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

| | |
|---|---|
| **DELEGATED PROCEDURE** | Delegation of Authority to:<br>☒ Prescribe a drug<br>☐ 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.<br><br>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.<br><br>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.<br><br>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.<br>• Absence of contraindication(s).<br>• **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]:<br>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. [11]<br>2. Individuals less than 12 years of age. The product monograph indicates that the safety and efficacy of Pfizer-BioNTech COVID-19 Vaccine in children under 12 years of age have not yet been established and NACI notes that Pfizer is authorized for use in Canada for individuals 12 years of age and older. However, the Province of Ontario has extended eligibility to the Pfizer vaccine to children born in 2009 or earlier. Starting on August 18, 2021, all children turning 12 years old before the end of 2021 are eligible for their first dose of COVID-19 vaccine based on the recommendation of the Chief Medical Officer of Health and health experts.<br>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 CONDITIONS** | Pfizer COVID-19 Vaccine is permitted for the following individuals under the *prescribed circumstances* described below:<br>1. 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.<br><br>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.<br><br>**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. [11]<br>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.<br><br>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.<br><br>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]<br><br>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.<br><br>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). [11]**<br><br>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.<br><br>**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]

**Bell's Palsy**

Very rare reports of Bell's Palsy following vaccination is noted as a post-market adverse reaction in the Pfizer-BioNTech product monograph.[1] Cases have been reported in a small number of people in Canada and internationally. The exact cause of Bell's Palsy is not known. Bell's Palsy is 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, 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.

**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]

<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]

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: For 3rd dose eligibility see the bottom of this table.

| **Age** | **First dose** | **Second dose** |
|---|---|---|
| Vaccination schedule for individuals born in 2009 or earlier (16 | 0.3 mL* IM | 0.3 mL* IM no sooner than 21 days after first dose and up to four months (112 days).<br><br>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 <u>first dose product</u>.**<br><br>See Moderna medical directive for further information.<br><br>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 <u>June 17 statement</u>, 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] |
| | 12 years and older | Third dose | A third dose should be offered at least two months after the second dose for the following groups of patients:<br>• Transplant recipients (including solid organ transplant and hematopoietic stem cell transplants.<br>• Those receiving treatment with an anti-CD20 agent such as rituximab, ocrelizumab, ofatumumab, commonly used for conditions such as multiple sclerosis, rheumatoid arthritis, leukemias/lymphoma etc.<br>• Individuals receiving active treatment (chemotherapy, targeted therapies, immunotherapy) for malignant hematologic disorders (e.g. acute myeloid leukemia, chronic myeloid leukemia, acute lymphoblastic leukemia, chronic lymphycytic leukemia). |

| | | | |
|---|---|---|---|
| | | | The exact timing should be decided with the treating provider in order to optimize the immune response.<br><br>A third dose should be offered at least five months after the second dose to the following groups:<br>• Residents of Long Term Care Homes, High-Risk.<br>• Retirement Homes and Elder Care Lodges. |

*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 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]<br><br><u>Thawed Vials Prior to Dilution</u><br>Vials may be thawed and stored at +2°C to +8 °C 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.<br>Do not refreeze thawed vials.[6,7]<br><br>Based on information from vaccine manufacturers, the Moderna and Pfizer-BioNTech COVID-19 vaccines at refrigerator temperatures may be rounded to the nearest whole degree:[13]<br>• Temperatures between +1.5°C and +1.9°C are rounded to +2.0°C<br>• Temperatures between +8.1°C and +8.4°C are rounded to +8.0°C<br><br>Moderna and Pfizer BioNTech 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 $COVAX_{ON}$ , troubleshooting should occur to ensure that temperatures are corrected and maintained between +2°C to +8°C. [13]<br><br>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 12 hour limit.[6]<br><br>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.<br><br><u>Vials After Dilution</u><br>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.<br><br>**<u>Non-medicinal ingredients</u>**:<br>• ALC-0315 = (4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)<br>• ALC-0159 = 2-[(polyethylene glycol*)-2000]-N,N-ditetradecylacetamide<br>• 1,2-distearoyl-sn-glycero-3-phosphocholine<br>• cholesterol<br>• dibasic sodium phosphate dihydrate<br>• monobasic potassium phosphate<br>• potassium chloride<br>• sodium chloride<br>• sucrose<br>• water for injection<br><br>*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.<br>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. August 4, 2021.<br>2. National Advisory Committee on Immunization (NACI): Recommendations on the Use of COVID-19 Vaccine(s). March 1, 2021; July 2, 2021.<br>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.<br>4. Vaccine Clinical Advisory Group (VCAG). Recommendations on Exceptions to Extended Dose Intervals for COVID-19 Vaccines. May 25, 2021 (or as current).<br>5. COVID 19 Vaccine Storage and Handling Guidance. June 24, 2021.<br>6. Administration of Pfizer-BioNTech COVID 19 Vaccine. May 28, 2021.<br>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.<br>9. Summary of National Advisory Committee on Immunization statement of June 17, 2021.<br>10. Sick Kids. June 16, 2021. FAQ – Reports of myocarditis/pericarditis after COVID-19 vaccination.<br>11. COVID 19 Vaccination Recommendations for Special Populations. Version 5.0. July 30, 2021.<br>12. Health Canada. August 6, 2021. Health Canada updates Pfizer-BioNTech COVID-19 vaccine label to reflect very rare reports of Bell's Palsy - Recalls and safety alerts (healthycanadians.gc.ca)<br>13. Ministry of health. August 5, 2021. – Guidance on Temperature Rounding for Moderna & Pfizer at Fridge Temperature<br>14. COVID 19 Vaccine Recommendations for Special Populations. Version 6.0. August 17, 2021.<br>15. News Release: Ontario Makes COVID 19 Vaccination Policies Mandatory for High Risk Settings. August 17, 2021<br>16. Memorandum to the Medical Officers of Health. From Dr Kieran Moore, Chief Medical Officer of Health of Ontario. Subject: Last Mile Strategy – School Based COVID 19 Vaccine Clinics. August 17, 2021.<br>17. Ontario's updated COVID-19 Vaccination Eligibility. August 17th, 2021 |
| **SIGNATURE AND DATE** | Signature: *Original Signed By* Date: August 18, 2021 |

R: August 2021