December 18, 2020

UPDATE TO ALL FAMILY AND FRIENDS

Hello, today St. Pat's remains Covid19 free. As you have seen in the news we have been fortunate enough to be one of the first 10 homes for staff to receive the vaccine. Today is the final day of this allotment of the vaccine at this time. We are hopeful that the next shipments will be available soon. Again, as soon as we know anything about when and how the families and residents will receive an opportunity to get the vaccine we will let everyone know.

Today we have attached some information on vaccines in general as well as the Pfizer vaccine that has been approved in Canada and the vaccine that is available right now. We would anticipate that the vaccine for resident use would be Moderna, not the Pfizer vaccine, which although a different vaccine shares the mRNA delivery mechanism. Once we know what and when we will provide further information. This information is being provided now to start the discussion and give everyone some information for their decision making. Today we have been asked to provide the total number of designated caregivers to Ottawa Public Health to facilitate their planning of vaccination clinics in the future. We may be provided with access to a vaccine without a lot of notice and would like you to be prepared!

Christmas is right around the corner. The celebration this year has been and will be very different however the Christmas Pyjama and Hot Chocolate day was great on Wednesday! We are all adjusting to a modified Christmas both at St. Pat's and in our own celebrations just like you are at home.

On Christmas Day, there will be a broadcast of Mass at the usual time for residents to tune into.

We will be serving a full turkey dinner at both lunch and dinner so that everyone has the opportunity to have a Christmas dinner in the dining room. Families who are here during a meal time in the dining room can join your loved one but we cannot offer the meal to you as you must keep your mask and eye protection on while here.

Designated caregivers are able to visit as per the guidelines in place due to Ottawa remaining in the orange-restrict category, which means that one of the two designated caregivers can visit at a time. Both designated caregivers can visit during the day just not at the same time. The weekly Covid19 test result is still a requirement at this time, and we anticipate it will continue throughout the Christmas season.

The residents who do not have a designated caregiver who is able to visit due to distance and who have been receiving virtual visits throughout the fall, will be able to schedule one virtual visit on Christmas Day. Recreation staff who have been doing these visits will be connecting with those people to determine a schedule of calls on Christmas Day for those who would like to have a virtual call. The nursing staff and support staff will be facilitating these calls.

We appreciate designated caregivers who have been facilitating virtual calls with the other members of your family and would ask that you make these virtual calls on Christmas Day as well. We will focus on those who do not have someone designated to visit.

Be well and stay safe,

Janet Morris
President and CEO

Ministry of Health

COVID-19 Vaccine Approval Process and Safety

Version 1 – December 12, 2020

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

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

The Government of Canada has prepared for months to ensure Canadians will have access to safe and effective vaccines against COVID-19. It has achieved this by carefully reviewing all of the scientific data and evidence for the vaccines, working on distribution plans, and accelerating purchases of the vaccines.

What you should know:

- **Ontarians can be confident.** Standards of safety, efficacy, and quality have not been compromised to expedite the approval of COVID-19 vaccines.
- **Health Canada oversight of COVID-19 vaccines will NOT stop at approval**. Monitoring of the vaccine's safety and effectiveness will continue now and into the future.

How can a vaccine be developed so quickly, when it usually takes years?	The development of vaccines for COVID-19 is progressing quickly for many reasons, including: ● Reduced time delays in the vaccine approval process ● Quick adaptation of existing research programs such as those focusing on mRNA- and viral-vector-based technology. ● International collaboration among scientists, health professionals, researchers, industry and governments. ● Increased dedicated funding. ● Quick recruitment of participants for clinical trials. ● Rapid set-up of clinical trials to demonstrate effectiveness of the vaccine.

The expedited process

On September 16, 2020, the Minister of Health signed an Interim Order (IO) introducing temporary regulatory pathway for COVID-19 related drugs and vaccines. The IO Provided greater flexibility and a more agile review process, which allows for the issuance of an expedited authorization of COVID-19 related vaccines without compromising patient safety.

