Order/Description of Procedure: COVID-19 Pfizer BioNTech Vaccine and Moderna COVID-19 mRNA-1273 Vaccine
Regulated Health Professions Act: Controlled Act #5: Administration of a substance by injection.

For administration of **COVID-19 Pfizer BioNTech Vaccine** to individuals 12 years of age and older **or Moderna COVID-19 mRNA-1273 Vaccine** to adults, and administration of a Third Dose or Booster Dose of the **COVID-19 Pfizer BioNTech Vaccine** or **Moderna COVID-19 mRNA-1273 Vaccine** at all Hamilton Health Sciences (HHS) sites, community members of the City of Hamilton (including staff of health care facilities), individuals residing in Residential and Long Term Care Facilities and other areas where Hamilton Health Sciences is the custodian and administrator for the COVID-19 vaccine as mandated by the Ontario Ministry of Health.

This medical directive applies to the following health care providers (HCPs) who have the knowledge, skill, and judgement:
Nursing Students, Nursing Externs, Internationally Trained Nurses (not yet licensed), Regulated Healthcare Providers of all disciplines where professional college and the MOH support the delegation of administering an injection, Retired regulated healthcare professionals who have been legislated to administer the COVID Vaccine through MOH Directives and Professional College authorization, Registered Nurses, Registered Practical Nurses, Registered Respiratory Therapists, Registered Part A Pharmacists, Physician Assistants, Midwives, who are either HHS employees or Midwives who are credentialed by HHS, and are administering COVID vaccines in areas where Hamilton Health Sciences is partnering with Public Health as the custodians and administrators for the COVID-19 vaccine as mandated by the Ontario Ministry of Health. All of the above HCPs must receive vaccine administration training at HHS or through Hamilton Public Health.

Registered Part A Pharmacists (RPh) at HHS who have completed the necessary injection training requirements set forth by the Ontario College of Pharmacists (OCP) may administer the **Pfizer-BioNtech COVID-19 Vaccine** to individuals 12 years of age and older **or Moderna COVID-19 mRNA-1273 Vaccine** to adults at all Hamilton Health Sciences (HHS) Sites, community members of the City of Hamilton (including staff of health care facilities), individuals residing in Residential and Long Term Care facilities and other areas where Hamilton Health Sciences is partnering with Public Health as the custodians and administrators for the COVID-19 vaccine as mandated by the Ontario Ministry of Health AND who have current CPR certification.

Ontario

Ministry of Health

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Nurses (RN/RPN) – Province Wide - COVID-19 mRNA Vaccination Order

Brief Description of the Procedure:

This order is made under section 5(1)(b) of the *Nursing Act, 1991*.

A Registered Nurse (RN) or Registered Practical Nurse (RPN) may initiate a COVID-19 mRNA Vaccination of vaccine recipients for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus (the "Procedure") on the terms and conditions set out in this order.

Authorization:

The RN/RPN may initiate the Procedure:

(a) In respect of only those persons described by the provincial criteria for screening and prioritization for vaccination as identified by the Ontario Ministry of Health.

(b) In accordance with all procedures and processes of the applicable public hospital, long-term care home or public health unit on whose behalf the RN/RPN is conducting the Procedure.

(c) If the RN/RPN is knowledgeable regarding the manner for obtaining consent for the Procedure, completes any reporting, data collection and documentation requirements (including those set out below), and is knowledgeable about the management of anaphylaxis events in respect of the Procedure, including being familiar with where an emergency and anaphylaxis kit is kept.

(d) If the RN/RPN has reviewed this document and has self-assessed to have the appropriate knowledge, skill and judgement to conduct the Procedure, including having completed any required education.

(e) In accordance with the **Medications Table** attached.

Documentation:

Documentation of the implementation of the order and the fact that consent for vaccination was obtained must be recorded in the provincial documentation and registration system.

Documentation must include the name of the order, date of implementation and name and electronic signature including credentials of the implementer.

