

## COVID-19 Immunization Program Questions and Answers for Immunization Providers October 2025

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## COVID-19 Disease

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

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

- Global: <https://data.who.int/dashboards/covid19/cases>
- Canada: <https://health-infobase.canada.ca/respiratory-virus-surveillance/>
- British Columbia: [https://bccdc.shinyapps.io/respiratory\\_outcomes/](https://bccdc.shinyapps.io/respiratory_outcomes/)

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

The COVID-19 pandemic caused significant morbidity and mortality, as well as social and economic disruption in Canada and worldwide. Although the COVID-19 pandemic was declared over by WHO in 2023, the endemic circulation of SARS-CoV-2 continues internationally and in Canada.

Since their introductions, COVID-19 vaccines have shown to be very effective at preventing severe disease, including hospitalization and death due to COVID-19. A recent study conducted an analysis to compare the real world scenario of global COVID-19 vaccination strategies with a scenario in which no COVID-19 vaccination were provided and identified major overall benefits from COVID-19 vaccination during the years of 2020-2024 with most benefits mainly seen in the older population and preventing more than 2.5 million deaths globally.<sup>(1)</sup>

COVID-19 vaccination protects not only the person being vaccinated but may also protect people around them. The more people in a community who are immunized and protected from COVID-19, the harder it is for COVID-19 to spread. Furthermore, people who are vaccinated and have been infected with SARS-CoV-2 have additional protection against post-COVID-19 condition (PCC). The available evidence suggests there is a positive relationship between the number of doses received and level of protection against PCC.<sup>(2)</sup>

Those at increased risk of SARS-CoV-2 continue to be recommended to receive COVID-19 vaccination with the updated vaccine strain. Vaccination is particularly important for seniors, as they have the highest hospitalization rates for COVID-19 compared to other age groups.

### 3. How effective are the COVID-19 vaccines and how long does immunity after vaccination last?

Several factors influence the COVID-19 vaccine effectiveness (VE) measures including time since the last dose of COVID-19 vaccine, the circulating strains of the virus and how closely they match the vaccine strain, infection pressures in the community, the population being studied and the outcomes being measured. In recent years, it has become more difficult for studies to capture the absolute VE (i.e., comparing vaccinated group to unvaccinated group) as a larger proportion of the

population have acquired immunity either through prior COVID-19 immunization or prior SARS-CoV-2 infection.<sup>(3)</sup>

New data suggests during the 2024/2025 season, COVID-19 KP.2 vaccines provided added protection against a SARS-CoV-2 infection in Canada. Between November 2024 and April 2025, the Canadian Sentinel Practitioner Surveillance Network assessed KP.2 vaccine effectiveness against outpatient COVID-19 by test-negative design. Based on their findings, the 2024/25 KP.2 mRNA vaccine halved the risk of COVID-19 outpatient medical visit for ARI amongst. Results also highlighted protection was greatest within two months post-vaccination, reducing the risk by about two-thirds, but rapidly declined to negligible protection by 3-4 months post-vaccination.<sup>(4)</sup>

Similarly, data from the US on COVID-19 VE for the 2024/2025 season suggested that the JN.1 and KP.2 formulations of COVID-19 vaccine provided additional protection against COVID-19 associated ER and urgent care centre (UCC) visits and hospitalizations among adults with and without immunocompromising conditions.<sup>(5)</sup>

Among adults aged  $\geq 18$  years, effectiveness of a 2024/2025 COVID-19 vaccine against a COVID-19–associated ED/UCC visit was 33% (95% CI = 28%–38%) during the first 7–119 days after vaccination, 36% (95% CI = 29%–42%) during the first 7–59 days after vaccination, and 30% (95% CI = 22%–37%) during the 60–119 days after vaccination.<sup>(5)</sup>

Based on the two data sources in the US, Virtual SARS-CoV-2, Influenza, and Other respiratory viruses Network (VISION) and Investigating Respiratory Viruses in the Acutely Ill (IVY) network, VE for COVID-19–associated hospitalization among adults aged  $\geq 65$  years without immunocompromising conditions ranged from 45% (95% CI = 36%–53%) with median interval of 53 days since receipt to 46% (95% CI = 26%–60%) with a median of 60 days after receipt of a 2024/2025 COVID-19 vaccine dose.<sup>(5)</sup>

