March 16, 2021

Dear Fellow Canadians:

We are four faculty members at the University of Guelph. Dr. Byram Bridle is a viral immunologist, Dr. Sarah Wootton is a virologist, and Drs. Mallard and Karrow are immunologists. Generally, policies for COVID-19 have been generated after consultations focusing mainly on the opinions of physicians, epidemiologists, and other public health experts. However, at its core, COVID-19 is a problem at the interface of immunology and virology, both in terms of its pathogenesis and the primary solution being sought, which is acquisition of immunity against the virus SARS-CoV-2. In addition to our group having in-depth knowledge of these fields, Drs. Bridle and Wootton have received funding from the federal government and the government of Ontario to develop vaccines for COVID-19. As such, our group has extensive expertise in this area.

Early in the pandemic, the goal was to 'flatten the curve' of documented cases of COVID-19 by implementing a lockdown for a few weeks; this was to facilitate hospitals being able to support us in learning how to live with SARS-CoV-2 without medical resources becoming overwhelmed. Although never clearly stated, the goal seems to have morphed into a 'zero tolerance policy' in which life will not return to normal until daily cases have been eliminated. The large amount of available scientific data suggests this will not be a feasible goal. Indeed, COVID-19 will almost certainly become endemic, akin to the annual outbreaks of influenza viruses.

Among the many reasons for this virus becoming endemic is the propensity of SARS-CoV-2 to mutate over time, which will result in the ongoing emergence of novel variants, and this problem is exacerbated by the fact that current vaccines against SARS-CoV-2 confer overly-focused immunity that targets a single protein known as the spike. These two major issues will combine to potentiate SARS-CoV-2 being able to escape vaccine-induced immunity. Indeed, this has already happened as demonstrated by the AstraZeneca vaccine failing in a clinical trial in South Africa against the South African variant, which is already circulating in Canada.

It has become clear that we can't continue to rely on continual lockdowns due to the impact on mental health, delays to other medical treatments, a sinking economy, and so on. Instead, we must return to the original goal of learning to live with this virus while maximizing the health and safety of our communities. It is also important to remember that the majority of cases of COVID-19 in Canada are mild-to-moderate, and the death rate has been quite low (22,514 deaths out of 914,697 cases or 592/million as of March 16 2021 - Coronavirus Dashboard [ncov2019.live]). Sadly, at least 70% of those deaths have been in people over 80 years of age, in long-term care (Dr. R. Bibby, Sociologist, University of Lethbridge; http://www.reginaldbibby.com/specialcovid19analyses.html). On the upside, there is now also good evidence that the majority of those recovered from COVID-19 have protective immunity (reviewed by Sette and Crotty, Adaptive immunity to SARS-CoV-2 and COVID-19, Cell (2021), DOI: https://doi.org/10.1016/j.cell.2021.01.007).

It is from this perspective that we have been advocating for several core strategies to support re-opening our country to in-person work and learning. An important aspect of this is offering strategically prioritized vaccinations. Specifically, we have been advocating for the administration of safe and **effective** COVID-19 vaccines **according the protocol that was used to have them approved** for emergency use, until further data is available and reviewed and approved by Health Canada to support alternative protocols. In support of this goal, we have two recommendations:

1. Consideration should be given to avoiding the use of the AstraZeneca vaccine, for which there is documented evidence of it being ineffective against the South African variant of SARS-CoV-2, which we reiterate is now in Canada. Specifically, it was shown to be only 10% effective against the South African variant, with the cut-off for approval being 50%. It has also proven to be less effective in a head-to-head comparison with Pfizer's vaccine (https://www.cell.com/cell/pdf/S0092-8674(21)00226-9.pdf). Additionally, its use has been suspended in at least ten European countries until undesirable potential side-effects can be further investigated. For Ontarians, the Chief Medical Officer definitively stated in a letter to pubic health units in the province that individuals may opt out of receiving the AstraZeneca vaccine on the basis that it is admittedly of lower efficacy than the others (see the highlighted text on page 2 of the attached letter).

2. The intervals for the two-dose COVID-19 vaccines should adhere to what was officially approved by Health Canada and the manufacturers, which is 21- and 28-days for the Pfizer and Moderna vaccines, respectively. The rationale for this is presented below…

The history of Canada's move to extend COVID-19 intervals to an unprecedented four months.

