Ontario

Ministry of Health

Administration of Pfizer-BioNTech COVID-19 Vaccine

Version 6.0 – June 18, 2021

Highlights of changes

- Link to COVID-19 Vaccine Series Second Dose Eligibility Quick Reference (Page 3)
- Storage requirements updated to refer to the Vaccine Storage and Handling Guidance (Pages 4, 11-12)
- Side Effects Section updated to include international reports of pericarditis/myocarditis (Page 8)
- Updated Point of Care Guidance for alternate mRNA vaccine product (Page 10)

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment or legal advice.

In the event of any conflict between this guidance document and any applicable emergency orders, or directives issued by the Minister of Health, Minister of Long-Term Care, or the Chief Medical Officer of Health (CMOH), the order or directive prevails.

- Please check the Ministry of Health (MOH) COVID-19 website regularly for updates to this document

What is COVID-19?

COVID-19 is a novel coronavirus disease 2019 that is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Anyone can be infected with SARS-CoV-2 (COVID-19). However, some populations are at increased risk of exposure to the virus (e.g., due to living or work settings), and some populations are at increased risk of severe disease and death due to

biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., low socioeconomic status, belonging to a racialized population) factors.

Additional information about the Pfizer-BioNTech COVID-19 Vaccine can be found in the product monograph.

General Clinic Precautions

All staff working in the clinic must take appropriate infection prevention and control measures, including donning appropriate personal protective equipment (PPE) when interacting with clients as they move through the immunization clinic and when responding to any adverse events following immunization (AEFI).

The Vaccine

Pfizer-BioNTech COVID-19 Vaccine	
Type of vaccine	Messenger ribonucleic acid (mRNA)
Date of authorization in Canada	December 9, 2020 May 5, 2021 (for ages 12-15)
Authorized ages for use	12 years of age and older. The safety and efficacy in children under 12 years of age has not yet been established.
Dose	30 mcg of mRNA per **0.3 mL** (after dilution- see product monograph for choice of diluent and dilution instructions)

Schedule	2 doses	
	Minimum Interval[1]	19 days
	Authorized Interval[2]	21 days
Schedule	Recommended interval	4 months*^ To increase the number of individuals benefiting from the first dose of vaccine, the province is following recommendations from the National Advisory Committee on Immunization (NACI) to extend the second dose of COVID-19 vaccine up to **4 months** after receipt of the first dose. ^Certain population groups exempt from the extended dose interval are described here: COVID-19 Vaccine Series Second Dose Eligibility Quick Reference
Booster doses	At present, there is no evidence for an additional boosters after the 2-dose series	
Route of administration	Intramuscular (IM) injection into the deltoid muscle	
Nature of the antigen	Prefusion spike (S) glycoprotein	
Adjuvant (if present)	None	

[1] National Advisory Committee on Immunization (NACI). Recommendation on the use of COVID-19 vaccines

[2] Health Canada: Product Monograph Pfizer-BioNTech COVID-19 vaccine

Storage requirements	
Frozen vials prior to use	Must be stored at ultra-low temperatures (-80°C to -60°C) and protected from light, in the original packaging until ready to use. Updated guidance on short term storage options and transportation of frozen vials for local redistribution is available in the **Vaccine Storage and Handling Guidance.**
Vials prior to dilution (unpunctured vials)	Prior to dilution, thaw and store at +2°C to +8 °C for up to 31 days or at room temperature (up to +25°C) 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.
Vials after dilution (punctured vials)	After dilution, store between +2°C to +25°C and use within 6 hours from the time of first puncture. During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. After dilution, can be handled in room light conditions. Do not refreeze.
Formats available	Multi-dose vial (6 doses) preservative free
Usage limit post-dilution (post-puncture)	6 hours from time of dilution at +2°C to +25°C
Drug Interactions	No interaction studies have been performed.

Evidence on vaccine effectiveness for COVID-19 vaccines currently authorized for use in Canada continues to evolve. For up to date information on vaccine efficacy and effectiveness, please consult the National Advisory Committee on Immunization (NACI) statements and publications on the Health Canada webpage.