Introduced under the Interim Order, a rolling review allows a drug manufacturer to submit their request for authorization before they have completed all phases of clinical trials. Health Canada begins its review right way using the information submitted by the applicants and accepts new evidence as it becomes available, until the application is deemed complete.

When a submission is received, Health Canada's clinical reviewers thoroughly review the submission by ensuring that the benefits of the vaccine outweigh the potential risks and have assurances that the product is manufactured in a licensed facility that is up to Health Canada standards.

A submission contains data from scientific studies and information about the manufacturing processes, including:

- Pre-clinical studies – toxicology studies and other studies in animals
- Pre-clinical studies – toxicology studies and other studies in animals
- Clinical studies – all phases of clinical trials in humans, including safety and efficacy data
- Manufacturing data – information about how the vaccine is made, and the processes in place to make it consistently

Vaccine safety

At the federal level, Health Canada and the Public Health Agency of Canada (PHAC) share the responsibility for ongoing monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry, international regulators and the public.

Pre-market scientific review	• Demonstrate that the vaccine can protect against disease. • Determine from the safety and efficacy review, that the benefits outweigh the risks and there are no safety concerns. • Put in place a plan to minimize any potential risks (e.g. having the manufacturer monitor for adverse events, requiring reporting to Health Canada).

Post-market surveillance	• **Health care providers** report adverse events to their local public health authority.
	• **Provincial and Territorial Public Health Authorities** report to PHAC's surveillance system. Public Health Ontario's program leads the surveillance of adverse events following immunization in Ontario. See their website for details: Vaccine Safety | Public Health Ontario.
	• **Health Canada:**
	  ○ Monitors safety and effectiveness of vaccines authorized for sale in Canada and can require further risk mitigation measures and additional safety information from the vaccine manufacturer.
	  ○ Monitors vaccine-related events in Canada and internationally.
	• **Public Health Agency of Canada**:
	  ○ The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is managed by PHAC and is an FPT post-market vaccine safety monitoring system that includes spontaneous, enhanced and active AEFI reporting processes.
	• **Manufacturers** monitor the safety and effectiveness of their products.
	  ○ For example, Pfizer-BioNTech is conducting clinical trials and following their participants for at least two years following the administration of the second dose of the vaccine. Should concerns arise, Pfizer-BioNTech is legally obligated to communicate this information to Health Canada.

Ministry of Health

COVID-19 About Vaccines

Version 1 - December 12, 2020

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

- Please check the Ministry of Health (MOH) COVID-19 website regularly for updates to this document, list of symptoms, other guidance documents, Directives and other information.

COVID-19 Vaccines: Overview

Representing a turning point in our fight against COVID-19, Health Canada has authorized the Pfizer-BioNTech mRNA vaccine. More vaccines will likely be authorized in the near future.

What you should know:

- Health Canada only approves a vaccine if it is supported by very robust scientific data and evidence.
- After approval, Health Canada and the Public Health Agency of Canada continue to monitor the ongoing safety and effectiveness of all approved vaccines.
- Canadians will have easy access to detailed information on the vaccine and the evidence behind the vaccine approval process through the Government of Canada's website.
- The benefits of vaccination greatly outweigh the risks, and many more illnesses and deaths would occur without vaccines. Vaccines prevent illness and disease and save lives and livelihoods. Mass vaccination will protect people's lives and help Canada recover from the COVID-19 pandemic.

After more than a decade of research and development on mRNA vaccines, this vaccine is the first mRNA vaccine approved for use in humans. To date, mRNA has been successfully used in cancer treatments, and research into its value for vaccinations has been ongoing for over ten years.