Based on the VISION data, VE for adults aged  $\geq 65$  years with immunocompromising conditions was 40% (95% CI = 21%–54%), with a median interval of 53 days after receipt of a 2024/2025 COVID-19 vaccination.<sup>(5)</sup>

Hospitalization data is limited on VE for children 5-17 years of age and adults 18-64 years of age due to low immunization rates and hospitalization rates. However, data from previous years have indicated that COVID-19 vaccines provide similar protection across all age groups.<sup>(5)</sup>

## Vaccine development and safety

### 4. How do we know that the COVID-19 vaccines 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 also has processes in place to share information with/from other countries' regulatory bodies including the US Food and Drug Administration and the European Medicines Agency.

Since the first introduction of COVID-19 vaccines, the scientific community has been closely monitoring the safety and effectiveness of the COVID-19 vaccines by conducting various studies. Based on the available surveillance data and results of these studies, NACI has been refining and updating their recommendation for the use of COVID-19 vaccines in Canada.

Visit [Vaccine Safety](#) to learn more about vaccine approval and safety surveillance.

## 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 [HealthLinkBC](#) websites for more information about COVID-19 vaccination. Continue the conversation about COVID-19 vaccination during future visits.

## 6. How is the safety of COVID-19 vaccines 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 regional public health authorities. In BC, health care providers report these events by submitting an Adverse Event Following Immunization (AEFI) case report form to the regional health authority where the individual resides. When these events meet the reporting criteria, they are 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 surveillance system called the Canadian Adverse Events Following Immunization System (CAEFISS) which is responsible for passive surveillance for immunization across Canada.

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.

In addition to passive surveillance, adverse events following COVID-19 immunization can also be captured in the pediatric population through active surveillance. SPRINT-KIDS is a pediatric hospital-based national active surveillance network for adverse events in children following immunization. This network consists of 15 pediatric hospitals across Canada, including the BC Children's Hospital (BCCH) in BC. The SPRINT-KIDS team at BCCH reviews emergency room visits and hospital admissions for select symptoms and diagnoses and identifies whether these events were preceded by immunization. After their thorough investigation, any events potentially related to immunizations are reported to the regional health authorities and to the Public Health Agency of Canada.

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.

In B.C, reports on adverse events following COVID-19 immunization from 2021 to 2023 are available on BCCDC's [COVID-19 Vaccine Safety](#) page.

The national reports on adverse events following COVID-19 immunization are available on Health Canada's [Reported Side Effects Following COVID-19 Vaccination in Canada](#) page.

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?

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. There is also a [short version of the AEFI](#) form available for community and acute care providers. Those providers who work in public health still need to use the long AEFI form.

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

## 8. Can COVID-19 vaccine cause infertility?

No. COVID-19 vaccines do not cause infertility and there is no scientific reason to believe that they will. Recent studies have shown that COVID-19 vaccines do not impact fertility.[\(6, 7\)](#)

The Society of Obstetricians and Gynaecologists of Canada (SOGC) addresses this rumor in their recent statement stressing, “there is absolutely no evidence, and no theoretic reason to suspect that the COVID-19 vaccine could impair male or female fertility” and added, that “the widespread social media concern stems from misinformation about the similarities between syncytin-1 (used for placental implantation) and the SARS-CoV-2 spike protein. While the two proteins have several similar amino acids, they remain vastly different. The antibodies produced against the SARS-CoV-2 spike protein would not have cross-reactivity with syncytin-1.”[\(8\)](#)

## General Questions

### 9. What are the current COVID-19 vaccination recommendations?

For the 2025-2026 COVID-19 vaccine program, the National Advisory Committee on Immunization (NACI) recommends the most recently updated COVID-19 vaccines (i.e., the vaccines targeting the L.P.8.1 variant).[\(2\)](#) Internationally, strain selection assessments for COVID-19 vaccines have been occurring on a regular basis, with the COVID-19 vaccines being updated once a year, prior to the fall/winter respiratory season.

