Nova Scotia COVID-19 Vaccine Program

Information for Health Care Professionals

Updated April 1, 2021

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.

COVID-19 Vaccines in Canada

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

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

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

At this time, there is one non-replicating viral vector vaccine approved and available for use in Canada and one authorized and not yet available in Canada (Janssen). Health Canada authorized two manufacturers to produce the vaccine developed by AstraZeneca and Oxford University: AstraZeneca and Serum Institute of India (SII). Health Canada has deemed SII and AstraZeneca vaccines to be comparable. AstraZeneca COVID-19 vaccine [COVISHIELD (manufactured by SII) and AstraZeneca COVID-19 vaccine (manufactured by AstraZeneca)] were authorized on February 26, 2021. COVISHIELD and AstraZeneca COVID-19 vaccine product monographs and information for health care professionals are available from:

- COVISHIELD: https://covid-vaccine.canada.ca/info/pdf/covishield-pm-en.pdf, and https://www.covishield-canada.ca/documents/COVISHIELD%20HCP%20Guide.pdf
- AstraZeneca: https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf, and https://www.azcovid-19.com/content/dam/azcovid/pdf/canada/ca-COVID-19-Vaccine-Guide-for-Health-Care-Professionals-EN.pdf

Additional information specific to the COVID-19 vaccines currently authorized for use in Canada can be found in the NACI Statement Recommendations on the use of COVID-19 Vaccines.

2. Who is eligible and how are key populations chosen to receive initial doses COVID-19 vaccine?

Nova Scotia's COVID-19 immunization plan includes 3 phases. Each phase identifies when different groups can receive the vaccine. The plan is flexible to allow for increases or decreases in vaccine supply. Every person in Nova Scotia who wants the COVID-19 vaccine and for whom vaccine is indicated will receive it for free. An overview of Nova Scotia's COVID-19 immunization plan is available here: https://novascotia.ca/coronavirus/docs/COVID-19-immunization-plan-overview-poster-en.pdf.

Initial doses of AstraZeneca vaccine are being offered to Nova Scotians who are 55 to 64 years of age on a an age-related and volunteer basis.

3. As a health care professional, how can I support patients in making an informed choice about receiving a specific type of COVID-19 vaccine?

All currently authorized COVID-19 vaccines are safe and effective. The current evidence shows that both mRNA COVID-19 vaccines are more efficacious than the AstraZeneca COVID-19 vaccine. However, delaying the interval between the first and second dose of AstraZeneca vaccine to 12 or more weeks increases efficacy of the series. NACI recommends that AstraZeneca COVID-19 vaccine should **not** be used in adults under 55 years of age at this time while the safety signal of Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) following vaccination with AstraZeneca COVID-19 vaccine is investigated further. This adverse event has not been identified following receipt of mRNA COVID-19 vaccines to date. While all available vaccines in Canada are safe and effective, NACI still recommends that in the context of limited vaccine supply and ongoing pandemic disease, initial doses of mRNA vaccines should be prioritized for those at highest risk of severe illness and death and highest risk of exposure to COVID-19. NACI provides information regarding management options for COVID-19 vaccines to assist with the decision on which vaccine to offer to different populations or groups. A comparison of mRNA and viral vector COVID-19 vaccines may be found in the NACI Statement Recommendations on the use of COVID-19 Vaccines.

Those who are initially eligible to receive AstraZeneca COVID-19 vaccine in Nova Scotia may choose not to receive it at this time. Individuals will continue to be eligible for COVID-19 vaccine in accordance with the phased plan. At this time, there is no evidence to support the interchangeability of mRNA vaccines and viral vector vaccines or effectiveness of a mixed vaccine series, however studies are ongoing.

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

A two-dose series of both mRNA vaccines have been shown to be >90% efficacious in the clinical trials. AstraZeneca COVID-19 vaccine series has been shown to be 62% efficacious in those aged 18 to 64 years. Data suggests that delaying the interval between the first and second dose of AstraZeneca vaccine to 12 or more weeks increases the effectiveness of the series to up to 82%. Observational data has shown a reduction in the risk of symptomatic disease and hospitalization starting from two weeks following one dose of AstraZeneca vaccine that appears to be comparable to persons of a similar age who received one dose of mRNA vaccine and also to efficacy estimates in the AstraZeneca COVID-19 vaccine clinical trials among adults 18 to 64 years of age. Data regarding efficacy and effectiveness continues

to evolve. For the most current information regarding efficacy of the COVID-19 vaccines, please consult the NACI's Recommendations on the Use of COVID-19 Vaccines statement.

