Vaccine Medical Directive and Delegation
Comirnaty (Pfizer BioNTech) COVID-19 Vaccine

DELEGATED PROCEDURE	Delegation of Authority to: ☒ Prescribe a drug ☐ Sell a drug
ORDER TO	☒ Administer ☐ Dispense ☐ Sell
AUTHORIZING MD	Dr. Imran Khan, Public Health Physician
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 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, 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	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine (COVID-19 mRNA Vaccine) for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older in whom contraindications are not present.[1]
SITUATIONAL CONDITIONS	• Informed consent. • Absence of contraindication(s). • In accordance with $COVAX_{ON}$ schedules logic.
CONTRAINDICATIONS	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine (COVID-19 mRNA Vaccine) is contraindicated for use by implementers authorized under this medical directive for the following individuals:

	• Individuals with a **history of a severe immediate (≤ 4 hours following vaccination) allergic reaction (e.g., anaphylaxis)** after previous administration of an mRNA COVID-19 vaccine, re-vaccination may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided[2]. Individuals should consult with an allergist/immunologist or another appropriate physician prior to re-vaccination.[3] Refer to the Warnings and Precautions section for more specific details. • Individuals with a **previous history of allergy to an mRNA vaccine or any component of the COVID-19 vaccine**, where consultation with an allergist or other appropriate physician precludes further vaccination with an mRNA vaccine.[3] Until clinically assessed and advised to receive the vaccine, administration of the vaccine is contraindicated. Referral to a MD or NP is recommended.[3] 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 a MD or NP. • Individuals **displaying current or recent history of chest pain or shortness of breath** should not be offered the COVID-19 vaccine. Refer to Warnings and Precautions section below for information on administration of an mRNA vaccine to individuals displaying these symptoms.[3] • Individuals who had **an episode of myocarditis (with or without pericarditis) within the 6 weeks following a previous administration of an mRNA vaccine** should not receive the vaccine. This includes any person who had an abnormal cardiac investigation including ECG, elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA COVID-19 vaccine.[2] Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations.[2] Refer to the Warnings and Precautions section below for information on administration of COVID-19 vaccine to individuals who experienced an episode of myocarditis or pericarditis after previous administration of an mRNA vaccine who have been assessed by a MD or NP. • **Children with a previous history of multi-inflammatory syndrome (MIS-C)** unrelated to any previous COVID-19 vaccination, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.[3]
WARNINGS AND PRECAUTIONS	The use of Pfizer Comirnaty (Pfizer BioNTech) COVID-19 Vaccine may be permitted, or must be deferred, for individuals in accordance with the following: **Acute Illness** ***Current infection with SARS-CoV-2*** Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, to minimize the risk of COVID-19 transmission at an immunization clinic/venue.[2] As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine.[2]

	Current chest pain or shortness of breath Individuals displaying current or recent symptoms of chest pain or shortness of breath should defer vaccination until they can consult with their health care provider for individual considerations and recommendations. **Individuals presenting with severe symptoms should be directed to the emergency department or instructed to call 9-1-1**.[3] **Hypersensitivity and allergies** ***Allergic reaction to a previous dose of an mRNA vaccine*** Individuals with a history of a severe, immediate (≤ 4h following vaccination) allergic reaction (e.g., anaphylaxis) to a previous dose of an mRNA COVID-19 vaccine, revaccination may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Consultation with an allergist or other appropriate physician should be sought prior to re-vaccination. If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.[2] ***Confirmed allergies to a component of a COVID-19 vaccine*** Ingredients of authorized COVID-19 vaccines that have been associated with allergic reactions within the Comirnaty (Pfizer BioNTech) Vaccine include polyethylene glycol [PEG] only (purple cap formulation). In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container (e.g., PEG), consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. In individuals with a serious PEG allergy in whom mRNA vaccination is precluded based on a consultation with an allergist or other appropriate physician, the Novavax (Nuvaxovid) vaccine may be preferred if these individuals are in the authorized age group and are without contraindications to the vaccine.[2] **Mild to moderate immediate allergic reactions to a COVID-19 vaccine or a vaccine excipient** In individuals with mild to moderate immediate allergic reactions (defined as limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration) to a previous dose of mRNA COVID-19 vaccine or any of its components, re-vaccination may be offered with the same vaccine or the same platform (i.e., mRNA). Assessment by a physician or nurse with expertise in immunization may be warranted prior to re-immunization.[2] Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, if re-vaccination is chosen, an extended period of observation post-vaccination of **at least** 30 minutes should be provided for the aforementioned individuals.[2] Individuals with known allergies to components of the vaccines may speak with an appropriate physician or NP for evaluation. This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of your physician. Documentation of the discussion with the physician/NP may be provided to the clinic and can include a vaccination care plan (including what types of parameters the clinic should meet to provide safe vaccination administration, such as availability of advanced medical care to manage anaphylaxis), 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.[3] Referral and consultation support for Physicians and Nurse Practitioners is available through Ontario's eConsult Service.[3]

