



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

<b>DELEGATED PROCEDURE</b>	Delegation of Authority to: <input checked="" type="checkbox"/> Prescribe a drug <input type="checkbox"/> Sell a drug
<b>ORDER TO</b>	<input checked="" type="checkbox"/> Administer <input type="checkbox"/> Dispense <input type="checkbox"/> Sell
<b>AUTHORIZING MD</b>	Dr. Penny Sutcliffe, Medical Officer of Health
<b>AUTHORIZED IMPLEMENTERS</b>	<p>Public Health Sudbury &amp; 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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
<b>CLINICAL INDICATIONS/PURPOSE</b>	Moderna (Spikevax) COVID-19 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.
<b>SITUATIONAL CONDITIONS</b>	<ul style="list-style-type: none"> <li>• Informed consent.</li> <li>• Absence of contraindication(s).</li> <li>• In accordance with COVAX schedules logic</li> </ul>
<b>CONTRAINDICATIONS</b>	<p>Moderna (Spikevax) COVID-19 Vaccine is contraindicated for use by implementers authorized under this medical directive for the following individuals:</p> <ul style="list-style-type: none"> <li>• Individuals who have had a severe immediate (<math>\leq 4</math> hours following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of COVID-19 vaccine, or any component of the COVID-19 vaccine, until clinically assessed and advised to receive the vaccine. Urgent referral to an allergist/immunologist is recommended. Refer to the warnings and precautions section below for information on administration of mRNA vaccine to individuals with severe allergies who have been assessed by an allergist/immunologist.<sup>1,2,3,4</sup></li> <li>• Individuals with mild to moderate immediate (<math>\leq 4</math> hours following vaccination) allergic reactions after previous administration of COVID-19 vaccine, or any component of a COVID-19</li> </ul>

	<p>vaccine, <b>or</b> with known or suspected allergies to components of the mRNA vaccines until clinically assessed and advised to receive the vaccine. Referral to an allergist/immunologist is recommended. Refer to the warnings and precautions section below for information on administration of COVID-19 vaccine to individuals with allergies who have been assessed by an allergist/immunologist.<sup>1,2,3,4</sup></p> <ul style="list-style-type: none"> <li>• Individuals who had an episode of myocarditis or pericarditis after previous administration of an mRNA vaccine. Subsequent doses of an mRNA COVID-19 vaccine should be deferred until more information is available.<sup>2,3,4</sup></li> </ul>
<p><b>WARNINGS/ PRECAUTIONS</b></p>	<p>The use of Moderna (Spikevax) COVID-19 Vaccine may be permitted, or must be deferred, for the individuals in accordance with the following:</p> <p><b>Acute Illness</b> Vaccination should be deferred in individuals with symptoms of SARS-CoV-2 infection, or those with respiratory symptoms until symptoms are completely resolved to minimize the risk of transmission of infection at an immunization clinic and to avoid attributing any complications resulting from infection to vaccine related AEFI.<sup>2,3</sup> Symptomatic and asymptomatic individuals who have been advised to self-isolate due to COVID-19 exposure should defer vaccination until their isolation period is over.<sup>2,3</sup></p> <p><b>Hypersensitivity and allergies</b> Individuals with mild, moderate, or severe allergies, or suspected allergies to a previous dose of COVID-19 vaccine or to any component contained in a COVID-19 vaccine who have been <b>evaluated by an allergist/immunologist* and benefits of vaccination</b> outweigh potential risks for the individual may receive COVID-19, <b>with informed consent</b>, when the conditions outlined below are met.</p> <p>Documentation of the consultation with the specialist is provided and includes a vaccination care plan outlining the parameters that must be met for safe vaccine administration</p> <ul style="list-style-type: none"> <li>• Details on the severity of the previous allergic episode(s)</li> <li>• Confirmation that counselling on the safe administration of vaccine was provided</li> <li>• The clinician’s name, signature, and contact information</li> <li>• The name and date of birth of the individual assessed.</li> </ul> <p>Individuals meeting the above criteria will be referred to Health Sciences North (HSN) for vaccination in a controlled setting upon approval of the Medical Officer of Health.</p> <p>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.<sup>2,3,4</sup></p> <p>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.<sup>1,2,3,4</sup></p> <p><b>Autoimmune conditions and immunodeficiencies</b> 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 <b>strongly encouraged to speak with their treating</b></p>

**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.<sup>2,3,4</sup>

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).<sup>2,3,4</sup>

### **Hematologic**

Individuals taking long-term anticoagulation (e.g., warfarin or heparin therapy) are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy (NACI). In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding.<sup>2,3,4</sup>

