_____

(Name of Agency)

MEDICAL DIRECTIVE: AstraZeneca COVID-19 Vaccine and COVISHIELD ®

Original Date: YYYY/MMM _____

Next Review Date: YYYY/MMM _____

Agency Contact Officer: _____

Order/Delegated Procedure

Administer injectable AstraZeneca and COVIDSHIELD® COVID-19 immunizations.

Recipient Clients

All individuals 30 years of age and older without contraindications to the AstraZeneca/COVISHIELD COVID-19 vaccine who live, work, or go to school in Ontario. As of May 11, 2021 Ontario has paused the rollout and administration of first doses of the AstraZeneca/COVISHIELD COVID-19 vaccine.[13] Therefore, AstraZeneca/COVISHIELD COVID-19 vaccine is currently administered to individuals who are receiving their second dose only.

Authorized Implementers

Health care providers of _____ including nurses, nursing
(Above Named Agency)

students under the supervision of a nurse, and contracted Agency Nurses in good standing with the College of Nurses of Ontario (CNO) and who have completed the required orientation, including a review of related policies, educations training at clinics and observation by _____ .
(Agency Designate)

Indications

AstraZeneca COVID-19 Vaccine (COVID-19 Vaccine (ChAdOx1-S [recombinant])) and COVISHIELD® are authorized for active immunization of individuals 18 years of age and over for the prevention of coronavirus disease 2019 (COVID-19).[1]

Contraindications

Clients are **NOT ELIGIBLE** for AstraZeneca and COVISHIELD® COVID-19 vaccine under this medical directive if there is a risk of serious adverse reaction identified during their

health assessment:

- Individuals with a proven severe allergic reaction (e.g., anaphylaxis) to any component of the AstraZeneca or COVISHIELD® COVID-19 vaccine or its packaging.[1] Components of the AstraZeneca and COVISHIELD® COVID-19 vaccine are listed in Appendix B.

The vaccine should not be administered in a general vaccine clinic. An urgent referral to an allergist/immunologist is recommended for these individuals. Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.[9]

Documentation using Ontario Ministry of Health and Long-Term care COVID-19 Vaccination: Allergy form after discussion with the health care provider is to be provided at the clinic including a vaccination care plan and **parameters the clinic should meet to provide safe vaccine administration.[10]**

Precautions

- Clients with the following concerns can only be immunized **IF** a health care provider who is familiar with their condition or pregnancy conducts a situational assessment and deems that the benefits outweigh the risks, **AND** informed consent is obtained, including discussion about the insufficient evidence from clinical trials. Verbal confirmation that the client received counselling should be provided at the time of vaccination as part of informed consent to receive the vaccine.

    - Individuals who have an autoimmune disease or are immunosuppressed (due to disease or treatment) that are receiving targeted therapies. – see Appendix C [9]
    - Pregnancy [9]

Reference the guidance document COVID-19 Vaccination Recommendations for Special Populations regularly for updates on evolving changes.

- Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g. intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.[2]

- Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g. foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination.[2]
- Clients with a bleeding disorder should be optimally managed prior to immunization.[2]
- Clients currently experiencing moderate/severe, acute illness should have their vaccination postponed until the illness has resolved.[2]

Additional Special Considerations include

- Individuals who are breastfeeding, the COVID-19 vaccine should be offered after recognizing the insufficiency of evidence for the use of COVID-19 vaccine in the breastfeeding population.[9]
- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.[2]
- Clients receiving anticoagulant therapy can be immunized if they are optimally managed, and after immunization they should be advised to apply firm pressure to the injection site for 5 to 10 minutes.[2]
- Clients who have received a dose of another vaccine in the previous 14 days should have their vaccination postponed until 14 days after they received that vaccine.
- In the absence of evidence, it would be prudent to wait for a period of at least 28 days after each vaccine dose of an mRNA or viral vector COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response. It would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine to prevent erroneous attribution of an AEFI to a particular vaccine. [2]
- The AstraZeneca COVID-19 should not be given simultaneously with other vaccines (live or inactivated).[2]

NACI recommends that:

- Persons who received a first dose of the AstraZeneca/COVISHIELD vaccine may receive either AstraZeneca/COVISHIELD vaccine or an mRNA vaccine (Pfizer-BioNTech or Moderna) for their second dose, unless contraindicated.