In addition, NACI recommends that certain individuals at increased risk (e.g., adults 80 and over) of severe COVID-19 disease receive an additional dose. The timing of this additional dose is determined by provinces and territories based on past and emerging epidemiological trends.[\(3\)](#)

For information on vaccine eligibility in BC see [COVID-19 Vaccine Eligibility](#) in [Part 4](#) of the BC Immunization Manual.

### 10. What is hybrid immunity?

Individuals who have developed immunity against COVID-19 have done so through one of the following circumstances:

- Infection-induced immunity which describes the immune protection in an unvaccinated individual after one or more SARS-CoV-2 infections.
- Vaccine-induced immunity which is the immunity achieved by an individual who has not been infected with SARS-CoV-2 but has a primary series of any COVID-19 vaccine or has received a booster vaccination.
- Hybrid immunity is defined as the immune protection in an individual who has had one or more doses of a COVID-19 vaccine and experienced at least one SARS-CoV-2 infection before or after receiving COVID-19 vaccine.[\(9\)](#)

Evidence demonstrates that hybrid immunity may provide superior protection against COVID-19 compared to vaccination or previous infection alone, particularly when hybrid immunity is in the context of a recent infection([2](#), [10](#)).

#### 11. Are the COVID-19 vaccines interchangeable?

Any of the available, updated age-appropriate COVID-19 vaccines can be used to complete a primary series started with another product and as a subsequent dose in those previously vaccinated, regardless of platform or manufacturer. When a COVID-19 vaccine is used to complete the primary series started with another COVID-19 vaccine formulation, the previous dose should be counted, and the series need not be restarted.([11](#))

#### 12. Can a COVID-19 vaccine be given concomitantly with other vaccines?

Yes. COVID-19 vaccines may be given concomitantly (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines).

#### 13. What is the minimum age for COVID-19 immunization?

The minimum age for COVID-19 immunization is 6 months (not 24 weeks). For premature infants, chronological age based on actual birth date should be used as opposed to corrected age.([12](#))

#### 14. What are the recommendations for pregnant people?

COVID-19 vaccination among pregnant people remains a priority.([13](#)) Pregnancy is a higher risk period for complications from COVID-19 infection. Pregnant people are more likely to be hospitalized and admitted to intensive care compared to their non-pregnant age-matched peers.([13](#), [14](#)) Infants born to mothers with COVID-19 are also at higher risk of severe outcomes, including stillbirth, admission to the neonatal intensive care unit, and death.([13](#), [15](#)) Pregnant people with complete or booster vaccine doses had reduced risk for severe symptoms, complications, and death.

Although, the primary indication for administration of COVID-19 vaccination is for maternal protection, IgG antibodies from the pregnant person are transferred to the fetus, potentially resulting in protective antibody titres in the neonatal bloodstream. ([16](#))

COVID-19 vaccination during pregnancy has not been shown to increase the risk of miscarriage, congenital anomalies, preterm delivery or other adverse perinatal outcomes.([17](#), [18](#))

While the safety and efficacy of the COVID-19 vaccines were not studied in people who were pregnant or breastfeeding in the clinical trials for these vaccines, evidence during the post-marketing period has accumulated. Outcomes in participants who became pregnant during the clinical trials and fetal outcomes are reported through registries, and real-world evidence (mostly with mRNA vaccination) is now available. 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. The 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.(19)

#### 15. Can a client who had a previous SARS-CoV-2 infection receive a COVID-19 vaccine? Is there a recommended interval between infection and vaccination?

NACI continues to recommend that COVID-19 vaccines should be offered to people who have previously been infected with SARS-CoV-2. There are no known safety risks with receiving a COVID-19 vaccine after a recent SARS-CoV-2 infection.(20)

COVID-19 vaccine may be offered to individuals without contraindications who have recovered from SARS-CoV-2 infection:

Individuals with a history of multisystem inflammatory syndrome in children or adults (MIS-C or MIS-A) should wait to be vaccinated for at least 90 days from diagnosis or clinical recovery, whichever is longer.(16)

#### 16. What are the recommendations on the timing of COVID-19 vaccination with Tuberculin skin tests (TST) or Interferon Gamma Release Assay tests (IGRA)?

