simcoe muskoka
DISTRICT HEALTH UNIT

Immunization Directive

Number:	**Imm - 14**
Topic:	**Administration of AstraZeneca COVID-19 Vaccine**
Approved:	March 15, 2021
Reviewed:	
Revised:	February 17,2022

Procedure

Administer intramuscularly the AstraZeneca COVID-19 vaccine.

Involvement of a Delegated Controlled Act: Yes ___X___ No ____

Controlled Act #5: Administering a substance by injection or inhalation. This is a controlled act, which is in the scope of nursing practice. A member of the College of Nurses may perform a procedure within the controlled acts authorized to nursing if a physician, dentist, chiropodist, nurse practitioner or midwife orders it.

Controlled Act #8: Prescribing, dispensing, selling or compounding a drug as defined in the Drug and Pharmacies Regulation Act, or supervising the part of a pharmacy where such drugs are kept.

Delegation of the Controlled Act

- This delegation applies to all student nurses, Registered Practical Nurses (RPN), Registered Nurses (RN) and Public Health Nurses (PHN) employed by the Simcoe Muskoka District Health Unit (SMDHU) who have the knowledge, skills and judgment to administer the vaccine safely.

- Delegation of Controlled Acts in the provision of a public health program under the authority of a Medical Officer of Health is acknowledged by the College of Physicians and Surgeons as falling under circumstances where the Controlled Act may be delegated in the absence of a physician order and in the absence of the doctor-patient relationship.

- Identification of Risks: The risk of treatment includes the potential for a serious reaction or allergy along with the possibility that the client will experience medication side effects. These risks are minimized by reviewing contraindications and medical history and by instructing clients where possible on how to reduce the occurrence or severity of side effects.

- See SMDHU Policy LG0104 – *Delegation of Controlled Acts* for responsibilities of the delegator, program manager and staff. See SMDHU Policy GEN0105 – *Directives & Standing Orders* for approval process and quality assurance. See SMDHU Policy LG0101 – *Consent for Treatment* for information pertaining to obtaining consent.

Indications

AstraZeneca COVID-19 Vaccine (COVID-19 Vaccine (ChAdOx1-S [recombinant])) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) in individuals 18 years of age and older.
Every effort should be made to immunize with an mRNA vaccine. The AstraZeneca COVID-19 vaccine should only be used when an mRNA vaccine is declined or medically contraindicated. Clients receiving the vaccine must

read the COVID-19 Vaccine Information for Individuals who received a first dose of the AstraZeneca/COVISHIELD COVID-19 vaccine to ensure informed consent.

Dosage and Administration:

Age	Dosage (mL)	Immunization Schedule	Minimum Interval	Authorized Interval	Alternate Interval
18 + years	0.5ml	2 dose	4 weeks	4-12 weeks	16 weeks

Individuals eligible for a booster dose are recommended to receive an mRNA vaccine (Pfizer-BioNTech or Moderna) unless there are contraindications to receive an mRNA vaccine.

If an individual has a medical contraindication to receiving an mRNA vaccine or chooses to not receive mRNA vaccine, a booster dose of a viral vector vaccine and be provided with informed consent including a discussion about the lack of evidence on the use and effectiveness of an additional dose of viral vector COVID-19 vaccine and the increased risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines.

Booster doses are recommended at 3 months (84 days) from last dose in primary series.

If an individual is later than their appropriate interval identified the vaccine should be given as soon as possible, and there is no need to restart the series.

AstraZeneca COVID-19 vaccine is to be administered intramuscularly in the deltoid muscle.

Vaccination Guidance Post-Infection

Individuals who experienced SARS-CoV-2 infection before starting or completing their primary COVID-19 vaccine series are suggested to receive their next dose 8 weeks after symptom onset or positive test (if asymptomatic).

Individuals 12 years of age and older, infected with COVID-19 after their primary series but before their booster dose, are suggested to receive their booster dose three months after symptom onset or positive test (if asymptomatic) and provided it is at least 6 months from completing the primary series. As per NACI, emerging evidence indicates that a longer interval between SARS-CoV-2 infection and vaccination is associated with improved antibody responses to COVID-19 vaccines.

