Nova Scotia COVID-19 Vaccine Program

Information for Health Care Professionals

Updated May 6, 2022

Electronic copy can be found here: https://novascotia.ca/dhw/cdpc/info-for-professionals.asp; Immunization Tab; COVID-19 Immunization.

This evergreen document will be updated as evidence on COVID-19 and COVID-19 vaccines evolves.

The Public Health Agency of Canada (PHAC) has developed the COVID-19 Vaccination Tool Kit for Health Care Providers. Within the tool kit, there are links to general information about COVID-19, an overview of authorized vaccines, guidance for managing COVID-19 vaccination clinics, an overview of vaccine safety, as well as a number of additional resources such as digital tools and communication materials.

The Nova Scotia Health Authority (NSHA) has developed a Pandemic Immunizer Education site as an educational resource designed for health care providers who will be supporting community immunization clinics.

COVID-19 vaccine information and resources may also be found on the NSHA COVID-19 Hub.

Table of Contents

COVID-19 Vaccines in Canada – Eligibility, Interchangeability, Efficacy and Immunity

1. Which COVID-19 vaccines are currently available for use in Nova Scotia?

There are two COVID-19 mRNA vaccines available for use in Nova Scotia:

- Pfizer-BioNTech Comirnaty COVID-19 vaccine was authorized by Health Canada on December 9, 2020. Pfizer BioNTech Comirnaty pediatric formulation (age 5 -11) received Health Canada approval on November 19, 2021. Pfizer Comirnaty vaccine information including the product monograph is available from: https://www.cvdvaccine.ca/.
- Moderna Spikevax COVID-19 vaccine was authorized on December 23, 2020. Moderna Spikevax information including product monograph is available from: https://www.modernacovid19global.com/ca/.

Novavax Nuvaxovid, a COVID-19 recombinant protein subunit vaccine was authorized by Health Canada on February 17, 2022. A small supply of Novavax Nuvaxovid is now available in Nova Scotia. The Novavax COVID-19 vaccine product monograph is available from https://covid-vaccine.canada.ca/info/pdf/nuvaxovid-pm-en.pdf.

Medicago Covifenz, a COVID-19 plant-based virus-like particle, recombinant, adjuvanted vaccine, was authorized by Health Canada on February 24, 2022. The delivery date of the Medicago COVID-19 vaccine to Canada has not been finalized. The Medicago COVID-19 vaccine product monograph is available from: https://covid-vaccine.canada.ca/info/pdf/covifenz-pm-en.pdf

There is a small supply of Janssen COVID-19 vaccine (non-replicating viral vector vaccine) available for use in Nova Scotia. Janssen COVID-19 vaccine was authorized by Health Canada on March 5, 2021. The Janssen COVID-19 vaccine product monograph is available from: https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf.

AstraZeneca Vaxzevria (non-replicating viral vector vaccine) is no longer available in Nova Scotia, but information will be retained in this document for the time being to guide any necessary response post-administration. AstraZeneca Vaxzevria COVID-19 vaccine was authorized on February 26, 2021. The AstraZeneca Vaxzevria product monograph is available from: https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf

- AstraZeneca vaccine doses currently in Nova Scotia have expired as of April 30, 2022. Providers are asked to return unused doses to the BioDepot. There are no plans to replenish the vaccine supply.

Additional information specific to the COVID-19 vaccines currently authorized for use in Canada can be found in the Canadian Immunization Guide – Part 4: Active vaccines – COVID-19 vaccine.

2. Who is eligible to receive COVID-19 vaccine?

Any person living in Nova Scotia who is 5 years of age or older is eligible to receive COVID-19 vaccine for free. Nova Scotia adopted a predominantly age-based roll out of COVID-19 vaccine, however healthcare workers, and those living in large congregate settings (public and private) were the first groups eligible to receive COVID-19 vaccine. The province also has ensured equitability and accessibility into its COVID-19 vaccine program by working with First Nations and African Nova Scotian stakeholders to develop culturally sensitive vaccination clinics. Outreach vaccine clinics with urban indigenous persons, shelters, persons with disabilities, community day programs and some large, specialized homes

have also occurred. Many factors are involved in the development of Nova Scotia's vaccine plan and are continually assessed as circumstances change.

3. With the information is available regarding interchangeability of authorized COVID-19 vaccines, and how can health care professionals support patients in making an informed choice about receiving a specific type of COVID-19 vaccine?

NACI has provided advice on the interchangeability of authorized COVID-19 vaccines in a two-dose primary series schedule for COVID-19 immunization. NACI recommends that:

- A complete series with an mRNA COVID-19 vaccine (Pfizer or Moderna) should be preferentially offered to individuals in the authorized age group without contraindications to the vaccine.
- COVID-19 mRNA vaccines should be considered interchangeable, however NACI also recommends that individuals aged 12 to 29 years of age preferentially receive the Pfizer COVID-19 vaccine.
- A COVID-19 mRNA vaccine is preferred as a subsequent dose for adults who received a first dose of AstraZeneca/COVISHIELD vaccine (viral vector vaccine). An mRNA vaccine is preferred as a subsequent dose due to evidence including the possibility of better immune response, and the safety of mixed schedules.
- Novavax COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine. Novavax COVID-19 vaccine may used in a homologous primary series, heterologous (mixed) primary series or as a booster dose in a homologous or heterologous prime-boost series.
- Medicago, while not yet available in Nova Scotia, may be offered as a homologous primary series to individuals in the authorized age group (18 to 64) without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine. Medicago has not been evaluated as a heterologous (mixed) primary series. Available evidence for other COVID-19 vaccine products indicates that mixed schedules have acceptable safety profiles. Informed consent should include a discussion of the benefits and risks given the absence of data available on mixed schedules with Medicago.
- A viral vector COVID-19 vaccine (Janssen or AstraZeneca) may be offered to individuals in the authorized age group without contraindications to the vaccine only when all other authorized COVID-19 vaccines are contraindicated. Informed consent should include discussion about the risks and symptoms of vaccine-induced immune thrombotic thrombocytopenia (VITT) as well as the need to seek immediate medical care should symptoms develop. AstraZeneca is not currently available in Nova Scotia.

Additional guidance on options and considerations of preferred COVID-19 vaccine types for certain populations are outlined in the Recommendations on the use of Novavax Novaxovid COVID-19 vaccine NACI statement.

Considerations

Mixed Vaccine Series

A COVID-19 mRNA vaccine series completed with a different mRNA vaccine product is considered valid and does not need to be repeated. Similar vaccines from different manufacturers are routinely used interchangeably, including vaccines for Hepatitis A, Hepatitis B, Influenza, and Measles, Mumps, Rubella (MMR). General vaccine principles indicate that to be considered interchangeable, vaccines should be authorized with the same indications and with similar schedules, for the same population, contain or produce comparable type(s) of antigen, and be similar in terms of safety,

reactogenicity, immunogenicity and efficacy. All currently authorized COVID-19 vaccines in Canada use the spike protein of the SARS-CoV-2 virus as the antigen.

Emerging evidence indicates that mixed COVID-19 vaccine schedules (i.e., viral vector vaccine followed by an mRNA vaccine) have an acceptable safety profile, may be associated with short-term increased systemic reactogenicity (i.e. headache, fatigue and feeling generally ill) and are immunogenic. Some data suggest that Pfizer COVID-19 vaccine followed by Moderna vaccine as a primary series results in slightly higher rates of myocarditis/pericarditis compared with a homologous Pfizer COVID-19 vaccine primary series.

Based on NACI recommendations, emerging evidence, including data which demonstrated that AstraZeneca followed by Pfizer COVID-19 vaccine resulted in an increased immune response compared to AstraZeneca followed by AstraZeneca, and the fact VITT is not a risk with mRNA vaccines, Nova Scotia recommends that **mRNA COVID-19 vaccine should be used for second doses among individuals who received AstraZeneca for their first dose of COVID-19 vaccine**.

mRNA vaccines in immunocompromised children and adolescents
For children aged **6 to 17 years**, the use of an age-appropriate dose of Pfizer Comirnaty is preferred to Moderna Spikevax to start or continue the primary vaccine series. This is due to the higher rare risk of myocarditis or pericarditis following vaccination with Moderna Spikevax (100mcg) as compared to Pfizer-BioNTech Comirnaty (30mcg) with a primary series in adolescents and young adults.

However, Moderna Spikevax may be offered as an alternative product for some children and adolescents who are moderately to severely immunocompromised. Data from adult populations (≥18 years of age) suggest that Moderna Spikevax (100 mcg) may result in higher vaccine effectiveness after a 2-dose primary series compared to Pfizer-BioNTech Comirnaty (30 mcg) and is associated with a higher seroconversion rate among adult immunocompromised patients. Given this potential benefit, an age-appropriate dose of Moderna Spikevax as a 3-dose primary series may be considered for some immunocompromised individuals **6 to 17 years of age** in Nova Scotia. An age-appropriate dose of Moderna Spikevax may also be considered as an alternative to Pfizer-BioNTech Comirnaty for some immunocompromised individuals who are eligible for a booster dose.

Health care providers who care for immunocompromised child and adolescent patients should assist this population in making an informed choice on the use of Moderna Spikevax versus Pfizer Comirnaty based on individual circumstances. This conversation should include a discussion of the potential benefits and risks of Moderna Spikevax versus Pfizer Comirnaty as well as the potential risks of COVID-19 disease.

Potential benefits of Moderna Spikevax versus Pfizer Comirnaty include the potential for improved immune response based on studies conducted in adults. It is important to discuss that while studies in adults have demonstrated higher seroconversion rates among adult immunocompromised patients with Moderna Spikevax as compared to Pfizer Comirnaty, not all immunocompromised patients will mount the same immune response following vaccination.

Potential rare risks include myocarditis/pericarditis. Although the risk of myocarditis/pericarditis with the Moderna Spikevax (50mcg) in children 6 to 11 years of age is unknown, with a primary series in adolescents and young adults the rare risk of myocarditis/pericarditis with Moderna Spikevax (100mcg) was higher than with Pfizer Comirnaty (30 mcg);

it was also higher in males, after the second dose, and with a shorter interval between doses. Safety surveillance data suggests that the risk of myocarditis or pericarditis may be lower in children aged 5 to 11 years following Pfizer Comirnaty (10 mcg) vaccination compared to adolescents and young adults who received a 30 mcg Pfizer Comirnaty dose. Among children 5 to 11 years of age following vaccination with Pfizer Comirnaty (10 mcg), very rare cases were most often reported following the second dose and among males. The risk of myocarditis or pericarditis following mRNA vaccination is rare, and though requiring hospitalization, most individuals have responded well to conservative therapy and tend to recover quickly.

The conversation should also include discussion on the risks associated with COVID-19 disease, which is typically mild in severity for children 6 to 17 years of age but can be more severe in those who are immunocompromised. In general, the known risks of COVID-19 illness (including complications like myocarditis/pericarditis) outweigh the potential harms of having an adverse reaction following mRNA vaccination. Further summary of evidence can be found within NACI's Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 to 11 years of age.

4. Is Nova Scotia offering additional doses of COVID-19 vaccine for individuals who are immunocompromised?

Yes. Individuals who are immunocompromised have a weakened immune system due to disease or treatment and are at higher risk of severe outcomes from COVID-19. Evidence shows that some immunocompromised individuals have a lower immune response to COVID-19 vaccines compared to the general population. Some individuals who are moderately to severely immunocompromised that either did not respond or had a reduced response after two doses of an mRNA vaccine can have an increased immune response after a third dose. The effectiveness of a third dose in immunocompromised individuals is not known in this population at this time, and some people may not respond to a third dose. The safety profile of mRNA vaccines in observational studies in this population has been comparable to what has been observed in the general population, with no unexpected safety signals to date, including no worsening of an immunocompromising condition that has been attributed to the vaccine.

