the BC Immunization Manual, [Part 4 – Biological Products](#), COVID-19 vaccines for complete information on the mRNA COVID-19 vaccines prior to administration.

## 16. What if a client presents later than the recommended interval for the COVID-19 mRNA vaccines?

If administration of the second dose of a COVID-19 vaccine is delayed, the second dose should be provided as soon as possible, and the series does not need to be restarted. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series as delays between doses do not result in a reduction in final antibody concentrations for most other vaccines requiring more than one dose for a series. Maximum protection may not be attained until the complete vaccine series has been administered.

## 17. What is the minimum interval for the second dose for each of the two mRNA vaccines?

For optimal response, immunizers should observe recommended intervals as much as possible, however, doses given earlier than recommended may still be considered valid and need not be repeated if minimum intervals are observed. The recommended minimum intervals between doses for the COVID-19 mRNA vaccines are as follows:

- Pfizer-BioNTech: 18 days
- Moderna: 21 days

## 18. What are the differences in the schedules, doses and administration between the two COVID-19 mRNA vaccines approved for use in Canada?

**Table 1 Schedules, doses and administration of COVID-19 mRNA vaccines**

Product	Pfizer BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
Authorized age for use	16 years of age and older	18 years of age and older
Dose	0.3 mL (30 mcg of mRNA)*	0.5 mL (100 mcg of mRNA)
Route	Intramuscular (IM)	Intramuscular (IM)
Schedule	2 doses, 35 days apart**	2 Doses, 35 days apart***
Diluent required	Yes Dilute with 1.8 mL of sodium chloride (0.9% normal saline)	No Ready for use
Formats available	Multi-dose vial (5 doses) After dilution, vaccine must be used within 6 hours	Multi-dose vial (10 doses) Must be used within 6 hours of first puncture

\*It is important to note that the dose for this vaccine (0.3 mL) is unique compared to that of most routine vaccinations. Special precaution should be taken to ensure the correct dose is taken from the multi-dose vial.

\*\* An acceptable range for administration of the second dose is 21-42 days after the first dose.

\*\*\*An acceptable range for administration of the second dose is 28-42 days after the first dose.

## 19. What if a client receives a COVID-19 mRNA vaccine less than 14 days following another live or inactivated vaccine?

As there are currently no data on the concomitant administration of COVID-19 vaccine with other vaccines, attempts should be made to avoid concomitant administration to maximize benefits of COVID-19 vaccination while minimizing any risks of harm, including the potential for immune interference and potential blunting of the immune response to either vaccine, or the erroneous attribution of an adverse event following immunization (AEFI) to a particular vaccine.

As such, it is recommended to wait a period of at least 14 days after the administration of another vaccine before administering a COVID-19 vaccine. However, if a COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, neither dose should be repeated. As well, operational considerations such as the likelihood that the individual can be immunized in the near future, may need to be considered and may necessitate immunizing earlier than recommended above, e.g., within 14 days of receipt of pneumococcal vaccine in the long term care resident setting.

## 20. What if a client receives another vaccine less than 28 day following the administration of either COVID-19 mRNA vaccines?

As above, due to the lack of data regarding concomitant administration of COVID-19 vaccines and other vaccines, it is recommended to wait a period of at least 28 days after the administration of the complete two-dose vaccine series of a COVID-19 mRNA vaccine before the administration of another vaccine, except in the case where another vaccine is required for post-exposure prophylaxis.

## Administration

### 21. Is there a recommendation on the size of needle to be used to dilute the Pfizer-BioNTech vaccine?

Yes. A 21-gauge needle or narrower is recommended to prevent a larger opening in the vial stopper that may allow vaccine to leak.

### 22. When diluting the Pfizer-BioNTech COVID-19 vaccine, is there a need to expel air from the vial to equalize the pressure?

Yes. After adding the diluent into the vaccine vial, withdraw 1.8 mL of air from the vaccine vial into the empty diluent syringe prior to removing the needle and attached syringe from the vial. This will prevent loss of vaccine from the vial through forceful expulsion under pressure.

### 23. What if there is remaining vaccine in the vaccine vial after 5 doses from the Pfizer-BioNTech vaccine vial, or 10 doses from the Moderna vaccine vial, have been removed?

If there is enough vaccine left in the vial for a complete 0.3 mL dose after 5 doses have been removed from a Pfizer-BioNTech vaccine vial, or a complete 0.5 mL dose after 10 doses have been removed from a Moderna vaccine vial, another dose can be drawn and administered.

Note: If there is less than the full dose of vaccine remaining in a vial, discard the leftover vaccine. It is not recommended to draw vaccine from two separate vials to make up a full dose.