There is a theoretical risk that mRNA vaccines could temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. However, there is no direct evidence for this interaction. Therefore, in the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, vaccination with COVID-19 vaccines may take place at any time before, after or at the same visit as the TST or IGRA test. Repeat TST or IGRA (at least 4 weeks post-COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis infection may be considered in order to avoid missing persons with TB infection. (14)

#### 17. 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. There is currently no evidence of benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.(14) While these medications may be considered for the management of adverse events (e.g., pain or fever,), 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.(21-23) If an individual has taken one of these medications prior to immunization for any reason, they should be immunized as planned.

## 18. Should women defer mammograms following receipt of COVID-19 vaccine?

Lymphadenopathy (reactive adenopathy related to the immune response generated by the vaccine) in the regional nodes draining the deltoid area can occur. Such enlarged nodes may be viewed in imaging studies such as mammograms and may be interpreted as abnormal and indicative of potential pathology.

The BC Cancer Agency recommends that scheduled screening mammograms should not be cancelled or delayed because of COVID-19 immunization. Those undertaking imaging within 6 weeks following vaccination should be asked for information about the site of vaccination so that this information can be recorded and considered in the interpretation of the radiograph.[\(24\)](#)

For those being vaccinated in the context of suspect or known breast malignancy, the vaccine should be given in the contralateral arm for both doses.

## 19. How do health care providers respond to questions from parents/guardians about the benefit of vaccinating their children when they are unlikely to experience severe illness with COVID-19?

It is normal for parents/guardians to have questions about what is best for their children. Healthcare providers continue to be a trusted source for immunization information and as parents/guardians consider the possible risk and benefits of vaccinating their children, healthcare providers can be there to address their questions.

In BC, COVID-19 vaccine is recommended for children 6 months of age and older who have underlying medical conditions (specifically people in CEV groups 1, 2, and 3). However, COVID-19 vaccines may be offered to any child 6 months and older if their parents request it.

## 20. Can vaccine providers aspirate with the administration of COVID-19 vaccine if requested by a client, even though this is not considered best practice?

As indicated in the [BC Immunization Manual, Appendix B – Administration of Biological Products](#), aspiration prior to injection of a vaccine is no longer recommended as there are no large blood vessels at the recommended immunization sites and aspiration can increase pain resulting from the combined effects of a longer needle-dwelling time in the tissues and shearing action (wiggling) of the needle.[\(25, 26\)](#) Aspiration was originally recommended for theoretical safety reasons, however the veins and arteries within reach of a needle in the anatomic areas recommended for vaccination are too small to allow an intravenous push of vaccine without blowing out the vessel.[\(26\)](#) While there is no evidence to support the need for aspiration, there is no *prohibition* on aspiration when administering a vaccine. Therefore, to avoid barriers and missed opportunities for COVID-19 immunization, this procedure could be done to accommodate case-by-case requests.

However, clients should be informed of the possibility of increased pain and discomfort at the injection site. Providing the rationale for not aspirating with injection may assist the client in making an informed choice on the procedure which may include the following information:

- There is no scientific evidence to support the need for aspiration
- There are no published reports of adverse effects associated with not aspirating
- The deltoid site used for intramuscular injection is not in close proximity to large blood vessels, therefore the possibility of inadvertently hitting a blood vessel is rare
- For aspiration to be effective, it must be sustained for at least 5-10 seconds
- Injection with aspiration is more painful, likely because aspiration, when performed correctly for 5-10 seconds, results in longer contact time between the needle and the tissue and movement of the needle within the tissue during aspiration is expected
- Bleeding at the injection site is common, and does not indicate incorrect injection technique or injection into a blood vessel

## 21. If the decision is to aspirate prior to injection for a client who requests it, how is this done?

Needle aspiration is performed by pulling back on the plunger (applying negative pressure) of the syringe after inserting the needle into the client and prior to injecting the vaccine and includes the following steps:

- After the needle pierces the skin, use the thumb and forefinger of the non-dominant hand to hold the syringe barrel
- Move the dominant hand to the end of the plunger
- Avoid moving the syringe
- Aspirate by holding the barrel of the syringe steady with your non dominant hand and by pulling back on the plunger with your dominant hand (27)

Effective aspiration may require 5 to 10 seconds prior to injection; if blood appears in the barrel of the syringe during this time, do not inject the vaccine and withdraw the needle, and properly discard the syringe.(28)