How does vaccination work?

mRNA vaccines	Use genetic instructions in molecules called mRNA to generate a coronavirus protein that initiates the body's natural production of antibodies and cellular immune response. mRNA vaccines are not live vaccines and cannot cause infection in the host. mRNA vaccines also cannot alter a person's DNA.
Viral vector vaccines	Use a genetically engineered virus that cannot cause disease but can produce coronavirus proteins to generate an immune response in the body.
Protein-based vaccines	Use harmless fragments of proteins or protein shells that mimic a coronavirus to generate an immune response in the body.
Inactivated or weakened virus vaccines	Use an inactivated or weakened form of the virus so it does not cause disease but does still generates an immune response in the body.

The Pfizer-BioNTech mRNA vaccine

The Pfizer-BioNTech mRNA vaccine is highly efficacious in the short-term against laboratory-confirmed symptomatic COVID-19 disease; trials are ongoing. The Pfizer-BioNTech mRNA vaccine is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2.

Clinical trial details

Participants	Of the clinical trial participants: ● Over 40,000 doses were administered. ● 42.3% of participants were aged 55 and older. ● 17% of participants were of diverse racial and ethnic backgrounds. ● 46.2 % of participants had pre-existing stable medical conditions (disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrolment) such as asthma, obesity, chronic lung disease, diabetes and high blood pressure. ● Participants with known stable infection were included, including those with HIV, hepatitis B, and hepatitis C virus.
Time followed	● At the time of the final primary efficacy analysis, participants had been followed for symptomatic COVID-19 disease for a median of 2 months, corresponding to 2,214 person-years for the Pfizer-BioNTech COVID-19 vaccine and 2,222 person-years in the placebo group. ● Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19 disease.
Protection	● Based on the results of the clinical trials, the best protection is not achieved until 7 days after the second dose, but it remains unknown how long the protection will last.
Efficacy	● Highest efficacy and immune response were observed after the second dose. ● Limited data on protection provided for only one dose. ● Efficacy was consistent across age groups for two-doses. ● Adverse events were generally milder and occurred less often in those 56 years of age and older. ● No difference in efficacy was observed between men and women or across different age groups, races or ethnicities. However, the size of groups for some comparisons were small.

Side effects

Like all vaccines, Pfizer-BioNTech COVID-19 Vaccine can cause side effects. Those observed during the clinical trials were commonly reported side effects of vaccines and do not pose a health risk.

- The most frequent adverse reactions were mild or moderate and resolved within a few days after vaccination.
- No major safety concerns were reported in the data submitted to Health Canada.

Very common side effects (may affect more than 1 in 10 people)	**Uncommon side effects** (may affect up to 1 in 100 people)
• Pain at injection site (84.1%*) • Fatigue (62.9%*) • Headache (55.1%*) • Muscle pain (38.3%*) • Chills (38.3%*) • Joint pain (38.3%*) • Fever (38.3%*) *subset (n=8183)	• Enlarged lymph nodes (0.008%*) *subset (n=7960)

FAQ's

Can recipients contract the coronavirus from this vaccine?	**No.** This is not a live vaccine and does not contain the virus; therefore, the vaccine cannot give recipients infection or disease (COVID-19).
Will this vaccine alter the recipient's DNA?	**No.** This vaccine does not affect, interact or alter DNA in any way. Our DNA resides in the nucleus of our cells and the mRNA does not travel into the nucleus. Therefore, there is no risk of altering DNA. It uses the body's natural defense response which breaks down and gets rid of the mRNA after it is finished using the harmless genetic instructions.

Do recipients of the vaccine still need to follow public health guidance (masking and distancing) after receiving the vaccine?	**Yes.** There is insufficient evidence at this time on the effectiveness of COVID-19 vaccines in preventing asymptomatic infection and reducing transmission of SARS-CoV-2.
If the patient gets mild side effects, should they receive the second shot?	**Yes.** Mild side effects are common for all vaccines and typically resolve in a few days. It is important to receive both doses. Protection offered by the first dose is lower than the efficacy achieved after the second dose.