Nova Scotia COVID-19 Vaccine Program

Information for Health Care Professionals

Updated July 9, 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.

Table of Contents

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

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

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 doses of COVID-19 vaccine?

Informed by NACI, our own Vaccine Expert Panel and many other authorities, Nova Scotia, like many jurisdictions, focussed on those at highest risk for exposure to COVID-19 disease due to their employment, the risk associated with age and congregate settings. As such, healthcare workers, those living in large congregate settings (public and private) and the elderly population living in community were the first groups eligible to receive COVID-19 vaccine. As vaccine supply has become more plentiful, Nova Scotia has adopted an age-based roll out to address the risk factor of age. An age-based rollout presents the greatest efficiency in providing vaccine doses to individuals and thereby protects more Nova Scotians more quickly.

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. For the First Nations approach, vaccine eligibility initially focussed on Elders, Knowledge and Language keepers, along with those that were > 55 years of age. For the African Nova Scotian community, eligible vaccine recipients are those who are > 55 years of age. Outreach vaccine clinics with urban indigenous, shelters, persons with disabilities, community day programs and some large, specialized homes are also occurring.

Initial doses of AstraZeneca vaccine were offered to Nova Scotians 55 to 64 years of age on an age-related and volunteer basis. This vaccine eligibility was opened to Nova Scotians between the ages of 40 and 64 years on April 30, 2021. Effective, May 12, 2021, Nova Scotia paused the use of AstraZeneca vaccine. This pause was due to an observed increase in the rare blood clotting condition known as Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT) linked to the AstraZeneca COVID-19 vaccine within Canada and globally, as well as sufficient supply of mRNA vaccines for the eligible age group that AstraZeneca has been approved for in Nova Scotia (≥40 years). Those individuals who received AstraZeneca COVID-19 vaccine have been provided with information regarding the very rare side effect of unusual blood clots accompanied by low levels of blood platelets, estimated to occur at a frequency of between 1 per 26,000 and 1 per 100,000 persons vaccinated with a first dose. Effective June 1, 2021, Nova Scotia resumed the use of AstraZeneca's COVID-19 vaccine for second doses only. Based on NACI recommendations, emerging evidence including a small study 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 that VITT is not a risk with mRNA vaccines, Nova Scotia recommends that mRNA vaccine should be used for second doses among individuals who received AstraZeneca for their first dose of COVID-19 vaccine. Individuals who preferred to receive AstraZeneca COVID-19 vaccine for their second dose and who were engaged in an informed consent process were able to receive this vaccine until June 30, 2021. Additionally, individuals who received a first dose of Pfizer or Moderna COVID-19 vaccine can receive a second dose of either Pfizer or Moderna COVID-19 vaccine.

On May 5, 2021, Health Canada expanded the Interim Order authorization for Pfizer COVID-19 vaccine to include use in adolescents 12 to 15 years of age. This age cohort is eligible for Pfizer COVID-19 vaccine in alignment with Nova Scotia's age-based rollout.

Nova Scotia's 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 with their first dose being given by the end of June. Many factors are involved in the development of Nova Scotia's vaccine plan and are continually assessed as circumstances change.

3. With the latest information regarding interchangeability of authorized COVID-19 vaccines, 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:

- Individuals who received a first dose of an mRNA vaccine, should be offered the same mRNA vaccine for their second dose if possible. However, NACI also recommends that another mRNA vaccine should be considered interchangeable and can be offered to complete the vaccine series.
- Individuals who received a first dose of AstraZeneca/COVISHIELD vaccine (viral vector vaccine), may be offered either AstraZeneca/COVISHIELD or an mRNA vaccine for the second dose, unless contraindicated. An mRNA vaccine is preferred as a subsequent dose due to emerging evidence including the possibility of better immune response, and the safety of mixed schedules.

- Individuals who have already received two doses of the AstraZeneca/COVISHIELD vaccine are considered protected and do not require further vaccination.