- Persons who received a first dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) should be offered the same mRNA vaccine for their second dose.

If the same mRNA vaccine is not readily available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.

- The previous dose should be counted, and the series need not be restarted.[12]
- For more information on eligibility and dosing intervals, refer to the Ministry of Health document: COVID-19 Vaccine Series Second Dose Eligibility Quick Reference, Version 1.0 June 4, 2021 (or as current).
- Ensure the client has read and understood the *COVID-19 Vaccine Information for Individuals who received a First Dose of the AstraZeneca/COVISHIELD information sheet from the Ministry of Health.*

Obtaining Consent

Appropriate informed consent must be obtained as per the *Guidelines for Implementing the Order/Delegated Procedure* and the client must NOT have any contraindications.

Guidelines for Implementing the Order/Delegated Procedure

Nurses and nursing students are expected to prepare and administer vaccine(s) to clients in a safe, effective, and ethical manner, and to be accountable for their actions. Nurses and nursing students are expected to meet the CNO's Medication Practice Standard by performing all the administration and verification steps to minimize the chance of error.
Nurses and nursing students are expected to consult with their Manager or designate if unable to perform their nursing duties in a safe and effective manner.
Responsibilities of the nurse and nursing student who implement the intervention include the following:

- Clarify that informed consent has been obtained.
- Assess the client to determine whether the specific client conditions and any situational circumstances identified in the directive have been met.
- Know the risks to the client of implementing the Order/Delegated Procedure
- Possess the knowledge, skills and judgement required to implement the directive safely.
- Know the predictability of the outcomes of the intervention.
- Determine whether management of the possible outcomes is within their practice; if so whether they are competent to provide management

of outcomes and if not, whether the appropriate resources are available to assist as required.

Administration of vaccine must be in accordance with the manufacturers' product information monographs and the NACI's Recommendations on the use of COVID-19 vaccine(s).[2]

At all clinics where immunizing agents are administered, the _____ will be available for consult.
(Agency Designate)

Informed Consent

To obtain informed consent, the nurse and/or nursing student must ensure:

- The purpose of the immunization, desired outcome, risks, and benefits are reviewed.
- The client has read and understood the *COVID-19 Vaccine Information for Individuals who received a First Dose of the AstraZeneca/COVISHEIELD information sheet from the Ministry of Health.*
- The client has read and understood the information on the appropriate AstraZeneca and COVISHIELD® COVID-19 Vaccine Fact Sheet(s). If the client cannot read the sheet, it should be read or explained to them. The nurse must ensure the client has no contraindications to the vaccine as specified in the "Who should not get the vaccine" section of the fact sheet, the "Contraindications" section of this Medical Directive and on the AstraZeneca and COVISHIELD® COVID-19 Vaccine Consent Form, and query regarding current health (e.g., immunosuppression, autoimmune condition).
- The client has had the opportunity to ask questions about the vaccine and had these questions answered to their satisfaction.
- The client has provided informed written or verbal consent to the nurse administering vaccine.

Capacity to provide consent

A client is capable of giving consent if they understand the information that is being presented to them and appreciate the foreseeable consequences of their decision or lack of decision.

