Vaccine Medical Directive and Delegation
Moderna (Spikevax) COVID-19 Vaccine

DELEGATED PROCEDURE	Delegation of Authority to: ☒ Prescribe a drug ☐ Sell a drug
ORDER TO	☒ Administer ☐ Dispense ☐ Sell
AUTHORIZING MD	Dr. Penny Sutcliffe, Medical Officer of Health
AUTHORIZED IMPLEMENTERS	Public Health Sudbury & Districts Public Health Nurses, Registered Nurses, Registered Practical Nurses, graduates of an accredited Nursing Program in Ontario, post-secondary nursing students, medical students of an accredited Medical Program in Ontario, Midwives, Radiation Therapists, Respiratory Therapists, Physician Assistants, Pharmacists and Paramedics who have completed their Certification of Competence Module. Paramedic students from Collège Boréal and Cambrian College who have received formal didactic and practical education in IM, medication administration, and sharp safety, in a formative and summative evaluation process, following the paramedic NOCP's (National Occupational Competency Profile). This was completed in a supervised setting with certified faculty from Collège Boréal and Cambrian College. Second year RPN students from Collège Boréal who have received formal didactic and practical education in IM, medication administration, and sharp safety, in a formative and summative evaluation process, as per Standards of Practice College of Nurses. This was completed in a supervised setting with certified faculty from Collège Boréal and Cambrian College. Pharmacy Technicians who have completed an approved injection course through the College of Pharmacists and who are working with a regulated health professional who can obtain informed consent and provide patient education may perform the act of injection under this medical directive.
CLINICAL INDICATIONS/ PURPOSE	Moderna (Spikevax) COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 Vaccine) for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older in whom contraindications are not present.
SITUATIONAL CONDITIONS	• Informed consent. • Absence of contraindication(s). • **The product monograph is available here.**
CONTRAINDICATIONS	Moderna (Spikevax) COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 Vaccine) is contraindicated for use by implementers authorized under this medical directive for the following individuals: [2,3] 1. Individuals who have had a severe allergic reaction or anaphylaxis to a previous dose of a COVID-19 vaccine or to any of its components should not receive the COVID-19 vaccine 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. [13]

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	2. Individuals who are **under the age of 18 years**. 3. Individuals who had an episode of myocarditis or pericarditis following an mRNA vaccine should be referred to their primary care provider for consideration of their second dose and/or referral to a specialist.
PRESCRIBED CIRCUMSTANCES	Moderna (Spikevax) COVID-19 Vaccine is permitted for the following individuals under the *prescribed circumstances* described below: 1. Individuals 18-24 years old can be offered Moderna (Spikevax) only with informed consent following counseling regarding the increased risk of myocarditis and pericarditis observed in Ontario for this age group as compared with Pfizer BioNTech (Comirnaty), particularly among males. [18] Individuals who have had an allergic reaction within 4 hours of receiving a previous dose of a COVID-19 vaccine or any components of the COVID-19 vaccine should not receive a COVID-19 vaccine unless they have been **evaluated by an allergist/immunologist*** and it is determined that the person can safely receive the vaccine. The components include polyethylene glycol, tromethamine and polysorbate. 2. Individuals with known or suspected allergies to components of the mRNA vaccines should be referred to an allergist/immunologist for a COVID-19 vaccination assessment. The allergist/immunologist assessment will enable the development of a vaccination care plan which may include recommending an alternative vaccine such as the AstraZeneca/COVISHIELD COVID-19 vaccine. **Documentation** of the discussion with the allergist/immunologist must be provided to the clinic and include a vaccination care plan (including what types of parameters the clinic should meet to provide safe vaccination administration, e.g., availability of advanced medical care), details/severity of the previous allergic episode(s), confirm that appropriate counselling on the safe administration of vaccine was provided, and include the date, the clinician's name, signature and contact information as well as the individual's name and date of birth. ([13] Individuals 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 the COVID-19 vaccines can receive the COVID-19 vaccine followed by observation for a minimum of 30 minutes. Individuals with a history of significant allergic reactions and/or anaphylaxis to any food, drug, venom, latex, or other allergens not related to the COVID-19 vaccine can receive the COVID-19 vaccine followed by observation for a minimum of 15 minutes. Individuals with allergy issues like allergic rhinitis, asthma and eczema can receive the vaccine followed by observation for a minimum of 15 minutes.