There is indirect evidence on third doses among adolescents 12 to 15 years of age who are not immunocompromised (Pfizer 30mcg formulation) which can be extrapolated to inform the potential safety of a third dose of Pfizer COVID-19 vaccine (10mcg) for children 5 to 11 years of age. Preliminary post-market data from Israel indicate that a third dose of Pfizer 30mcg COVID-19 vaccine is well tolerated among adolescents aged 12 to 15 years. Among 41,610 booster doses administered to individuals aged 12 to 15 years, two cases of myocarditis have been reported. Both cases were discharged from hospital in good condition.

In alignment with NACI's strong recommendations (adolescents/adults, children 5-11 years of age), the following is recommended for Nova Scotians who are moderately to severely immunocompromised and within the authorized age groups:

- Individuals who are 5 years of age and older and who meet moderate to severe immunocompromise criteria who have not yet been immunized or completed a primary series of COVID-19 vaccine are recommended to receive, and are eligible for a primary series of **three doses** of an age-appropriate mRNA COVID-19 vaccine. Individuals 12 years of age or older who are moderately to severely immunocompromised are also eligible for a booster dose 120 days after their third primary series dose.
- Individuals who become moderately to severely immunocompromised more than 14 days after completion of the two-dose COVID-19 primary series typically will not need a third primary series dose but should receive a

booster dose 120 days following completion of the two-dose primary series if they are 12 years of age or older.

The interval between each dose in the primary series for individuals who are moderately to severely immunocompromised should be 28 days to 56 days. A vaccine schedule of 28 days between dose one and dose two, and 56 days between dose two and dose three is recommended. To meet eligibility criteria for additional COVID-19 doses, moderately to severely immunocompromised is defined by specific criteria which may be found at:

- https://novascotia.ca/dhw/cdpc/documents/third-doses-Covid-19-vaccine-immunocompromise.pdf (eligibility criteria)
- https://novascotia.ca/dhw/cdpc/documents/immunosuppressive-medication-list.pdf (immunosuppressive medications), and
- https://novascotia.ca/dhw/cdpc/documents/primary-immunodeficiency-list.pdf (primary immunodeficiencies)

If immunization providers have questions regarding primary immunodeficiencies in adults, they may contact Dr. Gina Lacuesta at 902-425-3927 (office) or via the QEII switchboard at 902-473-2220. After reviewing the list of primary immunodeficiency conditions, if immunization providers have questions related to the 5- to 11-year-old age group, they may contact the Pediatric Immunologist on call via the IWK switchboard at 902-470-8888. After reviewing the list of immunosuppressive medications, if providers have questions regarding medication eligibility, they may contact the Nova Scotia Health COVID-19 Vaccine Pharmacist Consult Service by calling 1-833-768-1151. **The contact information for immunization provider support is not to be given to individuals presenting for immunization**.

Hematopoietic stem cell transplantation (HSCT) recipients are at significant risk of infection following transplant and prior to immune reconstitution. Ablation of hematopoietic cells in the bone marrow pre-transplant eliminates most or all immune memory. As such, HSCT recipients 5 years of age and older are recommended to receive and are eligible for re-immunization with 3 doses of COVID-19 vaccine after transplant.

5. Who is eligible for booster doses of COVID-19 vaccine in Nova Scotia?

First Booster Doses

In Nova Scotia, the following groups are eligible to receive their **first** booster dose of COVID-19 vaccine at the stated interval following completion of their primary COVID-19 series:

- Adolescents aged 12 to 17 at an interval of **168 days**
- Adults aged 18 to 69 at an interval of **168 days**
- Individuals who are pregnant at an interval of **140 days**
- Individuals aged 12 and older who are moderately to severely immunocompromised at an interval of **120 days**
- Adults in or from First Nations communities who are 55 years of age or older at an interval of **120 days**
- Adults aged 70 years and older at an interval of **120 days**
- Adult residents of long-term care and senior congregate living settings at an interval of **120 days**

To date, COVID-19 vaccines have been shown to provide strong protection against serious illness, hospitalization, and death from COVID-19. Evidence suggests protection against infection decreases with time from primary series

completion. Evidence also shows that shorter intervals between doses in a primary series may result in lower immune responses and more rapid waning of protection. People who received a complete vaccine series of a viral vector vaccine (AstraZeneca, Janssen) have somewhat lower initial vaccine effectiveness and may become susceptible to infection sooner than people who received a primary series that included at least 1 dose of an mRNA vaccine. Evidence also suggests that vaccine effectiveness against asymptomatic infection and mild COVID-19 disease decreases with time, which could contribute to increased transmission of infection, particularly with the highly transmissible Delta or Omicron variant. A booster dose of an mRNA COVID-19 vaccine produces a good immune response that is generally higher than the immune response after the primary series, has a favourable safety profile, and provides good short-term protection against infection and severe disease. As such, NACI has recommended that mRNA COVID-19 vaccines are preferred as a booster dose. NACI has also provided an off-label booster dose recommendation for individuals who are unable or unwilling to receive an mRNA COVID-19 vaccine booster dose. Novavax COVID-19 vaccine will be available in Nova Scotia as a booster dose for adults 18 years of age and older who would prefer to receive this vaccine rather than an mRNA vaccine.

Adolescent First Booster Doses

Health Canada has not approved the use of a COVID-19 booster dose for people under the age of 18 at this time. However, in the context of ongoing COVID-19 epidemiological risk, NACI has issued an off-label recommendation that adolescents aged 12 to 17 may be offered a booster dose and that adolescents who may be at higher risk of severe COVID-19 outcomes due to underlying medical or social conditions or who may experience systemic barriers to accessing healthcare *should* be offered a booster dose. This includes adolescents who:

- have an underlying medical condition (NACI's Rapid Response Summary) that may put them at high risk of severe illness due to COVID-19, including those who are immunocompromised and who have already received a three-dose primary series (for adolescents who are immunocompromised, a booster dose would be their fourth dose);
- are residents of congregate living settings, including shelters, group homes, quarters for migrant workers, correctional facilities;
- belong to racialized or marginalized communities disproportionately affected by COVID-19.

Preliminary safety data from booster doses in adolescents showed no additional safety concerns beyond those noted after receiving the first two doses of COVID-19 vaccine. The frequency of adverse events in adults following mRNA booster doses is comparable or lower than those reported after dose 2 of the primary series. While the safety data specific to adolescents 12 to 17 years of age are currently limited, a similar trend has been noted in that age group. Data on the rare risk of myocarditis and/or pericarditis following a booster dose of an mRNA vaccine in adolescents are still emerging.

For the 2-dose primary series, adolescents, particularly male adolescents, 12 to 17 years of age are among the age groups at highest risk for the rare adverse event of myocarditis/pericarditis following mRNA vaccine. Cases of myocarditis have also been reported following mRNA COVID-19 booster doses. In Israel and the United States (US), the rates of myocarditis following a booster dose in adults are in between the rates post dose 1 and post dose 2. However, preliminary data from the United Kingdom (UK) compared the risk of myocarditis following Pfizer BioNTech COVID-19 vaccine to the baseline risk and observed that among males aged 13 to 39 years, the estimated association was higher

after the third dose compared to after the second dose. The use of the Pfizer-BioNTech (30 mcg dose) booster dose is preferentially recommended to a Moderna (50 mcg dose) booster dose as there are currently limited data on the use of Moderna as a booster dose in adolescents 12-17 years of age. NACI will continue to monitor the evidence and will modify their recommendations as needed.

Health care providers should encourage families to review the information provided during the booking process regarding what is known and unknown about booster doses in this age group, including the low risk of severe illness in this age group and the rare risk of myocarditis and pericarditis following COVID-19 mRNA vaccines.

Adult First Booster Doses

It is important that individuals who are pregnant receive their booster dose when eligible. Evidence indicates that there is placental transfer of mRNA COVID-19 vaccine-derived antibodies, leading to passive protection in the neonate. Ensuring pregnant persons receive a booster dose of mRNA COVID-19 vaccine provides protection for them and their neonate against COVID-19 disease.

The use of the Pfizer-BioNTech 30 mcg booster dose is preferred to the Moderna 50 mcg booster dose among eligible 18- to 29-year-olds. This is a precautionary approach due to the lower reported rate of myocarditis/pericarditis following the Pfizer COVID-19 vaccine compared to the Moderna 100 mcg vaccine. Data specific to the lower Moderna 50 mcg booster dose are limited and will be assessed as it emerges.

In community-dwelling adults 30 years of age and older, Pfizer-BioNTech 30 mcg or Moderna 50 mcg can be considered as a first booster dose. Where no contraindications exist, Nova Scotia recommends the use of Moderna 100 mcg as a first booster dose for adult residents of long-term care and senior congregate living.

Although NACI preferentially recommends the use of an mRNA COVID-19 vaccine for booster doses, Novavax may be offered as a first booster dose to adults (18+) who are unable or unwilling to receive an mRNA COVID-19 vaccine.

Second Booster Doses

In response to NACI's statement regarding second booster doses, the following groups are eligible to receive their second booster dose, **120 days** following the receipt of their first booster dose:

- Adults aged 70 years and older
- Adult residents of long-term care and senior congregate living settings
- Adults in or from First Nations communities who are 55 years of age or older

An individual who is moderately to severely immunocompromised and does not otherwise belong to one of the groups listed above is not eligible for a second booster at this time.

Incidence of severe COVID-19 outcomes in Canada remain highest in adults 80 years of age and older, followed by those who are 70 to 79 years of age. Additionally, emerging evidence suggests that humoral immune responses after a first booster dose in older adults and long-term care residents wane over a period of approximately 15 weeks. Preliminary data indicates that a second booster dose provides additional protection compared to a first booster, including against severe disease, and induces humoral immune responses, including neutralizing antibody responses against Omicron

that are comparable to those observed shortly after the second dose of the primary series. However, the duration of protection is currently unknown, and the absolute benefit will depend on the residual protection from the first booster dose and on the level of circulating disease in the community. In general, longer intervals between doses of COVID-19 vaccine have been shown to result in a better immune response and somewhat better vaccine effectiveness than shorter intervals but must also be weighed against waning protection in the context of ongoing epidemiological risk.

No new safety signals have been identified with a second booster dose as compared to previous doses, though most evidence is derived from second booster administration in specific populations such as long-term care residents and older adults.

Either Moderna 50 mcg or Pfizer 30 mcg can be offered as a second booster dose in Nova Scotia. Where no contraindications exist, Moderna 50 mcg is the preferred dose for residents of long-term care and senior congregate living settings. Novavax Nuvaxovid may be offered as a second booster dose to individuals who are unable or unwilling to receive an mRNA COVID-19 vaccine.

Booster Doses Following COVID-19 Infection

Booster doses of COVID-19 vaccine will be offered to eligible individuals who have had previous COVID-19 infection. NACI has provided guidance on suggested intervals between COVID-19 infection and COVID-19 vaccination. At this time, NACI suggests that individuals who are recommended to receive a booster dose and who experienced COVID-19 infection after completing their primary series or first booster dose may receive a booster dose 3 months after symptoms started or after testing positive (if no symptoms were experienced) and provided the minimum recommended interval has passed since their last dose. More information regarding timing of COVID-19 vaccination following SARS-CoV-2 infection may be found in Table 6: Suggested intervals between previous COVID-19 infection and COVID-19 vaccination.

To assist in informed decision-making, information regarding booster doses is available for the general public via the *COVID-19 Booster Doses Information Sheet*.