Who Should Delay Receiving the Vaccine

- Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, those with an acute illness, or those with symptoms of COVID-19 in order to avoid attributing any complications resulting from infection with SARS-CoV-2 or other illnesses to vaccine-related adverse events and to minimize the risk of COVID-19 transmission at an immunization clinic/venue. It would be prudent to wait for all symptoms of an acute illness to completely resolve before receiving the vaccine.
- Symptomatic and asymptomatic individuals who have been advised to self-isolate due to suspected or confirmed SARS-CoV-2 infection or due to close contact with a COVID-19 positive case should not attend a vaccine clinic and should wait to get their vaccine until their isolation period is over.
    - Note: Please refer to Guidance for COVID-19 Immunization in Long-Term Care Homes and Retirement Homes for specific guidance on vaccinating high risk contacts, those with symptoms or confirmed SARS-CoV-2 infection in long-term care and retirement homes.
- Individuals who have received another vaccine within the past 14 days
- Individuals who intend to receive another vaccine within 4 weeks of receiving the COVID-19 vaccine.
    - Anyone who receives a dose of a COVID-19 vaccine should wait 28 days before receiving another vaccine (except in the case when another vaccine is required for post-exposure prophylaxis).

Considerations for other patient groups

- The Pfizer-BioNTech COVID-19 vaccine can safely be given to persons with evidence of a prior SARS-CoV-2 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
    - Having prolonged COVID–19 symptoms (sometimes called Long COVID or Post-Acute COVID-19 Syndrome) is not a contraindication to receiving the COVID-19 vaccine.
        - If the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be

considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. Common side effects of the vaccine (e.g., fatigue, myalgia, arthralgia) may be similar to ongoing prolonged COVID-19 symptoms

- Information on immunizing special populations, including individuals who are breastfeeding or pregnant, individuals with allergies, individuals with autoimmune conditions, or individuals who are immunocompromised due to disease or treatment, is available in the Vaccination Recommendations for Special Populations guidance document. Point-of-care guidance for these individuals can be found in the COVID-19 Vaccine – Pre-Screening Assessment Tool for Health Care Providers .

Precautions during vaccination should be taken for:

- Refer to Vaccination Recommendations for Special Populations for information on vaccination for all patients with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine or vaccine components).
    - A component of the Pfizer-BioNTech COVID-19 vaccine that may rarely cause type I hypersensitivity reactions is polyethylene glycol (PEG). Due to potential cross-reactivity with PEG, allergies to polysorbate must also be considered.
        - Allergic reactions to PEG are rare. PEG is found in products such as prescription medications, bowel preparation products for colonoscopy, over the counter products (e.g. laxatives, cough syrups), cosmetics, dermal fillers, skin care products, products such as ultrasound gel, and contact lens care solution. PEG also can be found in foods or drinks but is not known to cause allergic reactions from foods or drinks.
        - Allergic reactions to polysorbates are rare. Polysorbates can be found in products such as medical preparations (such as vitamin oils, tablets, and anticancer agents) or cosmetics among others.
- Individuals who fainted or became dizzy after receiving a vaccine or medical procedure, or those with high levels of fear about injections can receive the

vaccine. To reduce injuries due to fainting, they should be immunized while seated, or if considered at high-risk, while lying down. These individuals are also advised they may bring a support person.

- Individuals who have a bleeding disorder, bruise easily or are taking blood-thinners can safely receive the vaccine. 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 optimally managed prior to immunization to minimize the risk of bleeding.
    - There is some evidence to suggest that IM administration with a small gauge needle (23 gauge or smaller) may be preferred to minimize the risk of bleeding, with firm pressure applied to the injection site for 5 to 10 minutes.

For more detailed recommendations on people with allergies, as well as breastfeeding or pregnant individuals, individuals with autoimmune conditions, or individuals who are immunocompromised due to disease or treatment, please consult the Vaccination Recommendations for Special Populations guidance document.