These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised.

Nurses will store and handle the vaccine according to the instructions in the manufacture's product monograph.

AstraZeneca COVID-19 Vaccine is a colourless to slightly brown, clear to slightly opaque solution. The vaccine should be inspected visually for particulate matter and discolouration prior to administration. Discard the vial if the solution is discoloured or visible particles are observed

Reconstitution

AstraZeneca COVID-19 Vaccine must not be reconstituted, mixed with other AstraZeneca medicinal products, or diluted.

Unopened multidose vial (8 or 10 does vial)

AstraZeneca COVID-19 vaccine should be stored in refrigerator (2° to 8° C). Do not freeze. Store in outer carton in order to protect from light. Use the product before the expiration date on the vial label.

Opened multidose vial (8 or 10 dose vial)

After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than:

- 6 hours at room temperature, up to 30ºC, or
- 48 hours in a refrigerator (2 to 8ºC).

The vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours.

Contraindications

1. Those who have had severe allergic reaction or anaphylaxis to a previous dose of AstraZeneca COVID-19 vaccine or to any of its components should not receive the AstraZeneca COVID-19 vaccine in a community based vaccine clinic. These people need an urgent referral to an allergist or immunologist to determine how/if they will complete their series.

   For those who have had an allergic reaction within 4 hours and/or anaphylaxis that occurred with a vaccine or injectable medication that does not contain a component or cross-reacting component of Astra Zeneca COVID-19 vaccines, the vaccine can be given with an extended post-vaccination observation time of 30 minutes.

   Those with a history of significant allergic reaction and/or anaphylaxis to any food, drug, venom, latex or other allergens not related to the COVID-19 vaccine can receive the vaccine with an extended post-vaccination observation time of 30 minutes.

2. AstraZeneca COVID-19 Vaccine is contraindicated in those with an allergy to any component of the vaccine or an anaphylactic or other allergic reaction to a previous dose of this vaccine:

Vaccine	Vaccine Components	Contains Latex (Yes or No)
AstraZeneca COVID-19 Vaccine	□ COVID-19 Vaccine (ChAdOx1-S* recombinant) □ Disodium edetate dihydrate (EDTA) □ Ethanol □ L-Histidine □ L-Histidine hydrochloride monohydrate □ Magnesium chloride hexahydrate □ Polysorbate 80 □ Sodium chloride □ Sucrose □ Water for injection	No

3. AstraZeneca COVID-19 vaccine is not to be administered to anyone under 18 years of age.

4. Individuals with the following conditions should not receive the Astra-Zeneca COVID-19 vaccine:

   - History of blood clots with low platelets (i.e., major venous and/or arterial thrombosis with thrombocytopenia) following any vaccine
   - Thrombosis with thrombocytopenia syndrome (TTS) or vaccine induced immune thrombotic thrombocytopenia (VITT) following the AstraZeneca COVID-19 vaccine

- History of capillary leak syndrome (CLS)
- History of cerebral venous sinus thrombosis (CVST) with thrombocytopenia
- History of heparin-induced thrombocytopenia (HIT)
- Actively receiving monoclonal antibody therapy OR convalescent plasma therapy for the treatment or prevention of COVID-19

5. AstraZeneca COVID-19 vaccine should only be administered in SMDHU clinics to the following groups if they have consulted with their treating physician and it has been determined that the potential benefits of vaccination outweigh the potential risks:
    - Those who are receiving the following immunosuppressive therapies: stem cell therapy, CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g. rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors etc.)

In general, if a patient is 3 months post-chemotherapy and the cancer is in remission, or if immunosuppressive therapy 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 that are considered immunocompetent may be vaccinated. Those with stable Hep B and Hep C virus may also be vaccinated.

Pregnant & Breastfeeding Individuals

Evidence is now available from real world use of mRNA COVID-19 vaccines, which has not indicated any safety concerns for pregnant and breastfeeding populations. There is less evidence regarding the safety of the Astra-Zeneca vaccine including pregnant women and breastfeeding women. An mRNA COVID-19 vaccine is recommended by the National Advisory Committee on Immunization (NACI) since they have been shown to be more effective than viral vector vaccines and generally safer, with less side effects. Those who are pregnant or breastfeeding can receive Janssen vaccine under this directive with informed consent.

