

## COVID-19 Vaccine: Update #1

**Attention:** Physicians, Emergency Departments, Infection Control Practitioners, Occupational Health Practitioners, Walk-In Clinics/Urgent Care Clinics, Nurse Practitioners, EMS, Designated Officers, Midwives, Family Health Teams, Pharmacies, Central LHIN, NSM LHIN, Beausoleil First Nation, Moose Deer Point First Nation, Rama First Nation, Wahta First Nation, Long-term Care Homes, Retirement Homes, Hospices

**Date:** December 15, 2020

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As information is becoming more available on the upcoming COVID-19 vaccine campaign in Ontario, we wanted to provide an update on what we know so far:

- On December 9<sup>th</sup>, the first COVID-19 vaccine, Pfizer-BioNTech COVID-19 vaccine (COVID-19 mRNA vaccine), was authorized for use by Health Canada.
- This vaccine has unique storage and handling requirements as it must be stored at -60°C to -80°C and cannot be transported for administration. Therefore, at this time people will need to attend specific vaccination sites to receive this vaccine.
- There are currently three other COVID-19 vaccines being reviewed by the regulators, of which a second product by Moderna is anticipated to be approved for use in the coming weeks. While the Moderna vaccine requires freezer storage, it can be more readily transported.

Ontario has developed a three-phase implementation plan for its COVID-19 vaccination roll out. Phase one of the COVID-19 vaccine program in Ontario will target the following groups:

- Residents, staff, essential caregivers, and other employees of congregate living settings (e.g., long-term care homes and retirement homes) that provide care for seniors as they are at higher risk of infection and serious illness from COVID-19;
- Health care workers, including hospital employees, other staff who work or study in hospitals, and other health care personnel;
- Adults in indigenous communities, including remote communities where risk of transmission is high;
- Adult recipients of chronic home health care.

A pilot project is set to begin on Tuesday December 15<sup>th</sup> in Toronto and Ottawa, which will include the vaccination of over 2,500 health care workers, primarily long-term care home staff.

An additional 90,000 doses of the Pfizer-BioNTech vaccine is expected to be received by the end of December, and will be delivered to up to 14 hospital sites in Grey-Lockdown and Red-Control zones, to vaccinate health care workers in hospitals, long-term care homes, retirement homes and other congregate settings caring for seniors. 35,000 to 85,000 doses of the Moderna vaccine are also expected in the coming weeks, pending approval for use by Health Canada, which will enable vaccinations to be expanded to long-term care homes in the Grey-Lockdown areas.



In early 2021, expansion of additional hospital sites providing the Pfizer-BioNTech vaccine in Grey-Lockdown and Red-Control zones, with continued vaccination provided to health care workers and, with the appropriate safety protocols, to long-term care home and retirement home residents. It is anticipated that by end of January over 20 hospitals across the province will be administering the Pfizer-BioNTech vaccine.

**While we have not received confirmation of when and how much vaccine will be received in Simcoe Muskoka, we have begun planning for the rollout of this vaccine when it arrives.**

The first two vaccine products that are front runners to be used in Canada, the Pfizer-BioNTech vaccine and the Moderna/NIAID vaccine, are both mRNA vaccines. And while mRNA vaccines have been being studied for a number of years and been used for other treatments, these will be the first two mRNA vaccines licensed for use in humans. **Health care providers will play a key role in educating their clients and patients to ensure that people are confident in the safety and efficacy of this vaccine, which is critical to the success of this vaccine program.**

**What are messenger RNA (mRNA) vaccines?**

- Messenger RNA are strands of genetic material that direct protein production in cells.
- Scientists have developed mRNA that directs cells to produce proteins that imitate those found in SARS-CoV-2.
- When the mRNA vaccine is injected into the body, the cells use it to make viral proteins (antigens).
- The viral proteins trigger immune cells which lead to the production of antibodies.
- In the past, mRNA technology has been focused on cancer, with tumour mRNA being used to help people’s immune systems recognize and respond to the proteins produced by their specific tumours.
- mRNA vaccines are a promising alternative to conventional vaccine approaches because of high potency and the capacity for rapid and safe administration.
- mRNA vaccines to date, come with logistical challenges for delivery due to vaccine storage and handling requirements needed to keep the vaccine stable.