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

All COVID-19 vaccines induce both humoral and cellular immune response. For all COVID-19 vaccines, 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. Maximal humoral immune response was seen approximately 7 days after the second dose for each vaccine. Cellular immune responses increased after the second dose of mRNA vaccine, while responses for AstraZeneca COVID-19 vaccine were maintained or decreased after the second dose. The duration of protection after a two-dose series is currently unknown.

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

6. 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 will be held to the same high safety, effectiveness, 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, Health Canada (the regulator) monitors 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 safety reports received across the country 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.

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

Please see NACI Statement Recommendations on the use of COVID-19 Vaccines for a summary of adverse events identified in clinical trials of authorized COVID-19 vaccines. The COVID-19 Vaccine Information and Aftercare Sheet, developed by the NSHA, provides 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 and swelling are common or very common after administration. 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 adults 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.

Table 1: Frequency of solicited local adverse events in authorized populations[a]

AEFI	Pfizer-BioNTech		Moderna		AstraZeneca	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Pain at injection site	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Tenderness	NS	NS	NS	NS	Very Common	Very Common
Redness	Common	Common	Common	Common	Common	Common
Swelling	Common	Common	Common	Very Common	Common	Common
Lymphadenopathy/ Axillary swelling and Tenderness	NS	NS	Very Common	Very Common	NS	NS
Warmth	NS	NS	NS	NS	Very Common	Very Common
Pruritis	NS	NS	NS	NS	Common	Common
Induration	NS	NS	NS	NS	Common	Uncommon

Abbreviations: AEFI: adverse event following immunization; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

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 AstraZeneca COVID-19 vaccine. 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 adults. For AstraZeneca COVID-19 vaccine, systemic reactions are milder and reported less frequently after the second vaccine dose in all age groups.

Table 2: Frequency of solicited systemic adverse events in authorized populations[a]

AEFI	Pfizer-BioNTech		Moderna		AstraZeneca	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Fatigue	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Headache	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Muscle pain	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Chills	Very Common	Very Common	Common	Very Common	Very Common	Common
Joint Pain	Common	Very Common	Very Common	Very Common	Very Common	Very Common
Fever[b]	Common	Very Common	Uncommon	Very Common	Very Common	Uncommon
Feverishness[b]	NS	NS	NS	NS	Very Common	Very Common
Diarrhea	Common	Common	NS	NS	NS	NS
Nausea and/or Vomiting Vomiting[c]	Uncommon	Common	Common	Very Common	Very Common/ Common	Common/ Uncommon

Abbreviations: AEFI: adverse event following immunization; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients.

[b] Fever was objectively reported as having a temperature ≥38°C/100.4°F. Feverishness was a subjective, self-reported feeling of having fever.

[c] If two frequencies are reported the first reflects frequency of nausea and the second reflects the frequency of vomiting.

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 vaccines. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively. No rare or very rare solicited adverse events were reported among vaccinated participants in any COVID-19 vaccine clinical trial to date.

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.

8. Is AstraZeneca COVID-19 vaccine safe with the recent information regarding Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT)?

Rare cases of thrombosis and thrombocytopenia [called vaccine-induced prothrombotic immune thrombocytopenia (VIPIT)], some presenting as mesenteric vein or cerebral vein/cerebral venous sinus thrombosis, have been reported in Europe in persons who had recently received AstraZeneca COVID-19 vaccine, mostly occurring within 4 and 16 days after vaccination. VIPIT is associated with the development of antibodies that "activate" platelets, which stimulate the formation of clots and result in thrombocytopenia. The mechanism of action is similar to heparin-induced thrombocytopenia (HIT). The exact mechanism by which the AstraZeneca COVID-19 vaccine may trigger VIPIT is still under investigation. The rate of this adverse event is still to be confirmed. Based on information from the European Medicines Agency on March 18, 2021 it was originally estimated at approximately 1 per 1,000,000 people vaccinated with the AstraZeneca COVID-19 vaccine, however a higher rate of 1 per 100,000 was reported by the Paul-Ehrlich Institut in Germany. Additional information is being gathered to characterize more accurately the rate of VIPIT. Based on available information, the case fatality of VIPIT is approximately 40%, however, the case fatality may decrease with increased awareness of the condition and appropriate early treatment.