Oral analgesics may be considered post-vaccination for the management of pain attributed to the vaccine when aspiration is used if pain cannot be readily tolerated using non-pharmaceutical strategies-



*Aspirate plunger for blood return*

Source: [BCcampus OpenEd](#)

## COVID-19 mRNA vaccines

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

Both the Pfizer-BioNTech Comirnaty® and Moderna Spikevax® COVID-19 vaccines are mRNA vaccines. Messenger RNA (mRNA) is the 'blueprint' that cells use to synthesize proteins required for our physiology. The COVID-19 mRNA 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.[\(29-31\)](#)

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.

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

History of anaphylactic reaction to any component of the vaccine is generally considered a contraindication. Anaphylaxis has been reported to be very rare following mRNA vaccination. However, based on recent studies demonstrating that individuals who experienced anaphylaxis following their first dose of mRNA vaccine were able to receive their second dose of mRNA vaccine with either mild or no side effects, re-vaccination may be offered with the same vaccine or the same platform if a risk assessment deems that the benefits outweigh the potential risks for the individual, informed consent is provided, and the following criteria are met:[\(14, 32\)](#)

- consultation with an allergist or another appropriate physician before receiving future doses of a COVID-19 mRNA vaccine
- a controlled setting where the vaccine can be administered with expertise and equipment to manage anaphylaxis
- an observation period of **at least** 30 minutes after vaccination (the normal observation period for people who have not experienced a severe immediate allergic reaction after vaccination is 15 minutes).

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

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the vaccine should be administered in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation post-vaccination of at least 30 minutes.

For more information, refer to the [BC Immunization Manual, Part 3 – Management of Anaphylaxis in a Non-Hospital Setting, Supervision of Vaccinee Post-immunization](#).

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

Both Pfizer and Moderna COVID-19 mRNA vaccines 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.

#### 26. What is tromethamine, and is there a concern for those with an allergy to this vaccine component?

Tromethamine (Tris or trometamol) is used as a buffer in vaccines and medications, including those for use in children, to improve stability and prevent pH fluctuations in the solution. Tromethamine is widely used in several medications for topical, enteral or parenteral administration. It is also used in cosmetics as an emulsifier.<sup>(33)</sup> No safety concerns have been identified with tromethamine. While tromethamine has been identified as a potential allergen, a review of existing evidence did not identify any cases of allergic reactions to tromethamine in children.<sup>(34)</sup> Tromethamine has been identified as a potentially allergenic excipient and is present in the Pfizer-BioNTech and Moderna COVID-19 vaccines. However, there is increasing evidence that this is not the culprit excipient and/or the reactions are not IgE-mediated. This remains under investigation.<sup>(35)</sup>

#### 27. Why do the mRNA vaccines need to be used within a specified amount of time following first vial puncture or dilution?

The mRNA vaccines do not contain a preservative to prevent microbial contamination following first vial puncture or dilution and therefore they must be used within the specified time periods indicated within the respective product pages in the [BC Immunization Manual, Part 4 – Biological Products, COVID-19 Vaccines](#).

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

Additional information, including standard operating procedures can be found on the [COVID-19 Immunize BC Operations Centre: Standard Operating Procedures](#) page.

## COVID-19 protein subunit vaccine (Novavax)

### 28. What type of vaccine is the Novavax COVID-19 vaccine?

The Novavax COVID-19 vaccine is a recombinant protein subunit vaccine. While this type of vaccine technology has been used for other vaccines such as the hepatitis B vaccine, this is the first COVID-19 vaccine authorized in Canada which uses this technology. This vaccine has been available in the past in Canada, but it is not available for the 2025/2026 season.

Protein subunit vaccines are created by inserting a small piece of the virus's genetic code into another cell (Novavax uses the *Spodoptera frugiperda* insect cell line) which instructs the cell to start building the SARS-CoV-2 spike protein. The virus spike protein is then extracted from the cell, purified and used as the active ingredient in the vaccine to stimulate an immune response. The Novavax COVID-19 vaccine includes a new type of adjuvant, Matrix-M, which helps the vaccine produce a better immune response.