For information on dosing related to boosters, please see Table 4 and Table 5**.**

6. What is the efficacy of the COVID-19 vaccines?

The currently authorized mRNA COVID-19 vaccines (Pfizer and Moderna) have been shown to be highly efficacious in the short term against confirmed symptomatic COVID-19 disease. For mRNA vaccines, the highest efficacy within the primary series is seen after the second dose is administered. In clinical trials, the viral vector COVID-19 vaccines (AstraZeneca and Janssen) have shown moderate short-term efficacy against symptomatic COVID-19 disease. Clinical trials have shown that the Novavax COVID-19 vaccine provides good protection against COVID-19.

For the most current information regarding efficacy of Health Canada authorized COVID-19 vaccines, please consult the Canadian Immunization Guide.

7. How long does it take for an immune response to develop following vaccination?

All authorized COVID-19 vaccines induce both humoral and cellular immune response. Humoral immune responses were demonstrated approximately 2 weeks after the first dose and boosted by the second dose of the vaccine. Emerging population-based data suggest that in older individuals it may take up to 3 weeks to mount a response. In clinical trials, maximal humoral immune response during the primary series was seen after the second dose for each mRNA vaccine and for the AstraZeneca COVID-19 vaccine. The humoral immune response following the second dose of a two-dose vaccination schedule with mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) was non-inferior in adolescents compared to young adults. Cellular immune responses increased after the second dose of mRNA vaccine. Cellular immune responses do not appear to differ between age groups.

8. How long does protection last following vaccination?

Genetic mutations in the SARS-CoV-2 virus have been identified, some of which make the virus more infectious and transmissible. They may also affect the severity of disease and the level of protection offered by vaccines. The duration of protection against infection after a two-dose primary series has been shown to decline, with protection becoming minimal by six months since the second dose in adults, and a similar trend noted in adolescents. This waning protection tends to occur more rapidly in older adults compared to younger individuals. However, primary series protection against severe outcomes, such as hospitalization and death, remains more durable in both adults and adolescents, with slowly declining but good protection against severe outcomes observed in studies up to 150 days after primary series completion.

First booster doses have been demonstrated to re-elicit protection following a waning primary series and have been observed to add protection against severe disease above that offered solely by a primary series. While evidence is limited, studies in adults demonstrate waning protection from infection over time following the first booster dose, while protection against severe outcomes remains more durable. Emerging data demonstrate a similar trend in adolescent protection against infection as is seen in adults. The duration of protection offered by a second booster dose is currently unknown.

COVID-19 Vaccine Safety and Adverse Events Following Immunization (AEFI)

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

Like all vaccines authorized for use in Canada, COVID-19 vaccines are held to the same high safety, efficacy, and quality standards. Only COVID-19 vaccines that meet those standards will be approved. Once a COVID-19 vaccine has been authorized for use in Canada, both Health Canada (the regulator) and the Public Health Agency of Canada (PHAC) monitor its safety and effectiveness in individuals. Manufacturers are legally required to report specific adverse events to Health Canada. In addition, there is surveillance of vaccine safety within each province and continuous monitoring of vaccine safety reports received across the country at PHAC as part of Canada's post-marketing surveillance program.

Patients consistently rank healthcare providers as their most trusted source for vaccine information. A healthcare provider's recommendation to get the COVID-19 vaccine has a positive impact on individuals' intentions to be immunized. Be transparent about the latest vaccine information, reassure that there is a robust vaccine safety surveillance system in Canada, and emphasize vaccines' roles to protect recipients and the people around them.

Providers can use the PHAC's COVID-19 Vaccination Tool Kit for Health Care Providers as a resource to help clients and colleagues make informed decisions about COVID-19 vaccination by sharing credible information and resources with them.

Safety in Adolescents and Children

10. What evidence has emerged to demonstrate that the mRNA COVID-19 vaccines are safe for adolescents and children?

NACI strongly recommends that a complete series with an age-appropriate mRNA COVID-19 vaccine should be offered to adolescents and children who do not have contraindications to vaccine. For individuals aged 12 to 29 years of age, the use of Pfizer is preferred to Moderna COVID-19 vaccine. In individuals 12 to 29 years of age, the rare risk of myocarditis and pericarditis associated with mRNA vaccines appears more common after Moderna than Pfizer vaccine and when Moderna is given as a second dose of a heterologous primary series when Pfizer was given as the first dose. NACI recommends that the second dose of mRNA COVID-19 vaccine should be provided 8 weeks after the first dose as a longer interval between doses is associated with higher vaccine effectiveness and potentially lower risk of myocarditis/pericarditis.

Informed consent should include discussion about rare reports of myocarditis and/or pericarditis in the week following an mRNA vaccine dose and that there are many potential causes beyond receiving a COVID-19 mRNA vaccine for myocarditis and pericarditis. Myocarditis can also occur as a complication in people who are infected with COVID-19. Vaccine recipients should be advised of the symptoms of myocarditis/pericarditis and to seek immediate medical attention should symptoms develop. Important information for vaccine recipients about myocarditis and pericarditis for Pfizer and Moderna COVID-19 vaccines is available as a handout.

After reviewing available and reassuring real-world safety data, NACI strengthened its advice and now strongly recommends that children 5 to 11 years of age receive a complete primary series with an mRNA COVID-19 vaccine with an interval of at least 8 weeks. Overall, clinical trial data shows that the Pfizer COVID-19 vaccine was well tolerated in children 5-11 years of age. No serious adverse events related to the Pfizer (10 mcg dose) vaccine, no cases of multisystem inflammatory syndrome in children (MIS-C), myocarditis/pericarditis or deaths were reported in the clinical trial. At time of writing, rates of adverse events following immunization with COVID-19 vaccines in Canada are lowest among children aged 5 to 11 at 17.20 per 100, 000 doses administered (2,941,306 total doses administered), followed by adolescents aged 12 to 17 at 30.71 per 100,000 doses administered (4,849,109 total doses administered). Vaccine safety monitoring is ongoing. In the US, about 8.7 million doses of the Pfizer COVID-19 vaccine (10 mcg formulation) have been administered to children aged 5 to 11 years. These younger children report adverse reactions less frequently than those aged 12 to 15 years who received the Pfizer 30mcg vaccine. Real-world data suggest that the risk of myocarditis and pericarditis in 5 – 11-year-olds following COVID-19 mRNA vaccination appears to be lower than in adolescents and in adults. While the preliminary safety data available to date are reassuring, more information will assist in further assessment of the risk of myocarditis or pericarditis among children aged 5 to 11 years. NACI continues to review the evidence as it emerges and will update its recommendations as needed.

Mature Minor Consent

11. Is parental/guardian consent required for a provider to proceed with COVID-19 vaccination in adolescents?

There is no minimum age for giving consent for any health care decisions in Nova Scotia, including immunization. In Nova Scotia, like in other provinces and territories across Canada, the capacity to make a decision is not tied strictly to age. If, in the judgment of the health care professional, an individual has the capacity to consent (e.g. is mature enough to understand the nature and consequences of the decision to be immunized or not be immunized), the individual can give her/his own consent. Adolescents who are able to understand the benefits and possible reactions of the vaccine and the risk of not getting immunized can legally consent to or refuse to proceed with COVID-19 vaccination. Parental/legal guardian consent is not required. Mature minor authority to provide consent takes precedence over parental/guardian authority. Parents/guardians may provide consent for an adolescent to be immunized—it is preferable that the parent/guardian provides consent after discussing immunization with their child. However, before the immunization is given, every adolescent must be asked by the immunization provider if they understand, have any questions, and consent to be immunized. If the parent wishes the adolescent to be immunized and the adolescent refuses, the immunization should not be given. Providers must assess the adolescent's ability to consent. To assess consent, providers must consider the adolescent's ability to understand the:

- condition for which the vaccine is being offered,
- nature and purpose of the vaccine,
- risks and benefits of receiving the vaccine, and
- risks and benefits of not receiving the vaccine.

During the assessment, consider:

- the adolescent's ability to think and make choices
- the adolescent's ability to understand and communicate information relevant to the situation.

If the adolescent is assessed as being unable to give informed consent, a substitute decision maker must be involved, for example, a parent or guardian.

Clinical guidance regarding mature minor consent has been developed by the NSHA/IWK and is available on the COVID-19 Hub. Information regarding *Mature Minor Consent for COVID-19 Immunization* for the general public may be found on the Province of Nova Scotia's Coronavirus website.

Immunization Stress-Related Responses (ISRR)

12. What resources are available for health care providers to support patients who experience stress and anxiety related to immunizations?

Immunizations can cause stress and anxiety which could lead to non-adherence to schedules or missed doses of the COVID-19 vaccine. Immunization stress-related response (ISRR) is a response to the stress some individuals may feel when receiving an injection and can range from mild feelings of worry to symptoms such as increased heart rate, palpitations, difficulty breathing, fainting, nausea and/or vomiting. *Immunization Stress-Related Responses: A synopsis of the manual for program managers and health professionals to prevent, identify and respond to stress-related responses following immunization* has been produced by the World Health Organization.

Health care providers can offer a more positive experience for individuals through a patient-centred approach which promotes coping. Resources for health care providers, parents and caregivers include:

- Immunize Canada - reducing pain and fear in both adults and children during vaccination.
- The CARD system - promotes activities for vaccine recipients in order to have a more positive immunization experience. The interactive CARD game for children is available here: https://immunize.ca/card-game-kids.
- *Nervous about needles? 7 tips for making vaccinations more comfortable* – vaccination tip sheet for youth developed by the IWK/NSH
- IWK Health Comfort Promise COVID-19 Vaccine Toolkit - resources for parents and caregivers of children aged 5 to 11 years who will be receiving the COVID-19 vaccine
- Vaccination resources for children, youth and families – Comfort Promise: IWK Health; COVID-19 Vaccine Safety for Youth; Needle Phobias; How to talk about Vaccination

Side Effects and Adverse Events

13. What are the side effects and adverse events related to COVID-19 vaccines?

Monthly reports of AEFIs with COVID-19 vaccines in Nova Scotia are available here: https://novascotia.ca/coronavirus/alerts-notices/#adverse-events-following-immunization. Please see the Canadian Immunization Guide for more information regarding vaccine safety from COVID-19 clinical trials and post-licensure COVID-19 pharmacovigilance. The COVID-19 Vaccine Information and Aftercare Sheets (Pfizer and Moderna; AstraZeneca; Janssen; Novavax) provide information for vaccine recipients regarding side effects.

Very common and common adverse events

Common adverse events are defined as those that occur in 1% to less than 10% of vaccine recipients; very common adverse events occur in 10% or more of vaccine recipients.

Local

Pain at the injection site is very common after administration of the currently authorized COVID-19 vaccines. Redness/erythema and swelling are common or very common after administration. Clinical findings to date have indicated that the Pfizer COVID-19 vaccine is well tolerated in adolescents 12 to 15 years of age and children 5-11 years of age. Local reactions have been mostly mild to moderate in severity and occurred predominantly following the first dose. Compared to clinical trial participants ≥12 years of age (who received a 30 mcg dose), children 5-11 years of age that received a 10 mcg dose had similar frequencies of pain at the injection site and higher frequencies of swelling and redness. Localized axillary lymph node swelling and tenderness was a solicited adverse event in the Moderna COVID-19 clinical trial and was very common after administration with that vaccine. Local adverse events are usually mild or moderate and resolve within a few days of vaccination. Vaccine recipients who have experienced these local reactions can receive the second dose. For the authorized mRNA COVID-19 vaccines, pain at the injection site was slightly more frequent in younger authorized age groups including adolescents 12-15 years of age (Pfizer COVID-19 vaccine) compared to older adults. For AstraZeneca COVID-19 vaccine, local reactions were milder and reported less frequently after the second vaccine dose in all age groups.

Delayed reactions with pain, redness, swelling, and occasionally pruritus, at the injection site have been noted in those individuals who have received Moderna vaccine. Such reactions were observed in the Moderna clinical trials with onset

on or after day 8 following vaccination and were more likely to occur following the first dose than the second dose. Vaccine recipients who have experienced these delayed local reactions can safely receive the second dose.