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	Individuals who are breastfeeding or pregnant should be encouraged to be vaccinated following the same recommendations as the general population. These individuals should be informed of the latest evidence on the safety of mRNA COVID 19 vaccines in order to make informed decisions. [8] 3. Individuals in the authorized age group with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment that are receiving 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.) should be offered the vaccine. These individuals **are strongly encouraged to speak with their treating health care provider** regarding the timing of vaccination in relation to therapy for their underlying health condition and/or treatment modification in view of possible decreased vaccine effectiveness with the use of immunosuppressive therapy. See information in physician's order regarding third dose. All other individuals in the authorized age group with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment may choose to receive 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). [13]** 4. As a precautionary measure, the second dose in the mRNA COVID-19 vaccination series should be deferred in individuals who experience myocarditis or pericarditis following the first dose of an mRNA COVID-19 vaccine until more information is available. Individuals that have a history of myocarditis or pericarditis should consult with their primary care provider prior to immunization and be approved. [1, 2]
WARNINGS/ PRECAUTIONS	Caution is advised in the administration of intramuscular injections in people with bleeding disorders. Refer to the Injection Techniques Certification Module for further information. **Cardiovascular: Myocarditis and Pericarditis** Rare cases of myocarditis and/or pericarditis following vaccination with mRNA COVID-19 vaccine have been reported in Canada and internationally. These cases occurred most frequently in adolescents and younger adults under 25 years of age, more frequently in males compared to females, usually within a week after vaccination [(16)] and more commonly after the second dose. For individuals aged 18 to 24, (Pfizer BioNTech Comirnaty) should be preferentially used, but if a client requests Moderna (Spikevax), there must be informed consent regarding the increased risk of myocarditis with Moderna (Spikevax) as compared with Pfizer BioNTech (Comirnaty). When deciding whether to administer an mRNA vaccine to an individual with a history of myocarditis or pericarditis, consider the individual's clinical circumstances. Individuals who experience any of the following symptoms within several days of vaccination should seek medical attention immediately: chest pain, shortness of breath, feelings of a fast beating, fluttering or pounding heart. [1,2]

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Bell's Palsy
There have been very rare reports of Bell's Palsy reported after Moderna (Spikevax) vaccination. It is not always possible to reliably establish a causal relationship between the adverse reaction and product exposure, but this must be monitored due to it's potential of severity. The cause of Bell's Palsy is not known. Bell's Palsy can be described as temporary weakness or paralysis on one side of the face. This condition is typically temporary with sudden onset of symptoms which generally start improving after a few weeks. Individuals who experience a combination of the following symptoms after vaccination should seek medical attention: uncoordinated movement of the muscles that control facial expression, loss of feeling in the face, headache, tearing from the eye, drooling, loss of sense of taste on the front of the tongue, hypersensitivity to sound in one ear and/or inability to close an eye on one side of the face. (1)

Adverse Reactions
The most commonly reported adverse drug reactions after administration of Moderna COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 Vaccine) are injection site pain, fatigue, headache, muscle pain and stiffness, chills, nausea or vomiting, joint pain and fever. Uncommon reactions include swollen lymph nodes. Reactions are generally mild or moderate in intensity and of limited duration. Some adverse events, including fever, are more frequent after the second dose of vaccine.[1,2]

Drug: Drug Interactions
<u>Vaccines</u>
COVID 19 vaccines may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines. (17)

<u>Blood Products and Human Immunoglobulin</u>
COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.[2] In the post-exposure setting, expert clinical opinion should be sought on a case-by-case basis when deciding whether anti-SARS-CoV-2 monoclonal antibodies would be appropriate to administer after receipt of COVID-19 vaccine, taking into consideration the risk of exposure and the risk of severe COVID-19 disease in the individual.[2]
To date, there is also insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of non-COVID-19 disease. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.[2]

<u>Oral Analgesics and Antipyretics</u>
NACI recommends that **prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used** before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.[2]

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<table>
<tr><td></td><td>Analgesics and antipyretics were used in clinical trials of COVID-19 vaccine for the management of pain and/or fever after vaccination. There is currently no evidence on the benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.[2]

Drug: Food Interactions
None listed</td></tr>
<tr><td>PHYSICIAN'S ORDER</td><td>Moderna (Spikevax) COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 Vaccine) in accordance with the following table: (for 3rd dose eligibility see the bottom of this table)
<table>
<tr><th>Age</th><th>First dose</th><th>Second dose</th></tr>
<tr><td>18 years of age and older</td><td>0.5 mL IM</td><td>0.5 mL IM no sooner than 28 days after the administration of first dose and up to four months (112 days).