## Individuals who are immunocompromised

### 29. Why is an additional dose(s) of COVID-19 vaccine recommended for individuals who are moderately to severely immunocompromised?

To date, people with moderately to severely compromised immune systems have been observed to generally have lower antibody responses and lower vaccine effectiveness compared to immunocompetent individuals, although this varies depending on the underlying condition or immunosuppressive therapy.

NACI continues to recommend an additional dose of COVID-19 vaccine in the primary series for those who are moderately to severely immunocompromised to help improve the immune response and vaccine effectiveness.<sup>(14)</sup>

Unvaccinated individuals 5 years of age and older who are moderately to severely immunocompromised should receive 2 doses of COVID-19 vaccine, compared to the 1-dose schedule recommended for those in this age group who are not immunocompromised. In addition, previously unvaccinated individuals who are moderately to severely immunosuppressed with a recommendation by their health care provider are eligible to receive a 3-dose series. Although 2 doses can provide good protection, not all individuals with immunocompromising conditions will respond the same way to vaccination. Furthermore, not all individuals who are moderately to severely immunosuppressed have prior history of SARS-CoV-2 infection and they are lacking the additional protection offered by hybrid immunity. Hence, in some cases, a third dose would be needed to develop adequate protection.<sup>(2)</sup>

New HSCT and CART therapy recipients initiating their series are considered immunologically naïve and should receive a 3-dose series regardless of the COVID-19 vaccine formulation. This is consistent with the premise that three antigen exposures are helpful to establish a foundation of robust immunity.(2) Revaccination can occur as early as 3 months post-transplant.

Those 6 months to 4 years of age who are moderately to severely immunocompromised are recommended to receive 3 doses of Moderna COVID-19 vaccine. (2) If any dose in the series was a Pfizer COVID-19 vaccine, these individuals should have a total of at least 4 doses of COVID-19.

## Adverse Events Following Immunization

### 30. How common is anaphylaxis following COVID-19 vaccine administration and what are re-vaccination recommendations in this case?

Very rare cases of anaphylaxis have been reported following vaccination with mRNA COVID-19 vaccines. Most of the reported cases have occurred within 30 minutes of vaccination. Individuals tend to recover quickly with appropriate treatment and there have been no fatalities nor long-term morbidity observed with any of these severe immediate allergic reactions in Canada.

Studies have shown that individuals with a severe immediate allergic reaction after a previous dose of mRNA vaccine can be re-vaccinated with the same vaccine or another mRNA COVID-19 vaccine following an appropriate medical assessment and provided certain criteria are met – see the PRECAUTIONS section within the respective product pages within the [BC Immunization Manual, Part 4 – Biological Products, COVID-19 Vaccines](#). In these studies, re-vaccination was safe and well tolerated with predominantly no, or mild, reactions after re-vaccination when provided in a controlled environment. Available evidence also suggests that most of the reported severe immediate allergic reactions following mRNA COVID-19 vaccines are likely not immunoglobulin E (IgE)-mediated and therefore have a low risk of recurrence following future vaccine doses.(14)

Reports of reactions to COVID-19 vaccines have increased concerns about their safety for individuals with allergies. The Canadian Society of Allergy and Clinical Immunology (CSACI) guidelines stress that there is a low risk for allergic reactions to vaccines, and non-allergic reactions to vaccines are more common than allergic reactions. In addition, non-allergic reactions to vaccines also include anxiety-related adverse events that can mimic allergic reactions.(36) It is important to note that other, less serious reactions may mimic allergic reactions such as vasovagal syncope which are not contraindications to further vaccination.(29)

Additional information regarding allergies and COVID-19 vaccine for the public can be found in the CSACI's [COVID-19 Vaccines FAQ](#) resource.

For more information review the contraindications and precautions sections in the COVID-19 vaccine product pages of the [BC Immunization Manual, Part 4 – Biological Products, COVID-19 Vaccines](#). To learn more about anaphylaxis refer to the [BC Immunization Manual, Part 5 – Adverse Events Following Immunization](#).



### 31. What steps should be taken when an individual presents for their subsequent COVID-19 vaccine dose and reports they had an allergic reaction following their previous dose?

It is important to first determine whether the reaction was an anaphylactic reaction. For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the vaccine should be administered in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation post-vaccination of at least 30 minutes.