Systemic

Fatigue, headache, muscle pain, chills, and joint pain are all either common or very common after the administration of the currently authorized COVID-19 vaccines. Fever was very common after administration of the second dose of the currently authorized mRNA COVID-19 vaccines and common after any dose of the AstraZeneca COVID-19 vaccines. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination. Systemic adverse events are usually mild or moderate intensity and resolve within a few days of vaccination. Vaccine recipients who have experienced these systemic reactions can receive the second dose. For the mRNA COVID-19 vaccines, systemic reactions are more frequent after the second vaccine dose and in younger authorized age groups including adolescents 12-15 years of age (Pfizer COVID-19 vaccine). Compared to individuals 18 to 55 years of age, adolescents 12 to 15 years of age demonstrated increased frequency of headache, chills, and fever. For AstraZeneca COVID-19 vaccine, systemic reactions are milder and reported less frequently after the second vaccine dose than the first in all age groups.

Uncommon, Rare and Very Rare Adverse Events

Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. While not solicited, lymphadenopathy was uncommonly reported after administration of the Pfizer-BioNTech and AstraZeneca COVID-19 vaccine. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively. The probability of detection of very rare adverse events in clinical trials is low given clinical trial population sizes; therefore, ongoing post-marketing vaccine safety surveillance is essential.

Myocarditis and Pericarditis

14. Is there an established association between COVID-19 vaccines and myocarditis or pericarditis?

There have been rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines. The Public Health Agency of Canada and Health Canada are monitoring reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines internationally and in Canada through passive and active Canadian safety surveillance systems. The Canadian weekly online adverse events report provides updates on the latest numbers. Nova Scotia specific data is available here: https://novascotia.ca/coronavirus/alerts-notices/#adverse-events-following-immunization. Available information indicates that these cases occur:

- more commonly after the second dose,
- typically, within several days after vaccination, and most are reported within a week after vaccination,
- mainly in adolescents and adults under 30 years of age, and
- more often in males than females.

Data suggests that this occurs more frequently following the Moderna COVID-19 vaccine compared to the Pfizer vaccine and when Moderna is given as a second dose of heterologous primary series when Pfizer was given as the first dose. Additionally, data from older age groups suggests an extended interval may be associated with a reduced risk of myocarditis/pericarditis following a second dose of mRNA COVID-19 vaccine.

There are preliminary data on mild cases of myocarditis and/or pericarditis following the administration of Novavax COVID-19 vaccine from the clinical trial data. Post-market safety surveillance will be closely monitored to determine whether this is an adverse event of interest associated with Novavax COVID-19 vaccine and to identify risk factors and the rate at which this adverse event occurs.

NACI has advised that the second dose of an mRNA COVID-19 vaccine series should be provided 8 weeks after the first dose as a longer interval between doses appears to be associated with a lower risk of myocarditis/pericarditis.

Myocarditis and pericarditis both involve inflammation of the heart in response to an infection or some other trigger. Immunization providers should inform those individuals receiving mRNA COVID-19 vaccines of the rare risk of myocarditis and/or pericarditis following immunization. Individuals should be advised to seek immediate medical attention if they develop symptoms. Symptoms can include:

- shortness of breath,
- chest pain or pressure,
- unexplained sweating,
- cough,
- the feeling of a fast, pounding or fluttering heartbeat,
- swelling in the ankles and feet.

While myocarditis can be serious, cases reported after receipt of COVID-19 mRNA vaccines appear to be generally mild and have responded well to conservative treatment and rest, with quick symptom improvement. **Healthcare providers should consider myocarditis and pericarditis in the evaluation of acute chest pain or pressure, arrhythmias, shortness of breath or other clinically compatible symptoms after vaccination.** Providers should consider doing an electrocardiogram (ECG), troponins, and an echocardiogram, in consultation with a cardiologist. It would also be important to rule out other potential causes of myocarditis and pericarditis. As such, consultation with infectious diseases and/or rheumatology is recommended to assist in this evaluation, particularly for acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (e.g., detection of SARS-CoV-2 nucleocapsid antibodies), and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing). **All cases of myocarditis or pericarditis following vaccination should be reported to local public health.**

As a precaution and in alignment with NACI, individuals in Nova Scotia who experienced myocarditis with or without pericarditis within 6 weeks of receiving a dose of COVID-19 mRNA vaccine **should defer** further doses until more information is available. This includes any person who had an abnormal cardiac investigation including ECG, elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine. However, individuals with a **history compatible with pericarditis** and who either had **no cardiac workup** or had **normal cardiac investigations**, can receive subsequent doses of mRNA vaccine once they are **symptom free and at least 90 days has passed since vaccination**.

If individuals who experienced myocarditis and/or pericarditis following their last dose of an mRNA COVID-19 vaccine wish to proceed with their next dose, they may choose to do so following a discussion about risks and benefits with a health care provider. If another dose of vaccine is offered, they should be offered the Pfizer Comirnaty 30 mcg vaccine

due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer Comirnaty 30 mcg vaccine compared to the Moderna 100 mcg vaccine.

Individuals with a medical history of myocarditis not related to mRNA COVID-19 vaccination should consult their health care provider for individual considerations and recommendations. Individuals previously diagnosed with myocarditis but who are no longer being followed by a medical professional for heart issues should receive the vaccine.

Vaccine recipients should be encouraged to review the *Important Information about Myocarditis and Pericarditis for Pfizer and Moderna COVID-19 Vaccines* handout and have a discussion with their provider if they have questions about symptoms after vaccination or when to seek medical care if symptoms develop. Informed consent should also include discussion about the individual's personal risk of severe COVID-19 disease, risk of infection and local epidemiology (including circulation of variants of concern), complications of COVID-19 (which may include myocarditis and pericarditis), and protection offered by COVID-19 vaccination. The benefits of receiving COVID-19 vaccine outweigh the rare risk of myocarditis/pericarditis in people of all ages.

Thrombosis with Thrombocytopenia Syndrome/Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)

15. Are viral vector COVID-19 vaccines safe with the recent information regarding Thrombosis with Thrombocytopenia Syndrome (TTS)/Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)?

The terminology for this adverse event is evolving. TTS refers to very rare cases of serious blood clot or thrombosis (at unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis) associated with thrombocytopenia. In Canada, TTS cases that test positive for a biomarker, anti-PF4 (antibodies to platelet factor 4-polyanoin complexes), represent a subset of events and are being referred to as Vaccine-induced thrombotic thrombocytopenia (VITT).

Cases of TTS and VITT have been observed following vaccination with viral vector vaccines (Astrazeneca Vaxzevria or Janssen COVID-19 vaccine). This adverse event has not been reported in those who receive an mRNA COVID-19 vaccine. The exact mechanism by which the viral vector COVID-19 vaccines trigger this syndrome is still under investigation. Viral vector vaccines appear to trigger a presentation similar to spontaneous heparin-induced thrombosis (HIT)/autoimmune heparin-induced thrombosis, where antibodies to platelet factor 4 (PF4)-polyanion complexes induce platelet activation, which causes thrombosis and thrombocytopenia.

Cases of TTS usually occur between 4 and 28 days after receipt of viral vector COVID-19 vaccine, and patients should be monitored up to 42 days after administration of these vaccines. The rate of TTS after the first dose is estimated to be between 1 per 26,000 and 1 per 100,000 doses of AstraZeneca Vaxzevria COVID-19 vaccine administered and 1 per 300,000 doses of Janssen COVID-19 vaccine administered. The frequency of TTS following a second dose of AstraZeneca Vaxzevria vaccine appears to be lower at about 1 per 520,000 doses administered. After the first dose, there was a higher reported incidence rate of TTS in younger adults compared to older adults. The reported incidence was also higher in women compared to men in some age groups. Cases have occurred in viral vector vaccine recipients of all ages. Many cases have been reported to have serious long-term morbidity, including neurologic injury and the case fatality rate ranges between 20 and 50%. This rate may be modified with early diagnosis and treatment so it is very important that anyone receiving a viral vector COVID-19 vaccine should be informed of the adverse event of TTS and advised to seek immediate medical attention if they develop symptoms following vaccination.

Symptoms of TTS may include:

- shortness of breath
- chest pain
- leg swelling or pain
- persistent abdominal pain
- sudden onset of severe headaches
- persistent or worsening headaches
- blurred vision
- confusion or seizures
- skin bruising (other than at the site of vaccination) or petechiae

Individuals who have experienced TTS following vaccination with a viral vector COVID-19 vaccine should not receive a subsequent dose of a viral vector COVID-19 vaccine. There is no evidence that individuals with previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia not related to a viral vector vaccine or people with previous heparin-induced thrombocytopenia (HIT) not related to a viral vector vaccine are at increased risk of TTS compared to other individuals after receiving a viral vector vaccine. However, similar to other individuals, an mRNA vaccine is preferred.

All cases of VITT should be reported to local public health. More information regarding abnormal blood clotting, thrombocytopenia, and unusual bleeding following vaccination with viral vector vaccines may be found in the Janssen Information and Aftercare Sheet and the AstraZeneca Information and Aftercare Sheet. Updated case numbers of VITT in Canada, may be found in the "Serious and non-serious adverse events reported" section of Reported side effects following COVID-19 vaccination in Canada.

16. What clinical guidance regarding Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT) is available for health care providers?

Clots related to VITT can be very aggressive and challenging to treat. They cannot be managed the same way as clots related to oral contraceptives, immobility, or long-haul flights, and have an entirely different biologic pathophysiology. Thrombosis Canada's Clinical Guide: Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) provides information for health care professionals to assist in the diagnosis and management of VIPIT, also known as VITT. Thrombosis Canada provides resources regarding COVID-19 vaccines and blood clots in the form of an FAQ, infographic, and webinars. These resources may be found here: https://thrombosiscanada.ca/covid-19-vaccines-and-blood-clots-faqs/. To support clinicians, Thrombosis Canada has identified key contacts in provinces and territories across Canada as provincial thrombosis champions. Dr. Sudeep Shivakumar is available to assist Nova Scotia clinicians with possible cases of VITT and to direct in diagnosing/ruling out and managing cases of VITT. Dr. Shivakumar may be reached via email at sudeep.shivakumar@nshealth.ca or cell at 902-789-7558.

Venous Thromboembolism (VTE)

17. What information is available regarding Venous Thromboembolism (VTE) following vaccination with authorized COVID-19 vaccines?

Venous thromboembolism has been observed rarely following vaccination with the Janssen COVID-19 vaccine. In individuals with a pre-existing risk for thromboembolism, the possible increased risk of VTE with vaccine use should be considered. Individuals who have received a viral vector COVID-19 vaccine and subsequently develop symptoms of VTE should seek prompt medical care.

Immune Thrombocytopenia (ITP)

18. What information is available regarding Immune Thrombocytopenia following vaccination with authorized COVID-19 vaccines?

Cases of immune thrombocytopenia with very low platelet levels (<20,000 per uL) have been reported very rarely after vaccination with Janssen and AstraZeneca Vaxzevria COVID-19 vaccines, usually within the first four weeks after receiving Janssen COVID-19 vaccine. This included cases with bleeding and cases with fatal outcome. Some of these cases occurred in individuals with a history of ITP. If an individual has a history of ITP, the risks of developing low platelet levels should be considered before vaccination, and platelet monitoring is recommended after vaccination. Individuals who have received a viral vector COVID-19 vaccine and subsequently develop symptoms of ITP should seek prompt medical care.