Side effects

The Pfizer-BioNTech COVID-19 vaccine, like medicines and other vaccines can cause side effects. In clinical trials most of the side effects experienced were mild to moderate and on average did not last longer than three days. Please see the product monograph for a complete list of reported side effects.

Very common side effects	May affect more than 1 in 10 people	• Pain at injection site • Fatigue • Headache • Muscle pain • Chills • Fever (common after first dose for adults)
Common side effects	May affect 1 to less than 10 in 100 people	• Localized redness or swelling at injection site • Joint pain (very common after second dose) • Diarrhea • Nausea and/or vomiting (uncommon after first dose for adults)
Uncommon side effects	May affect up to 1 in 100 people	• Enlarged lymph nodes

Source: National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.

There have been international reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines, including Pfizer-BioNTech vaccine. Available information indicates that cases have been mild, occuring more commonly after the second dose of vaccine and more often in male adolescents and young adults. Symptoms have been reported to start within several days after vaccination. This situation is being monitored closely in Canada and internationally. Based on reports received to date, the Public Health Agency of Canada (PHAC) and Health Canada are not seeing higher rates than would normally be expected in the

population. To date, **no clear causal association has been established between myocarditis/pericarditis and mRNA vaccines.** mRNA COVID-19 vaccines continue to be recommended in all eligible individuals in Canada and in other countries where these mRNA vaccines are being used. For more information consult Public Health Ontario's Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines resource and the Myocarditis/Pericarditis FAQ resource for Health Care Providers resource from SickKids.

Adverse Events Following Immunization

All health care providers administering vaccines must be familiar with the anaphylaxis protocols for their clinic sites and ensure availability of anaphylaxis management kits (refer to the Public Health Ontario resource on the Management of Anaphylaxis Following Immunization in the Community and the Canadian Immunization Guide for additional information).

Those administering vaccines should ensure that the vaccine recipients or their parents/guardians are advised to notify clinic staff, or if they have left the clinic, call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop any of the following symptoms:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40 °C or 104 ° F)
- Convulsions (seizures)
- Other serious reactions

Guidance on reporting adverse events following immunization (AEFI) for health care providers

- Health care providers administering vaccines are required to inform vaccine recipients or their parent/guardian of the importance of immediately reporting adverse events following immunization to a physician or nurse in accordance with Section 38 of the *Health Protection and Promotion Act* (HPPA). Vaccine recipients or their parent/guardian may also contact their local public health unit to ask questions or to report an adverse event following immunization.

- Specified health care providers (e.g., physicians, nurses and pharmacists) have a duty under s.38 of the HPPA, to report adverse events following immunizations (AEFIs) to their local public health unit. Reports should be made using the Ontario AEFI Reporting Form.
- See Public Health Ontario's vaccine safety webpage and Fact Sheet - Adverse Event Following Immunization Reporting For Health Care Providers In Ontario (publichealthontario.ca) for additional guidance.
- The Ontario Ministry of Health in collaboration with Public Health Ontario monitors reports of AEFIs. This monitoring is done in collaboration with the Public Health Agency of Canada and Health Canada.

Point-of-care Guidance

- The Pfizer-BioNTech COVID-19 is a two-dose series. Individuals may not be optimally protected until up to 2 weeks after their second dose of vaccine. It is essential to complete the vaccine series to boost the initial immune response and because it is anticipated to provide protection in the long term.
- Do not mix the Pfizer-BioNTech COVID-19 vaccine with other vaccines/products in the same syringe.
- Pfizer-BioNTech COVID-19 vaccine should not be given simultaneously with other live or inactivated vaccines (except in the case when another vaccine is required for post-exposure prophylaxis).
- The National Advisory Committee on Immunization (NACI) recommendations on the use of a different COVID-19 vaccine product to complete a COVID-19 vaccine series is being followed in Ontario:
    - NACI recommends that, if readily available*, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine.
    - However, when the same mRNA COVID-19 vaccine product is not readily available*, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered and should be offered to complete the vaccine series.
    - The previous dose should be counted, and the series need not be restarted.