	<b>Pfizer-BioNTech</b>	<b>Moderna/NIAID</b>
Long-term storage temp.	-80°C to -60°C	-20°C
End-stage storage in refrigerator	Up to 5 days	Up to 30 days
Dosing schedule	2 doses, 21 days apart	2 doses, 28 days apart
Route of administration	Intramuscular	Intramuscular
Effectiveness*	95% effective across diverse subgroups	94.5% effective across diverse subgroups

\*Based on Phase 1/2 studies and preliminary phase 3 data

**Key Information about the Pfizer-BioNTech COVID-19 vaccine**

According to the National Advisory Committee on Immunization (NACI) Pfizer-BioNTech COVID-19 vaccine should not be administered to the following groups until further evidence is available on its use in these groups:

- Those who are pregnant or breastfeeding
- Those under 16 years of age
- Those with auto-immune disorders
- Those who are immunosuppressed due to disease or treatment

COVID-19 vaccines are not interchangeable. This is why in Ontario the second dose is being set aside for each person vaccinated to ensure they have vaccine to complete their series with the same product.

Currently there is no evidence available to support the efficacy of this vaccine in preventing asymptomatic infection, reducing viral shedding or in prevention of transmission of the COVID-19 virus. Therefore it is important that people continue to practice public health measures to decreased transmission even after they are vaccinated.

- Protection offered from the first dose is lower than the efficacy achieved after the second dose. In most people, a cellular immune response is achieved by one week after the second dose.
- People who have had previous COVID-19 infection can be immunized, but initial doses may be prioritized for those who have not had previous infection.

Pfizer-BioNTech COVID-19 vaccine should not be given simultaneously with other live or inactivated vaccines at this time, unless other vaccines are required for post-exposure prophylaxis.

- In the absence of evidence it would be prudent to wait for a period of at least 28 days after the administration of the complete 2 dose series before receiving any other vaccine. And for those who have received a vaccine recently, it would be prudent to wait at least 14 days to receive COVID-19 vaccine.
- COVID-19 vaccine should not be given simultaneously with monoclonal antibodies or convalescent plasma. There is insufficient evidence on the potential interference of COVID-19 vaccine and any monoclonal antibodies therefore expert opinion should be sought on a case by case basis.

### Vaccine Safety

No serious safety concerns were identified in the clinical trials. Studies are ongoing.

Very common adverse events (occur in 10% or more of vaccinees)	Pain at the injection site – more than 80% experienced this, and more frequent in those less than 56 years  Fatigue, headache, muscle pain, chills, joint pain and fever <ul style="list-style-type: none"> <li>• more than ½ experienced headache and/or fatigue</li> <li>• more frequent after the 2<sup>nd</sup> dose and in those less than 56 years</li> </ul>
Common adverse events (occur in 1% to less than 10% of vaccinees)	Redness and swelling at injection site
Uncommon adverse event (occur in 0.1% to less than 1% of vaccinees)	Lymphadenopathy

The probability of detecting a rare or very rare (occurring in less than 0.1% of vaccinees) adverse events in clinical trials is low given clinical trial population sizes. Therefore ongoing vaccine safety monitoring is critical, as it is with all vaccines, as the vaccine is used in larger numbers of people to be on alert for any safety signals.

There are a number of COVID-19 resources and documents available through our Health Professional Portal at [www.smdhu.org/hpportal](http://www.smdhu.org/hpportal) as well as through [Public Health Ontario](http://www.publichealthontario.ca/)<sup>i</sup> and the [Government of Ontario](http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/2019_guidance.aspx).<sup>ii</sup>

<sup>i</sup> <https://www.publichealthontario.ca/>

<sup>ii</sup> [http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/2019\\_guidance.aspx](http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/2019_guidance.aspx).