Vaccine Medical Directive and Delegation
Pfizer-BioNTech COVID-19 Vaccine

DELEGATED PROCEDURE	Delegation of Authority to: ☒ Prescribe a drug ☐ Sell a drug
ORDER TO	☒ Administer ☐ Dispense ☐ Sell
AUTHORIZING MD	
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	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.
SITUATIONAL CONDITIONS	• Informed consent • Absence of contraindication(s) • **The use of Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) is permitted under a Health Canada interim authorization delivered in accordance with section 5 of the COVID-19 Interim order (IO). The interim order is available here. The product monograph is available here.**

CONTRAINDICATIONS	Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) is contraindicated for use by implementers authorized under this medical directive for the following individuals[2,3]: 1. Individuals with a **history of anaphylaxis after previous administration** of the vaccine. 2. Individuals who have ever had an **anaphylactic reaction to any component of an mRNA vaccine** or its packaging. Refer to the vaccine component section for product specific component information. 3. Individuals who are **under the age of 12 years**.
PRESCRIBED CONDITIONS	Pfizer COVID-19 Vaccine is permitted for the following individuals under the *prescribed circumstances* described below: 1. Individuals who have had an **allergic reaction within 4 hours** of receiving **a previous dose of an mRNA COVID-19**, or any components of the mRNA COVID-19 vaccine (including polyethylene glycol [PEG]), or polysorbate, *only if they have been evaluated by an allergist/immunologist and it is determined that the person can safely receive the vaccine, and the individual provides documentation as required.[7 8] (or as current reference)* 2. 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.[9] 3. Individuals with **autoimmune conditions and immunocompromised** persons should follow the same recommendations for COVID vaccination as for the general adult population. They should be informed of the latest evidence on the safety of mRNA COVID 19 vaccines in order to make decisions. Individuals who are immunosuppressed from disease or treatment should be informed that they may have a reduced immune response to any authorized COVID-19 vaccine series.[9] 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 30 years of age, more frequently in males compared to females, and more commonly after the second dose. 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]

Allergic Reactions

For 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 mRNA COVID-19 vaccines, the mRNA COVID-19 vaccine can be given with an extended observation post-vaccination of 30 minutes in the clinic.

Persons with allergy issues like allergic rhinitis, asthma and eczema can receive the vaccine with an extended observation post-vaccination of 15-30 minutes in the clinic.

Adverse Reactions

The most commonly reported adverse drug reactions after administration of Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) are injection site pain, fatigue, headache, muscle pain, chills, 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 should not be given simultaneously with other live or inactivated vaccines at this time, unless other vaccines are required for post-exposure prophylaxis.[2] In the absence of evidence, it would be prudent to wait for a period of at least **28 days after each vaccine dose of an mRNA** COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response.[2] It would be prudent to wait for a period of at least **14 days after the administration of another vaccine** before administrating a COVID-19 vaccine.[2]

<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]

Oral Analgesics and Antipyretics

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]

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

PHYSICIAN'S ORDER

Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) in accordance with the following table:

Age	**First dose**	**Second dose**
Vaccination schedule for individuals 12 years of age and older	0.3 mL* IM	0.3 mL* IM no sooner than 21 days after 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, Moderna may be given as a second dose to those **18 years of age or older**,

			at the minimal interval of 21 days from the first Pfizer dose in order to complete the series.[8] Individuals must be apprised of the NACI recommendation as follows: ***Persons who received a first dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) should be offered the same mRNA vaccine for their second dose. If the same mRNA vaccine is not readily available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.*** **When mixing mRNA vaccines, the minimum dosing interval to complete the series is determined by the product monograph of the first dose product.** See Moderna medical directive for further information. Individuals who received their first dose of the AstraZeneca vaccine and who choose to receive an mRNA vaccine for their second dose, may receive one dose of the Pfizer BioNTech or Moderna vaccine as per the Physician's Order in each directive.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 [(10).] 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 if an interval less than 12 week is

			appropriate. 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.[8]

*0.3 mL dose is unique compared to that of most routine vaccinations. Special precaution should be taken to ensure the correct dose is taken from the multi-dose vial.