Individuals meeting the above criteria will be referred to Health Sciences North (HSN) for vaccination in a controlled setting. 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.[2]

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.[2]

Autoimmune conditions and immunodeficiencies
Moderately to severely immunocompromised individuals in the authorized age group who are immunosuppressed due to disease or treatment including stem cell therapy, Hematopoietic Stem Cell Transplant (HSCT) and chimeric antigen receptor T (CAR-T)-cell therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g., rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors, PARP inhibitors, anti-CD20, CD19, CD22 targeting antibodies, or BiTEs, etc.). should be offered a 3-dose primary series plus booster doses of 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.[2,3]

It is recommended that re-vaccination with a new COVID-19 vaccine primary series be initiated post-transplantation for hematopoietic stem cell transplant (HSCT), hematopoietic cell transplants (HCT) (autologous or allogeneic) and recipients of CAR-T-cell therapy given the loss of immunity following therapy or transplant. Optimal timing for re-vaccination should be determined on a case-by-case basis in consultation with the clinical team.[3] Person requesting revaccination in these circumstances should consult with their health care provider/specialist regarding the optimal timeline for re-vaccination.[3]

All other individuals in the authorized age group with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment should be offered the vaccine. **These individuals may choose to consult with their health care provider prior to vaccination** (for example, to discuss immunosuppressive medication management/timing in relation to their vaccination).[2,3]

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. In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding.[2]

Myocarditis and Pericarditis

All vaccine recipients

All individuals receiving mRNA COVID-19 vaccine should be informed of the very rare risk of myocarditis and pericarditis. Cases of myocarditis with or without pericarditis following mRNA COVID-19 vaccination have been shown to occur more often in adolescents and young adults, more often after the second dose, and more often in males than females. Individuals should be advised to seek medical attention immediately if they develop symptoms including chest pain, shortness of breath, palpitations (pounding or heart racing), or feeling of rapid or abnormal heart rhythm in the week following vaccination.[2,3] **As a precaution, Pfizer-BioNTech is preferentially recommended for persons 12 – 29 years of age who are receiving their primary series.**[3]

Individuals with a history of myocarditis unrelated to mRNA COVID-19 vaccination

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.[2]

Individuals with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA COVID-19

In most circumstances, and as a precautionary measure until more information is available, individuals with a diagnosed episode of myocarditis (with or without pericarditis) within 6 weeks of receipt of a previous dose of an mRNA COVID-19 vaccine should defer further doses of the vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram, or cardiac MRI after a dose of an mRNA vaccine.[2]

Some individuals 12 years of age and older with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA COVID-19 vaccine may choose to receive another dose of vaccine after discussing the risk and benefit with their healthcare provider.[2,3] Individuals can be offered the next dose once they are symptom free and at least 90 days have passed since vaccination.[3]

If another dose of vaccine is offered, they should be offered Pfizer 30 mcg due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30mcg vaccine compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop.[2,3]

Diagnosis uncertain

In situations where there is uncertainty regarding **myocarditis** diagnosis, discussion should occur with an appropriate physician or nurse practitioner on potential options for (re)immunization with the same or alternative COVID-19 vaccine, including a risk-benefit analysis for the individual. The individual qualifies for a medical exemption if the physician or nurse practitioner has

determined that the individual is unable to receive any COVID-19 vaccine. Those with a history compatible with **pericarditis** and who either had no cardiac workup or had normal cardiac investigations, can be re(immunized) once they are symptom free and at least 90 days has passed since vaccination.[2,3]