When in doubt about informed consent or a medical condition of the client, do not administer the vaccine and consult with the _____ .
(Agency Designate)

AstraZeneca and COVISHIELD® COVID-19 Vaccines

Dose and Schedule for the AstraZeneca and COVISHIELD® COVID-19 Vaccine:

Dose:

One dose (0.5 ml) of AstraZeneca and COVISHIELD® COVID-19 Vaccine contains:

- COVID-19 Vaccine (ChAdOx1-S* recombinant) 5 x 1010 viral particles (not less than 2.5 x 108 infectious units)

Volume:

- 0.5 mL

Schedule:

- 2 doses
- The second dose should be administered between 4 and 12 weeks after the first dose.[1]

Storage Requirements

Unopened multidose vial

- Store in a refrigerator (2 to 8ºC).
- Do not freeze.
- Store in outer carton in order to protect from light.
- Use the product before the expiration date on the vial label. [1]

Opened multidose vial

- For storage conditions after first opening of the medicinal product, see below.
- 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). [1]

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. [1]

Reconstitution

AstraZeneca and COVISHIELD® COVID-19 Vaccines **must not** be reconstituted, mixed with other medicinal products, or diluted. [1]

Special Handling Instructions

Disposal

AstraZeneca COVID-19 Vaccine contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in accordance with local requirements. Spills should be disinfected with an appropriate antiviral disinfectant. [1]

Administration

Follow the *Injection Technique Policy and Procedure of* _____ as well as the following steps:
(Above Named Agency)

- Visually inspect each dose in the dosing syringe prior to administration. The AstraZeneca and COVISHIELD® COVID-19 Vaccines are a colourless to slightly brown, clear to slightly opaque solution. During the visual inspection:
    - verify the final dosing volume of 0.5 mL.
    - confirm there are no particulates and that no discolouration is observed.
    - do not administer if vaccine is discoloured or contains particulate matter.
- Administer AstraZeneca and COVISHIELD® COVID-19 Vaccines intramuscularly in the deltoid muscle.
    - Do not inject the vaccine intravascularly, subcutaneously or intradermally.
    - AstraZeneca and COVISHIELD® COVID-19 Vaccines are packaged in (not all pack sizes may be available):
        - 5 mL of solution in a 10-dose vial (clear type 1 glass) with stopper (elastomeric with aluminum overseal).
        - 4 mL of solution in a 8-dose vial (clear type 1 glass) with stopper (elastomeric with aluminum overseal). [1]

Additional information on dosage forms, strengths, composition and packaging can be found in the vaccine product monograph.

Documentation and Communication

Documentation of administered doses into the COVax database post-vaccination should be followed in conjunction with the _____ documentation
(Named Agency)

and the College of Nurses of Ontario's Documentation Practice Standard.] [6]

Adverse Reactions

Refer to the *Precautions* section of this medical directive for guidance on post-vaccination observation period and hypersensitivity or non-anaphylactic allergy information.

As per s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine.[5] Specifically, the client should be monitored for:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40C or 104F)
- Convulsions (seizures)

If a reaction as described above occurs while at _____ clinic,
(Named Agency)
refer to the *Medical Directive for Anaphylaxis Management.*

Nurses and nursing students may administer Adrenaline (Epinephrine hydrochloride) and diphenhydramine hydrochloride (Benadryl®) according to the *Medical Directive for Anaphylaxis Management,* the Canadian Immunization Guide, Public Health Agency of Canada, and manufacturers' specifications.

Approving Physician(s)/Authorizer(s):

NAME: **SIGNATURE:**	**DATE:**

Appendix A – NACI Recommendations: Key populations prioritized for COVID-19 vaccination

The objective of this advisory committee statement is to provide guidance for the equitable, ethical, and efficient allocation of authorized COVID-19 vaccines in the context of staggered arrival of vaccine supply that will necessitate offering vaccines to some populations earlier than others. This guidance builds on the foundational framework of NACI's preliminary guidance with updates informed by current evidence on COVID-19 and authorized COVID-19 vaccines. [3]

NACI categorizes key populations according to 3 stages:

Stage 1:

- Residents and staff of congregate living settings that provide care for seniors.
- Adults ≥70 years of age, beginning with ≥80 years, then decreasing age limit by 5-year increments
- Frontline healthcare workers (all who work in healthcare settings and personal support workers whose work involves direct care with patients)
- Adults in Indigenous communities (where infection can have disproportionate consequences. [3]

Stage 2:

- Adults in or from Indigenous communities not offered vaccine in Stage 1.
- Residents and staff of other congregate living settings. (e.g., quarters for migrant workers, shelters, correctional facilities, group homes)
- Adults 60-69 years of age, beginning with ≥65 years, then decreasing age limit to 60 years
- Adults in racialized and marginalized communities disproportionately affected by COVID-19.
- First responders (e.g., police, firefighters)
- Frontline essential workers who cannot work virtually.
- Essential primary caregivers for individuals who are at high risk of severe illness from COVID-19 due to advanced age. [3]

Stage 3:

- Adults 16-59 years of age with an underlying medical condition at high risk of severe illness due to COVID-19 and their essential primary caregivers.
- Adults 50-59 years of age without an underlying medical condition, beginning with ≥55 years then decreasing age limit to 50 years.
- Non-frontline healthcare workers needed to maintain healthcare capacity.
- Non-frontline essential workers. [3]

A complete vaccine series with a currently authorized COVID-19 vaccine **may be** offered to individuals in the authorized age group (16 years or older) without

contraindications to the vaccine who have had previously polymerase chain reaction (PCR) SARS-CoV-2 infection. [2]

In the context of limited vaccine supply, initial doses may be prioritized for those who have not had previously PCR-confirmed SARS-CoV-2 infection. Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination. [2]

Appendix B – Components of the AstraZeneca COVID-19 Vaccine and its Packaging

One dose (0.5 ml) of AstraZeneca COVID-19 Vaccine contains: COVID-19 Vaccine (ChAdOx1-S* recombinant) 5 x 1010 viral particles (not less than 2.5 x 108 infectious units).[1]

*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the unmodified SARS-CoV-2 Spike (S) glycoprotein (GP) produced in genetically modified human embryonic kidney (HEK) 293 cells by recombinant DNA technology.
Non-medicinal ingredients:

- Ethanol,
- Disodium edetate dihydrate (EDTA),
- L-Histidine, L-Histidine hydrochloride monohydrate,
- Magnesium chloride hexahydrate,
- Polysorbate 80,
- Sodium chloride,
- Sucrose,
- Water for injection[1]

For a comprehensive list of components in the vaccine and packaging, please consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.[2]

Appendix C - Immunosuppression

- Long-term immunosuppressive therapy is used for various disease conditions including cancer, organ transplantation, GVHD following HSCT, and chronic inflammatory conditions (e.g., inflammatory bowel disease, inflammatory arthritis, psoriasis, systemic lupus erythematosus). Therapies include cancer chemotherapy, radiation therapy, long term high-dose steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), cytotoxic drugs, calcineurin inhibitors, biological response modifiers and antibodies that target lymphocytes.
- 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.
- Individuals living with HIV that are considered immunocompetent can be vaccinated. Individuals with stable Hepatitis B or C infection can also be vaccinated.[8]
- If there is uncertainty regarding whether or not a client qualifies as being immunosuppressed, consult the MOH.

References

1. Product Monograph – Astrazeneca COVID-19 Vaccine

2. NACI's Recommendations on the use of COVID-19 vaccines(s)

3. NACI's Guidance on the Prioritization of key populations for COVID-19 Vaccine(s)

4. Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic

5. Health Protection and Promotion Act

6. College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019.

7. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine-relevant information and planning resources

8. Canadian Immunization Guide, Immunization of Immunocompromised Persons Part 3- Vaccination of Specific Populations.

9. Ministry of Health and Long-Term Care Guidance document: COVID-19 Vaccination Recommendations for Special Populations. Version 3.0 March 11, 2021.

10. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine: Allergy Form. Version 3.0 March 11, 2021-or as current.

11. NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults

12. NACI Rapid Response: Interchangeability of Authorized COVID-19 Vaccines.

13. Ministry of Health and Long-Term Care Guidance document: Administration of AstraZeneca COVID-19 Vaccine/COVISHIELD Vaccine. Version 3.0 May 25, 2021.