*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.

Reconstitution:
Remove a thawed vial of Pfizer-BioNTech COVID-19 Vaccine from the refrigerator and allow it to come to room temperature OR if using a frozen vial of Pfizer-BioNTech COVID-19 Vaccine, thaw for 30 minutes at room temperature.[1]

Prior to dilution, invert the thawed vaccine vial gently 10 times to mix (do not shake).[1]

Obtain sterile 0.9% Sodium Chloride Injection, USP (not bacteriostatic 0.9% Sodium Chloride Injection). Cleanse the vial stopper with a single-use antiseptic swab. Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the Pfizer-BioNTech COVID-19 Vaccine vial using a sterile needle 21-gauge or narrower. Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe. Gently invert the vaccine 10 times to mix (do not shake). Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.[1]

Vials at room temperature must be diluted within 2 hours.
The diluted product must be used within 6 hours of being reconstituted.[1]

After dilution, one vial contains a minimum of 6 doses of 0.3 mL.[7]

ADDITIONAL DOSES FROM VACCINE VIALS **(6)**

It may be possible to withdraw an additional 0.3 ml dose from a vial.
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.
- The lot number of the diluent is the same.
- 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 6 hours after dilution in order to have enough vaccine to make up a full extra dose.

VACCINE STORAGE, STABILITY AND DISPOSAL	Vials must be kept frozen between -80°C to -60°C and protected from light, in the original cartons, until ready to use. However, vials can also be stored at -25°C to -15°C for up to 2 weeks or transported at -25°C to -15°C and may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and not exceed 2 weeks.[1] <u>Thawed Vials Prior to Dilution</u> Vials may be thawed and stored at +2oC to +8 oC for up to 31 days or at room temperature (up to +25oC) for no more than 2 hours. During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions. Do not refreeze thawed vials.[6,7] Vials may be transported at 2°C to 8°C for up to 12 hours. Any hours used for transport at 2°C to 8°C count against the 120 hour limit.[6] Frozen vials may also be thawed at room temperature [up to 25°C]. Prior to dilution, the multiple dose vial may be stored at room temperature for no more than 2 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions. Do not refreeze thawed vials. <u>Vials After Dilution</u> After dilution, multiple dose vials of Pfizer-BioNTech COVID-19 Vaccine must be stored between 2°C to 25°C) and used within 6 hours from the time of dilution. Any vaccine remaining in vials must be discarded after 6 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. After dilution, the vaccine vials can be handled in room light conditions. Do not freeze. If the vaccine is frozen, it must be discarded.
TRANSPORTATION OF SYRINGES ([6])	While not recommended as routine practice, in exceptional circumstances a single dose of Pfizer BioNTech 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.[6] Drawn up vaccine must be administered within 6 hours from the time the vial was first punctured. Transport time is a maximum of 6 hours.[6]
VACCINE PRESENTATION	Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) presents as a white to off-white frozen suspension for intramuscular injection. It must be diluted prior to administration. The diluted vaccine will be an off-white suspension. Inspect vials to confirm there are no particulates and no discoloration, prior to administration.[1]

VACCINE COMPONENTS	Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2 and several non-medicinal ingredients listed below. Each 0.3 mL dose contains 30 µg mRNA. **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 • dibasic sodium phosphate dihydrate • monobasic potassium phosphate • potassium chloride • sodium chloride • sucrose • 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. 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. Ontario Ministry of Health. Sequencing of Phase One Priority Populations for Vaccination with Vaccine Supply Resumption Memorandum to MOH and Hospital CEOs. February 14, 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 Vaccine Storage and Handling Guidance. June 24, 2021 6. Administration of Pfizer-BioNTech COVID 19 Vaccine. May 28, 2021. 7. 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. 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. Summary of National Advisory Committee on Immunization statement of June 17, 2021 10.

SIGNATURE AND DATE	Signature: *Original Signed By* Date: July 3, 2021

R: July 2021