Last week, the CBC launched a story to highlight the path that has led many jurisdictions in Canada to begin implementing an interval of up to four months for both the Pfizer and Moderna COVID-19 vaccines (https://www.cbc.ca/news/health/canada-covid-19-vaccine-delay-risk-1.5939134). It apparently began with a letter from an epidemiologist at the British Columbian Centre for Disease Control to the editor of *The New England Journal of Medicine* (https://www.nejm.org/doi/full/10.1056/NEJMc2036242). In this letter it was claimed that Pfizer failed to realize the efficacy of its own vaccine and that its effectiveness as a single-dose regimen is actually a remarkable 92%. It is important to note that this is based on an extrapolation of a statistically underpowered, biased, limited data set from a trial that was never designed to test single-dose efficacy. Further, the extrapolation required several assumptions to be made that may or may not be true; there simply is no empirical data to know either way.

What many do not realize is that the researchers for Pfizer published a rebuttal to this letter in which they stated: "**In response to Skowronski and De Serres**: we would like to emphasize that **alternative dosing regimens of BNT162b2 have not been evaluated**." Pfizer's own data has suggested that single-dose effectiveness might be just over 50%, with their admission of the caveat that their study was never designed to test this properly. Nonetheless, the idea that extended intervals will work well is being propagated, despite a lack of empirical evidence. Indeed, Dr. Bridle has confirmed via interviews with people coming out of local vaccine clinics that some of them are being told that a single dose has been shown to be 92% effective based on 'published data'. This is simply untrue and not the way science is supposed to work. The validity of alternative protocols is up for debate in the scientific community.

Any intervals that deviate from what Health Canada and the vaccine manufacturers have agreed to, represents experimentation, especially in the absence of any new validated data from a phase 3 clinical trial. However, in Ontario and many other jurisdictions in Canada, the change in the vaccine interval has been proposed. See the attached letter from Ontario's Chief Medical Officer as an example of this. In short, the intervals have been lengthened without sufficient empirical data to justify it. In contrast, the intervals provided by Health Canada are based on empirical data. The effectiveness of the two-dose regimens with 3- or 4-week intervals is known. The effectiveness of the two-dose regimens with any other interval is a 'best guess'. This background leads into a potentially more serious issue regarding informed consent...

Is informed consent being practiced properly in COVID-19 vaccine clinics?

In Ontario, the attached consent form should be hard-signed by everybody prior to receiving one of the experimental vaccines. Please note that this form requires a person to have read or to have read to them the vaccine information sheet (see the highlighted text on page 3 of the consent form). Please note the highlighted text on pages 4 and 6 of the vaccine information sheet that is appended to this letter. Consent is being given to receiving the dose at Health Canada's recommended interval of 3- (Pfizer) or 4-weeks (Moderna). No alternative intervals are described. Remarkably, however, many (if not most) attendees at the COVID-19 vaccine clinics are being told after receiving their first dose (*i.e.* once they are committed to the treatment) that they will likely have to wait up to four months to receive the second dose. **People are consenting to the 3-4-week interval** (3 weeks for Pfizer's vaccine; four weeks for the Moderna vaccine) **but are then being told that they cannot receive the second dose for another four months**. For those who would like to insist on receiving their vaccine as per Health Canada's recommended interval, we suggest you take a hard-copy of the vaccine information sheet to the clinic and have

them confirm that they will adhere to the protocol you are consenting to prior to letting them administer the first dose.

Why might the interval for two-dose vaccines matter?

Some proponents of lengthening the interval argue there can be no harm. However, there is some scientific basis for suggesting that lengthening intervals could cause harm: 1. The companies themselves suggest a single dose is significantly less efficacious than two doses. This could put individuals at prolonged risk of getting infected while waiting for the second dose. This could be a particular problem for those who are at high risk. 2. It is unknown if the duration of immunity (i.e. how long a person is protected) conferred by a single dose extends to four months; it is possible that there may be no protection at this point. 3. It is unknown if immunological memory conferred by the first vaccine will last long enough for a second dose, given four months later, to serve as a proper 'booster vaccine'. If a proper boost is not conferred, the two-dose effectiveness could be reduced below the 95% effectiveness shown with the approved interval. 4. Induction of long-term, relatively weak immunity could potentially promote the emergence of immune-evasive mutants. This would be similar to what has been observed over and over again with the emergence of dangerous antibiotic-resistant bacteria; it is potentiated by the misuse of the therapeutic agents designed to effectively treat the pathogens. Promotion of immune-evasive SARS-CoV-2 would put everyone at greater risk. Although these are cautionary possibilities, **they are no less valid than the speculations that led to adopting untested long intervals**. Given these are novel nucleic acid vaccine platforms, approved for emergency use only, it might be wise to err on the side of caution. The take-home message is: Longer intervals might be OK, but they also might create problems. We simply don't know yet. On this basis, **those who want to receive the vaccines according to how they were approved for emergency use should be entitled to this**. However, **public health officials seem to be over-riding this right, even though it contradicts their own informed consent procedure, Health Canada, and the vaccine manufacturers**.