Individuals who received a first dose of an mRNA COVID-19 vaccine (Pfizer or Moderna) can receive a second dose of either vaccine. Currently, there is no evidence to suggest that an mRNA vaccine series completed with a different mRNA vaccine product would result in any additional safety issues or deficiency in protection. Similar vaccines from different manufacturers are routinely used interchangeably, including vaccines for Hepatitis A, monovalent 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 schedules (e.g., 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.

The rate of VITT in the UK, after the second dose of AstraZeneca vaccine, is estimated to be approximately 1 in 600,000 (17 cases out of 10.7 million second doses administered). It should be noted that with increased observation times, VITT rates have generally increased. Individuals who have experienced venous or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine should not receive a second dose of a viral vector COVID-19 vaccine.

Based on NACI recommendations, emerging evidence, including a small study 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 that VITT is not a risk with mRNA vaccines, Nova Scotia recommends that **mRNA vaccine should be used for second doses among individuals who receive AstraZeneca for their first dose of COVID-19 vaccine**.

Completing the two-dose COVID-19 vaccination schedule remains essential. The first dose offers very good protection against COVID-19 infection, hospitalization and death. The second dose enhances and strengthens that protection over the longer term any may improve protection against emerging variants of concern

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. In study participants 12 to 15 years of age, the estimate of vaccine efficacy of Pfizer COVID-19 vaccine was 100%. 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 increases the effectiveness of the series, with the largest increase beyond 12 weeks (81.6%). 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 NACI's Recommendations on the Use of COVID-19 Vaccines statement.

5. How long does it take for immunity 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 was seen after the second dose for each mRNA vaccine and for the AstraZeneca COVID-19 vaccine. The humoral immune response to the Pfizer COVID-19 vaccine was non-inferior in adolescents 12 to 15 years of age compared to individuals 16 to 25 year of age. Cellular immune responses increased after the second dose of mRNA vaccine, while responses for AstraZeneca COVID-19 vaccine did not appear to increase after the second dose. Cellular immune responses do not appear to differ between age groups. 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.

Safety in Adolescents

7. What new evidence has emerged to demonstrate that the Pfizer COVID-19 vaccine is safe for adolescents?

On May 5, 2021, Health Canada expanded its authorization for the Pfizer COVID-19 vaccine from use in those 16 years and older to also include adolescents 12 to 15 years of age. NACI has since released a statement recommending that

a complete series of the Pfizer COVID-19 vaccine be offered to individuals 12 to 18 years of age without contraindications to the vaccine. Informed consent should include discussion about very rare reports of myocarditis and/or pericarditis in the week following an mRNA vaccine dose. Important information for vaccine recipients about myocarditis and pericarditis for Pfizer and Moderna COVID-19 vaccines is available as a one-page handout.

Based on a phase 3 clinical trial that included 2,260 children 12 to 15 years of age, the Pfizer COVID-19 vaccine was 100% effective at preventing symptomatic COVID-19. In clinical trials, the immune response elicited of those aged 12 to 15 years of age was consistent with the immune response elicited from those 16 to 25 years of age. **No new safety issues were identified during this clinical trial**. The study used the same two-dose regimen tested in individuals 16 years of age and older.

Mature Minor Consent

8. 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 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)

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

Immunizations can cause unnecessary stress and anxiety which could lead to non-adherence to schedules or missed second 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. Immunize Canada provides resources for health care providers to help reduce 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. Locally, the IWK/NSHA has developed a vaccination tip sheet for youth (*Nervous about needles? 7 tips for making vaccinations more comfortable*).

Side Effects and Adverse Events

10. 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 Sheets (Pfizer and Moderna; AstraZeneca/COVISHIELD), 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. Local reactions have been mostly mild to moderate in severity and occurred predominantly following the first dose. 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.

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/erythema	Common	Common	Common	Common	Very 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	Common
Pruritis	NS	NS	NS	NS	Very Common	Common
Induration	NS	NS	NS	NS	Common	Common

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 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.

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	Common	Common
Feverishness[b]	NS	NS	NS	NS	Very Common	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 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. 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.