Capillary Leak Syndrome (CLS)

19. What information is available regarding capillary leak syndrome (CLS) and viral vector COVID-19 vaccines?

On June 29, 2021, Health Canada updated the AstraZeneca product monograph and issued a Health Product Risk Communication. These updates highlight that capillary leak syndrome (CLS) has been observed very rarely following vaccination with the AstraZeneca COVID-19 vaccine and provide further guidance for healthcare professionals and vaccine recipients. Janssen COVID-19 vaccine is contraindicated in individuals with a history of CLS. CLS is a serious, potentially fatal condition causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (due to low blood pressure) leading to organ damage. Individuals should seek medical attention immediately if they develop these symptoms following vaccination. CLS is a life-threatening condition characterized by acute episodes of limb edema, hemoconcentration, hypoalbuminemia and hypotension leading to organ damage. Patients with an acute episode of CLS following vaccination require an urgent medical assessment. Intensive supportive therapy is usually warranted for this life-threatening condition. Individuals who have previously experienced episodes of CLS should not be vaccinated with AstraZeneca COVID-19 vaccine and should discuss options for COVID-19 vaccines with their healthcare professional. **All cases of CLS following vaccination should be reported to local public health.**

Guillain-Barre Syndrome (GBS)

20. What information is available regarding Guillain-Barre Syndrome following vaccination with authorized COVID-19 vaccines?

Guillain-Barre syndrome (GBS) is a rare but potentially serious immune-mediated neurologic disorder that results in pain or numbness, muscle weakness, and paralysis in severe cases. Most people fully recover from GBS but some have lasting

deficits or symptoms and rarely, fatal cases can occur. GBS can result from different causes, including infections, and occurs more frequently in males and persons aged 50 years or more. Symptoms of GBS may include:

- weakness or tingling sensations, especially in the upper or lower limbs, that worsens and spreads to other parts of the body
- coordination problems and unsteadiness
- difficulty walking
- weakness in the limbs, chest or face
- difficulty with bladder control and bowel function
- double vision or difficulty moving eyes
- difficulty with facial movements, including swallowing, speaking, or chewing

GBS has been reported very rarely following COVID-19 vaccination. To date, no increased risk of GBS has been identified following vaccination with the authorized mRNA COVID-19 vaccines (Pfizer and Moderna). There have been reports of an increased risk of GBS following vaccination with the authorized viral vector COVID-19 vaccines (AstraZeneca and Janssen).

The risk of GBS recurrence after COVID-19 vaccination amongst those with a past history of GBS appears to be very low. A causal association between GBS recurrence and COVID-19 vaccination has not been established. More information regarding the number of cases of GBS reported in Canada is available through the PHAC weekly AEFI report.

Individuals with a past history of GBS should receive an authorized mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of an authorized COVID-19 vaccine may receive a second dose of an mRNA COVID-19 vaccine following specialist consultation, a risk-benefit discussion and following informed consent.

Transverse Myelitis

21. What information is available regarding Transverse Myelitis following vaccination with authorized COVID-19 vaccines?

Transverse myelitis is a neurological disorder where inflammation of the spinal cord causes weakness, sensory symptoms or problems with bladder or bowel function. There is a very rare increased risk of transverse myelitis following receipt of Janssen COVID-19 vaccine, which is not seen following vaccination with mRNA COVID-19 vaccines such as Pfizer or Moderna. Symptoms of transverse myelitis include:

- Weakness in the legs and arms
- Sensory symptoms such as tingling, numbness, pain or loss of pain sensation
- Problems with bladder or bowel function

Reporting Adverse Events

22. When should I report an adverse event following immunization (AEFI)?

An AEFI is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of a vaccine. All adverse events not normally expected (i.e. listed in the product monograph) that are temporally related to the administration of the vaccine need to be reported to local public health in accordance

with It's the Law: Reporting of Adverse Events Following Immunization. These reports are reviewed as they are received and are summarized at the provincial and national level as part of Canada's post-marketing surveillance program.

23. How do I report an adverse event following immunization (AEFI)?

Providers reporting an AEFI to public health can obtain the AEFI form and the User Guide from the Public Health Agency of Canada. Serious adverse events must be reported within **one** working day. Other adverse events must be reported within **five** working days. Information regarding serious and other adverse events may be found here: https://novascotia.ca/dhw/cdpc/documents/Reporting-Adverse-Events-Following-Immunization.pdf

Adverse Events of Special Interest (AESI)

24. What is an Adverse Event of Special Interest (AESI)?

An AESI is a specific adverse event that has been identified by international health authorities to be monitored as part of COVID-19 vaccine safety surveillance. The conditions have been included because they have been associated with COVID-19 disease or there is a theoretical/proven association with vaccines in general or a vaccine platform. Further information regarding AESIs is available via the Brighton Collaboration. The Brighton Collaboration AESI list may be found here: https://brightoncollaboration.us/wp-content/uploads/2021/01/COVID-19-updated-AESI-list.pdf. Examples of AESIs include but are not limited to acute cardiovascular injury, coagulation disorders, acute kidney or liver injury, acute pancreatitis, and rhabdomyolysis. These events should also be reported to public health by providers.

Storage, Dosing, Scheduling, and Administration

25. What are the differences in the storage and handling requirements and administration considerations between the COVID-19 vaccines approved in Canada and available for use in Nova Scotia?

Table 1: mRNA COVID-19 Vaccines authorized for use in Canada

Product Brand Name	Pfizer BioNTech Comirnaty adult/adolescent COVID-19 vaccine	Pfizer BioNTech Comirnaty pediatric COVID-19 vaccine	Moderna Spikevax COVID-19 vaccine
Type of vaccine	mRNA	mRNA	mRNA
Authorized Ages	12 years of age and older	5 – 11 years of age	6 years of age and older
Indications	For use in individuals aged 12 years and older without contraindications to the vaccine. Preferred for most individuals younger than 30 years of age.	For use in individuals aged 5 to 11 years without contraindications to the vaccine.	For use in individuals aged 30 years and older without contraindications to the vaccine. For use with age-appropriate dose in some immunocompromised individuals aged 6 to 17. Can be given with informed consent for those younger than 30 years of age, but Pfizer recommended for use in most persons younger than 30 years of age.

Product Brand Name	Pfizer BioNTech Comirnaty adult/adolescent COVID-19 vaccine	Pfizer BioNTech Comirnaty pediatric COVID-19 vaccine	Moderna Spikevax COVID-19 vaccine
Dose	0.3 mL (30 mcg of mRNA)	0.2 mL (10 mcg of mRNA)	See Table 4 and Table 5
Schedule	See Table 4 and Table 5	See Table 4 and Table 5	See Table 4 and Table 5
Route of administration	IM	IM	IM
Diluent	Yes (1.8 ml per vial)	Yes (1.3 ml per vial)	No
Primary storage requirements pre-puncture	-90°C to -60°C	-90°C to -60°C	-25°C to -15°C
Additional storage requirements pre-puncture [1]	Frozen vials: -25°C to -15°C for up to 2 weeks [2] Thawed under refrigeration: 1 month at +2°C to +8°C Thawed at room temperature: 2 hours up to +25°C	Up to 10 weeks at +2°C to +8°C AND/OR 12 hours prior to dilution	30 days at +2°C to +8°C **and/or** 24 hours at +8°C to +25°C
Usage limit post-puncture	6 hours at +2°C to +25°C [3]	12 hours at +2°C to +25°C [4]	24 hours at +2°C to +25°C
Formats available	Multi-dose vial (6 doses) [5], preservative-free	Multi-dose vial (10 doses), preservative-free	Multi-dose vial (10 doses), preservative-free

Abbreviations: mRNA: Messenger ribonucleic acid; HC: Health Canada; IM: intramuscular

1 Protected from light during storage.

2 Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.

3 After dilution, vaccine must be used within 6 hours.

4 Vial labels and cartons may state that a vial should be discarded 6 hours after dilution. The information in this Product Monograph supersedes the number of hours printed on vial labels and cartons.

5 After dilution, one vial contains 6 doses of 0.3 mL each. However, vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. Information in the product monograph supersedes the number of doses stated on vial labels and cartons. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial. Refer to the product monograph for choice of diluent, dilution instructions and type of syringes which can be used to extract 6 doses from a single vial.

Interim national guidelines on vaccine storage, handling and transportation for ultra-low temperature and frozen temperature COVID-19 vaccines is available from the Public Health Agency of Canada: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/vaccine-storage-handling-transportation-ultra-low-temperature-frozen.html#a1.1. Information on the specific vaccine storage and handling requirements for the mRNA COVID-19 vaccines is available from: Pfizer BioNTech: https://www.cvdvaccine.ca/ and Moderna: https://www.modernacovid19global.com/ca/.

Table 2: Novavax Nuvaxovid characteristics

Product Brand Name	Novavax Nuvaxovid COVID-19 vaccine
Type of vaccine	Recombinant protein subunit
Adjuvant	Co-formulation with Matrix-M (50 mcg); novel saponin-based adjuvant
Authorized Ages	18 years of age and older
Indications	May be offered to individuals in the authorized age group without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine.
Dose	0.5 mL (5 mcg SARS-CoV-2 recombinant spike protein)
Route of administration	IM
Schedule	See Table 4 and Table 5
Diluent	No
Primary storage requirements pre-puncture	+2°C to +8°C for a maximum of 6 months. Do not freeze. Protect from light.
Usage limit post-puncture	6 hours at +2°C to 25°C after first needle puncture
Formats available	Multi-dose vial (10 doses), preservative-free

Table 3: Viral Vector COVID-19 Vaccines authorized for use in Canada

Product Brand Name	AstraZeneca Vaxzevria COVID-19 vaccine	Janssen COVID-19 vaccine
Type of vaccine	Non-replicating viral vector (ChAd)	Non-replicating viral vector (Ad26)
Authorized Ages	18 years of age and older	18 years of age and older
Indications	May be offered to individuals in the authorized age group without contraindications to the vaccine only when all other authorized COVID-19 vaccines are contraindicated.	May be offered to individuals in the authorized age group without contraindications to the vaccine only when all other authorized COVID-19 vaccines are contraindicated.
Dose	0.5 mL (5 x 10^{10} viral particles)	0.5 mL (5 x 10^{10} viral particles)
Route of administration	IM	IM
Schedule	See Table 4 and Table 5	See Table 4 and Table 5
Diluent	No	No
Primary storage requirements pre-puncture	+2°C to +8°C	+2°C to +8°C[1]

Product Brand Name	AstraZeneca Vaxzevria COVID-19 vaccine	Janssen COVID-19 vaccine
Additional storage requirements pre-puncture [2]	+2°C to +8°C	+2°C to +8°C
Usage limit post-puncture	6 hours at room temperature (up to +30°C) OR 48 hours at +2°C to 8°C	3 hours at room temperature (up to +25°C) or 6 hours at +2°C to +8°C[3]
Formats available	Multi-dose vial (10-doses), preservative-free	Multi-dose vial (5 doses), preservative-free

Abbreviations: ChAd: Chimpanzee adenovirus; IM: intramuscular

[1] If Janssen COVID-19 vaccine is received frozen (-25°C to -15°C), the expiry date for frozen storage is printed on the vial and carton after "EXP". The vaccine can be stored at +2°C to +8°C for a single period of up to 6 months, not exceeding the original expiry date. Upon moving the product to a +2°C to +8°C state, the updated expiry date must be written on the carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable. **DO NOT RE-FREEZE ONCE THAWED**.

[2] Protected from light during storage

[3] Maximum hold times for these two temperature ranges post-puncture are not cumulative (i.e. the vaccine cannot be held at room temperature for 3 hours and then held refrigerated for another 6 hours). If the 3-hour time limit at room temperature is not met, the punctured vial may be transferred to a refrigerated storage unit between 2°C to 8°C for the remaining time, up to the 3 hour time limit. For example, a vial held at room temperature for 1 hour after first puncture can be stored in the refrigerator (between 2°C to 8°C) for no more than 2 hours before using or discarding. If the 3-hour time limit at room temperature has been met, the vial must be discarded and cannot be transferred to the refrigerator.
If stored refrigerated after the first puncture, the vaccine can be moved to room temperature for brief periods of time for dose withdrawal. This does not impact the maximum 6-hour hold period in the refrigerator.