Persons with Autoimmune Conditions & Immunocompromised Persons (due to disease or treatment)

While those receiving the severely immunosuppressive treatments outlined in contraindication #5 must speak with their treating HCP prior to vaccination, all other individuals with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment should be offered the vaccine. These individuals may choose to consult with their health care provider prior to vaccination (for example, to discuss immunosuppressive medication management/timing in relation to their vaccination).

Rare cases of serious thrombosis (blood clots) and thrombocytopenia (low platelets): VITT (Vaccine-Induced Immune Thrombotic Thrombocytopenia)

A combination of thrombosis and thrombocytopenia (TTS), in some cases accompanied by bleeding, that resembles HIT (heparin-induced thrombocytopenia) have been observed very rarely following vaccination with AstraZeneca COVID-19 Vaccine. This includes severe cases at unusual sites such as cerebral venous sinus thrombosis (CSVT) and splanchnic vein thrombosis, as well as arterial thrombosis, with thrombocytopenia.

Nurses administering the AstraZeneca COVID-19 vaccine under this directive must inform clients to seek immediate medical attention for symptoms of thromboembolism and/or early signs of thrombocytopenia.

Symptoms to monitor for include: shortness of breath, chest pain, leg swelling or pain, persistent abdominal pain, skin bruising (other than at the site of vaccination) or petechiae (red or purple spots or blood blisters under skin); and neurological symptoms such as sudden onset of severe headaches, persistent or worsening headaches, blurred vision, double vision, confusion or seizures, difficulty speaking or moving a part of the body particularly those persisting or occurring approximately 4 days to 3-4 weeks after vaccination.

Guillain-Barré syndrome (GBS)

Guillain-Barré syndrome (GBS) is a rare but potentially serious immune-mediated neurologic disorder that results in pain or numbness, muscle weakness, and paralysis in severe cases. Most people fully recover from GBS but some have residual deficits or symptoms and rarely, fatal cases can occur. To date, no increased risk of GBS has been identified following vaccination with the mRNA COVID-19 vaccines (Pfizer-BioNTech Comirnaty and Moderna Spikevax). Investigations have identified an increased risk of GBS following vaccination with the viral vector COVID-19 vaccines (AstraZeneca Vaxzevria and Janssen). Among cases reported in Canada as of December 3rd 2021, symptoms occurred between 6 hours and 25 days after vaccination, the median age was 56 years (range 40 to 77 years old) and 26 (74%) were males.

Nurses administering the AstraZeneca COVID-19 vaccine under this directive must inform clients to seek medical attention if they develop symptoms of GBS.

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

Precautions & Other Important Information

- NACI has stated that COVID-19 vaccine can be given at the same time or at any time before or after receiving other vaccines including live, non-live, adjuvanted or unadjuvanted vaccines. As a precaution, NACI previously recommended that COVID-19 vaccines be given at least 28 days before and 14 days after other vaccines. After reviewing the evolving evidence on COVID-19 vaccines and considering the extensive data and experience of giving other routine vaccines at the same time or within days of each other, NACI has determined that a precautionary approach is no longer necessary.
- Tuberculin skin testing (TST) or interferon gamma release assay (IGRA) - There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing 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 since these are theoretical considerations. 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 in order to avoid missing cases due to potentially false-negative results.COVID-19 vaccine should not be given simultaneously with monoclonal antibodies or convalescent plasma. There is insufficient evidence on the potential interference of COVID-19 vaccine and any monoclonal antibodies therefore expert opinion should be sought on a case-by-case basis.
- Currently there is limited evidence available to support the efficacy of this vaccine in preventing asymptomatic infection, reducing viral shedding or in prevention of transmission of the COVID-19 virus. Therefore, it is important that people continue to practice public health measures to decreased transmission even after they are vaccinated.
- Protection offered from the first dose is lower than the efficacy achieved after the second dose. In most people, a cellular immune response is achieved by one week after the second dose.
- AstraZeneca COVID-19 vaccine may be offered to those who have had previously PCR-confirmed SARS-CoV-2 infection, but this will be in the context of vaccine availability and initial doses may be prioritized for those who have not had previous infection. People who are eligible for vaccination who have recently tested positive for COVID-19 can be vaccinated once they have cleared isolation and their symptoms are resolving.
- Vaccination of those who may currently have SARS-CoV-2 infection is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals to avoid attributing any complications resulting from infection to being vaccine related.