While it is preferable to provide the same vaccine product to complete an mRNA series, if there is operational or logistic necessity, including the availability of vaccine products, a 'mixed mRNA model' is acceptable. Provision of a second dose of vaccine should not be significantly delayed in order to complete a vaccine series using the same mRNA product, unless clinically indicated. In these instances, Pfizer BioNTech (Comirnaty) may be given as a second dose, at the minimal interval of 28 days from the first Moderna (Spikevax) dose in order to complete the series.[7] Individuals must be apprised of the NACI recommendation as follows:

Persons who received a first dose of an mRNA vaccine (Pfizer BioNTech (Comirnaty) or Moderna (Spikevax)) should be offered the same mRNA vaccine for their second dose, except in regards to individuals between the ages of 18 – 24 years, who should be offered Pfizer BioNTech (Comirnaty) as per the above concerns regarding the increased risk of myocarditis and pericarditis.. If the same mRNA vaccine is not readily available or unknown, another mRNA vaccine can be considered interchangeable for those over the age of 25, and should be offered to complete the vaccine series.When mixing mRNA vaccines, the minimum dosing interval to complete the series is determined by the product monograph of the <u>first dose product</u>.

See Pfizer BioNTech (Comirnaty) medical directive for further information.

Individuals who received their first dose of AstraZeneca vaccine and who choose to receive an mRNA vaccine for their second dose, may receive one dose of the Pfizer BioNTech (Comirnaty)or a Moderna (Spikevax) vaccine as per the Physician's Order in each directive. In the case of an individual aged 18 – 24, Pfizer BioNtech (Comirnaty) should be offered due to the increased risk of pericarditis and</td></tr>
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			myocarditis with Moderna (Spikevax). In their June 17 statement, NACI recommends that an mRNA vaccine is now preferred as the second dose for individuals who received their first dose of AstraZeneca/COVISHIELD vaccine. [(11)] This second dose is given at an interval between 8 to 12 weeks or more following the AstraZeneca vaccine.9 If eligible for an exception to the extension of the interval, the individual should consult with their health care provider to determine the recommended interval between four and 12 weeks. Upon receiving proof of this recommendation, this medical directive provides authority to the immunizer to administer vaccine at the prescribed interval if it is between 4 to 12 weeks following the first dose.[7]
	18 years and older	Third dose [(15)]	As per the Ministry of Health COVID-19 Vaccine Third Dose Recommendations, select individuals are eligible for a third dose of an mRNA COVID-19 vaccine. These individuals include: 1. Moderately to severely immunocompromised. 2. Vulnerable elderly in congregate settings. Eligible individuals should receive a third dose of an mRNA COVID-19 vaccine, and the same vaccine product as their second dose if readily available[19]. Individuals that received AstraZeneca/COVISHIELD COVID-19 vaccine for their first and second dose are recommended to receive an mRNA vaccine for their third dose unless contraindicated[19]. **Moderately to Severely Immunocompromised:** Recommended interval between the last dose of the initial primary series and the third dose is at least 2 months (8 weeks). Exact timing should be decided with the treating provider in order to optimize the immune response and minimize delays in in management of their underlying condition.[19] For a detailed list of eligible conditions see the Ministry of Health guidance document. Note: for this population, 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).[19] Active treatment for patients receiving B-cell depleting therapy includes patients who have completed treatment within 12 months.[19] Individuals with moderate to severe immunocompromising conditions that make them eligible for a third dose may present to the clinic with a referral form or select prescription medications.

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				Individuals who present with a referral form must have the form (English, French) signed by a primary care provider, a specialist provider, or a pharmacist. The form must have: • Physician stamp preferable at the top/front of the form and a physician name and signature at the back/bottom of the form. • Patient name. The PHN Lead will perform a healthcare professional assessment and review the referral form with the client to validate eligibility and specific treatment considerations and scheduling (per active treatment definition and special instructions from treating provider). If a client presents to a clinic with a prescription of their medication, the immunizer should refer to **Clinic Guide to Verifying Immunosuppressive Prescriptions for Third Doses of COVID 19 Vaccine** in order to verify the prescription details. A complete list of generic and brand drug names is also found within the document.[20] As the dosing information may not be included on the patient's prescription, confirmation of the dosage from the individual presenting their prescription is sufficient.[19] If a client is receiving an immunosuppressive biologic agent and they do not have a prescription, or their drug prescription is not listed below, they can receive a referral form/letter from their health care provider for a third dose. **Vulnerable Elderly in Congregate Settings** A third dose should be offered at least five months (20 weeks) after the second dose to the following groups: • Residents of Long-Term Care Homes, High-Risk Retirement Homes, Elder Care Lodges, and elderly living in other congregate settings (e.g., assisted-living facilities, chronic care hospitals, naturally occurring congregate retirement settings/congregate senior's apartment buildings, etc.). Note that practically, some residents may receive a shorter interval due to operational considerations when boosting entire facilities.
	*If administration of the second dose is delayed it should be given as soon as possible. Every effort should be made to vaccinate with the second dose as outlined above.			
ADDITIONAL DOSES FROM VACCINE VIALS (6)	It may be possible to withdraw an additional 0.5 ml dose of vaccine i.e. an 11th (5ml vial) or 15th dose (8ml vial).[10]			