Upon reviewing occurrences of VIPIT after AstraZeneca COVID-19 vaccine and assessing risk of COVID-19 disease by age, and considering that mRNA vaccines are available, from what is known at this time, there is substantial uncertainty about the benefit of providing AstraZeneca COVID-19 vaccine to adults under 55 years of age given the potential risks associated with VIPIT. As a precautionary measure, NACI has recommended that the AstraZeneca COVID-19 vaccine **not** be offered to adults under the age of 55 at this time. Adults 55 years of age and older may still be offered the AstraZeneca vaccine with informed consent, given the increased risk of hospitalization and death due to COVID-19 disease in this population and since VIPIT appears to be a rarer event in that age group. Healthcare professionals are urged to be alert for symptoms of VIPIT, possible cases of thromboembolism, disseminated intravascular coagulation (DIC) or cerebral venous sinus thrombosis (CVST) occurring in vaccinated individuals. **Symptoms to be vigilant for include**: shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms including sudden onset of severe or persistent worsening headaches or blurred vision, skin bruising (other than at the site of vaccination) or petechiae. Providers should ensure that individuals who receive the AstraZeneca COVID-19 vaccine are informed of the low potential risk of these rare thromboembolic side effects.

9. What clinical guidance regarding vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) is available for health care providers?

The Ontario COVID-19 Science Advisory Table's *Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) Following AstraZeneca COVID-19 Vaccination* guidance provides information for health care professionals regarding the pathophysiology, presentation, diagnostic work-up and treatment of VIPIT[1]. Nova Scotia thrombosis experts have reviewed such guidance and support these recommendations for investigation and management. Guidance from Thrombosis Canada is forthcoming. In the interim, the Ontario guidance is appropriate.

10. What do I tell my patients about the risk of thromboembolic side effects from AstraZeneca COVID-19 vaccine?

Providers should inform their clients that the AstraZeneca COVID-19 vaccine is not associated with an increased overall risk of blood clotting disorders. There have been very rare cases of unusual blood clots accompanied by low levels of blood platelets after vaccination. Doctors are calling this vaccine-induced prothrombotic immune thrombocytopenia (VIPIT). To date, this adverse event has not been reported in Canada. As the reported cases were almost all in individuals younger than 55 years of age, NACI has recommended an immediate pause in the use of AstraZeneca COVID-19 vaccine in this age group as this is investigated further. Adults 55 years of age and older may older may still be offered the AstraZeneca vaccine, given the increased risk of hospitalization and death due to COVID-19 disease in this population and since VIPIT appears to be a rarer event in that age group. Currently, in Nova Scotia, individuals 60 to 64 years of age are being offered the AstraZeneca COVID-19 vaccine. It is not believed that VIPIT is more common in people who have had blood clots before, people with a family history of blood clots, people with low platelets, or pregnant women, because VIPIT does not develop through the same process as usual types of bleeding or clotting problems. Healthcare providers should inform their patients to seek immediate medical attention for symptoms of thromboembolism and/or thrombocytopenia between days 4 and 16 following receipt of AstraZeneca COVID-19 vaccine. Patients should be advised that if they experience any of the following symptoms, they need to call 911 or seek medical assistance right away, ensuring they mention they have received the vaccine:

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

A handout for patients receiving the AstraZeneca COVID-19 vaccine may be found on the NSHA COVID-19 Hub.

[1] Nova Scotia healthcare professionals will continue to follow AEFI reporting requirements as per the Nova Scotia Health Protection Act and the Regulations under the Act in accordance with *It's the Law: Reporting of Adverse Events Following Immunization*.

11. 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.

12. 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/13087_AdverseEventsPoster_En.pdf

13. 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

14. What are the differences in the storage requirements, authorized schedules, doses and administration between the COVID-19 vaccines approved for use in Canada?