Ordering Physician:

Name: _____
Title: **Chief Medical Officer of Health**
Date: **February 5, 2021**

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
tozinameran	Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) **Route:** intramuscularly (IM) **Site:** deltoid muscle. **Dose:** 0.3 mL after reconstitution **Number of Doses:** 2 **Schedule:** • Minimum interval: 19 days Recommended interval: 21-28 days (must be given before 42 days)	The following applies for both the first and second dose administrations. Vaccine Recipients presenting to be vaccinated and meeting the criteria of the targeted vaccination group must: • Pass the COVID-19 Screening Criteria • Be 12 years of age and older AND • Provide Informed Consent AND	Do not administer the vaccine if: • Particulates or discoloration are present upon visual inspection of the vial Do not administer the vaccine if the Vaccine Recipient has any of the following: • Administration of another vaccine in the last 14 days • Severe allergic reaction to a previous dose of an mRNA vaccine, to the active substance or to any of the following excipients: - ALC-0315 = (4-hydroxybutyl) azanediyl)bis(hexane - 6,1-diyl)bis(2-hexyldecanoate	Individuals with the following conditions, or receiving the following therapies, may be directed to consult with their health care provider who is most familiar with their medical history prior to vaccination: • Autoimmune disease, immunocompromised or receiving immunosuppressant therapy • Pregnant

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
tozinameran (cont.)	Reconstitution of thawed suspension with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP using a 21 gauge or narrower needle using aseptic technique. The diluted product must be used within 6 hours of being reconstituted.	• Indicate no contraindications based on the list of known contraindications during the consent process for vaccination	- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide - 1,2-distearoyl-sn-glycero-3-phosphocholine - Cholesterol - Dibasic sodium phosphate dihydrate - Monobasic potassium phosphate - Potassium chloride - Sodium chloride - Sucrose • Temperature of greater than or equal to 38 degrees Celsius	For individuals who have a bleeding disorder, bruise easily or use a blood-thinning medication, IM administration may be safer when given with a small gauge needle (23 gauge or smaller) and when firm pressure is applied to the injection site for 5 to 10 minutes.

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
NA-1273 SARS-CoV-2	Moderna COVID-19 Vaccine **Route:** IM **Site:** deltoid muscle. **Dose:** 0.5 mL **Number of Doses:** 2 **Schedule:** • Minimum interval: 21 days • Recommended interval: 28 days Intact vials can remain at room temperature for up to 12 hours. After puncture they must be discarded after 6 hours.	The following applies for both the first and second dose administrations. Vaccine Recipients presenting to be vaccinated and meeting the criteria of the targeted vaccination group must: • Pass the COVID-19 Screening Criteria • Be 18 years of age and older AND • Provide Informed Consent AND	Do not administer the vaccine if: • Particulates or discoloration are present upon visual inspection of the vial Do not administer the vaccine if the Vaccine Recipient has any of the following: • Administration of another vaccine in the last 14 days • Severe allergic reaction to a previous dose of an mRNA vaccine, to the active substance or to any of the following excipients: - 1, 2-distearoyl-sn-glycero-3-phosphocholine (DSPC) - Acetic acid - Cholesterol - Lipid SM-102	Individuals with the following conditions, or receiving the following therapies, may be directed to consult with their health care provider who is most familiar with their medical history prior to vaccination: • Autoimmune disease, immunocompromised or receiving immunosuppressant therapy • Pregnant

NA-1273 SARS-CoV-2 (cont.)	Once a dose is withdrawn from the vial, it should be administered immediately.	• Indicate no contraindications based on the list of known contraindications during the consent process for vaccination	- PEG2000 DMG 1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol - Sodium acetate - Sucrose Tromethamine - Tromethamine hydrochloride • Temperature of greater than or equal to 38 degrees Celsius	For individuals who have a bleeding disorder, bruise easily or use a blood-thinning medication IM administration may be safer when given with a small gauge needle (23 gauge or smaller) and when firm pressure is applied to the injection site for 5 to 10 minutes.

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
Alpha and beta-adrenergic agonist	Epinephrine HCL 1:1,000 (1 mg/mL) IM STAT. **Route:** IM **Site:** mid-anterolateral thigh **Dose:** In individuals older than 12 years: 0.5 mL Dose may be repeated twice, administered 3 to 5 minutes apart	Vaccine Recipient observed or indicates Anaphylaxis or acute hypersensitivity reaction to administration of vaccine		• Epinephrine dosing may be repeated twice, administered 3 to 5 minutes apart • Call for assistance as per the clinic's escalation protocol including calling 911 • Transfer patient to an Emergency Department immediately

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
Antihistamines	{RUPALL} rupatadine 10 mg PO {CLARITIN} loratadine 10 mg PO {BEXTEN} bilastine 20 mg PO	Vaccine Recipient observed or reporting hives	Do not administer if Vaccine Recipient has: • A history of hypersensitivity to {RUPALL} rupatadine and/or {CLARITIN} loratadine and/or {BEXTEN} bilastine * Avoid use in persons with history of QT prolongation and/or torsade de pointes, including congenital long QT syndromes, history of cardiac arrhythmias or use of other QTc-prolonging drugs *Avoid use of rupatadine with known CYP3A4 inhibitors e.g., ketoconazole or erythromycin	May cause somnolence, impaired physical or mental abilities. Use in caution when performing tasks that require mental alertness.