Information on the specific vaccine storage and handling requirements for the viral vector COVID-19 vaccines is available from:

- AstraZeneca: https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf
- Janssen: https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf

26. What are the recommendations for schedule and dosage for COVID-19 vaccines currently available for use in Nova Scotia?

See Below the following tables:
Table 4 - COVID-19 Vaccine Summary recommendations for Use in Nova Scotia (Non-immunocompromised) and
Table 5 - COVID-19 Vaccine Summary recommendations for Use in Nova Scotia (Moderately to Severely Immunocompromised.

Table 4: COVID-19 Vaccine Summary Recommendations for Use in Nova Scotia *(Non-immunocompromised)*			
Population	**Product**	**Dosage**	**Schedule** (consider also recent COVID-19 infection)
Children 5-11			
Primary series	Pfizer Comirnaty Pediatric (ORANGE CAP, 1.3 mL of diluent)	0.2 mL (10 mcg)[1]	• 2 doses • 8 weeks between first and second dose
Adolescents 12-17			
Primary series	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 2 doses • 8 weeks between first and second dose
First booster dose[4]	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 1 dose • 168 days from completion of primary series
Adults 18-69 (community dwelling)			
Primary series	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent) *Preferentially recommended for adults <30	0.3 ml (30 mcg)	• 2 doses • 8 weeks between first and second dose
	Moderna Spikevax[3] *Pfizer preferred for adults <30[2]	0.5 ml (100 mcg)	
	Novavax Nuvaxovid[5] *May be offered to those unable or unwilling to receive mRNA vaccine	0.5 ml	
	AstraZeneca Vaxzevria *May be offered when all other authorized COVID-19 vaccines are contraindicated; no active provincial supply	0.5 ml	
	Janssen COVID-19 Vaccine *May be offered when all other authorized COVID-19 vaccines are contraindicated	0.5 ml	• 1 dose
First booster dose	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent) *Preferentially recommended for adults <30	0.3 ml (30 mcg)	• 1 dose • 168 days after completion of primary series[6]
	Moderna Spikevax *Pfizer preferred for adults <30[2]	0.25 ml (50 mcg)	
	Novavax Nuvaxovid [4,5] *May be offered to those unable or unwilling to receive mRNA vaccine	0.5 ml	

Table 4: COVID-19 Vaccine Summary Recommendations for Use in Nova Scotia *(Non-immunocompromised)*			
Population	**Product**	**Dosage**	**Schedule** (consider also recent COVID-19 infection)
Adults 70+ **Adult residents of long-term care (LTC) and senior congregate living** **Adults in or from First Nations communities who are 55+**			
Primary series	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 2 doses • 8 weeks between first and second dose
	Moderna Spikevax *Moderna Spikevax (100mcg) induces somewhat higher antibody levels and longer-lasting protection against infection and severe disease compared to Pfizer.	0.5 ml (100 mcg)	
	Novavax Nuvaxovid *May be offered to those unable or unwilling to receive mRNA vaccine	0.5 ml	
	AstraZeneca Vaxzevria *May be offered when all other authorized COVID-19 vaccines are contraindicated; no active provincial supply	0.5 ml	
	Janssen COVID-19 Vaccine *May be offered when all other authorized COVID-19 vaccines are contraindicated	0.5 ml	• 1 dose
First booster dose	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 1 dose • 120 days after completion of primary series
	Moderna Spikevax[3] *Preferred for residents of LTC and senior congregate living	0.25 ml (50 mcg) or 0.5 ml[4] (100 mcg)[7]	
	Novavax Nuvaxovid[4] *May be offered to those unable or unwilling to receive mRNA vaccine	0.5 ml	
Second booster dose[4]	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 1 dose • 120 days after completion of primary series
	Moderna Spikevax *Preferred for residents of LTC and senior congregate living	0.25 ml (50 mcg)	
	Novavax Nuvaxovid *May be offered to those unable or unwilling to receive mRNA vaccine	0.5 ml	

[1] Children who receive the 10-mcg dosage for their first dose and who have turned 12 by the time their second dose is due should receive the 30-mcg dose to complete their primary series. If 10 mcg is given, the dose should still be considered valid and the series complete.
[2] Informed consent for Moderna Spikevax in this age group should include an age-appropriate discussion on the known or unknown rare risk of myocarditis/pericarditis with Moderna Spikevax.
[3] Evidence has shown that Moderna Spikevax (100mcg) induces somewhat higher antibody levels and longer-lasting protection against infection and severe diseased compared to Pfizer.
[4] Off-label use.
[5] Safety and efficacy of Novavax Nuvaxovid has not been assessed in individuals who are pregnant or breastfeeding.
[6] May be offered 140 days after completion of primary series for individuals who are pregnant.
[7] Moderna 100 mcg dose is recommended for use as the first booster in adult residents of long-term care and senior congregate living.

Table 5: COVID-19 Vaccine Summary Recommendations for Use in Nova Scotia *(Moderately to Severely Immunocompromised)*			
Population	**Product**	**Dosage**	**Schedule** (consider also recent COVID-19 infection)
Children 5-11			
Primary series	Pfizer Comirnaty Pediatric (ORANGE CAP, 1.3 mL of diluent)	0.2 mL (10 mcg)[1]	• 3 doses • 28 days between first and second dose • 56 days between second and third dose[2]
Children 6-11			
Primary series	Moderna Spikevax[3,4] *Can be considered for some immunocompromised individuals due to potential for higher vaccine effectiveness compared to Pfizer and balancing the potential increased rare risk of myocarditis/pericarditis following vaccine	0.25 ml (50 mcg)	• 3 doses • 28 days between first and second dose • 56 days between second and third dose[2]
Adolescents 12-17			
Primary series	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 3 doses • 28 days between first and second dose • 56 days between second and third dose[2]
	Moderna Spikevax[3,4] *Can be considered for some immunocompromised individuals due to potential for higher vaccine effectiveness compared to Pfizer and balancing the potential increased rare risk of myocarditis/pericarditis following vaccine	0.5 ml (100 mcg)	• 3 doses • 28 days between first and second dose • 56 days between second and third dose[2]
First booster dose[5]	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 1 dose • 120 days from completion of primary series
	Moderna Spikevax[3,4] *Can be considered for some immunocompromised individuals due to potential for higher vaccine effectiveness compared to Pfizer and balancing the potential increased rare risk of myocarditis/pericarditis following vaccine	0.25 ml (50 mcg)	• 1 dose • 120 days from completion of primary series
Adults 18-69 (community dwelling)			
Primary series	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent) *Preferentially recommended for adults <30	0.3 ml (30 mcg)	• 3 doses • 28 days between first and second dose • 56 days between second and third dose[2]
	Moderna Spikevax[3] *Pfizer preferred for adults <30[4]. Can be considered for some immunocompromised individuals <30 due to potential for higher vaccine effectiveness compared to Pfizer and balancing the potential increased rare risk of myocarditis/pericarditis following vaccine	0.5 ml (100 mcg)	
	Novavax Nuvaxovid[6] *May be offered to those unable or unwilling to receive mRNA vaccine	0.5 ml	
	AstraZenec Vaxzevria *May be offered when all other authorized COVID-19 vaccines are contraindicated; no active provincial supply	0.5 ml	
	Janssen COVID-19 Vaccine *May be offered when all other authorized COVID-19 vaccines are contraindicated	0.5 ml	• 1 dose with additional dose of mRNA vaccine (preferred) or 2 doses of Janssen • 56 days between first and second dose

Table 5: COVID-19 Vaccine Summary Recommendations for Use in Nova Scotia *(Moderately to Severely Immunocompromised)*			
Population	**Product**	**Dosage**	**Schedule** (consider also recent COVID-19 infection)
First booster dose	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent) *Preferentially recommended for adults <30	0.3 ml (30 mcg)	• 1 dose • 120 days after completion of primary series
	Moderna Spikevax[3] * Pfizer preferred for adults <30[4]. Can be considered for some immunocompromised individuals <30 due to potential for higher vaccine effectiveness compared to Pfizer and balancing the potential increased rare risk of myocarditis/pericarditis following vaccine	0.25 ml (50 mcg) or 0.5 ml[5] (100 mcg)[7]	
	Novavax Nuvaxovid[5,6] *May be offered to those unable or unwilling to receive mRNA vaccine	0.5 ml	
Adults 70+ **Adult residents of long-term care (LTC) and senior congregate living** **Adults in or from First Nations communities who are 55+**			
Primary series	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 3 doses • 28 days between first and second dose • 56 days between second and third dose[2]
	Moderna Spikevax *Moderna Spikevax (100mcg) induces somewhat higher antibody levels and longer-lasting protection against infection and severe disease compared to Pfizer	0.5 ml (100 mcg)	
	Novavax Nuvaxovid *May be offered to those unable or unwilling to receive mRNA vaccine	0.5 ml	
	AstraZenec Vaxzevria *May be offered when all other authorized COVID-19 vaccines are contraindicated; no active provincial supply	0.5 ml	
	Janssen COVID-19 vaccine *May be offered when all other authorized COVID-19 vaccines are contraindicated	0.5 ml	• 1 dose with additional dose of mRNA vaccine (preferred) or 2 doses of Janssen • 56 days between first and second dose
First booster dose	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 1 dose • 120 days after completion of primary series
	Moderna Spikevax[3] *Preferred for residents of LTC and senior congregate living. Moderna Spikevax (100mcg) induces somewhat higher antibody levels and longer-lasting protection against infection and severe disease compared to Pfizer.	0.25 ml (50mcg) or 0.5 ml[5] (100 mcg)[7]	
	Novavax Nuvaxovid [5,6] *May be offered to those unable or unwilling to receive mRNA vaccine	0.5 ml	
Second booster dose[5]	Pfizer Comirnaty Adult/Adolescent (PURPLE CAP, 1.8 ml of diluent)	0.3 ml (30 mcg)	• 1 dose • 120 days after completion of primary series
	Moderna Spikevax *Preferred for residents of LTC and senior congregate living. Moderna Spikevax (100mcg) induces somewhat higher antibody levels and longer-lasting protection against infection and severe disease compared to Pfizer	0.25 ml (50 mcg)	

Table 5: COVID-19 Vaccine Summary Recommendations for Use in Nova Scotia *(Moderately to Severely Immunocompromised)*			
Population	**Product**	**Dosage**	**Schedule** (consider also recent COVID-19 infection)
	Novavax Nuvaxovid[6] *May be offered to those unable or unwilling to receive mRNA vaccine.	0.5 ml	

[1] Children who receive the 10-mcg dosage for their first or second dose and who have turned 12 by the time their subsequent dose is due should receive the 30-mcg dose to complete their primary series. If 10 mcg is given, the dose should still be considered valid and the series complete.
[2] May receive at an interval of 28 days between second and third dose. Longer intervals may result in a better immune response but may result in being susceptible for longer between doses.
[3] Evidence has shown that Moderna Spikevax (100mcg) induces somewhat higher antibody levels and longer-lasting protection against infection and severe diseased compared to Pfizer.
[4] Informed consent for Moderna Spikevax in this age group should include an age-appropriate discussion on the known or unknown rare risk of myocarditis/pericarditis with Moderna Spikevax.
[5] Off-label use
[6] Safety and efficacy of Novavax Nuvaxovid has not been assessed in individuals who are moderately to severely immunocompromised.
[7] Moderna 100 mcg dose is recommended for use as the first booster in adult residents of long-term care and senior congregate living.