Table 3 COVID-19 vaccines authorized for use in Canada

Product	**Pfizer BioNTech COVID-19 vaccine**	**Moderna COVID-19 vaccine**	**AstraZeneca COVID-19 vaccine**
Type of vaccine	mRNA	mRNA	Non-replicating viral vector (ChAd)
Ages for use	HC: 16 years of age and older	HC: 18 years of age and older	**NS: 55 to 64 years of age**
			HC: 18 years of age and older
Dose	0.3 mL (30 mcg of mRNA)[1]	0.5 mL (100 mcg of mRNA)	0.5 mL (5 x 10^{10} viral particles)
Route of administration	IM	IM	IM
Schedule	**NS: 2 Doses, 4 months apart**	**NS: 2 Doses, 4 months apart**	**NS: 2 Doses, 4 months apart**
	HC: 2 Doses, 3 weeks apart[2]	HC: 2 Doses, 4 weeks apart [2]	HC: 2 Doses, 4 to 12 weeks apart[2]
Adjuvant (if present)	None	None	None
Diluent	Yes	No	No
Primary storage requirements pre-puncture	-80°C to -60°C [3] until expiry date on label **or** -25°C to -15°C [3] for up to 2 weeks [4]	-25°C to -15°C [3, 5]	+2°C to +8°C [3]
Storage requirements pre-puncture [3]	120 hours (5 days) at +2°C to +8°C **and/or** 2 hours up to +25°C	30 days at +2°C to +8°C **and/or** 12 hours at +8°C to +25°C	+2°C to +8°C
Usage limit post-puncture	6 hours at +2°C to +25°C [6]	6 hours at +2°C to +25°C	6 hours at room temperature (up to +30°C) OR 48 hours at +2°C to 8°C
Formats available	Multi-dose vial (6 doses) [1], preservative-free	Multi-dose vial (10 doses), preservative-free	Multi-dose vial (8-and 10-dose presentations), preservative-free

Abbreviations: mRNA: Messenger ribonucleic acid; ChAd: Chimpanzee adenovirus; HC: Health Canada; NS: Nova Scotia; IM: intramuscular

1 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.

2 Authorized schedule. For NACI recommendations on intervals between doses refer to NACI Recommendations on the use of COVID-19 vaccines and NACI Rapid Response document – Extended Dose Intervals.

3 Protected from light during storage.

4 Pfizer BioNTech COVID-19 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.

5 Do not store on dry ice or below -40°C.

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

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

- Pfizer BioNTech: https://www.cvdvaccine.ca/
- Moderna: https://www.modernacovid19global.com/ca/
- COVISHIELD: https://covid-vaccine.canada.ca/info/pdf/covishield-pm-en.pdf and AstraZeneca: https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf

15. Why is Nova Scotia only using AstraZeneca COVID-19 vaccine for those who are 55 to 64 years of age?

NACI has expanded its recommendation for the use of AstraZeneca vaccine to people over the age of 18, now including those 65 years of age and older. While all the vaccines in Canada are safe and effective, NACI still recommends that in the context of limited vaccine supply and ongoing pandemic disease, initial doses of mRNA vaccines should be prioritized for those at highest risk of severe illness and death and highest risk of exposure to COVID-19. Individuals 65 years of age and older are at increased risk of severe illness and will be offered mRNA vaccines at this time. AstraZeneca COVID-19 vaccine will **not** be offered to individuals under 55 years of age at this time as per the March 29th, 2021 recommendation provided by NACI.

16. Why is the Nova Scotia schedule for second dose of COVID-19 vaccine different than the Health Canada authorized schedule?

NACI's Rapid Response on extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada recommends that in the context of limited supply, individuals should receive their second dose of COVID-19 **four months following their first dose**. Effectiveness data suggest that the first dose of vaccine offers protection for at least two months without waning. In addition, delaying the interval between the first and second dose of AstraZeneca vaccine to 12 or more weeks increases effectiveness of the series. By extending the second dose of COVID-19 vaccine to four months after the first, we will be able to provide access to first doses of highly efficacious vaccines to more Nova Scotians earlier. Protecting more Nova Scotians more quickly will reduce the risk of severe disease outcomes for more Nova Scotians which is expected to increase health equity faster.

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

18. What is the minimum interval for the second dose for each of the COVID-19 vaccines?

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

- Pfizer-BioNTech: 19 days
- Moderna: 21 days
- AstraZeneca: 28 days

19. 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 always important; however this is critical for COVID-19 vaccines given vaccine supply issues. 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.

20. 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.

21. 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.

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

In the absence of evidence regarding simultaneous administration of COVID-19 vaccine with other vaccines, the National Advisory Committee on Immunization (NACI) recommends the following with regard to other (non-COVID-19) vaccines and other medications.