    *readily available = easily available at the time of vaccination without delay or vaccine wastage

- In alignment with NACI recommendations, an mRNA COVID-19 vaccine product may be offered for the subsequent dose in a vaccine series started with an AstraZeneca/COVISHIELD COVID-19 vaccine. The previous dose should be counted, and the series need not be restarted. For more information on second doses for individuals who received a first dose of the AstraZeneca/COVISHIELD COVID-19 vaccine, please see the AstraZeneca/COVISHIELD COVID-19 Vaccine Second Dose Q&A for Health Care Providers document and COVID-19 Vaccine Information for Individuals who received a first dose of the AstraZeneca/COVISHIELD COVID-19 vaccine.

- When a different vaccine product is used to complete the vaccine series, the earliest interval at which the vaccine can be given is the Health Canada product monograph authorized interval of the vaccine used for the first dose (i.e. 21 days where Pfizer-BioNTech is a first dose, 28 days where a Moderna COVID-19 vaccine is a first dose, and 4-12 weeks where AstraZeneca/COVISHIELD COVID-19 vaccine is a first dose). For current guidance on second dose eligibility and intervals, consult the COVID-19 Vaccine Series Second Dose Eligibility Quick Reference.

Vaccine Preparation:

Additional information on vaccine preparation and transport can be found in the product monograph and the COVID-19: Vaccine Storage and Handling Guidance

- The Pfizer-BioNTech COVID-19 vaccine multiple dose vial contains a frozen suspension that does not contain preservative and **must be thawed and diluted prior to administration.** See the COVID-19: Vaccine Storage and Handling Guidance for details.
- Once thawed, unpunctured vails may be stored for up to 31 days at +2 °C to +8 °C or at room temperature (up to +25 °C) for no more than 2 hours.
    - Appropriate labelling including "must use by dating/timing" can provide visual cues to indicate product viability of use.
- Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.
- Before dilution, the vial must be inverted gently 10 times to mix the vaccine. **Do not shake.**
- The contents of the vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP. ONLY use 0.9% Sodium Chloride Injection, USP as the

diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

- After dilution, the vial containing the Pfizer-BioNTech COVID-19 vaccine should be gently inverted 10 times to mix. **Do not shake.**
- The vaccine is authorized as a 6-dose vial. The following is recommended:
  - Ensure the correct amount of diluent is added to the vial (1.8 mL)
  - Draw up the full dose (0.3 mL)
- For guidance on what to do when there is leftover solution in the vial or if more than 6 doses can be obtained, please see the Vaccine Storage and Handling Guidance document.
- After dilution, the vaccine will be an off-white suspension. Inspect vial to confirm there are no particulates and no discolouration is observed.
- The time and date of dilution must be recorded on the vial label and the vial must be stored between +2°C to +25°C. Post-puncture (after dilution), vials are to be used within 6 hours (stored at +2°C to +25°C). Any unused vaccine must be discarded 6 hours after dilution.
- Strict adherence to aseptic techniques must be followed.

Vaccine Administration:

- It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Safety engineered needles must be used as required under O. Reg. 474/07 made under the *Occupational Health and Safety Act*.
- Refer to the Canadian Immunization Guide, Table 3: Needle selection guidelines for assistance in selecting appropriate needle length and gauge.
- Visually inspect each dose in the dosing syringe prior to administration. The diluted vaccine will be an off-white suspension.
- During the visual inspection:
  - Verify the final dosing volume of **0.3 mL**, and
  - Confirm there are no particulates and that no discolouration is observed.
- **If the visual inspection fails, do not administer the vaccine**.
- Administer Pfizer-BioNTech COVID-19 vaccine intramuscularly in the deltoid muscle.
- Do not inject the vaccine intravascularly, subcutaneously or intradermally.

All clients should be reminded to continue to practice recommended public health measures for prevention and control of COVID-19 infection and transmission regardless of receipt of COVID-19 vaccine.

Information on vaccine storage, stability and disposal can be found in the Vaccine Storage and Handling Guidance document.