Bell's Palsy

Very rare reports of Bell's Palsy (facial paralysis and facial paresis) following vaccination with COVID-19 mRNA vaccines have been reported.[1,3] This condition is typically temporary with sudden onset of symptoms which generally start improving after a few weeks. The exact cause of Bell's Palsy is not known; however, it is believed to be the result of swelling and inflammation of the nerve that controls muscles on the face.[3] Currently available information is insufficient to determine a causal relationship with the Comirnaty vaccine as noted as a post-market adverse reaction in the Pfizer BioNTech (Comirnaty) product monograph.[1]

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, lost 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.[3]

Guillain-Barre Syndrome (GBS)

Individuals with a past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine.[2] 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 (i.e., if the benefits outweigh the risk and informed consent is provided).[2] To date, no increased risk of GBS has been identified following vaccination with an mRNA COVID-19 vaccine. The risk of GBS recurrence after COVID-19 vaccination amongst those with a past history of GBS appears to be low.[2]

Adverse Reactions

Reactions are generally mild to moderate in intensity and of limited duration.[3] Very common and common side effects include: localized redness/erythema, swelling and or pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, fever, nausea/vomiting. Uncommon reactions include swollen lymph nodes. Rare or very rare adverse events include pericarditis/myocarditis.

Drug: Drug Interactions

Vaccines

For individuals aged 5 and older, 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.[2,3]

Tuberculin skin testing (TST) or Interferon gamma release assay (IGRA)

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

	Blood Products and Human Immunoglobulin COVID-19 vaccines should not be given concurrently with anti-SARS-CoV-2 monoclonal antibodies. Administration of these products concurrently may result in decreased effectiveness of the COVID-19 vaccine and/or anti SARS-CoV-2 monoclonal antibodies. Anti SARS-CoV-2 monoclonal antibodies have high affinity for the spike protein expressed by COVID-19 vaccines, which could prevent the production of antibodies stimulated by the vaccine or binding of vaccine antigen to the monoclonal antibody may neutralize the antibody.[2] ***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.[2] There is currently no evidence of benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.[2] 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] ***Drug: Food Interactions*** None listed **Pregnancy and Breastfeeding** Pregnant and breastfeeding individuals should receive all recommended doses of a COVID-19 vaccine (including booster doses) as soon as they become eligible.[3] Compared to non-pregnant persons, SARS-CoV-2 infection in pregnancy may increase the risk of complications requiring hospitalization and intensive care, as well as poorer pregnancy outcomes including premature birth, stillbirth, and caesarian delivery.[2] All pregnant and breastfeeding individuals in the authorized age group are eligible and should receive all recommended doses of a COVID-19 vaccine (including booster doses) as soon as possible. The Society of Obstetricians and Gynaecologists of Canada recommend COVID-19 vaccination during pregnancy and in any trimester and while breastfeeding, if no contraindications exist. While all available COVID-19 vaccines approved in Canada can be used during pregnancy and breastfeeding, preference is given to the use of mRNA vaccinations during pregnancy as more data on safety and efficacy on pregnancy is available for these vaccines.[2,3] 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.[2,4] Those that are trying to become pregnant do not need to avoid pregnancy after vaccination with an mRNA vaccine.[2]
PHYSICIAN'S	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine (COVID-19 mRNA Vaccine) in accordance with Tables 1, 2, 3, and 4 below.