With sincere concern for our fellow Canadians,

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Date: March 8, 2021

Memorandum to: Medical Officers of Health
Hospital CEOs

From: Dr. David Williams, Chief Medical Officer of Health Ontario

Subject: **COVID-19 Vaccine Updates**

As a follow-up to Friday's provincial announcement, I would like to provide further details about key changes to Ontario's COVID-19 vaccination program which will assist in accelerating our first dose vaccination efforts to ensure Ontarians receive a first dose of protection as quickly as possible.

Changes to Second Dose Intervals

To increase the number of individuals benefiting from a first dose of vaccine in the context of a limited COVID-19 vaccine supply, the province is following recommendations from the National Advisory Committee on Immunization (NACI) to extend the time interval of the second dose of COVID-19 vaccines up to 16 weeks. This 16-week interval for the second dose applies to the three two-dose vaccines currently approved by Health Canada (Pfizer-BioNTech, Moderna and AstraZeneca/COVISHIELD).

- Current evidence from real-world experience with the Pfizer-BioNTech and Moderna vaccines indicates high vaccine effectiveness against symptomatic disease, hospitalization and death from COVID-19 for two months after the first dose, including among older populations. Clinical trials with the AstraZeneca/COVISHIELD vaccine indicate that vaccine efficacy increases with the length of the interval between doses over 12 weeks. Based on immunological principles, vaccine science and modelling, this short-term protection is not expected to rapidly wane.
- The effectiveness of an extended dose interval will be monitored and assessed, including effectiveness against variants of concern.
- Reducing the risk of hospitalizations and deaths at the population level remains a priority and will have great impact.

This program transition to extend the interval between first and second dose to 16 weeks will occur on March 10th, 2021 at 00:01hr.

The following groups will continue to receive vaccine at the initial intervals as described in the product monographs:

- residents of long-term care homes, retirement homes, Elder Care Lodges and Assisted Living facilities who are at the greatest risk of both exposure to COVID-19 and serious illness and death; and,
- remote and isolated First Nation communities (currently supported by Operation Remote Immunity) given the potential seriousness of COVID 19 infection in these communities with limited available health care facilities and resources. Further discussion on dosage intervals for administering to the Indigenous population beyond Operation Remote Immunity will occur.

We thank you for your assistance and recognize the additional work this change will cause as your teams reschedule appointments.

Distribution of AstraZeneca/COVISHIELD COVID-19 vaccine

In alignment with the recommendations from NACI, the AstraZeneca/COVISHIELD vaccine can be offered to all healthy Ontarians aged 18-64 years, without contraindications, if:

- the advantages of earlier vaccination outweigh the limitations of vaccinating with a less efficacious vaccine;
- the ease of transport, storage and handling of this vaccine facilitates access to vaccination which may otherwise be challenging; and
- informed consent is provided which includes discussion about current vaccine options (e.g. efficacy) and the timing of future vaccine options.

Beginning with Ontarians aged 60-64 years and then decreasing in age, the AstraZeneca/COVISHIELD vaccine will be offered with informed consent. Individuals over 65 years of age may also receive this vaccine product but must be advised about the potential benefits of waiting for a more efficacious vaccine.

While AstraZeneca/COVISHIELD has a lower vaccine effectiveness score than the mRNA vaccines, it is still significant and has been shown to reduce serious COVID-19 illness, hospitalization and death.

The delivery of this vaccine product will occur separate from Pfizer and Moderna, which will continue to follow the sequencing and prioritization set out for phases one and two of Ontario's plan.

Starting the week of March 8th:

- some pharmacies in Toronto, Kingston and Windsor-Essex will be allocated and begin to deliver the AstraZeneca/COVISHIELD vaccine, and
- primary care partners will also begin to deliver the AstraZeneca/COVISHIELD vaccine in Hamilton, Toronto, Guelph, Peterborough, Simcoe-Muskoka, and Peel.

Over the coming weeks, pharmacies and primary care partners in additional regions will be provided vaccine.