Except in the case where another vaccine is required for post-exposure prophylaxis, it is prudent not to administer:

- Any other (non-COVID-19) vaccines at the same time as the COVID-19 vaccine;
- A COVID-19 vaccine if the client has received another vaccine in the preceding 14 days[2]
- Another (non-COVID-19) vaccine until 28 days after each dose of a COVID-19 vaccine (except in the case where another vaccine is required for post-exposure prophylaxis);
- COVID-19 vaccines simultaneously with monoclonal antibodies or convalescent plasma. The interval between receipt of these products and COVID-19 vaccine is under review.

If a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.

23. 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

[2] If there are logistical challenges with supply/scheduling vaccine appointments **and** there has been no adverse reaction from the other vaccine, the second dose of COVID-19 vaccine may be given.

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.

24. Are the COVID-19 vaccines interchangeable?

As there are currently no data on the interchangeability of COVID-19 vaccines, NACI recommends that the **vaccine series be completed with the same COVID-19 vaccine product**.

If the vaccine product used for a previous dose is not known, attempts should be made to identify which vaccine was given for the first dose in order to give the same product for the second dose. If the same product is not available, complete the vaccine series with a similar type of COVID-19 vaccine (e.g., complete a series started with an mRNA vaccine with another mRNA vaccine). Such a series should be considered as valid, without need to restart a two-dose series with a new product. At this time, it is not recommended that vaccines of different types (e.g., mRNA vaccine and viral vector vaccine) be used in the same series. **Accurate recording of vaccines received is critical.**

25. 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.

26. 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 may be found here: https://www.youtube.com/watch?v=k_IxCPcbRGk

27. What if there is remaining vaccine in the vaccine vial after 6 doses from the Pfizer-BioNTech vaccine vial, or 10 doses from the Moderna vaccine vial, or 10 doses from the AstraZeneca vial have been removed?

If there is enough vaccine left in the vial for a complete 0.3 mL dose after 6 doses have been removed from a Pfizer-BioNTech vaccine vial, or a complete 0.5 mL dose after 10 doses have been removed from a Moderna vaccine vial, or a complete 0.5mL dose after 10 doses have been removed from an AstraZeneca vial, additional doses can be drawn and administered.

Pooling of residual vaccine, the process of drawing-up leftover vaccine from a maximum of **two** vials after all full doses have been withdrawn, 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 residual 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 6 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.**

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

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

Special Considerations

29. 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. Vaccine may be offered to individuals in these populations in some circumstances on a case-by-case basis with a risk-benefit analysis (where the risk of exposure and/or severe COVID-19 disease outweighs the risk of vaccination), and with transparency about the insufficiency of evidence. These recommendations may change as more evidence becomes available.

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 has been developed by the members of the Nova Scotia Vaccine Expert Panel (VEP) and the Reproductive Care Program of Nova Scotia and is available as a Decision Aid Tool.

Guidance for health care providers to provide informed consent for COVID-19 vaccination to immunocompromised persons and persons with underlying autoimmune diseases has been developed by the members of the Nova Scotia VEP and may be found in Appendix 1.

Recommendations for the use of COVID-19 vaccine in immunosuppressed persons, persons with an autoimmune condition, pregnant or breastfeeding individuals and individuals 12 – 15 years of age (Pfizer BioNTech specifically) are also available in NACI's Recommendations on the use of COVID-19 vaccines statement.

30. Can an individual who has previous lab-confirmed SARS-CoV-2 infection receive the COVID-19 vaccine?

Yes. NACI currently recommends that a complete series with a COVID-19 vaccine should be offered to individuals with prior PCR-confirmed SARS-CoV-2 infection. This recommendation may be modified as further evidence emerges.

Contraindications

31. What are the contraindications to the COVID-19 vaccines?

An authorized COVID-19 vaccine should not be offered routinely to individuals with 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). If a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided, an authorized COVID-19 vaccine using a different platform may be considered for re-immunization (i.e. individuals with anaphylaxis post mRNA vaccine may be offered a viral vector vaccine.)

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 and https://covid-vaccine.canada.ca/info/pdf/covishield-pm-en.pdf

Note: None of the authorized COVID-19 vaccines, including the mRNA vaccines nor the viral vector vaccine, are contraindicated in people who are immunosuppressed. The Astra Zeneca vaccine uses a non-replicating adenovirus that is incapable of replication, unlike a live-attenuated viral vaccine.