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	As an interim measure, an additional dose of COVID-19 vaccine may be extracted from up to **3 vials** of the same vaccine using aseptic technique as follows: • Prepare vaccine in a clean, designated medication area away from where vaccination is occurring. • Ensure that all of the vaccine vials accessed to extract an additional dose of vaccine are from the same vaccine lot. • Combine vaccine from vials with residual volume only (i.e. not full vials) and do not save up vials until the end of clinic before combining for extra dose. • The different vials accessed have been under the same vaccine storage and handling conditions – do not combine vials that have been thawed and stored at +2[c] to +8 [C] with those that have just been removed from a freezer. Vials cannot be placed into a refrigerator beyond the permitted 24 hours post puncture in order to have enough vaccine to make up a full extra dose.
VACCINE STORAGE, STABILITY AND DISPOSAL [(6)]	This vaccine can be stored in refrigerator or frozen (needs to be thawed before use), however **DO NOT** store on dry ice. **Refrigerator** Vials can be stored refrigerated between 2-8 degrees Celsius for up to 30 days prior to first use. Based on information from vaccine manufacturers, the Moderna (Spikevax) and Pfizer BioNTech (Comirnaty) COVID-19 vaccines at refrigerator temperatures may be rounded to the nearest whole degree:[14] • Temperatures between +1.5°C and +1.9°C are rounded to +2.0°C • Temperatures between +8.1°C and +8.4°C are rounded to +8.0°C Moderna (Spikevax) and Pfizer BioNTech (Comirnaty) COVID-19 vaccines exposed to temperatures between +1.5°C and +8.4°C are considered to be in refrigerated temperatures and the incident does not need to be recorded as a temperature excursion and entered in COVAXON, troubleshooting should occur to ensure that temperatures are corrected and maintained between +2°C to +8°C.[14] Once the vial has been entered (needle-punctured), it can be stored at room temperature or refrigerated (between +2°C to +25°C) but must be discarded after 24 hours. Do not refreeze.[1] Remember to time and date when vial is first punctured. The dose in the syringe should be used as soon as feasible and no later than 24 hours after the vial was first entered (needle-punctured).[1] **Freezer** Moderna (Spikevax) COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 vaccine) is stored frozen between -25 degrees to -15 degree Celsius and should be stored in the original carton to protect from light. Vials must be thawed before use by removing the required number of vial(s) from storage and thaw in the refrigerated conditions between 2 degrees to 8 degrees Celsius for 2 hours and 30 minutes. Then, let each vial stand at room temperature for 15 minutes before administering.

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	Vials alternatively can be thawed at room temperature between 15 degrees to 25 degrees for 1 hour. After thawing, DO NOT refreeze. This vaccine is preservative-free. Any unused vaccine should be disposed of in accordance with local requirements.
TRANSPORTATION OF SYRINGES	While not recommended as routine practice, in exceptional circumstances a single dose of Moderna (Spikevax) vaccine may be transported in a syringe whilst careful attention is taken to adhere to the parameters as outlined in the following documents referenced below.[12] Available data support transportation of one or more thawed vials in liquid state for up to 12 hours at 2° to 8°C (36° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (36° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized .[(12)] Drawn up vaccine must be administered within 24 hours from the time the vial was first punctured. [(11)] This process will only be enacted for exceptional circumstances only with the approval and support of the Medical Officer of Health.
VACCINE PRESENTATION	Moderna (Spikevax) COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 Vaccine) presents as a white to off-white frozen suspension for intramuscular injection. It may contain white or translucent product –related particulates. Inspect the vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
VACCINE COMPONENTS	Moderna (Spikevax) COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 vaccine) contains a lipid nanoparticle (LNP) comprised of messenger Ribonucleic acid (mRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2 and four lipids. Moderna (Spikevax) COVID-19 vaccine does not contain any preservatives, antibiotics, adjuvants or human or animal derived materials. **<u>Non-medicinal ingredients</u>**: • 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) • Acetic acid • Cholesterol • Lipid SM-102 • PEG2000 DMG 1,2-dimyristoyl-racglycerol, • methoxy-polyethylene glycol* • Sodium acetate • Sucrose • Tromethamine • Tromethamine hydrochloride • Water for injection Moderna (Spikevax) COVID-19 vaccine is supplied in a multi-dose 10R type 1 glass vial (either 5ml or 8ml) with a 20mm FluroTec® coated chlorobutyl elastomer stopper, 20mm flip off aluminum seal. The 5ml vials contain 10 (maximum 11 doses) while the 8 ml vials each contains 14 doses (maximum 15 doses).