Required Education:

The HCPs will complete any required education and will be evaluated by a clinical supervisor to ensure competency.

Implementation:

Pfizer-BioNTech:

- The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator (2 degrees Celsius to 8 degrees Celsius) or at room temperature (up to 25 degrees Celsius)
- Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.
- The contents of the vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP to form the Pfizer- BioNTech COVID-19 Vaccine.
- After dilution, the vial contains 5 doses of 0.3 mL.
- After dilution, the vaccine will be an off-white suspension. Inspect vials to confirm there are no particulates and no discolouration is observed.
- Strict adherence to aseptic techniques must be followed.
- Never shake the vaccine vial
- Vaccine vials must be used within 6 hours of dilution and stored at a temperature between 2 degrees Celsius and 25 degrees Celsius.
- Do not mix Pfizer-BioNTech COVID-19 Vaccine with other vaccines or products in the same syringe.
- Individuals who have received one dose of the Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of the Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Moderna COVID-19 Vaccine:

- Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates.
- Inspect Moderna COVID-19 Vaccine vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Never shake the vaccine vial.
- Moderna COVID-19 Vaccine is preservative free. Once a dose is withdrawn from the vial, it should be administered immediately.
- Once the vial has been entered (needle-punctured), it should be discarded after 6 hours.
- Do not mix Moderna COVID-19 Vaccine with other vaccines or products in the same syringe.
- Individuals who have received one dose of the Moderna COVID-19Vaccine should receive a second dose of the Moderna COVID-19Vaccine to complete the vaccination series.

For both vaccines:

- Individuals may not be protected until at least 7 days after their second dose of the vaccine.
- Adverse reactions from clinical studies include but may not be limited to:

Arthralgia, myalgia	Very common
Headache	Very common
Injection site pain, fatigue, chills, pyrexia	Very common
Redness at injection site, injection site swelling	Common
Nausea	Common
Malaise	Uncommon
Lymphadenopathy	Uncommon
Anaphylaxis	Rare

Third Dose of Primary COVID-19 Vaccine Series:

A third dose of the mRNA COVID-19 vaccine will be offered for the following populations eligible for vaccination with the vaccine product authorized for their age group, to complete the primary COVID-19 vaccine series:

1. Individuals receiving active treatment2 (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumor or hematologic malignancies.
2. Recipients of solid-organ transplant and taking immunosuppressive therapy o Recipients of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy).
3. Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).
4. Individuals with stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome.
5. Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies3 (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the CIG for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive.

Active treatment includes patients who have completed treatment within 3 months. Active treatment is defined as chemotherapy, targeted therapies, immunotherapy, and excludes individuals receiving therapy that does not suppress the immune system (e.g. solely hormonal therapy or radiation therapy). See Ontario Health/Cancer Care Ontario's Frequently Asked Questions for more information. Active treatment for patients receiving B-cell depleting therapy includes patients who have completed treatment within 12 months

COVID-19 Third Dose Interval:

The Ontario recommended interval between the last dose of the initial primary series and the third dose is at least two months (56 days). As per NACI, the minimum interval should be 28 days; however, an interval longer than the minimum 28 days between doses is likely to result in a better immune response. Exact timing should be decided with the treating provider in order to optimize the immune response from the vaccine series and minimize delays in management of their underlying condition. Additionally, the interval should consider risk factors for exposure (including local epidemiology and circulation of variants of concern) and risk of severe disease from COVID-19 infection. Some immunocompromised individuals may still be susceptible after the 1 or 2-dose primary series, so their period of susceptibility until receipt of the additional dose will also increase if the interval between doses is increased.