32. 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 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 AstraZeneca COVID-19 vaccine (AstraZeneca and COVISHIELD) contains polysorbate 80 which can be found in medical preparations (e.g. 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

Appendix 1 – Guidance for Health Care Providers - to provide informed consent for COVID-19 vaccination in special populations (e.g. immunocompromised persons and persons with underlying autoimmune diseases)

The following guidance has been developed by members of Nova Scotia's Vaccine Expert Panel.

The safety and efficacy of COVID-19 vaccine in immunocompromised persons and those with underlying autoimmune conditions have not yet been established because the vaccine has not been studied in these groups. Persons who are immunocompromised may not mount an adequate immune response. In some immunocompromised clients, a less than optimal response to a vaccine may provide some benefit as they may be at higher risk of morbidity and mortality from COVID-19. For clients with severe immunodeficiency, administration of inactivated vaccines is often not harmful, but may not provide full protection.

Currently, there are very limited data on COVID-19 vaccination in individuals who have an autoimmune condition. Persons with autoimmune diseases represented a very small proportion of trial participants and represent a very narrow

range of autoimmune conditions. The relative degree of autoimmunity in individuals with autoimmune conditions is variable depending on the underlying condition, the severity and progression of the disease and use of medications that impact immune function. Therefore, the balance of risks and benefits must be made on a case-by-case basis. Other applications of mRNA technologies have been used for the treatment of cancer, which required an immune response directed against an individual's cancer cells. This raised the theoretical concern that mRNA vaccines for infectious diseases would behave similarly, eliciting inflammation and possibly exacerbating existing autoimmune diseases. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk.

Guidance for the approach to consent for special populations (e.g. underlying immunocompromise or autoimmune conditions)

The approach to consent for COVID-19 vaccines requires an assessment of an individual's underlying medical conditions in order to identify situations where more detailed information and consent process may be required. For each person, a Category is assigned, and the following Management Pathway may be followed to document consent.

Category 1	Category 2	Category 3	Category 4	Category 5
• Splenic disorders • HIV • Chronic kidney disease • Chronic liver disease • Type 1 or 2 Diabetes mellitus • Hypothyroidism • Stable anticoagulation/ bleeding disorders • Radiation therapy alone • Asthma/COPD/ hypertension/ coronary artery disease/other medical conditions (including frailty) not associated with immunosuppres	• Pregnant individuals beyond the 1st trimester • Breastfeeding individuals	• Mild – moderate reactions to a prior dose of COVID-19 vaccine • Pregnant individuals in the first trimester (consider delaying until at least the second trimester) • On immune suppressing doses of prednisone (> 20 mg/day > 2 weeks) • On anti-SARS-CoV-2 monoclonal antibodies, plasma therapy, or plasmapheresis	• Active/unstable autoimmune condition* • Solid organ transplant with acute rejection • Any cancer on IV chemotherapy • Acute leukemia • Within 3 months of stem cell transplant • On check point inhibitor • Within 3 months of CAR-T procedure • Interferono-Pathy	• Anaphylaxis or severe reaction to prior dose of COVID-19 vaccine • Anaphylaxis to any component of the COVID-19 vaccine

Category 1	Category 2	Category 3	Category 4	Category 5
sion or autoimmunity • Anaphylaxis to another vaccine or injectable medication (observe for 30 minutes)		(delay 3 months) • Primary immune deficiency requiring IVIG or SCIG • Chronic granulomatous disease • Hyper IgE syndrome • Complement deficiency • Solid organ transplant after 1 month & no acute rejection • Stem cell transplant after 3 months & no GVHD • Any cancer not on therapy or on only oral cancer therapy • Stable autoimmune condition • Stable immunomodulator therapy • History of Guillain Barre syndrome • History of Bell's palsy		

*In category 4, Active/unstable autoimmune condition requires discretion by the provider. It is intended to address those patients with severe, unstable disease. Recognizing that these patients have a high risk of experiencing worsening of their disease even in the absence of vaccine, and that patients and providers may attribute a temporal worsening to the vaccine, it seems prudent to involve the treating specialist in the decision about vaccination. Examples of the types of patients this

might apply to include progressive MS, unstable/progressive lupus nephritis, severe IBD with concerns for imminent need for surgery, etc. If the provider initially contacted by these patients feels that the patient has reasonably stable disease and understands the lack of safety data but wishes to proceed, that is acceptable at the discretion of the provider.