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	*Polyethylene glycol (PEG) is found in bowl preparation products for colonoscopy, laxatives, cough syrup, cosmetics, skin care products and some food and drinks, however this list is not exhaustive. The vial stopper does not contain natural rubber latex. Vials are packaged in a secondary carton containing a total of ten mRNA-1273 vaccine vials per carton.
EXPIRY DATE AND LOT NUMBER	The expiration date is not printed on the USA cartons or vials. This will be available on Moderna (Spikevax)'s Canadian Website: https://www.modernacovid19global.com/ca.[10] **A list of expiry dates and lot numbers for USA products can be found in Moderna lots expiry.** The Lead PHN shall check each lot number utilized prior to preparation and distribution at each shift and clinic. For US products they will check the website linked above for the expiration date and for other producers they will find the expiration date on the box or vials.
REFERENCES	1. Moderna Therapeutics Inc. COVID 19 vaccine Moderna COVID-19 Vaccine xp (mRNA-1273 SARS-CoV-2 vaccine) Product Monograph. June 30, 2021. 2. National Advisory Committee on Immunization (NACI): Recommendations on the Use of COVID-19 Vaccine(s). March 1, 2021; July 2, 2021. 3. Ministry of Health. Clarification on Moderna Second Dose Interval & Firefighter Eligibility Email dated February 23, 2021. 4. Vaccine Clinical Advisory Group (VCAG). Recommendations on Exceptions to Extended Dose Intervals for COVID-19 Vaccines. May 25, 2021 (or as current). 5. COVID 19 Vaccination Recommendations for Special Populations. March 11, 2021. 6. National Advisory Committee on Immunization (NACI). An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)- NACI Rapid Response: Interchangeability of Authorized COVID-19 Vaccines. June 1, 2021. 7. NACI Recommendations on the use of COVID-19 Vaccines-update on Special Populations and Extended Dose Intervals. Media Lines. May 28, 2021. 8. Ministry of Health. June 12, 2021. Ontario Accelerates Second Doses of AstraZeneca COVID-19 Vaccine: Second Dose of mRNA or AstraZeneca can be Administered at an Eight Week Interval with Informed Consent. 9. Moderna COVID-19 Vaccine US Supply Communication June 14, 2021. 10. Summary of National Advisory Committee on Immunization statement June 17, 2021. 11. COVID 19 Handling and Storage Guidance. Version 6.1. June 24, 2021. 12. Sick Kids. June 16, 2021. FAQ – Reports of myocarditis/pericarditis after COVID-19 vaccination. 13. COVID 19 Vaccination Recommendations for Special Populations. Version 5.0 July 30, 2021. 14. Ministry of health, August 5, 2021. – Guidance on Temperature Rounding for Moderna & Pfizer at Fridge Temperature

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	15. COVID- 19 Vaccination Recommendations for Special Populations. Version 6.0 August 17, 2021 16. NACI Recommendations on the use of mRNA COVID 19 Vaccines in Adolescents 12 – 17 years of age. August 27, 2021. 17. NACI Recommendations on the use of mRNA COVID 19 Vaccines September 28, 2021. 18. Chief Medical Officer of Health Statement "Ontario Recommends the use of Pfizer BioNTech COVID 19 Vaccine for Individuals Aged 18 – 24 Years Old. September 29, 2021. 19. COVID 19 Vaccine Third Dose Recommendations Version 2.0. October 7, 2021. 20. Clinic Guide to Verifying Immunosuppressive Prescriptions for Third Doses of COVID-19 Vaccine.
SIGNATURE AND DATE	Signature: *Original Signed By* Date: October 14, 2021

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