ORDER

Some general principles regarding the Comirnaty (Pfizer BioNTech) Vaccine Schedule:

- Pfizer BioNTech COVID-19 Vaccine is the preferred vaccine for individuals **12-29 years of age who are completing their primary series.**
- Bivalent vaccine products indicated for booster immunization are recommended over monovalent vaccine products used as booster doses.[3] There is no preferential recommendation between bivalent Moderna (50 mcg) or bivalent Pfizer-BioNTech (30 mcg) as a bivalent booster for persons aged 18+.[3]
- Individuals aged 12-17 years of age are preferentially recommended to receive the bivalent Pfizer-BioNTech COVID-19 vaccine for their booster doses. It is the only authorized product for this age group[3] Moderna (50 mcg) may be offered for immunocompromised persons in this age group off-label
- The intervals listed in Tables 1, 2, 3, and 4 below may change as listed for individuals with a previous or current SARS-CoV-2 infection. Refer to Table 5 for suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination.[3]
- For those vaccinated outside of Ontario or Canada please refer to the most current version of the COVID-19 Vaccine Administration guidance document.[3]

Table 1: Primary Series for Immunocompetent Individuals[3]

This table is to be referenced for all immunocompetent adults and adolescents 12 years of age and older.

- 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.[3]
- An 8-week interval between the first and second dose of mRNA vaccine should be provided as a longer interval between doses is associated with higher vaccine effectiveness and potentially lower risk of myocarditis/pericarditis.[2]

<table>
<tr><th>Schedule: Primary Series (Eligible and Recommended)</th><th>First Dose</th><th>Second Dose: Recommended[A] and Minimum[B] Intervals</th></tr>
<tr><td>Schedule: 2 dose primary series

Eligible: Individuals 12+</td><td>0.3mL (30mcg) IM</td><td>0.3mL (30mcg) IM in accordance with the following product-specific intervals:
<table>
<tr><th>Vaccine for first dose</th><th>Interval Between First and Second Dose</th></tr>
<tr><td>Pfizer (Pediatric Formulation)</td><td>Recommended: 8 weeks (56 days)
Minimum: 28 days with informed consent*</td></tr>
<tr><td>Pfizer (Adult Formulation)</td><td>Recommended: 8 weeks (56 days)
Minimum: 28 days with informed consent*</td></tr>
<tr><td>Moderna</td><td>Recommended: 8 weeks (56 days)
Minimum: 28 days with informed consent*</td></tr>
<tr><td>Astra Zeneca (1 dose)</td><td>Recommended: To complete the primary series: 8 weeks (56 days)
Minimum: 28 days with informed consent*</td></tr>
<tr><td>Janssen</td><td>Not applicable – primary series is complete. Any additional doses</td></tr>
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			would be considered booster doses.
		Novavax	**Recommended:** 8 weeks (56 days) **Minimum:** 28 days with informed consent*
		Medicago	**Recommended:** 8 weeks (56 days) **Minimum:** 28 days with informed consent*

[A] 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.

[B] Minimum interval is the minimum interval identified in the most current version of the Ministry of Health COVID-19 Vaccine Guidance document.

*Informed consent = advising client of recommended interval and that greater interval= greater protection.

Table 2: Primary Series for Immunocompromised Individuals[3]

This table is to be referenced for all moderately to severely immunocompromised individuals 12 years of age and older.

Moderately to severely immunocompromised individuals include:[3]

- Individuals receiving dialysis (hemodialysis or peritoneal dialysis).
- 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).
- Individuals with HIV with prior AIDS defining illness or prior CD4 count ≤ 200/mm3 or prior CD4 fraction ≤ 15% or (in children 5-11 years) perinatally acquired HIV infection.
- *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. Refer to the most current version of the COVID-19 Vaccine Booster Recommendations document for the definition of *active treatment*.[3]

Schedule: Primary Series (Eligible and/or Recommended)	**First Dose**	**Second Dose: Recommended[A] and Minimum[B] Intervals**	**Third Dose: Recommended[A] and Minimum[B] Intervals**
Schedule: 3 dose primary series **Eligible:** Individuals 12+ **Recommended:** Individuals 12+	0.3mL (30mcg) IM	**Dose:** 0.3mL (30mcg) IM **Recommended:** Refer to Table 1 for recommended intervals **Minimum:** Refer to Table 1 for minimum intervals	**Dose:** 0.3mL (30mcg) IM **Recommended:** 8 weeks (56 days) after second dose **Minimum:** 28 days after second dose with informed consent and with a referral from their Health

			Care Provider* (however an interval longer than 28 days is likely to result in a better immune response with exact timing to be decided with treating provider)

[A] 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.