For guidance on the timing of vaccination for transplant recipients and those requiring immunosuppressive therapies, for a more fulsome list of conditions leading to primary immunodeficiency, and for further information on immunosuppressive therapies, refer to Immunization of Immunocompromised Persons in the Canadian Immunization Guide (CIG), Part 3 – Vaccination of Specific Populations. https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-3-vaccination-specific-populations/page-8-immunization-immunocompromised-persons.html

Booster Doses for Specific Populations:

At this time a booster dose of an mRNA COVID-19 vaccine will be offered for the following groups:

1. Residents of Long-Term Care Homes (LTCH), Retirement Homes (RH), Elder Care Lodges, and older adults living in other congregate settings5 (e.g. assisted-living facilities, chronic care hospitals, naturally occurring congregate retirement settings/congregate senior's apartment buildings, older adults living in congregate settings for people with developmental disabilities, mental health and addictions issues, etc.).

The recommended interval for residents of LTCH, RH and Elder Care Lodges and older adults living in other congregate settings is 6 months or longer (168 days) after the second dose.

2. At this time a booster dose of an mRNA COVID-19 vaccine will be offered for the following groups: All Ontarians aged 70 and older.

The recommended interval for individuals aged 70 years of age and older is 6 months or longer (168 days) after the second dose.

3. At this time a booster dose of an mRNA COVID-19 vaccine will be offered for the following groups: Health Care Workers who received their second dose of the COVID-19 vaccine at least 6 months (168 days) ago. Health Care Workers include: Any regulated health professionals and any staff member, contract worker, student/trainee, registered volunteer, or other designated essential caregiver currently working in-person in a health care organization, including workers that are not providing direct patient care and are frequently in the patient environment (i.e. cleaning staff, research staff, other administrative staff). Workers providing healthcare service or direct patient service in a congregate, residential or community setting outside of a health care organization.

Refer to the Ontario Ministry of Health COVID-19 Vaccine Third Dose Recommendations reference document for a detailed list and definition of eligible health care professionals. https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_third_dose_recommendations.pdf

4. At this time a booster dose of an mRNA COVID-19 vaccine will be offered for the following groups: First Nations, Inuit and Métis adults, including non-Indigenous household members.

The recommended interval for First Nations, Inuit and Metis adults and their nonindigenous household members is 6 months or longer (168 days) after the second dose.

5. At this time a booster dose of an mRNA COVID-19 vaccine will be offered for the following individuals: Individuals who received two doses of AstraZeneca/COVISHIELD COVID-19 vaccine, Individuals who received one dose of Janssen/Johnson & Johnson COVID-19 vaccine

The recommended interval for these individuals is 6 months or longer (168 days) after the completion of the primary series.

Vaccine Doses of the COVID-19 Pfizer BioNTech or Moderna COVID-19 mRNA-1273 Vaccine:

1. Either mRNA COVID-19 vaccine may be used as a booster dose, regardless of which COVID-19 vaccine was used in the primary series.
2. If offering the Pfizer-BioNTech Comirnaty mRNA vaccine, a full dose (30 mcg) should be used.
3. If offering the Moderna Spikevax mRNA vaccine, a full dose (100 mcg) should be used for adults living in long-term care homes for seniors or other congregate living settings that provide care for seniors and adults 70 years of age and older. A half dose (50 mcg) should be used for other adults recommended to receive a booster dose.

Informed consent should include discussion about what is known and unknown about the risks and benefits of providing a booster dose, including the off-label status of NACI's recommendation.

Reference for the Third Dose and Booster Dose of the COVID-19 vaccine:

Ontario Ministry of Health COVID-19 Vaccine Third Dose Recommendations https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_third_dose_recommendations.pdf November 3, 2021.

Summary of National Advisory Committee on Immunization (NACI) Statement of October 29, 2021.
https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/statement-guidance-booster-doses/summary/summary.pdf

This directive is an extension of the Vaccine Medical Directive signed by the Ontario Minister of Health on February 5, 2021 authorizing the administration of both the Pfizer-BioNtech COVID-19 and Moderna COVID-19 mRNA-1273 vaccine by Registered Nurses and Registered Practical Nurses. The MOH provides frequent updates, supporting documents, and guidelines for both of these vaccines. This additional letter of authorization to nursing and non-nursing staff as outlined within this document, authorizes said staff to follow ONLY the MOH Directive through authorization of the Hamilton Health Sciences Medical Advisory Committee. This authorization ensures that any changes to the MOH vaccination guidelines and subsequently the medical directive will be aligned and based on the most recent and evolving information.

Dr. Smita Halder
Chair of the HHS Medical Advisory Committee
Academic &

Dr. Michael Stacey
Executive Vice President,

Chief Medical Executive