Quality Assurance

The program managers will ensure that:

- The directive is reviewed and updated as needed.
- Nurses are provided a comprehensive orientation program, including a review of all relevant resources as outlined below.
- A current list of nurses who have received directive training is maintained.
- All medication errors are reviewed as per agency policy.

References

Product Monograph for AstraZeneca (VAXZEVRIA™) COVID-19 Vaccine, November 19, 2021

Canadian Immunization Guide: COVID-19 vaccine Chapter

Ontario Ministry of Health. COVID-19 Vaccine Administration. November 26, 2021.

Ontario Ministry of Health. COVID-19 Vaccination Recommendations for Special Populations. December 31, 2021.

Ontario Ministry of Health. COVID-19 Third Dose Recommendations. February 17, 2022.

National Advisory Committee on Immunization. Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2. https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/naci-rapid-response-updated-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2.pdf - Revised February 4, 2022

Ontario Ministry of Health. COVID-19 Vaccine Storage and Handling Guidance – Revised January 5, 2022

College of Nurses of Ontario (CNO), Practice Guideline, 41019, Directives Revised January 2018
https://www.cno.org/globalassets/docs/prac/41019_medicaldirectives.pdf

CNO, Practice Standard, 41007, Medication Revised January 2019
http://www.cno.org/docs/prac/41007_Medication.pdf

CNO, Practice Standard, 41071, Decisions about Procedures and Authorities Revised March 2018
https://www.cno.org/globalassets/docs/prac/41071_decisions.pdf

The College of Physicians and Surgeons Policy #5-12 - Delegation of Controlled Acts (revised Sept 2012)
https://www.cpso.on.ca/admin/CPSO/media/Documents/physician/polices-and-guidance/policies/delegation-of-controlled-acts.pdf

Educational Resources

- Immunization Program Guidebook
- Canadian Immunization Guide, Evergreen Edition
  http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

Authorized to

All student nurses, RPNs, RNs and PHNs employed by the Simcoe Muskoka District Health Unit, who have received the directive training and who have the following qualifications are authorized to administer these vaccines:

- Registered Nurses and Registered Nurses (temporary) listed as a member with the College of Nurses of Ontario with no restrictions or limitations on their registration.
- Registered Practical Nurses and Registered Practical Nurses (temporary) listed as a member with the College of Nurses of Ontario with no restrictions or limitations on their registration. Registered Practical Nurses that were registered with the College of Nurses prior to 2005 must also have an advanced medication course certificate.
- Current CPR certification Level C (updated annually).

Authorization and Approval

The steps outlined in this directive, and training and resources available provide staff with the necessary knowledge and skills to safely, effectively and ethically administer this vaccine in a clinic setting.

Charles Gardner
Medical Officer of Health

Date

Colin Lee
Associate Medical Officer of Health

Date

Lisa Simon
Associate Medical Officer of Health

Date

Deanna Thompson
Acting Vice President - Immunization

Date

Review/Revision History

April 2, 2021 – update on interval for transplant and cancer patients
April 27, 2021 – updated wording for those that are pregnant
May 21, 2021 – updated eligibility for earlier second dose, updated indication, updated pregnancy section
June 3, 2021 – Interchangeability of COVID-19 vaccines
June 6, 2021 – Interval for earlier 2nd dose for those who received AstraZeneca Vaccine first dose
June 14, 2021 – Interval change to 8 to 12 weeks, and hx of CVST or HIT
July 5, 2021 – Eligibility update
January 17, 2022 – Updated to allow those who are contraindicated to receiving mRNA vaccine or preference not to can receive this vaccine with informed consent
February 17, 2022 – Post Infection Vaccination