Areas of Focus for Phase 2 Vaccinations

Ontario's Phase 2 vaccination rollout is expected to begin in April 2021, depending on vaccine availability. The target populations in Phase 2 are based on *age and risk* in order to prevent further death, hospitalization and transmission of COVID-19. People from the following groups will be offered vaccines:

- Adults aged 60-79, beginning with those 75 years of age and older, and decreasing in five-year increments over the course of the vaccine rollout
- People who live and/or work in high-risk congregate settings (e.g. shelters, community living) as well as some primary caregivers
- Individuals with high-risk chronic health conditions and some primary caregivers of those with highest risk health conditions
- People who live in hot spots with high rates of death, hospitalizations and transmission of infection
- Certain workers who cannot work from home, including but not limited to first responders, education workers and those in the food processing industry

We will continue to keep you apprised of changes to Ontario's COVID-19 situation and appreciate your ongoing partnership and dedication to this critical work.

Sincerely,

David C. Williams, MD, MHSc, FRCPC
Chief Medical Officer of Health

c:

Helen Angus, Deputy Minister, Ministry of Health
Mario Di Tommaso, Deputy Minister, Ministry of the Solicitor General
Richard Steele, Deputy Minister, Ministry of Long-Term Care
Denise A. Cole, Deputy Minister, Ministry for Seniors and Accessibility
Shawn Batise, Deputy Minister, Ministry of Indigenous Affairs
Matthew Anderson, President and CEO, Ontario Health
Ken Chan, Assistant Deputy Minister, Ministry of the Solicitor General
Erin Hannah, Associate Deputy Minister, Ministry of Long-Term Care
Alison Blair, Associate Deputy Minister, Ministry of Health
Dr. Dirk Huyer, Chief Coroner, Ministry of the Solicitor General

COVID-19 Vaccine Screening and Consent Form

SCREENING AND CONSENT FORM –COVID-19 Vaccine

Version 2.0 – January 23, 2021

Last Name	First Name		Identification (e.g., health card number)	
Sex: ☐ Female☐ Male ☐ Non-Binary ☐ Prefer not to answer			Primary Care Clinician (Family Physician or Nurse Practitioner)	
Home Phone	Mobile Phone	Email Address		
Street Address	City		Province	Postal Code
Date of Birth (month, day, year) _____ / _____ / _____	Age	Is this your **first or second dose** of the vaccine? ☐ First ☐ Second If second, please indicate the date of the first dose: _____ / ____ / ____ (month, day, year)		

Please answer all questions below:

Do you have symptoms of COVID-19 or feel ill today*?, ☐ No ☐ Yes	If yes, please provide details
Have you previously had a severe allergic reaction (e.g.. anaphylaxis) to a previous dose of a COVID mRNA vaccine or to any of its components or its container? ☐ No ☐ Yes	If yes, please provide details
Do you have a suspected hypersensitivity or have you had an immediate allergic reaction *(this would include an allergic reaction that occurred within 4 hours that cause hives, swelling, or respiratory distress, including wheezing*) **to:**	If yes, please provide details
• **A previous dose of an mRNA COVID-19 vaccine** ☐ No ☐ Yes	
• **Any components of the mRNA COVID-19 vaccine (including polyethylene glycol [PEG])**** ☐ No ☐ Yes	
• **Polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)**** ☐ No ☐ Yes	

Have you ever had a severe (e.g. anaphylaxis) or an immediate allergic reaction to any other vaccine or injectable therapy (e.g. intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbates)? *(this would include an allergic reaction that occurred within 4 hours that cause hives, swelling, or respiratory distress, including wheezing)* ☐ No ☐ Yes	If yes, please provide details
Have you ever had a severe allergic reaction (e.g.. anaphylaxis) not related to vaccines or injectable medications – such as allergies to food, pet, venom, environmental, or latex etc.? ☐ No ☐ Yes	If yes, please provide details
Have you received another vaccine (not a COVID-19 vaccine) in the past 14 days? ☐ No ☐ Yes	If yes, please provide details
Are you or could you be pregnant? ☐ No ☐ Yes	If yes, please provide details
Are you breastfeeding? ☐ No ☐ Yes	If yes, please provide details
Do you have any problems with your immune system or are you taking any medications that can affect your immune system (e.g., high dose steroids, chemotherapy)? ☐ No ☐ Yes	If yes, please provide details
Do you have an autoimmune disease? ☐ No ☐ Yes	If yes, please provide details
Do you have a bleeding disorder or are taking medications that could affect blood clotting (e.g., blood thinners)? ☐ No ☐ Yes	