### **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 and more commonly after the second dose.<sup>2,3,4</sup> Based on observational data, there have been an increased number of reports in Ontario of pericarditis/myocarditis following vaccination with Moderna relative to Pfizer-BioNTech COVID-19 vaccine in the 18- to 24-year-old age group, particularly among males. All individuals receiving mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention immediately if they develop symptoms including chest pain, shortness of breath, palpitations in the week following vaccination.<sup>2,3,4</sup> As a precaution, Pfizer-BioNTech is preferentially recommended for persons 12 to 24 years of age.<sup>4</sup>

Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their health care provider for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine.<sup>2,3,4</sup>

### **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 its 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.<sup>1</sup>

### **Guillain-Barre Syndrome (GBS)**

Individuals with past history of GBS should receive an mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of an authorized COVID-19 vaccine may receive an mRNA vaccine for subsequent dose(s) after consultation with their health care provider.<sup>2</sup>

### **Adverse Reactions**

Very common and common side effects after administration of Moderna Spikevax COVID-19 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. Rare or very rare adverse events include pericarditis/myocarditis. 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.<sup>1,2,3</sup>

#### **Drug: Drug Interactions**

##### Vaccines

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.<sup>2,3</sup>

##### TST/IGRA

There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST/IGRA results. If TB skin testing/IGRA is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccine may take place at any time after TST has been completed. In cases of urgency the test should be performed, with re-testing 4 weeks post-immunization where there is a high index of suspicion of TB infection.<sup>2</sup>

##### Blood Products and Human Immunoglobulin

COVID-19 vaccines should not be given simultaneously with monoclonal antibody therapy or convalescent plasma therapy for the treatment or prevention of COVID-19 disease.<sup>2</sup> To-date, there is 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.<sup>2,3,4</sup>

##### Oral Analgesics and Antipyretics

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.<sup>2</sup>

#### **Drug: Food Interactions**

None listed

#### **Pregnancy and Breastfeeding**

All pregnant individuals in the authorized age group are eligible and recommended to be vaccinated as soon as possible, at any stage in pregnancy, as COVID-19 infection during pregnancy can be severe (increased risk for hospitalization, ICU admission, mechanical ventilation and death compared to non-pregnant individuals) and the benefits of vaccination outweigh the risks. Vaccination may be considered at any gestational age, including the first trimester. While pregnant individuals were not included in Phase III trials for COVID-19 vaccines, real-world safety data for hundreds of thousands of pregnant individuals that have received COVID-19 vaccines are now available and did not reveal any safety signals.<sup>2,4</sup>

COVID-19 vaccines can be safely given to breastfeeding individuals and recent data shows that mRNA from vaccines do not transfer into breast milk. Anti-COVID-19 antibodies produced by the breastfeeding person have been shown to transfer through the milk and provide protection to the infant. The vaccines are safe for the breastfeeding person and should be offered to those eligible for vaccination.<sup>2,4</sup>

**PHYSICIAN'S ORDER**

Moderna (Spikevax) COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 Vaccine) in accordance with Tables 1, 2, 3 and 4 below:

**Table 1: Immunocompetent Individuals 18 Years of Age and Older<sup>2,3,5</sup>**

Population	Schedule	First Dose	Second Dose												
Individuals 18 years of age and older  Pfizer-BioNTech COVID vaccine is preferred for individuals 18-24 years of age, <sup>3</sup> however should Moderna (Spikevax) COVID-19 vaccine be requested by this age group it may be given with informed consent.	2 dose primary series	0.5 mL IM	0.5 mL IM in accordance with the following product-specific* intervals												
			<table border="1"> <thead> <tr> <th>Vaccine for first dose</th> <th>Vaccine for second dose</th> <th>Recommended<sup>A</sup> and minimum<sup>B</sup> intervals between doses</th> </tr> </thead> <tbody> <tr> <td>Pfizer</td> <td>Moderna</td> <td>Recommended<sup>A</sup> interval 8 weeks. Minimum<sup>B</sup> interval 21 days upon MOH approval.</td> </tr> <tr> <td>Moderna</td> <td>Moderna</td> <td>Recommended<sup>A</sup> interval 8 weeks. Minimum<sup>B</sup> interval 28 days upon MOH approval.</td> </tr> <tr> <td>Astra Zeneca</td> <td>Moderna</td> <td>At least 8 weeks</td> </tr> </tbody> </table>	Vaccine for first dose	Vaccine for second dose	Recommended <sup>A</sup> and minimum <sup>B</sup> intervals between doses	Pfizer	Moderna	Recommended <sup>A</sup> interval 8 weeks. Minimum <sup>B</sup> interval 21 days upon MOH approval.	Moderna	Moderna	Recommended <sup>A</sup> interval 8 weeks. Minimum <sup>B</sup> interval 28 days upon MOH approval.	Astra Zeneca	Moderna	At least 8 weeks
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<sup>A</sup> Recommended interval refers to the Ministry of Health recommendation that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness. Recommended intervals between doses must be adhered to for the purposes of this directive.