[B] Minimum interval is the minimum interval identified in the most current version of the Ministry of Health COVID-19 Vaccine Guidance document.

*Informed consent = advising client of recommended interval and that greater interval= greater protection.

Booster Doses for all Immunocompetent Individuals[3]

Booster dose(s) are recommended based on ongoing risk of infection due to waning immunity, the ongoing risk of severe illness from COVID-19, the societal disruptions that result from transmission of infections, and the adverse impacts on health system capacity from the COVID-19 pandemic.[3]

Bivalent boosters (in authorized age groups) are recommended over monovalent boosters.[3] Refer to the Moderna Spikevax Bivalent medical directive and the Pfizer-BioNTech Bivalent medical directives for further information. Monovalent Pfizer may be used for eligible persons in the authorized age groups for booster doses when bivalent products are refused, with informed consent.[2]

Individuals who are at higher risk of severe disease from COVID-19 infection and are **recommended** to get **booster** doses as soon as they become eligible, include:[3]

- Residents of long-term care homes, retirement homes, Elder Care Lodges, and individuals living in other congregate settings
- Individuals 65 years of age and older
- Individuals who are 12 years and older with moderately to severely immunocompromising conditions
- Individuals 12 and older with an underlying medical condition that places them at risk of severe COVID-19 including cardiac or pulmonary disorders, diabetes and other metabolic diseases, cancer, renal disease, anemia or hemoglobinopathy, neurologic or neurodevelopmental conditions, class 3 obesity (BMI of 40 and over)
- Adults who identify as First Nation, Inuit and Métis, and their adult non-Indigenous household members.
- Pregnant individuals
- Health care workers who belong to a high-risk group themselves or who provide care for high-risk patients.
- Adults in racialized and/or marginalized communities disproportionately affected by COVID-19.

Table 3: Pfizer Comirnaty Booster Dose Recommendations for Eligible Persons in Authorized Age Groups Who Refuse Bivalent mRNA vaccines:[1]

Population	Dose	Recommended and Minimum Intervals
Individuals 16 years of age and older	0.3 mL IM	**Recommended:** Booster dose(s) 6 months (168 days) after last COVID-19 vaccine received **Minimum:** Booster dose(s) 3 months (84 days) after last COVID-19 vaccine received. For persons in high-risk groups as outlined above the recommended interval is 3 months (84 days) from previous dose.

Table 4: Suggested Intervals Between Previous SARS-CoV-2 Infection and COVID-19 Vaccination[3]

Ontario, in alignment with NACI, continues to recommend that COVID-19 vaccines should be offered to individuals with previous SARS-CoV-2 infection without contraindications to the vaccine. Below are suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination.

Infection Timing Relative to COVID-19 Vaccination	Population	Suggested Interval Between Infection** and Vaccination
Infection prior to completion or initiation of primary vaccination series.	Individuals 6 months of age and older who are not considered moderately to severely immunocompromised with no previous history of multisystem inflammatory syndrome in children (MIS-C).	Receive the vaccine 2 months (56 days) after symptom onset or positive test (if asymptomatic).
	Individuals 6 months of age and older who are moderately to severely immunocompromised and with no history of multisystem inflammatory syndrome (MIS-C)	Receive the vaccine dose 1 to 2 months (28 to 56 days) after symptom onset or positive test (if asymptomatic)
	Individuals 6 months of age and older with a previous history of multisystem inflammatory syndrome MIS-C (regardless of immunocompromised status).	Receive the vaccine dose when clinical recovery has been achieved or ≥ 90 days since the onset of MIS-C, whichever is longer.
Infection after primary series but before first booster dose and/or second booster dose	Individuals currently eligible for booster dose(s)	A minimum of 3 months (84 days) after symptom onset or positive test (if asymptomatic); however, a 6 month (168 day) interval may provide a better immune response of product given.