If an individual experienced a serious adverse event following immunization (AEFI), an AEFI report may be available in the provincial immunization data system. The AEFI report will contain details about the event as well as the Medical Health Officer (MHO) recommendation on further immunization.

Although anaphylaxis occurs rarely after vaccination, it is potentially life threatening and requires immediate treatment. It is characterized by sudden onset, rapid progression of signs and symptoms affecting multiple organ systems which sets it apart from simple allergic. Anaphylaxis that has been proven to be causally associated with vaccines is estimated at a frequency of 1.3 episodes per 1,000,000 doses of vaccines administered.[\(37\)](#)

For individuals with a history of anaphylactic reaction to a previous dose of a COVID-19 mRNA vaccine, re-vaccination (i.e., administration of a subsequent dose in the series when indicated) may be offered with an mRNA vaccine if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Prior to re-vaccination, consultation with an allergist or another appropriate physician (e.g., Medical Health Officer) is advised. If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation of at least 30 minutes after revaccination.

History of anaphylactic reaction to a previous dose of Novavax COVID-19 vaccine or to any component of the vaccine is considered a contraindication to receipt of this vaccine. These individuals should be offered a COVID-19 mRNA vaccine and observed for at least 30 minutes after immunization.

**The checklist below can be used as a tool to assist health care providers to determine how to proceed when an individual reports an allergic reaction following a COVID-19 vaccine.**

- Was the event considered a severe allergic reaction or physician-diagnosed anaphylaxis?
- Is there a history of anaphylactic reaction to any component of COVID-19 vaccine?
- Was the event reported to public health as an AEFI?
- If reported to public health, is an MHO recommendation available?
- Did the MHO recommendation indicate that a COVID-19 vaccine from a different vaccine platform be provided?



### 32. What were the common adverse events following COVID-19 vaccination in children?

Clinical trials showed that local reactions including pain, redness and swelling were very common, appearing 1-2 days after any dose and typically resolved within 1-3 days. Systemic symptoms (fatigue, headache, muscle pain, chills, fever, joint pain) were also common and usually mild or moderate in severity. Onset of systemic events was within 1-4 days after vaccine receipt.

Post-market vaccine safety data from V-safe, Vaccine Safety Datalink (VSD) and Vaccine Adverse Event Reporting System (VAERS) in the US as of September 2022 show that the Moderna Spikevax (25 mcg) and Pfizer-BioNTech Comirnaty (3 mcg) COVID-19 mRNA vaccines are well tolerated among children aged 6 months to 5 years. No significant safety signals (including myocarditis) have been identified after administration of about 1.5 million vaccine doses.[\(11\)](#) The most frequent reactions reported for children aged 6 months to 2 years included irritability or crying, sleepiness, and loss of appetite. These reactions are common after childhood vaccination.[\(11\)](#)

### 33. What is the risk of myocarditis and pericarditis associated with COVID-19 vaccines?

Myocarditis is an inflammation of the heart muscle; if it is accompanied by pericarditis, an inflammation of the thin tissue surrounding the heart (the pericardium), it is referred to as myopericarditis. Symptoms can include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. Symptoms can be accompanied by abnormal tests (e.g., electrocardiogram, serum troponins, echocardiogram). These are inflammatory disorders of the outer lining of the heart and heart muscle, and occur for a variety of reasons including in association with viral infections.

As such, myocarditis can occur as a complication of COVID-19 infection. In Israel, COVID-19 infection has been estimated to cause myocarditis at a rate of 11 events per 100,000 persons among individuals aged 16 years and older. A retrospective study from the US found myocarditis (or pericarditis or myopericarditis) rates after primary COVID-19 infection to be as high as 45 cases per 100,000 patients in young males aged 12-17 years.