In adolescents, no serious adverse events related to the Pfizer COVID-19 vaccine and no deaths have been reported to date. Follow up will continue in adolescent trial participants for at least 2 years following the second dose for ongoing safety reporting to Health Canada.

Myocarditis and Pericarditis

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

There have been very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with mRNA COVID-19 vaccines including Pfizer and Moderna reported in Canada and internationally, including from Israel, the United States and Europe. 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. 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.

There are no data yet on myocarditis/pericarditis using an extended schedule or a mixed vaccine schedule.

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 very 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 rapid or abnormal heart rhythm,
- 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 responded well to conservative treatment and rest, with quick symptom improvement. **Healthcare providers should consider myocarditis and pericarditis in 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 and/or pericarditis following their first dose of an mRNA vaccine **should defer** their second dose until more information is available. If individuals who experienced myocarditis and/or pericarditis following their first dose of an mRNA vaccine wish to proceed with their second dose they may choose to do so following an informed consent discussion with a health care provider. All 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 very small risk of myocarditis/pericarditis in people of all ages.

Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)

12. Is the AstraZeneca COVID-19 vaccine safe with the recent information regarding Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)?

Very rare cases of thrombosis associated with thrombocytopenia [called Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)], some presenting as mesenteric vein or cerebral vein/cerebral venous sinus thrombosis, have been reported globally in persons who had recently received AstraZeneca COVID-19 vaccine usually occurring between 4 and 28 days after vaccination. This adverse event has not been reported in those who receive an mRNA vaccine. VITT 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 VITT is still under investigation. The frequency of this adverse event is not known with certainty but appears to occur between 1 per 26,000 to 1 per 100,000 people vaccinated with a **first dose** of AstraZeneca COVID-19 vaccine. As of June 1, 2021, PHAC has estimated the rate of VITT in Canada to be 1 in 73,000 doses administered, however, as investigations continue, this rate could be as high as 1 in 50,000. 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. The rate of VITT in the UK, after the **second dose** of AstraZeneca COVID-19 vaccine, is estimated to be approximately 1 in 600,000 (17 cases out of 10.7 million second doses administered). It should be noted that with increased observation times, VITT rates have generally increased. Many cases have been reported to have serious long-term illness, including neurologic injury. Cases have occurred in vaccine recipients of all ages and there do not appear to be any risk factors. The case fatality rate of VITT varies between countries, and ranges between 20 and 50%. This rate may be modified with early diagnosis and treatment so it is very important that individuals are made aware of signs and symptoms of concern and instructed to seek immediate medical attention should they occur. Individuals should monitor for symptoms up to 42 days after receiving AstraZeneca/COVISHIELD COVID-19 vaccine.

Health Canada has advised that if individuals experience rare blood clots with low platelets following their first dose of the AstraZeneca or COVISHIELD COVID-19 vaccine, it is not recommended that they receive a second dose of any version

of the AstraZeneca vaccine. Healthcare professionals are urged to be alert for symptoms of VITT, possible cases of thromboembolism, disseminated intravascular coagulation (DIC) or cerebral venous sinus thrombosis (CVST) occurring in vaccinated individuals. **Symptoms to be vigilant for include**: sudden onset of severe or persistent worsening headaches, shortness of breath, chest pain, leg pain, swelling and redness in a limb, pallor and coldness in a limb, persistent abdominal pain; visual changes, including blurred or double vision, confusion, episodes suspicious for seizure; or unusual bleeding, multiple small bruises, or reddish or purplish spots or blood blisters under the skin (other than at the site of vaccination). Providers should ensure that individuals who receive the AstraZeneca COVID-19 vaccine are informed of the potential risk of these rare thromboembolic side effects and instructed to seek immediate medical attention should they develop any of the signs or symptoms described following receipt of the vaccine. Individuals should monitor for symptoms up to 42 days after receiving AstraZeneca/COVISHIELD COVID-19 vaccine. A handout for patients receiving the AstraZeneca COVID-19 vaccine may be found on the NSHA COVID-19 Hub.

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

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.