### 24. Are the COVID-19 mRNA vaccines interchangeable?

As there are currently no data on the interchangeability of COVID-19 vaccines, NACI recommends that the vaccine series be completed with the same COVID-19 vaccine product. However, the spike proteins that encode the authorized mRNA vaccines have the same sequence and are stabilized in the same manner to remain in the pre-fusion confirmation, though other vaccine components like the lipid nanoparticle may be different.

If the vaccine product used for a previous dose is not known, attempts should be made to identify which vaccine was given for the first dose in order to give the same product for the second dose. If the same product is not available, complete the vaccine series with a similar type of COVID-19 vaccine (e.g., mRNA vaccine). Such a series should be considered as valid, without need to restart a two dose series with a new product.

## **25. Are prophylactic oral analgesics or antipyretics recommended before or at the time of vaccination?**

Prophylactic oral analgesics or antipyretics (e.g., acetaminophen or non-steroidal anti-inflammatory drugs such as ibuprofen) should not be routinely used before or at the time of vaccination. While these medications may be used after vaccination (see below), it is not known whether these may blunt the antibody response to vaccine. This phenomenon has been observed in some studies of other vaccines in children, although its clinical significance is unknown.

If an individual has taken one of these medications prior to immunization for any reason, they should be immunized as planned.

Oral analgesics or antipyretics may be considered for the management of symptoms attributed to the vaccine (e.g., pain, fever, headache, myalgia) if these cannot be readily tolerated using non-pharmaceutical strategies.

## **Special Considerations**

### **26. Are there groups in which the approved vaccines have not been specifically studied?**

NACI has provided the following recommendations for COVID-19 immunization in some specific populations who were either excluded from, or were represented by small numbers of participants in clinical trials. The recommendations for these groups are evolving, and more data will be available in the future about both protection from the vaccine and its safety.

#### **Pregnant and lactating people**

Safety and efficacy of the COVID-19 mRNA vaccines has not been established in people who are pregnant or breastfeeding, as they were not included in the clinical trials. While a cautionary approach has been taken historically to immunization during pregnancy and lactation, accumulating data on safety of immunization with a variety of vaccines during pregnancy and breastfeeding over several decades has led to expanded recommendations for use of vaccines in pregnancy. Both NACI and the Society of Obstetricians and Gynaecologists of Canada (SOGC) have pre-existing general recommendations that inactivated viral vaccines can be safely given in pregnancy. While the current NACI statement on COVID-19 vaccines is cautionary, SOGC recommends that pregnant people, those contemplating pregnancy, and those who are breastfeeding who are at high risk of infection and/or morbidity from COVID-19 should be offered the vaccine.

Nevertheless, both NACI and SOGC recommend that the pregnant or lactating person be informed about the lack of clinical trial data specifically designed to address the performance and safety of the vaccine in pregnancy and lactation. This information should include the findings that in some studies, pregnant individuals with COVID-19 infection are at higher risk of invasive ventilation compared to non-pregnant age-matched individuals. Severe morbidity in pregnancy is associated with similar risk factors to those seen in non-pregnant people, including older age, asthma, obesity, diabetes, hypertension and heart disease. There is no specific reason why healthy pregnant or lactating women or those with stable underlying chronic diseases such as those enrolled in the phase 3 clinical trials should not mount a good immune response to either vaccine. Regarding theoretical risks of vaccine receipt, the mRNA vaccines are not live virus vaccines, and there is not a basis to consider that these would be harmful neither to the fetus nor to the breastfed infant. A small number of pregnant women were inadvertently enrolled in the phase 3 clinical trials and are being followed to the end of their pregnancy to assess outcomes.

### Immunocompromised

Individuals who are immunosuppressed due to disease or treatment were not included in the initial COVID-19 mRNA vaccine clinical trials and as such there are limited data in these populations (NACI).

Individuals who are immunosuppressed due to disease or treatment, may have a diminished immune response to the vaccine.

A complete COVID-19 vaccine series may be offered to individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in these populations.

Advise those who are immunosuppressed due to disease or treatment to have a discussion with the care provider who knows their condition the best, as they would be most familiar with the client's disease and treatment. If such a client presents for immunization and indicates that they have had this discussion with their care provider and they understand the benefits and risks and absence of evidence on the use of COVID-19 vaccine in these populations, this would be sufficient for the immunizer to proceed with vaccination.

People living with stable HIV that are considered immunocompetent may receive the COVID-19 vaccine.