<sup>B</sup> Minimum interval is the Health Canada authorized interval. Although the recommended intervals between doses are always advised, shorter intervals may be considered in the context of local epidemiology and compassionate care (i.e., travel to provide palliative care, prior to a scheduled medical procedure or starting immunosuppressive treatments, etc.). MOH approval is required when minimum intervals are being considered.

\*When the first dose in a series is an mRNA vaccine, the same mRNA vaccine product should be offered for the subsequent dose(s) if readily available, if unavailable another mRNA product recommended for that age group can be considered interchangeable and should be offered to complete the series. Where a different product is used to complete the vaccine series, the second dose should be given at the recommended interval.<sup>3</sup>

Interruption of a vaccine series resulting in a greater than suggested interval between doses does not require restarting the series since a delay between doses does not result in reduced protection.<sup>2</sup>

**Table 2: Immunocompromised Individuals 18 Years of Age and Older<sup>2,3,5</sup>**

Population	Schedule	First Dose	Second Dose	Third Dose***
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<p>Moderately to severely immuno-compromised* individuals 18 years of age and older</p> <p><b>Pfizer-BioNTech COVID vaccine is preferred for individuals 18-24 years of age,<sup>3</sup> however should Moderna (Spikevax) COVID-19 vaccine be requested by this age group it may be given with informed consent.</b></p>	<p>3 dose primary series</p>	<p>0.5 mL IM</p>	<p>0.5 mL IM in accordance with the following product-specific** intervals</p>			<p>0.5 mL IM ≥ 2 months (56 days) from previous dose to complete primary series</p> <p>Minimum interval (28 days) upon MOH approval<sup>B</sup></p>	
			<p>Vaccine for first dose</p>	<p>Vaccine for second dose</p>	<p>Recommended<sup>A</sup> and minimum<sup>B</sup> intervals between doses</p>		
			<p>Pfizer</p>	<p>Moderna</p>	<p>Recommended<sup>A</sup> interval 8 weeks. Minimum<sup>B</sup> interval 21 days upon MOH approval.</p>		
			<p>Moderna</p>	<p>Moderna</p>	<p>Recommended<sup>A</sup> interval 8 weeks. Minimum<sup>B</sup> interval 28 days upon MOH approval.</p>		
<p>Astra Zeneca</p>	<p>Moderna</p>	<p>At least 8 weeks</p>					

<sup>A</sup> Recommended interval refers to the Ministry of Health recommendation that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness. Recommended intervals between doses must be adhered to for the purposes of this directive.

<sup>B</sup> Minimum interval is the Health Canada authorized interval. Although the recommended intervals between doses are always advised, shorter intervals may be considered in the context of local epidemiology and compassionate care (i.e., travel to provide palliative care, prior to a scheduled medical procedure or starting immunosuppressive treatments, etc.). MOH approval is required when minimum intervals are considered.

\* Moderately to severely immunocompromised persons:<sup>2,3,5,6</sup>

- Active treatment (e.g., chemotherapy/targeted therapy/immunotherapy) for solid tumour/hematologic malignancy
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or [taking immunosuppression therapy](#))
- Moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome
- Active treatment with the following categories [of immunosuppressive therapies](#): anti-B cell therapies (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.

**Eligibility:**

Individuals meeting the above conditions for a third dose must present with a completed referral form ([English/French](#)) from a HCP/specialist or pharmacist. Alternatively, individuals may present a prescription for their medication which is to be cross-referenced with the [Clinic Guide](#) for confirmatory purposes. Confirmation of dosage from the client is sufficient verification of dose if it is not on the prescription.