Guidance for Consent Management pathways

Nova Scotians with general questions about COVID-19 vaccine should speak to their primary care provider, pharmacist or specialist. The following table outlines the requirements for consent in special populations.

	Pathway 1	**Pathway 2**	**Pathway 3**	**Pathway 4**	**Pathway 5**
Category	1	2	3	4	5
Education/Consent discussion	Self	Self	Primary care provider, nurse practitioner, pharmacist, clinic consult RN or specialist	Specialist or vaccine consultant (infectious diseases specialist)	Allergist
Consent documentation	Usual	Usual + confirmation	Usual + confirmation	Usual + confirmation	Usual + confirmation

In general, if a patient is 3 months post-chemotherapy and the cancer is in remission, or if immunosuppression has been discontinued for at least 3 months (6 months or more for anti-B cell antibodies), the person is no longer considered immunocompromised.

People living with HIV may be vaccinated with the COVID-19 vaccine. Persons with stable hepatitis B or C may also be vaccinated.

Clients on blood thinners can also be vaccinated using a small gauge needle and applying pressure post-vaccination. There is no specific need to measure a blood thinning level (INR test) prior to vaccination.

Autoimmune Conditions

- Acquired aplastic anemia
- Acute disseminated encephalomyelitis, including non-infectious encephalitis, encephalomyelitis, myelitis, myeloradiculomyelitis
- Addison's diseases
- Alopecia areata
- Ankylosing spondylitis
- Antineutrophil cytoplasmic antibody (ANCA) positive vasculitis
- Antiphospholipid syndrome
- Antisynthetase syndrome
- Autoimmune
    - cholangitis

  - hemolytic anemia
  - hepatitis
  - myocarditis/cardiomyopathy
  - thrombocytopenia
- Behcet's syndrome
- Buerger's disease/thromboangiitis obliterans
- Celiac disease
- Chronic hives/urticaria
- Chronic inflammatory demyelinating polyneuropathy
- Churg Strauss/allergic granulomatous angiitis/eosinophilic granulomatous polyangiitis (EGPA)
- Cranial nerve disorders
- CREST syndrome
- Dermatomyositis
- Dermatitis herpetiformis
- Diabetes mellitus (Type 1)
- Erythema nodosum
- Giant cell arteritis/Takayasu's arteritis/temporal arteritis
- Glomerulonephritis (membranous, membranoproliferative, mesangioproliferative, rapidly progressive)
- Goodpasture syndrome
- Granulomatosis with polyangiitis (Wegener's granulomatosis)
- Grave's or Basedow's disease
- Guillain Barre syndrome and variants, including Miller Fisher syndrome
- Hashimoto's thyroiditis
- Henoch Schonlein purpura (HSP)
- Idiopathic pulmonary fibrosis
- Idiopathic thrombocytopenic purpura (ITP)
- IgA nephropathy
- Immune-mediated peripheral neuropathies and plexopathies, including chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy, monoconal gammopathy-associated polyneuropathies
- Inflammatory bowel disease (ulcerative colitis, ulcerative proctitis, and Crohn's disease)
- Juvenile dermatomyositis
- Juvenile idiopathic arthritis
- Kawasaki Disease
- Leukocytoclastic vasculitis
- Lichen planus
- Lupus erythematosus, cutaneous and systemic
- Microscopic polyangiitis
- Mixed connective tissue disease/disorder
- Morphoea
- Multiple sclerosis

- Myasthenia gravis, including Lambert-Eaton myasthenic syndrome
- Narcolepsy
- Necrotizing vasculitis
- Optic neuritis
- Pemphigoid/pemphigus
- Pernicious anemia
- Polyarteritis nodosa
- Polymyalgia rheumatica
- Polymyositis
- Primary biliary cirrhosis
- Primary sclerosing cholangitis
- Psoriasis/psoriatic arthritis
- Pyoderma gangrenosum
- Raynaud's phenomenon
- Reactive arthritis/Reiter's syndrome
- Relapsing polychondritis
- Rheumatoid arthritis
- Sarcoidosis
- Scleroderma
- Sjogren's syndrome
- Small fibre sensory neuropathy
- Stevens-Johnson syndrome
- Sweet's syndrome
- Systemic sclerosis
- Transverse myelitis
- Undifferentiated spondyloarthritis
- Uveitis
- Vitiligo

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