Have you ever felt faint or fainted after a past vaccination or medical procedure? ☐ No ☐ Yes	If yes, please provide details

* Symptoms of COVID-19 can include fever, new onset of cough or worsening of chronic cough, shortness of breath, difficulty breathing, sore throat, difficulty swallowing, decrease or loss of smell or taste, chills, headaches, unexplained tiredness / malaise / muscle aches, nausea / vomiting, diarrhea or abdominal pain, pink eye, or runny nose or nasal congestion without other known cause or, for those over 70 years of age,,an unexplained or increased number of falls, acute functional decline, worsening of chronic conditions or delirium	** Polyethylene glycol (PEG) can rarely cause allergic reactions and is found in products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, cosmetics, skin creams, medical products used on the skin and during operations, toothpaste, contact lenses and contact lens solution. PEG also can be found in foods or drinks, but is not known to cause allergic reactions from foods or drinks. Polysorbate may also cause allergic reactions because of cross-reactivity with PEG.

Consent to Receive the Vaccine

I have read (or it has been read to me) and I understand the 'COVID-19 Vaccine Information Sheet'

- I have had the opportunity to ask questions and to have them answered to my satisfaction.
- I have had the opportunity to speak with my primary care provider regarding any special considerations that apply to me in respect of the COVID-19 vaccine.

☐ I consent to receiving the vaccine

Acknowledgement of Collection, Use and Disclosure of Personal Health Information

The personal health information on this form is being collected for the purpose of providing care to you and creating an immunization record for you, and because it is necessary for the administration of Ontario's COVID-19 vaccination program. This information will be used and disclosed for these purposes, as well as other purposes authorized and required by law. For example,

- it will be disclosed to the Chief Medical Officer of Health and Ontario public health units where the disclosure is necessary for a purpose of the *Health Protection and Promotion Act*. And
- it may be disclosed, as part of your provincial electronic health record, to health care providers who are providing care to you.

The information will be stored in a health record system under the custody and control of the Ministry of Health.

Where a Clinic Site is administered by a hospital, the hospital will collect, use and disclose your information as an agent of the Ministry of Health.

☐ **I acknowledge that I have read and understand the above statement.**

You may be contacted by a hospital, local public health unit, or the Ministry of Health for purposes related to the COVID-19 vaccine (for example, to remind you of follow up appointments and to provide you with proof of vaccination). If you consent to receiving these follow up communications by email or text/SMS, please indicate this using the boxes below.

I consent to receiving follow-up communications:
☐ by email ☐ by text/SMS

Consent to Being Contacted About Research Studies

Many research studies will be conducted in respect of COVID-19 vaccines.

You have the option of consenting to be contacted by researchers about participation in COVID-19 vaccine related research studies. If you consent to be contacted, your personal health information will be used to determine which studies may be relevant to you, and your name and contact information will be disclosed to researchers. Consenting to be contacted about research studies does not mean you have consented to participate in the research itself. Participating in research is voluntary. You may refuse to consent to be contacted about research studies without impacting your eligibility to receive the COVID-19 vaccine.

If you consent to be contacted about research studies, and then change your mind, you may withdraw your consent at any time by contacting the Ministry of Health at Vaccine@ontario.ca.

I consent to be contacted about COVID-19 vaccine related research studies:

☐ by email ☐ by text/SMS ☐ by phone ☐ by mail

☐ I do not consent to be contacted about COVID-19 related research studies:

Signature	Print Name	Date of Signature

If signing for someone other than yourself, indicate your relationship to that other person:

_____

☐ If signing for someone other than myself, I confirm that I am the parent / legal guardian or substitute decision maker.

Specific Issues re: Long-Term Care Homes Act, 2007

The resident's consent to receive the vaccine may be withdrawn or revoked at any time.

Statement respecting section 83 of the Act:

Please note the following legal protection:

Every licensee of a long-term care home shall ensure that no person is told or led to believe that a prospective resident will be refused admission or that a resident will be discharged from the home because,

(a) a document has not been signed;
(b) an agreement has been voided; or
(c) a consent or directive with respect to treatment or care has been given, not given, withdrawn or revoked.