\*\*When the first dose in a series is an mRNA vaccine, the same mRNA vaccine product should be offered for the subsequent dose(s) if readily available, if unavailable another mRNA product recommended for that age group can be considered interchangeable and should be offered to complete the series. Where a different product is used to complete the vaccine series, the second dose should be given at the recommended interval.<sup>3</sup>

\*\*\*Where third doses are given, individuals should receive the same vaccine product as their second dose if possible.<sup>5</sup>

Interruption of a vaccine series resulting in a greater than suggested interval between doses does not require restarting the series since a delay between doses does not result in reduced protection.<sup>2</sup>

**Table 3 Special Populations: Older Adults**

Population	Schedule	First Dose	Second Dose	Third Dose**												
<p>Long-term care home and retirement home residents</p> <p>Residents of Elder Care Lodges</p> <p><b>Older adults</b> living in other congregate care settings: (e.g., assisted-living facilities, chronic care hospitals, naturally occurring congregate retirement settings/seniors; apartment buildings; older adults living in congregate settings for people with developmental disabilities, mental health, and additions issues)</p> <p>Adults 70 years of age and older</p>	2 dose primary series plus booster dose	0.5 mL IM	<p>0.5 mL IM in accordance with the following product-specific* intervals</p> <table border="1"> <thead> <tr> <th>Vaccine for first dose</th> <th>Vaccine for second dose</th> <th>Recommended<sup>A</sup> and minimum<sup>B</sup> intervals between doses</th> </tr> </thead> <tbody> <tr> <td>Pfizer</td> <td>Moderna</td> <td>Recommended<sup>A</sup> interval 8 weeks. Minimum<sup>B</sup> interval 21 days upon MOH approval.</td> </tr> <tr> <td>Moderna</td> <td>Moderna</td> <td>Recommended<sup>A</sup> interval 8 weeks. Minimum<sup>B</sup> interval 28 days upon MOH approval</td> </tr> <tr> <td>Astra Zeneca</td> <td>Moderna</td> <td>At least 8 weeks</td> </tr> </tbody> </table> <p><sup>A</sup> Recommended interval refers to the Ministry of Health recommendation that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness. Recommended intervals between doses must be adhered to for the purposes of this directive.</p> <p><sup>B</sup> Minimum interval is the Health Canada authorized interval. Although the recommended intervals between doses are always advised, shorter intervals may be considered in the context of local epidemiology and compassionate care (i.e., travel to provide palliative care, prior to a scheduled medical procedure or starting immunosuppressive treatments, etc.). MOH approval is required when minimum intervals are being considered.</p>	Vaccine for first dose	Vaccine for second dose	Recommended <sup>A</sup> and minimum <sup>B</sup> intervals between doses	Pfizer	Moderna	Recommended <sup>A</sup> interval 8 weeks. Minimum <sup>B</sup> interval 21 days upon MOH approval.	Moderna	Moderna	Recommended <sup>A</sup> interval 8 weeks. Minimum <sup>B</sup> interval 28 days upon MOH approval	Astra Zeneca	Moderna	At least 8 weeks	<p>0.5 mL IM ≥ 6 months (168 days) after second dose</p> <p>(Currently no minimum interval – MOH direction required<sup>B</sup>)</p> <p><b>Given as a booster dose</b></p>
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Astra Zeneca	Moderna	At least 8 weeks														

See footnotes below Table 4

**Table 4 Special Populations: Adults (18+) with Other Risk Factors**

Population	Schedule	First Dose	Second Dose	Third Dose**
<p>Adults aged 18 and over who are:</p> <p>Select regulated <a href="#">health professionals</a>.***</p>	2 dose primary series plus booster dose	0.5 mL IM	0.5 mL IM in accordance with the following product-specific* intervals	0.25 mL IM ≥ 6 months (168 days) after