14. Is Acetylsalicylic Acid (ASA) recommended for the prevention or treatment of VITT?

No. There is no evidence that ASA prevents or treats VITT. ASA blocks thromboxane action in platelets. This action of ASA has no effect on the coagulation abnormalities associated with VITT. It is important to note that ASA has bleeding side effects and could cause harm. More information regarding VITT may be found via the PHAC webinar, COVID-19 Vaccine Emerging Issues Webinar: Vaccine-induced Immune Thrombotic Thrombocytopenia.

Capillary Leak Syndrome (CLS)

15. What information is available regarding capillary leak syndrome (CLS) and the AstraZeneca COVID-19 vaccine?

On June 29, 2021, Health Canada updated the AstraZeneca and COVISHIELD Product Monographs 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. 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. The European Medicines Agency

reviewed 6 CLS cases following vaccination with AstraZeneca COVID-19 vaccine in depth, and a history of CLS was noted in 3 of these cases. One of these cases had a fatal outcome. As of June 18, 2021, one case of CLS following vaccination with the AstraZeneca COVID-19 Vaccine has been reported in Canada. 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 or COVISHIELD 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.**

Reporting Adverse Events

16. 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.

17. 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

Adverse Events of Special Interest (AESI)

18. 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

19. 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 Brand Name	Pfizer BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	AstraZeneca COVID-19/COVISHIELD vaccine
Type of vaccine	mRNA	mRNA	Non-replicating viral vector (ChAd)
Ages for use	HC: 12 years of age and older	HC: 18 years of age and older	**Second doses only; 40 – 64 years old**
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	2 Doses, 3 weeks – 4 months apart[2]	2 Doses, 4 weeks – 4 months apart[2]	2 Doses, 4 weeks – 4 months apart[2]
Adjuvant (if present)	None	None	None
Diluent	Yes	No	No
Primary storage requirements pre-puncture[3]	-80°C to -60°C	-25°C to -15°C [4]	+2°C to +8°C
Additional storage requirements pre-puncture [3]	-25°C to -15°C for up to 2 weeks [5] OR 1 month at +2°C to +8°C AND/OR 2 hours up to +25°C	30 days at +2°C to +8°C **and/or** 24 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]	24 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; US label multi-dose vial (14 doses), preservative-free	Multi-dose vial (8-and 10-dose presentations), preservative-free

Abbreviations: mRNA: Messenger ribonucleic acid; ChAd: Chimpanzee adenovirus; HC: Health Canada; 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 Do not store on dry ice or below -40°C.
5 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.
6 After dilution, vaccine must be used within 6 hours.

US labeled Moderna COVID-19 vaccine is similar to the Health Canada authorized Moderna COVID-19 vaccine in aspects such as formulation, strength and route of administration. Providers should continue to reference the Canadian Product Monograph for all product use in Canada. A Health Product Risk Communication regarding US labeled Moderna COVID-19 vaccine supply, labelling and packaging is available here: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75807a-eng.php.

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 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

Maximum and Minimum Intervals

20. 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.

21. What is the minimum interval for the second dose for the Pfizer BioNTech and Moderna 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

Providers' Responsibilities in Ensuring Proper Storage of Vaccines

22. 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.

23. 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

24. 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

25. 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, NACI recommends the following with regard to other (non-COVID-19) vaccines and other medications.

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
- Another (non-COVID-19) vaccine until 28 days after each dose of a COVID-19 vaccine
- COVID-19 vaccines simultaneously with anti-SARS-COV2 monoclonal antibodies (e.g. bamlanivimab) or convalescent plasma. The interval between receipt of these products and COVID-19 vaccine is under review.

NACI advises that the minimum waiting period between vaccines is precautionary and 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.
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;
- when it will enable a pregnant person to receive the Tdap vaccine at 32 weeks gestation or earlier; and
- at the clinical discretion of the healthcare provider.

The potential for immune interference is not known with simultaneous administration of or shortened intervals between non-COVID and COVID-19 vaccines. In addition, administering the COVID-19 vaccine alone assists with the assessment of any adverse event following immunization. If a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent is provided, a shorter waiting period or simultaneous administration of COVID-19 vaccines with other vaccines (live or inactivated) may be considered.