** A previous infection with SARS-CoV-2 is defined as:

- A COVID-19 case confirmed by a molecular (e.g., PCR) or rapid antigen test, or
- Symptomatic AND a household contact of a confirmed COVID-19 case.[3]

Note: When considering whether to administer vaccine doses following the suggested intervals outlined in the table, biological and social risk factors for exposure (local epidemiology, circulation of VOCs, living settings) and severe disease should be

	considered. These intervals are a guide and clinical discretion is advised. A longer interval between infection and vaccination may result in a better immune response.[3] Before vaccination, the individual should no longer be considered infectious, symptoms of acute illness should be completely resolved, and their isolation period must be completed.
OBSERVATION PERIOD	Vaccine recipients should be kept under observation for at least 15 minutes after immunization; 30 minutes is a preferred interval when there is a specific concern about a possible vaccine reaction.[1]
PREPARATION OF VACCINE	**Reconstitution:** Remove a thawed vial of Comirnaty (Pfizer BioNTech) COVID-19 Vaccine from the refrigerator and allow it to come to room temperature OR if using a frozen vial of Comirnaty (Pfizer BioNTech) COVID-19 Vaccine, thaw for 30 minutes at room temperature.[1] **NO DILUTION REQUIRED**. **DO NOT DILUTE PRIOR TO USE.** Invert the thawed vaccine vial gently 10 times to mix (do not shake).[1] Each vial contains 6 doses of 0.3 mL.[1] Vials should be discarded 12 hours after first puncture.[1]
VACCINE STORAGE, STABILITY AND DISPOSAL	Refer to the Ontario Ministry of Health, Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines, Version 2.2 October 13/22 for guidance on: • Storing, distributing, and/or administering COVID-19 vaccines. • Assessing temperature excursions, including the vaccine return process.
TRANSPORTATION OF VIALS	Refer to the Ontario Ministry of Health, Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines, Version 2.2 October 13/22 for guidance on the onward transportation of the COVID-19 vaccines beyond the initial point of delivery. This section applies to the distribution of unopened vials of COVID-19 vaccine only. Transport refers to taking the vaccine from one site to another using a vehicle on ground, air, or water. Walking the vaccine is not considered transport when it is for a short period (i.e., up to 15 minutes).
TRANSPORTATION OF DILUTED VACCINE	Refer to the Ontario Ministry of Health, Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines, Version 2.2 October 13/22. Transportation is recommended in a syringe over an opened vial to prevent agitation of the product in an opened vial. This should only be completed when necessary for vaccination and should not be part of routine practices.[4] It is recommended that the vaccine is only transported at +2°C to +8°C once. Under exceptional circumstances, based on a risk assessment, the vaccine may be transported at +2°C to +8°C more than once if and per normal process ensure the following: • The cold chain has been properly monitored and documented. • Syringes are packed in order to minimize movement and agitation

	The pre-drawn syringes should be labeled with the name and dosage of vaccine, exact beyond-use date and time, lot number, and initials of preparer. If the syringe being transported is from a vial that was previously transported at fridge temperature, then the total transportation time – the time the syringe (drawn up dose) and the time the vial was transported (i.e., time that the vial was in transport at +2°C to +8°C) should not exceed 12 hours.
VACCINE PRESENTATION	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine, mRNA presents as a white to off-white frozen suspension for intramuscular injection. Inspect vials to confirm there are no particulates and no discoloration, prior to administration.[1]
VACCINE COMPONENTS	Comirnaty (Pfizer BioNTech) COVID-19 Vaccine, mRNA contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2 (original strain) and several non-medicinal ingredients listed below.[1] **Non-medicinal ingredients**: • ALC-0315 = ((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) • ALC-0159 = 2-[(polyethylene glycol*)-2000]-N,N-ditetradecylacetamide • 1,2-distearoyl-sn-glycero-3-phosphocholine • cholesterol • sodium chloride • sucrose • tromethamine • tromethamine hydrochloride • water for injection *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. The vial stopper does not contain natural rubber latex.
REFERENCES	1. Pfizer Canada ULC. Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) Product Monograph. September 9/22. 2. National Advisory Committee on Immunization (NACI). COVID-19 vaccine: Canadian Immunization Guide - Canada.ca. Updated October 31/22. Accessed November 9/22. 3. Ontario Ministry of Health. COVID-19 Vaccine Guidance. Version 3.1 November 7/22. 4. Ontario Ministry of Health, Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines, Version 2.2 October 13/22.
SIGNATURE AND DATE	Date: November 30, 2022