	<p>Workers providing healthcare service or direct patient service in a congregate, residential or community setting outside of a health care organization.</p> <p>First Nations, Inuit, and Metis adults, including non-indigenous household members</p> <p>Received two doses of AstraZeneca COVISHIELD COVID-19 vaccine</p> <p>Received one dose of Janssen/Johnson &amp; Johnson COVID-19 vaccine</p>			<table border="1"> <tr> <th>Vaccine for first dose</th> <th>Vaccine for second dose</th> <th>Recommended<sup>A</sup> and minimum<sup>B</sup> intervals between doses</th> </tr> <tr> <td>Pfizer</td> <td>Moderna</td> <td>Recommended<sup>A</sup> interval 8 weeks. Minimum<sup>B</sup> interval 21 days upon MOH approval.</td> </tr> <tr> <td>Moderna</td> <td>Moderna</td> <td>Recommended<sup>A</sup> interval 8 weeks. Minimum<sup>B</sup> interval 28 days upon MOH approval</td> </tr> <tr> <td>Astra Zeneca</td> <td>Moderna</td> <td>At least 8 weeks</td> </tr> </table>	Vaccine for first dose	Vaccine for second dose	Recommended <sup>A</sup> and minimum <sup>B</sup> intervals between doses	Pfizer	Moderna	Recommended <sup>A</sup> interval 8 weeks. Minimum <sup>B</sup> interval 21 days upon MOH approval.	Moderna	Moderna	Recommended <sup>A</sup> interval 8 weeks. Minimum <sup>B</sup> interval 28 days upon MOH approval	Astra Zeneca	Moderna	At least 8 weeks	<p>second dose (Currently no minimum interval – MOH direction required<sup>B</sup>)</p> <p><b>Given as a booster dose</b></p>	
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<p><b>VACCINE STORAGE, STABILITY AND DISPOSAL</b></p>	<p><b>Refrigerator</b>  Vials can be stored refrigerated between 2-8 degrees Celsius for up to 30 days prior to first use.<sup>1</sup></p> <p>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.<sup>1</sup>  Time and date when vial is first punctured.<sup>1</sup></p> <p>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).<sup>1</sup></p> <p><b>Freezer</b>  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.<sup>1</sup></p> <p>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.<sup>1</sup></p> <p>Vials alternatively can be thawed at room temperature between 15 degrees to 25 degrees for 1 hour.<sup>1</sup></p> <p>Swirl the vial gently after thawing. Do not shake.<sup>1</sup></p> <p>After thawing, DO NOT refreeze. This vaccine is preservative-free.<sup>1</sup></p> <p>Refer to the current <a href="#">Vaccine Storage and Handling Guidance</a> document for further information on the storage and handling of COVID-19 vaccines.</p>
<p><b>VACCINE PRESENTATION</b></p>	<p>Moderna (Spikevax) COVID-19 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.</p>
<p><b>VACCINE COMPONENTS</b></p>	<p>Moderna (Spikevax) COVID-19 Vaccine contains Elasmomeran (mRNA), encoding the pre fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2). Moderna (Spikevax) COVID-19 vaccine does not contain any preservatives, antibiotics, adjuvants or human or animal derived materials.<sup>1</sup></p> <p><b><u>Non-medicinal ingredients:</u></b><sup>1</sup></p> <ul style="list-style-type: none"> <li>• DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine)</li> <li>• Acetic acid</li> <li>• Cholesterol</li> <li>• Lipid SM-102</li> <li>• PEG2000 DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethylene glycol)*</li> <li>• Sodium acetate trihydrate</li> <li>• Sucrose</li> <li>• Trometamol</li> <li>• Trometamol hydrochloride</li> <li>• Water for injection</li> </ul> <p>*Polyethylene glycol (PEG) is found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, skin care products and some food and drinks, however this list is not exhaustive.<sup>3</sup></p> <p>The vial stopper does not contain natural rubber latex.</p>

<b>EXPIRY DATE AND LOT NUMBER</b>	<p>The expiration date is not printed on the USA cartons or vials. This will be available on Moderna (Spikevax)'s Canadian Website: <a href="https://www.modernacovid19global.com/ca">https://www.modernacovid19global.com/ca</a>.<sup>10</sup></p> <p><b>A list of expiry dates and lot numbers for USA products can be found in <a href="#">Moderna lots expiry</a>.</b></p> <p>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.</p>
<b>REFERENCES</b>	<ol style="list-style-type: none"> <li>1. ModernaTX, Inc. Spikevax™ Elasmolan mRNA Vaccine <a href="#">Product Monograph</a>. Updated November 12, 2021.</li> <li>2. National Advisory Committee on Immunization (NACI): Recommendations on the Use of COVID-19 Vaccine(s). Updated October 22, 2021.</li> <li>3. Ontario Ministry of Health. COVID-19 Vaccine Administration. Version 2.0. November 15, 2021.</li> <li>4. Ontario Ministry of Health. COVID 19 Vaccination Recommendations for Special Populations. Version 8.0. September 29, 2021.</li> <li>5. Ontario Ministry of Health. COVID-19 Vaccine Third Dose Recommendations. Version 3.1. November 12, 2021.</li> <li>6. National Advisory Committee on Immunization (NACI): Interim Guidance on Booster COVID-19 Vaccine Doses in Canada. October 29, 2021.</li> </ol>
<b>SIGNATURE AND DATE</b>	<p>Dr. Penny Sutcliffe, Medical Officer of Health</p> <p>Signature: <i>Original Signed By</i> <span style="float: right;">Date: November 22, 2021</span></p>

R: November 2021

APPROVED