### Autoimmune disorders

Although participants with autoimmune conditions who were not immunosuppressed were not excluded from trials, they constitute a very small proportion of trial participants and represent a very narrow range of autoimmune conditions. The spectrum of autoimmune conditions is diverse. The relative degree of autoimmunity in individuals with autoimmune conditions is variable depending on the underlying condition, the severity and progression of disease, and use of medications that impact immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis. Other applications of mRNA technologies for the treatment of cancer required anti-self immune response, which raised a theoretical concern that mRNA vaccines for

infectious diseases would behave similarly. Previous mRNA vaccine technologies may have elicited inflammation and theoretically exacerbated existing autoimmune disease. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk. (NACI)

A complete COVID-19 vaccine series may be offered to individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in these populations.

Advise those with autoimmune disorders to have a discussion with the care provider who knows their condition the best, as they would be most familiar with the client's disease and treatment. If such a client presents for immunization and indicates that they have had this discussion with their care provider and they understand the benefits and risks and absence of evidence on the use of COVID-19 vaccine in these populations, this would be sufficient for the immunizer to proceed with vaccination.

## **27. Can the COVID-19 mRNA vaccines be given simultaneously with blood products or human immunoglobulin?**

To date, there is insufficient evidence on the receipt of both a COVID-19 vaccine and anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention. Therefore, timing of administration and potential interference between these two products are currently unknown. Administration of these products close together may result in decreased effectiveness of a COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies because the monoclonal antibodies have high affinity for the spike protein expressed by the vaccines.

For persons who received monoclonal antibodies or convalescent plasma for treatment of COVID-19, at least 90 days should elapse prior to vaccination with a COVID-19 vaccine. A second infection is unlikely to occur in that time period, and a period of 90 days or more will minimize the risk of blunting of the vaccine induced immune response, accounting for the estimated half-life of these treatments.

People receiving other antibody therapies unrelated to COVID-19 treatment (e.g., IVIG, RhoGAM) may receive mRNA COVID-19 vaccine at the same time or any interval before or after these therapies, as these are deemed unlikely to interfere with the immune response to the vaccine.

## **28. Can a client who has previous lab-confirmed SARS-CoV-2 infection receive the COVID-19 vaccine?**

Yes. NACI recommends that a complete series with a COVID-19 vaccine should be offered to individuals with prior PCR-confirmed SARS-CoV-2 infection. In the context of limited supply, to allow for the protection of a larger number of at-risk individuals, vaccination with a COVID-19 vaccine may be delayed for 3 months following a PCR-confirmed infection, as reinfections reported to date have been rare within the first three months following infection.

## Contraindications

### 29. What are the contraindications to the COVID-19 mRNA vaccines?

The authorized COVID-19 mRNA vaccines are contraindicated in individuals with:

- A history of anaphylactic reaction to a previous dose of the vaccine or to any component of the vaccine.

Of note, clinical trials of the authorized COVID-19 vaccines excluded individuals with a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

For a list of components in the vaccine and packaging consult the respective COVID-19 mRNA vaccine product monographs found at:

- **Pfizer BioNTech:** <https://www.cvdvaccine.ca/>
- **Moderna:** <https://www.modernacovid19global.com/ca/>

### 30. What are the potential allergens in the COVID-19 vaccines that are known to cause type 1 hypersensitivity reactions?

The authorized COVID-19 mRNA vaccines in Canada contain **polyethylene glycol (PEG)** which can be found in various products such as: bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin care products and as an additive in some food and drinks. No cases of anaphylaxis to PEG in foods and drinks have been reported.

### 31. What if there is a suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components?

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted; alternately, the vaccine can be administered in an emergency room setting, also with a prolonged observation period.

## Vaccine storage and handling

### 32. Why do the COVID-19 mRNA vaccines need to be administered within 6 hours once reconstituted (Pfizer-BioNTech) or first punctured (Moderna)?

As neither mRNA vaccine contains preservatives to prevent microbial contamination, the Pfizer-BioNTech vaccine must be used within 6 hours of dilution and the Moderna vaccine must be used within 6 hours of first puncture to the vial.

### 33. Where can I find information on the specific vaccine storage and handling requirements for the mRNA vaccines?

- **Pfizer BioNTech:** <https://www.cvdvaccine.ca/>
- **Moderna:** <https://www.modernacovid19global.com/ca/>

For more information specific to receiving and handling the Pfizer-BioNTech vaccine, go to the BC Immunization Manual, Appendix E: Management of Biologicals, [Guidance for Receiving and Handling the Pfizer-BioNTech COVID-19 mRNA Vaccine \(including dry ice procedures\)](#).



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