#### **mRNA COVID-19 Vaccines:**

Myocarditis following mRNA COVID-19 vaccination tends to have a similar epidemiologic profile to classic myocarditis (unrelated to COVID-19), as it occurs more commonly in adolescents and young adult males. Classic myocarditis is less common in younger children.[\(38\)](#)

Cases of myocarditis/pericarditis following COVID-19 mRNA vaccination occur most commonly in adolescents and young adults (12 to 29 years of age) however, the risk is considered rare. It is important to note, as well, that teens and adults are at higher risk of developing myocarditis/pericarditis following COVID-19 infection compared to COVID-19 mRNA vaccination; as such, the risk of experiencing myocarditis is greater in an unvaccinated person than a vaccinated person. [\(39\)](#)

When cases of myocarditis and/or pericarditis following vaccination with COVID-19 mRNA vaccines were first detected, NACI recommended Pfizer BioNTech Comirnaty as the preferred product over Moderna Spikevax for the primary series in individuals 12-29 years due to the higher risk of myocarditis and/or pericarditis observed following the Moderna Spikevax 100 mcg original monovalent vaccine primary series (especially after the second dose). However, this product preference is no longer being recommended. Compared to the original monovalent primary series, the risk of myocarditis and/or pericarditis is now expected to be lower due to the use of a 1-dose schedule in most individuals and potentially due to a lower dosage of the available Moderna Spikevax vaccine (50 mcg in current formulation compared to 100 mcg in the original monovalent formulation).[\(40\)](#)

Myocarditis/pericarditis usually occurs within a week of vaccination and is more common:

- After the second dose
- In males than females
- After receipt of the Moderna vaccine than the Pfizer-BioNTech vaccine.

In both Canada and the US, no deaths attributed to COVID-19 mRNA vaccine-related myocarditis have been identified in adolescents or young adults.

Available data indicate that most individuals affected have responded well to conservative therapy and have recovered quickly. [\(29\)](#) Evidence suggests myocarditis and/or pericarditis risk is lower after mRNA vaccination than SARS-CoV-2 infection. In addition, risk of COVID-19 hospitalization after SARS-CoV-2 infection remains much higher than the risk of myocarditis post-vaccination.[\(41\)](#)

#### **Protein Subunit Vaccine:**

Pericarditis and myocarditis in association with Novavax COVID-19 vaccine have been reported internationally and in Canada per Public Health Agency of Canada. A longer interval of 8 weeks between doses in the primary series may reduce the likelihood of pericarditis and myocarditis. Most cases recover fully. The exact cause of these events is not known but is thought to be related to the immune response to the spike protein which is also important in immunity against COVID-19 virus.

#### **Current recommendations on re-vaccination following myocarditis or pericarditis:**

As a precautionary measure until more information is available, further doses of mRNA COVID-19 vaccines should be deferred among individuals who have experienced myocarditis and/or pericarditis within 6 weeks following a previous dose of an mRNA COVID-19 vaccine in most circumstances. This includes any person who had an abnormal cardiac investigation including ECG, elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA COVID-19 vaccine.

Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can receive the next dose once they are symptom-free and at least 90 days have elapsed since vaccination.

Some individuals with confirmed myocarditis and/or pericarditis after a dose of an mRNA COVID-19 vaccine may choose to receive another dose of vaccine after discussing the risk and benefit with

their healthcare provider. If another dose of vaccine is offered, it should be with a Pfizer-BioNTech Comirnaty COVID-19 vaccine product.<sup>(16)</sup>

Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 vaccines and are no longer being followed by a medical professional for heart issues.

Informed consent should emphasize the unknown risk of recurrence of myocarditis and/or pericarditis for these individuals and the importance of seeking immediate medical assessment and care should these symptoms develop.

In BC, we have ensured that health care providers are aware of this observation and the possibility of it being causally linked to the vaccine, and how to diagnose and report this event when it occurs after a COVID-19 vaccine.

#### 34. What if the allergic reaction following a previous COVID-19 vaccine dose was not reported to public health and an MHO recommendation is not available?

Any health professional who is aware of an adverse event following immunization must report the event to the medical health officer as per the Public Health Act. Information on AEFI reporting can be found on the BCCDC COVID-19 Vaccination Healthcare Provider Toolkit on the [Adverse Events Following Immunization \(AEFIs\)](#) page. More information about reporting anaphylaxis and other allergic reactions can be found in the [BC Immunization Manual, Part 5 – Adverse Events Following Immunization](#). In addition, the [Report of Adverse Event Following Immunization](#) is a shortened two-page form available for non-public health professionals reporting AEFI.

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