FOR CLINIC USE ONLY						
Agent	COVID-19	Product Name		Lot #		Dose	
Anatomical Site	☐ Left deltoid ☐ Right deltoid			Route	Intramuscular	Dose #	
Date Given	_____ / _____ / _____ (m/d/yyyy)		Time Given	____ : ____ am pm	AEFI?	☐ Yes ☐ No	
Given By (Name, Designation)			Location		Authorized By		
Reason for Immunization	☐ Healthcare worker ☐ Healthcare worker: LTC Home ☐ Healthcare worker: Retirement Home ☐ LTC Home: Resident ☐ Retirement Home: Resident ☐ Advanced age: community dwelling ☐ Other employees in acute care, LTC, RHs ☐ Indigenous community ☐ Chronic conditions						
Reason Immunizations Not Given	Healthcare provider: ☐ Determines immunization is contraindicated ☐ Recommends immunization but no consent received ☐ Determines that immunization will be temporarily deferred						
Your dose 2 of 2 is scheduled for:	_____ / _____ / _____ (m/d/yyyy)		____ : ____ am pm				

Ontario

Ministry of Health

Information Sheet

Pfizer-BioNTech and Moderna COVID-19 Vaccines

Version 2.0 – December 30, 2020 (amended January 7, 2021)

Highlights of changes

- Updated to include information on Moderna vaccine (throughout)
- Updated information for breastfeeding women (page 4)
- Reference and hyperlink to Vaccination Recommendations for Special Populations guidance document (throughout)

Ministry of Health

Information Sheet

Pfizer-BioNTech and Moderna COVID-19 Vaccines

Version 2.0 – December 30, 2020 (amended January 7, 2021)

This information sheet provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment. For more information about the Pfizer-BioNTech COVID-19 vaccine, please refer to the Pfizer-BioNTech Product Monograph authorized by Health Canada. For more information about the Moderna COVID-19 vaccine, please refer to the Moderna Product Monograph, authorized by Health Canada. Additional information on the use of COVID-19 vaccines is available in statements and publications by the National Advisory Committee on Immunization (NACI).

Please read this information sheet carefully and ensure all your questions have been answered by a healthcare provider before receiving the vaccine. The Pfizer-BioNTech and Moderna COVID-19 vaccines have been evaluated and authorized for use in Canada by Health Canada, using rigorous standards. Health Canada will continue to monitor to ensure it is safe and effective.

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, list of symptoms, other guidance documents, Directives and other information.

What is COVID-19?

- COVID-19 is an infection caused by a new coronavirus (SARS-CoV-2). COVID-19 was recognized for the first time in December 2019 and has since spread around the world to cause a pandemic. COVID-19 is mainly passed from an infected person to others when the infected person coughs, sneezes, sings, talks or breathes. It is important to note that infected people can spread the infection even if they have no symptoms.
- Symptoms of COVID-19 can include cough, shortness of breath, fever, chills, tiredness and loss of smell or taste. Some people infected with the virus have no symptoms at all, while others have symptoms that range from mild to severe.
- Of people diagnosed with COVID-19 in Canada, about 1 in 13 require hospitalization and about 3 out of every 100 people diagnosed with COVID-19 die. Even people with mild symptoms may feel unwell for a long time after a COVID-19 infection.

How do the Pfizer-BioNTech and Moderna COVID-19 vaccines protect against COVID-19?

All vaccines work by presenting our body with something that looks like the infection so that our immune system can learn how to produce natural protection. This natural protection then helps to keep us from becoming sick if we come into contact with the real virus in the future.

Both vaccines use a method called messenger RNA (mRNA). The mRNA is like a code that tells the cells in your body how to make a piece of the outer lining of the virus, for a short time. This piece of the virus cannot hurt you, but it is enough for your immune system to learn how to recognize and be ready to fight off the virus. More information on mRNA vaccines can be found on Public Health Ontario's (PHO) COVID-19 Vaccines webpage. In large studies where people were given 2 doses of either vaccine, the vaccine was shown to work very well at preventing people from becoming sick with COVID-19. The immunized group of people were about 95% less likely to become sick with COVID-19 compared to the group that did not receive the vaccine. **You cannot get COVID-19 from the vaccine.**

Who can receive this vaccine and who cannot?

A complete vaccine series should be offered to individuals without contraindications to the vaccine.

- The Pfizer-BioNTech vaccine: 2 doses given 21 days apart to individuals who are 16 years of age and older.
- The Moderna vaccine: 2 doses given 28 days apart to individuals who are 18 years of age and older.