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

26. 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

27. 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.

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.

29. 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

30. How do providers maximize doses and minimize waste when withdrawing Moderna COVID-19 vaccine from the US labeled Moderna 14 dose vials?

The U.S. Pharmacopeia provides guidance for maximizing doses from the Moderna COVID-19 14 dose vials. This guidance may be retrieved by accessing: https://www.usp.org/covid-19/vaccine-handling-toolkit and completing the form to download an instructional fact sheet.

31. 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

Pooling of Residual Vaccine

32. What if there is remaining vaccine in the vaccine vial after 6 doses from the Pfizer-BioNTech vaccine vial or 10 or 14 doses from the Moderna vaccine vial, have been removed?

If there is enough vaccine left in the vial for a complete 0.3 mL dose after 6 doses have been removed from a Pfizer-BioNTech vaccine vial, or a complete 0.5 mL dose after 10 or 14 doses have been removed from a Moderna vaccine 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.**

Special Considerations

Pregnancy, Breastfeeding, Immunosuppression and Autoimmune Conditions

33. 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, real-world data from the use of COVID-19 vaccines in these populations is accumulating. 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 emerging evidence on the safety of mRNA COVID-19 vaccines in pregnant and breastfeeding individuals. There is accumulating information on the safety of the COVID-19 vaccine in pregnancy and in breastfeeding individuals and 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 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 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 Information Handout.

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. 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 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. Emerging data suggests that people with an autoimmune condition and normal immune system have a similar response to COVID-19 vaccines than people without these conditions. Few individuals who have an autoimmune condition were included in the trials testing COVID-19 vaccines, however 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. 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.

Summary of evidence and rationale for recommendations in special populations is available in NACI's Recommendations on the use of COVID-19 vaccines statement.

Previous Lab-confirmed SARS-CoV-2 Infection and COVID-19 vaccines

34. 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. Individuals may receive COVID-19 vaccine following SARS-CoV-2 infection once they are past their infectious stage from COVID-19 and no longer under the requirement from Public Health to be self-isolating. This recommendation may be modified as further evidence emerges.

COVID-19 Vaccines Received out of Canada

35. There may be individuals who have received COVID-19 vaccines out of country which are not authorized for use in Canada. Is Nova Scotia recognizing these vaccines as valid?

With input from Nova Scotia's Vaccine Expert Panel, the Office of the Chief Medical Officer of Health provides advice for the Interim Management of Individuals with Non-Health Canada Authorized COVID-19 Vaccines. Individual clinical assessment will be required to determine validity of such doses and subsequent COVID-19 vaccine recommendations. These interim recommendations may change when national guidance is provided.

Contraindications

36. 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.)

AstraZeneca COVID-19 or COVISHIELD vaccine is contraindicated in individuals who have previously experienced episodes of capillary leak syndrome and in those who experienced major venous and/or arterial thrombosis with thrombocytopenia following vaccination with AstraZeneca COVID-19 Vaccine/COVISHIELD.

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/

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.

Allergens

37. 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.

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**
• Pregnant individuals • Breastfeeding individuals • 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 immunosuppression or autoimmunity	• Mild – moderate reactions to a prior dose of COVID-19 vaccine • On immune suppressing doses of prednisone (> 20 mg/day > 2 weeks) • On anti-SARS-CoV-2 monoclonal antibodies, plasma therapy, or plasmapheresis (delay 3 months) • Primary immune deficiency requiring IVIG or SCIG • Chronic granulomatous disease • Hyper IgE syndrome	• Active/unstable autoimmune condition* • Solid organ transplant with acute rejection • Any cancer on IV chemotherapy therapy • Acute leukemia • Within 3 months of stem cell transplant • On check point inhibitor • Within 3 months of CAR-T procedure • Interferonopathy	• 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
• Anaphylaxis to another vaccine or injectable medication (observe for 30 minutes)	• 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 3, 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 Category

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

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

References & Resources

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