Table 6: Suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination

Timing of infection	Population	Suggested interval between COVID-19 infection and vaccination
Infection before start or completion of primary vaccination series	5 years of age and older; not considered moderately to severely immunocompromised; no previous history of MIS-C	8 weeks after symptom onset or positive test (if asymptomatic)
	5 years of age and older; moderately to severely immunocompromised; no previous history of MIS-C	4 to 8 weeks after symptom onset or positive test (if asymptomatic)
	5 years of age and older; previous history of MIS-C (regardless of immunocompromised state)	Receive the vaccine dose when clinically recovered or ≥90 days since the onset of MIS-C, whichever is longer
Infection after primary series but before booster dose	12 years of age and older	3 months after symptom onset or positive test (if asymptomatic) AND minimum interval from primary series completion

Individual benefit/risk assessment and clinical discretion are advised, including risk factors for exposure and severe outcomes. Some people may choose to receive a vaccine dose after acute symptoms of COVID-19 have resolved and they are no longer infectious. Suggested intervals may change as additional evidence on the extent and duration of protection provided by infection emerges. People who have already received a dose of vaccine immediately after recovering from a COVID-19 infection do not need to repeat the dose.

Valid Intervals

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

Currently, no data on a maximum interval between doses or on long-term efficacy of COVID-19 vaccines are available. 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.

28. When is a dose of a Health Canada authorized COVID-19 vaccine considered valid?

Although not the recommended schedule, a dose of COVID-19 vaccine would be considered valid if the interval between first and second doses are as follows:

- Pfizer-BioNTech Adult/Adolescent formulation (30 mcg, ≥12 years): 19 days
- Moderna Spikevax: 21 days
- Novavax: 21 days
- AstraZeneca: 28 days

For mixed COVID-19 vaccine schedules, the valid interval between doses should be based on the interval of the product used for the first dose (e.g., Pfizer COVID-19 vaccine should be offered a minimum of 21 days after Moderna COVID-19 vaccine; Moderna COVID-19 vaccine should be offered a minimum of 19 days after Pfizer COVID-19 vaccine)

While these intervals are authorized by Health Canada, and doses of COVID-19 vaccine which have been given at the above intervals will be considered valid, recommended intervals in Table 4 and Table 5 should be followed when circumstances allow. A longer interval gives the opportunity to establish optimal longer-term immunity and is associated with a higher vaccine effectiveness and potentially lower risk of myocarditis and pericarditis.

Providers' Responsibilities in Ensuring Proper Storage of Vaccines

29. Why is it a provider's responsibility to ensure vaccine storage conditions are maintained?

Vaccines are sensitive biological products that may be less effective, or even destroyed, when exposed to temperatures outside the recommended range. There is a need to ensure that an effective product is being used. Vaccine failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine-preventable disease. Careful management of resources is important. Vaccines are expensive and can be in short supply. Loss of vaccine may result in the cancellation of immunization clinics, resulting in lost opportunities to immunize. Revaccination of clients who received an ineffective vaccine may also cause loss of public confidence in vaccines and/or the health-care system.

30. What should I do if the storage conditions of vaccines have been compromised?

All cold chain breaks must be reported to the local Public Health office. Vaccine that is exposed to a cold chain break must be bagged, dated, labelled "Do not use" and refrigerated while waiting to receive direction from Public Health on the use of affected vaccines.

Pre-filling Syringes for Onward Transport

31. Are providers able to pre-fill syringes with COVID-19 vaccine doses and transport syringes to clients?

Pre-filling syringes for onward transportation of COVID-19 vaccine doses may be warranted in exceptional situations and is permissible if specific criteria are followed as outlined in the OCMOH document *Pre-filling syringes for onward transportation of COVID-19 vaccine doses in exceptional situations*.

Exceptional situations where pre-filling syringes for onward transportation of COVID-19 vaccine doses may be warranted include:

- where the risk assessment demonstrates that movement of the vaccine would be a safer alternative for the person being immunized
- home visits for individuals who are unable to leave their home
- congregate living settings for a small number of residents who are unable to access the immunization clinic

Pre-filling syringes with COVID-19 vaccine doses for onward transportation is not to be implemented as part of routine practice.

Simultaneous Administration of COVID-19 Vaccines with Other Vaccines

32. Can individuals receive COVID-19 vaccines simultaneously with non-COVID-19 vaccines?

As a precaution, NACI recommends that **COVID-19 vaccines for children 5-11 years old** should not routinely be given concomitantly with other vaccines. **It is prudent to wait for a period of at least 14 days before or after** the administration of another vaccine before administering a COVID-19 vaccine for children 5 – 11 years old. Administering the COVID-19 vaccine alone in this age group assists with the assessment of any adverse event following immunization.

There may be circumstances in which a dose of COVID-19 vaccine and a non-COVID-19 vaccine needs to be administered simultaneously, or a shortened interval between these vaccines may be necessary on an individual basis in children. These circumstances may include:

- when another vaccine is required for post-exposure prophylaxis;
- when individuals require accelerated vaccination schedules prior to immunosuppressive therapy or transplant;
- when there is a risk of the individual being unable to complete an immunization series due to limited access to health services or being unlikely to return at a later date; and
- at the clinical discretion of the healthcare provider.

NACI recommends that COVID-19 vaccines for adolescents/adults may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines. Informed consent should include a discussion of the benefits and risks given the limited data available on concomitant administration of COVID-19 vaccines with other vaccines. Studies to assess the safety and immunogenicity of simultaneous administration of COVID-19 vaccines with other vaccines are ongoing.

It is currently not known if the reactogenicity of COVID-19 vaccines is increased with concomitant administration of other vaccines. While no specific safety concerns have been identified for various other vaccines with co-administration, there is potential for increased reactogenicity with concomitant administration of COVID-19 vaccines with other vaccines, particularly those known to be more reactogenic, such as newer adjuvanted vaccines. If more than one type of vaccine is administered at a single visit, they should be administered at different injection sites using separate injection equipment.

NACI continues to recommend that COVID-19 vaccines should not be given simultaneously with anti-SARS-CoV-2 monoclonal antibodies (i.e. sotrovimab, casirivimab/imdevimab) or convalescent plasma. The interval between receipt of these products and COVID-19 vaccine is under review.

33. Can a client receive COVID-19 vaccine following tuberculin skin testing (TST) or Interferon Gamma Release Assay (IGRA)?

There is a theoretical risk that mRNA vaccines or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If a TST or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed. In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed. However, re-testing (at least 4 weeks

post immunization) of individuals with negative results for whom there is high suspicion of TB infection may be prudent to avoid missing cases due to potentially false negative results.

Vaccine Preparation and Administration Techniques to Minimize Vaccine Waste

34. 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.

35. 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 adult formulation 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. After adding diluent and before removing the needle from the pediatric vaccine vial, withdraw 1.3 ml of air into the empty diluent syringe. This will prevent loss of vaccine from the vial through forceful expulsion under pressure.

36. Is there a recommendation on the size of the syringe to be used to withdraw and administer the Pfizer BioNTech vaccine?

Yes. A 1ml low dead-volume syringe is recommended to maximize doses. Information regarding low-dead volume syringes may be found here: https://www.cvdvaccine.ca/files/PfizerCovid_6doseWithdrawalGuide-EN.pdf. An instructional video on 6th dose extraction of Pfizer vaccine (30 mcg dose) may be found here: https://www.youtube.com/watch?v=k_IxCPcbRGk.

37. What steps can immunization providers take to ensure all ten doses of the Pfizer Comirnaty pediatric formulation (10 mcg dose) can be obtained from the multi-dose vial (MDV)? Is pooling of the Pfizer Comirnaty pediatric vaccine a supported practice?

Pfizer Comirnaty's product monograph indicates that each MDV contains a volume of 1.3 mL to which 1.3 mL of diluent is added. After dilution, each vial of the pediatric formulation contains 10 doses of 0.2 mL. Low dead-volume syringes and/or needles (e.g., low dead-volume luer lock syringes) are recommended for use to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Immunization providers are encouraged to review Pfizer's dose preparation guide which includes information regarding dilution, equalizing vial pressure and administration. **In order to ensure consistent withdrawal of 10 doses of 0.2 mL, it is important to adhere to minimizing volume loss during dose extraction.**

In response to provider reports of obtaining 9 doses of Pfizer Comirnaty (10 mcg) per vial and to mitigate the risk of pediatric vaccine appointment cancellations, pooling of Pfizer pediatric vaccine (10 mcg), the process of drawing-up vaccine from a maximum of **two** vials, is a supported practice in Nova Scotia provided adherence to the following steps are taken to mitigate any theoretical contamination risk:

1) Pooling is done using volume from only **two** vials and the vials **must be the same product and lot number**.
2) The date and time of first puncture or dilution are written on each vial.
3) Immunizers must ensure that vaccine used for pooling is administered within 12 hours of the first vial punctured.

4) Strict aseptic technique must be followed in diluting and/or drawing up the vials (e.g., hand hygiene before process; use of a new alcohol swab for the stopper for each puncture of all vials; and allow the stopper to dry before puncture).
5) Only residual amounts from a vial should be used to pool (i.e., do not top up a partial dose with vaccine from a vial that has one or more full doses remaining in it; pool only with residuals that will not alone allow a full dose to be obtained).
6) The pooling should be from vials that have been used as close to each other as possible (e.g., do not reserve vials with residual volume until the end of the day).
7) Administer syringes that have pooled vaccine in them as soon as feasible.

Pooling is not recommended by manufacturers due to concerns that this process increases the risk of contamination of the vaccines, which have no preservatives, due to the cumulative multiple punctures from each vial. However, this risk is a **theoretical concern** that can be **mitigated with good infection prevention and control practices**. **The risk of contamination of pooled vaccines is very small relative to losing doses of the vaccines which are important to prevent morbidity and mortality from COVID-19.**

38. How do providers balance minimizing COVID-19 vaccine wastage with opportunities to vaccinate all eligible individuals?

Given that only multi-dose vials of COVID-19 vaccine are available in Canada, some wastage is inevitable as efforts are made to immunize remaining unvaccinated or partially vaccinated people, particularly when vaccines are offered outside of larger immunization clinics (e.g., when vaccines are offered in pharmacies, health care providers' offices, and remote and isolated communities). All efforts should be made to minimize wastage including:

- Having plans to immunize as many people as possible when a vial is opened/reconstituted (e.g. preparing a waitlist of clients that providers can call at the end of the day; utilizing social media to advertise extra available COVID-19 vaccines);
- If it is anticipated that a full vial may not be used in a particular location, attempting to use an alternative product with less doses per vial thereby incurring less wastage (i.e., use the Pfizer-BioNTech product if it is available, which has fewer doses per vial than the Moderna product).

Vaccinating individuals should be prioritized over minimizing open-vial wastage of COVID-19 vaccines. There may be circumstances where a new COVID-19 vial must be opened to vaccinate only one or a few people, and plans cannot be implemented to use the remaining doses in the vial. In these cases, **providers should take every opportunity to vaccinate every eligible person who presents for vaccination,** even if it requires puncturing a multi-dose vial and results in the remainder of the vial being discarded in accordance with the product monograph or best practices**.**

39. How do providers use the Sol-Guard safety syringe to activate the safety mechanism with cap protection?

Please view the video which provides a demonstration of the Sol-Guard safety syringe:
https://www.youtube.com/watch?v=jHH_xtgkJEk

40. How do providers ensure successful auto-retraction of the Wealy SSFNO1-25-02 needle/syringe combination product when in use?

Please view the video which provides a demonstration of the Wealy needle/syringe product: https://www.youtube.com/watch?v=YQB9W7Kt8b4. Providers must inject slowly. Injecting too fast may unseat the "O" ring or cause needle non-retraction.