If you have any symptoms that could be due to COVID-19, you should not receive the vaccine at this time. You should also wait 14 days after receiving any other vaccine before receiving the COVID-19 vaccine.

Talk with your healthcare provider or where available, call Telehealth Ontario (1-866-797-0000) about your symptoms and getting a COVID-19 test. Your healthcare provider will advise you when you are able to receive the vaccine.

See below for more details regarding who should not get this vaccine.

Who should not receive the vaccine?

The Pfizer-BioNTech and Moderna COVID-19 vaccines are contraindicated in:

- Individuals who have ever had a severe allergic reaction (i.e. anaphylaxis) to a previous dose of an mRNA vaccine or to any of its components (including polyethylene glycol (PEG) and/or polysorbate, see below) or its container, should not get either mRNA COVID-19 vaccine. Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with symptoms of COVID-19. To minimize the risk of COVID-19 transmission, symptomatic individuals who arrive at an immunization clinic/venue, should be instructed to follow current local public health measures, and be encouraged to get tested.
- Individuals who have received another vaccine (not a COVID-19 vaccine) in the past 14 days.
- Vaccine should not be offered to individuals who are not in the authorized age group.

Considerations for other patient groups:

- Guidance for special populations, including for example breastfeeding or pregnant individuals, 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

Precautions during vaccination should be taken with:

- Patients who have a bleeding problem, bruise easily or use a blood-thinning medicine should receive the vaccine. Individuals receiving long-term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized through the the intramuscular route as recommended, without discontinuation of their anticoagulation therapy.
    - There is some evidence to suggest that intramuscular administration may be safer when given with a small gauge needle (23 gauge or smaller) and when firm pressure is applied to the injection site for 5 to 10 minutes
- Individuals with a history of severe allergic reactions (i.e. anaphylaxis) not related to vaccines or injectable medications—such as allergies to food, pet, venom, environmental, or latex, etc. should be offered the COVID-19 vaccines.
    - An extended period of observation post-vaccination of 30 minutes is recommended for these groups
    - For more detailed recommendations on people with allergies, please consult the Vaccination Recommendations for Special Populations guidance document

What are the non-medicinal ingredients in the vaccine?

Non-medical ingredients in the Pfizer-BioNTech COVID-19 vaccine include:

- 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

Non-medical ingredients in the Moderna COVID-19 vaccine include:

- 1, 2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
- Acetic acid
- Cholesterol
- Lipid SM-102
- PEG2000 DMG 1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol
- Sodium acetate
- Sucrose
- Tromethamine
- tromethamine hydrochloride
- water for injection

It is important to review this list carefully as some people may be allergic to these ingredients, including **polyethylene glycol**. Polyethylene glycol can rarely cause allergic reactions and is found in some products such as medications, bowel preparation products for colonscopy, laxatives, cough syrups, cosmetics, skin creams, medical products used on the skin and during operations, toothpaste, contact lenses and contact lens solution. Polyethylene glycol can also be found in food or drinks, but is not known to cause allergic reactions from foods or drinks. Due to potential cross-reactive hypersensitivity with the vaccine ingredient polyethylene glycol, those with a suspected hypersensitivity or who have had an immediate allergic reaction to **polysorbate** should speak to their health care provider before vaccination.

How is the vaccine administered?

The vaccine is given as a needle in the upper arm (into the deltoid muscle) and will require two doses of the same vaccine product given:

- 21 days apart for the Pfizer-BioNTech vaccine
- 28 days apart for the Moderna vaccine

What are the side effects of the vaccine?

Ongoing studies on the Pfizer-BioNTech and Moderna vaccine indicate **no serious side effects found to-date**. People who have received the vaccine in these studies continue to be monitored for any longer-term side effects.

As with other vaccines, **some people can develop mild side effects in the days following immunization that are generally not serious** and go away on their own. In the study, side effects included one or more of the following symptoms: pain where the needle was given, redness and swelling, tiredness, headache, muscle pain, joint pain, chills, mild fever, and/or swollen glands (less frequently). These types of side effects are expected and simply indicate the vaccine is working to produce protection. These side effects are more likely to occur after your second dose.

As with any medicines and vaccines, allergic reactions are rare but can occur after receiving a vaccine. Symptoms of an allergic reaction include hives (bumps on the skin that are often very itchy), swelling of your face, tongue or throat, or difficulty breathing. Clinic staff are prepared to manage an allergic reaction should it occur. If you are concerned about any reactions you experience after receiving the vaccine, contact your healthcare provider. You can also contact your local public health unit to ask questions or to report an adverse reaction.

Can you get COVID-19 from the vaccine?

You cannot get COVID-19 infection from the vaccine. The vaccines are not live vaccines and do not cause the disease they are designed to prevent.

What measures have been put in place to safely provide immunizations during COVID-19?

Healthcare providers are being very careful to prevent the spread of COVID-19 when offering immunizations. Examples of extra safety measures include the following:

- You will be asked about any COVID-19 symptoms when you arrive at the clinic. People with symptoms of COVID-19 should not attend the clinic or receive the vaccine.
- You will be asked to wear a mask while at the clinic, as well as to clean your hands, and to stay at least 2 metres (6 feet) from others

- Other measures may also be put in place in clinics. Be sure to read and follow any signs or instructions provided.

What should you do before coming to the clinic?

- Wear a short-sleeve shirt or shirt with sleeves that are easy to roll up.
- Have something to eat before coming to the clinic to prevent feeling faint while being vaccinated.
- Wear your mask.
- Bring any identification required by the clinic, such as your health card.
- Bring your immunization record with you to record this vaccine with other vaccines that you have received.

Before receiving the vaccine, tell the healthcare provider if:

- You are currently feeling unwell or have signs and symptoms of COVID-19
- You are currently breastfeeding.
- You are or could be pregnant.
- You have fainted after receiving past vaccines or medical procedures. Your healthcare provider may recommend that you receive the vaccine lying down to prevent fainting.
- You have a bleeding disorder or are taking medication that could affect blood clotting. This information will help the healthcare provider prevent bleeding or bruising from the needle.
- You have had a previous allergic reaction to any vaccine or any non-medical ingredients of the COVID-19 vaccine.
- You have experienced an immediate or serious allergic reaction, including anaphylaxis, to another vaccine or injectable therapy. You should talk to your healthcare provider before you receive the vaccine.
- You have experienced a serious allergic reaction, including anaphylaxis, to food, pet, venom, environmental, or latex
- You are immunosuppressed due to disease or treatment or have been diagnosed with an autoimmune disorder.
- When receiving your second dose of COVID-19 vaccine, tell the healthcare provider if you had any side effects after the first dose.

- You have received any other vaccine (not a COVID-19 vaccine) in the past 14 days. You will be asked to wait 14 days from the time you received the other vaccine.

What should you do after receiving the vaccine?

You will be asked to **wait at least 15 minutes after receiving** the vaccine to be sure you are feeling well. You may be asked by the healthcare provider to wait in the clinic, or if an adult is with you and you have a warm, dry place to wait (such as in your vehicle), you may be asked to wait outside of the clinic. Inform a healthcare provider right away if you feel unwell while waiting. You should not leave the clinic (or clinic parking lot) for at least 15 minutes after receiving your vaccine.

When should I seek medical attention?

Serious side effects after receiving the vaccine are rare. However, should you develop any of the following adverse reactions within three days of receiving the vaccine, seek medical attention right away or call 911 if you are severely unwell:

- hives
- swelling of the face or mouth
- trouble breathing
- very pale colour and serious drowsiness
- high fever (over 40˚C)
- convulsions or seizures
- other serious symptoms (e.g., "pins and needles" or numbness).

Do I need to continue to follow public health measures now that I have received the vaccine?

Continue to follow the advice of public health officials to prevent COVID-19, such as wearing a mask, and maintaining a physical distance of 2 metres from people outside of your household.

When can I receive other vaccines?

- COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines.

- Do not receive any other vaccines until at least 28 days after you receive the second dose of the COVID-19 vaccine, unless required for post-exposure prophylaxis.
- You should wait 14 days after receiving another vaccine before receiving the COVID-19 vaccine.

When should I return for my second dose?

If this is your first dose of the COVID-19 vaccine, be sure to return for your second dose. If you are receiving the Pfizer-BioNTech COVID-19 Vaccine, you should return for your second dose in 21 days. If you are receiving the Moderna COVID-19 Vaccine, you should return for your second dose in 28 days.

You should book an appointment to receive the next dose right away. It is important that you receive 2 doses of the vaccine. Protection against COVID-19 is not complete until after the second dose of vaccine is received.

Bring your immunization record when you come for your second dose. **It is very important that you receive the second dose even if you experienced mild side effects the first time**.

Who should I contact with any questions?

If you have any questions, please speak with the person providing the vaccine or a designated contact.