Administration Errors and Deviations

41. What approach can immunization providers take after recognizing a COVID-19 vaccine has been administered in a manner that differs from a manufacturer's and/or NACI's recommendations?

There is limited evidence to guide the management of COVID-19 vaccine administration errors and deviations. PHAC provides guidance for these situations via the: COVID-19 Vaccine Guide for Youth and Adults (12 years and over) and Quick Reference Guide on use of COVID-19 vaccine for Children 5 to 11 years of age. This guidance is to be used only to manage errors or deviations that have already occurred. Clinical judgment in certain situations may also be applied in vaccine error management decisions. For example, if an adolescent aged 12 to 17 years receives the Pfizer COVID-19 10 mcg dose, in general, the dose(s) may be considered valid. However, based on clinical judgment (e.g. the adolescent received two doses of 10 mcg Pfizer COVID-19 vaccine), a repeat dose of Pfizer-BioNTech 30 mcg may be administered at an interval of at least 8 weeks after the dose given in error to complete the primary series. Providers may call the COVID-19 Vaccine Pharmacist Consult Service at 1-833-768-1151 for questions which may require clinical judgment discussion.

Special Considerations

Pregnancy, Breastfeeding, Immunosuppression and Autoimmune Conditions

42. Are there groups in which the approved vaccines have not been specifically studied?

NACI has provided recommendations for COVID-19 immunization in some specific populations who were either excluded from or were represented by small numbers of participants in the clinical trials as there was no or limited evidence of safety or efficacy in these populations. However, considerable real-world data from the use of COVID-19 vaccines in these populations continues to accumulate. These recommendations may change as more evidence becomes available.

NACI preferentially recommends that a complete mRNA COVID-19 vaccine series (Pfizer or Moderna) should be offered to individuals in the authorized age group who are pregnant. NACI recommends that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are breastfeeding. Informed consent should include discussion about the evidence on the safety of mRNA COVID-19 vaccines in pregnant and breastfeeding individuals. There have not been any unique safety concerns raised about negative health effects from mRNA COVID-19 vaccine for pregnant individual or their babies. There are concerns about the treatment of the rare side effect of blood clotting with low blood platelets during pregnancy, should it occur following the administration of the AstraZeneca/COVISHIELD or Janssen COVID-19 vaccine. Evidence is showing that pregnant individuals develop immunity from COVID-19 vaccines in the same way as non-pregnant individuals and that vaccination in pregnancy may provide some protection for babies after they are born. Evidence is also showing that antibodies from mRNA COVID-19 vaccines are present in breast milk after maternal vaccination with mRNA vaccines which may provide some protection for breastfed babies. Information to assist in informed decision-making about whether to receive a COVID-19 vaccine for

those who are pregnant, planning a pregnancy or breastfeeding is available via the Know the Facts. Get the Vax. Video series: COVID-19 Vaccine and Pregnancy and Fertility.

NACI preferentially recommends that a complete COVID-19 vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are immunosuppressed due to disease or treatment and to individuals in the authorized age group with an autoimmune condition. In addition, individuals with moderate to severe immunosuppression should have an additional dose of a COVID-19 mRNA vaccine. Informed consent should include discussion about the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines and that evidence is emerging on the safety of mRNA COVID-19 vaccines in individuals with an autoimmune condition. Individuals who are immunocompromised were not included in the trials testing COVID-19 vaccines, however many immunocompromised individuals have received Pfizer and Moderna mRNA vaccines during the pandemic. There have not been any unique safety concerns raised about negative health effects from vaccine for immunocompromised individuals. Few individuals who have an autoimmune condition were included in the trials testing COVID-19 vaccines, however numerous individuals with autoimmune conditions have received Pfizer and Moderna mRNA COVID-19 vaccines during the pandemic. There have not been any unique safety concerns raised about negative health effects from the mRNA COVID-19 vaccines for autoimmune individuals at this time.

Previous SARS-CoV-2 Infection and Multisystem Inflammatory Syndrome in Children (MIS-C)

43. Can an individual who has experienced previous SARS-CoV-2 infection receive the COVID-19 vaccine?

Yes. NACI has provided updated guidance on suggested intervals between SARS-CoV-2 infection and COVID-19 vaccination. This guidance is based on available evidence on immunity following infection and vaccination, basic principles of vaccinology and immunology, and expert opinion informed by knowledge of other viral diseases. The optimal interval between infection and vaccination remains unknown. COVID-19 vaccination continues to be very important even for those with a history of prior infection, as vaccination is expected to broaden and strengthen the response in order to provide longer protection against current and future variants.

It is advised that individuals who have experienced previous SARS-CoV-2 infection, inclusive of individuals who are moderately to severely immunocompromised or who have experienced multisystem inflammatory syndrome in children (MIS-C), receive COVID-19 vaccines at intervals as described in Table 6: Suggested intervals between previous SARS CoV-2 infection and COVID-19 vaccination.

Individual benefit/risk assessment and clinical discretion are advised, including risk factors for exposure and severe outcomes. Some people may choose to receive a vaccine dose after acute symptoms of COVID-19 have resolved and they are no longer infectious. Suggested intervals may change as additional evidence on the extent and duration of protection provided by infection emerges. Evolving evidence will continue to be evaluated. People who have already received a dose of vaccine immediately after recovering from a COVID-19 infection do not need to repeat the dose.

44. Can a child with a previous history of MIS-C vaccination receive the COVID-19 vaccine?

For individuals with a previous history of MIS-C, COVID-19 vaccination should be postponed until clinical recovery has been achieved or until it has been 90 days or more since diagnosis, whichever is longer.

COVID-19 Vaccines Received out of Canada

45. Are individuals who received non-Health Canada authorized COVID-19 vaccines eligible to receive a COVID-19 vaccine in Nova Scotia?

The immunogenicity, efficacy and effectiveness of authorized COVID-19 vaccines vary. The World Health Organization's (WHO) Emergency Use Listing (EUL) assesses the quality, safety and efficacy of COVID-19 vaccines for use during public health emergencies. The authorization status of COVID-19 vaccines within the WHO EUL process may be found here: https://extranet.who.int/pqweb/vaccines/covid-19-vaccines (under EUL Submissions, Status of COVID-19 vaccines within the WHO EUL/prequalification evaluation process). Vaccines which have been authorized through the WHO EUL process have a "finalized" status of assessment.

Individuals who have received one dose of a COVID-19 vaccine not approved by Health Canada that is authorized by the WHO and are within the WHO authorized age group are recommended to receive and are eligible for one dose of an mRNA COVID-19 vaccine (Pfizer or Moderna) to be considered fully vaccinated. These individuals (12 years of age and older) may also receive mRNA COVID-19 booster dose(s) as eligible and at the appropriate interval described in Question 5.

Individuals who have received a full series of a COVID-19 vaccine not approved by Health Canada that is authorized by the WHO and are within the WHO authorized age group are considered fully vaccinated. It is recommended that these individuals receive one dose of an mRNA vaccine to achieve optimal protection against COVID-19 disease. These individuals (12 years of age and older) may also receive mRNA COVID-19 booster dose(s) as eligible and at the appropriate interval described in Question 5.

Individuals who have received a COVID-19 vaccine that is not authorized by the WHO and not approved by Health Canada are eligible to receive two doses of mRNA COVID-19 vaccine to be considered fully vaccinated and optimally protected against COVID-19 disease. These individuals (12 years of age and older) may also receive mRNA COVID-19 booster dose(s) as eligible and at the appropriate interval described in Question 5.

Healthcare professionals caring for individuals that received non-Health Canada, WHO authorized approved vaccines outside of the WHO authorized age group should call the COVID-19 Vaccine Pharmacist Consult Service at 1-833-768-1151 for recommendations to provide one or two doses of mRNA COVID-19 vaccine.

Medical Exemptions

46. What are the criteria in Nova Scotia for a medical exemption against COVID-19 vaccination?

Medical contraindications against receiving a COVID-19 vaccine which would permit an individual to be considered exempt from COVID-19 vaccination are limited in number and include:

- a history of severe allergic reaction (e.g. anaphylaxis) after previous administration of a COVID-19 vaccine using a similar platform (mRNA or viral vector)
- an allergy to any component of the specific COVID-19 vaccine or its container [polyethylene glycol (PEG) for Pfizer and Moderna COVID-19 vaccines; tromethamine (trometamol or Tris) for Moderna COVID-19 vaccine;

polysorbate 80 for viral vector vaccines (AstraZeneca and Janssen/Johnson & Johnson COVID-19 vaccines) and Novavax COVID-19 vaccine]

- a history of major venous and/or arterial thrombosis with thrombocytopenia following vaccination with AstraZeneca COVID-19 vaccine
- a history of capillary leak syndrome (CLS) following vaccination with AstraZeneca COVID-19 vaccine
- a history of myocarditis and/or pericarditis after a first dose of an mRNA COVID-19 vaccine
- a history of a serious adverse event following immunization (AEFI) after the first dose of a COVID-19 vaccine, with "serious" defined using the WHO standard definition: *an AEFI that results in death, is life-threatening, requires in-patient hospitalization or prolongs an existing hospitalization, results in persistent or significant disability/incapacity, or in a congenital anomaly/birth defect.*

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

- Pfizer BioNTech: https://www.cvdvaccine.ca/
- Moderna: https://www.modernacovid19global.com/ca/
- AstraZeneca: https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf
- Janssen : https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf
- Novavax : https://covid-vaccine.canada.ca/info/pdf/nuvaxovid-pm-en.pdf

Studies have shown that individuals with a severe immediate allergic reaction after a previous dose of mRNA COVID-19 vaccine can be re-vaccinated with the same vaccine or another mRNA COVID-19 vaccine following an appropriate allergist assessment. 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.

NACI recommends that:

- It is possible for people who experienced a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine to safely receive future doses of the same or another mRNA COVID-19 vaccine in a controlled setting after consulting with an allergist or another appropriate physician.
- People with a history of a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine should:
    - Consult with an allergist or another appropriate physician before receiving future doses of an mRNA COVID-19 vaccine;
    - Receive future doses of an mRNA COVID-19 vaccine in a controlled setting with someone who is experienced in managing anaphylaxis and
    - Be observed for 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).

Note: None of the authorized COVID-19 vaccines, including the mRNA vaccines nor the viral vector vaccine, are contraindicated in people who are immunosuppressed. As such, people who are immunosuppressed and people with autoimmune diseases should be vaccinated with COVID-19 vaccines. Ideally, the COVID-19 vaccine series should be completed 2 weeks before starting immunosuppressive therapy or when immunosuppressive therapy is the lowest but

can be given when needed. This ensures that COVID-19 protection is provided sooner. People who are pregnant and breastfeeding should also be vaccinated with COVID-19 vaccines.

Allergens

47. 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: over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care solutions, products such as ultrasound gel.

The Moderna COVID-19 vaccine and Pfizer Comirnaty pediatric formulation (10 mcg) also contains tromethamine (trometamol or Tris) which is a component in contrast media, and oral and parenteral medications. In the literature, one case report of anaphylaxis to tromethamine has been described. The Canadian Society of Allergy and Clinical Immunology provides guidance for health care professionals regarding vaccination in individuals with confirmed or suspected allergic conditions.

The authorized COVID-19 viral vector vaccines (AstraZeneca and Janssen) and the Novavax COVID-19 vaccine contain polysorbate 80. Polysorbates may be found in medical preparations such as vitamin oils, tablets, and anticancer agents and cosmetics.

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of vaccine. Therefore, if there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, or if an individual has a history of anaphylaxis to another vaccine or to an injectable medication or product, an extended period of observation post-vaccination of 30 minutes may be warranted. For current information regarding anaphylaxis management please refer to the Canadian Immunization Guide: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-4-early-vaccine-reactions-including-anaphylaxis.html#a16

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