

## COVID-19 Vaccine Information for Substitute Decision Makers

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MOH COVID-19 About Vaccines

**MOH Information Sheets Vaccines** 

Sample Ministry Of Health COVID -19 Vaccine Screening and Consent Form

# Why should individuals be vaccinated against COVID-19?

Vaccination is one of the most effective ways to prevent the spread and reduce the impact of infectious diseases. Safe and effective vaccines for COVID-19 are becoming available to protect the population against COVID-19.

While many people infected with COVID-19 experience only mild illness, others may get a severe illness or even die. Individuals with intellectual disabilities and other complex health needs are at greater risk for severe complications. There is no way to know how COVID-19 will affect each person, even if they are not at increased risk of severe complications. COVID-19 vaccination helps protect individuals by creating an antibody response without having to experience the illness of COVID-19.

Individuals who are supported by CLNB share their home with other individuals and have many support staff. Even though we are very proud of the public health measures we have put in place and the diligence shown by our staff, the very nature of the living environment also puts our individuals at greater risk of getting the COVID-19 virus.

## Which vaccines are approved in Canada?

Two COVID-19 vaccines are currently approved in Canada. In clinical trials, both vaccines were higher than 90% effective.

- **1. Pfizer-BioNTech COVID-19 Vaccine** can be given to people 16 years of age and older, including older adults. <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html</a>
- **2. Moderna COVID-19 Vaccine** can be given to people 18 years of age and older, including older adults. <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html</a>

### Information videos

COVID-19
Vaccine
(Pfizer-BioNTech)

What you need to know!

#### **DISCUSSIONS FROM EXPERTS ABOUT COVID-19 VACCINES**

The following video link is from our partners at Sun Life. Within the video, Dr. Alan Bernstein discusses and answers questions about COVID-19 Vaccines.

https://sunlife.hubs.vidyard.com/watch/1x8J6NNKVgYdy3My2SZoCd?fbclid=IwAR0p5o6jv RqumHRK-fPwljab2-TUVEOj0qxpHFQ4JS9rZegeKXSVqvH0AWw

- Important Time Stamps for the above video
  - o 01:45 How mRNA vaccines work and safety around the new type of vaccine
  - 04:44 **Effectiveness (***Moderna and Pfizer vaccines*)
  - 07:15 **Storage** (*Moderna and Pfizer vaccines*)
  - 10:40 Viral vector vaccines (likely method the next two vaccines to be approved will use)
  - 14:40 Goal for a successful vaccine
  - 18:35 Public health measures after being vaccinated.
  - o 22:00 Importance of receiving both doses of mRNA vaccine
  - o 23:00 Skepticism around COVID-19 Vaccines
  - 28:00 Risk of not getting a COVID-19 Vaccine
  - o 29:30 **Vaccine Durability** (how long will immunity last)
  - 34:40 Getting a COVID-19 Vaccine if you have already had COVID-19
  - 40:00 **Q** and **A** session

# When will people supported and staff get the vaccine?

Congregate care settings have been identified as a tier 2 priority, but we have already seen some group homes in Ontario be vaccinated in the tier 1 rollout.

There is a good chance that if there is vaccine left over from a scheduled clinic in the North Bay area, they may call us and offer us whatever doses are left over from the clinic. Therefore, we are preparing now. We may only be given one day notice that a team is coming to vaccinate our organization.

# Will everyone at CLNB be vaccinated at the same time?

The vaccine will most likely be offered to us in batches as they become available. We may have to prioritize people supported as well as staff based on work location and job responsibilities.

This will be completed in collaboration with the Nipissing Parry Sound District Health Unit.

Will you be offering the vaccine to essential visitors?	The provincial planning table for developmental services has identified this as a priority.  We would like to be able to offer the vaccine to essential caregivers but it will depend on the availability of doses. We hope to have more information in the coming weeks.
Where will vaccinations take place?	This decision will be made in collaboration with the Health Unit. Likely for congregate care settings, the vaccinations may happen in their home. A clinic may also be set up to allow for faster immunization at one site.
Will the vaccine be mandatory for people supported and staff members?	No. The vaccine will not be mandatory. If you choose to decline the vaccine for your loved one, their care and support will not change.  The vaccine is not mandated for staff members. Information is being provided to staff as it is to families and people supported to help everyone make the best decision for themselves.  Some people may not able to get vaccinated due to medical reasons, religious exemptions and personal choice.
What will change once individuals receive the vaccine?	Having the vaccine will give protection against contracting the virus. However, it will take time for health officials to evaluate how the vaccine is impacting the infection rate and severity of the virus to determine at what point things can start to go back to normal. All health measures and restrictions will likely stay in place for many months as they vaccinate more of the general population.  Also, during clinical trials it was determined that the vaccine provides protection to the individual that has been vaccinated. It has not yet been proven to prevent the spread of Covid-19 from a person that is immunized to someone that is not.

How the COVID vaccine works.	The vaccine does not prevent Covid-19 from entering your body, it teaches your immune system to target it and fight it off.						
	The COVID-19 vaccine is made using mRNA rather than the live virus. mRNA vaccines teach						
	our cells how to make a protein that will trigger an immune response without using the live						
	virus that causes COVID-19. Once triggered, our body then makes antibodies. These						
	antibodies help us fight the infection if the real virus does enter our body in the future.						
	'RNA' stands for ribonucleic acid, which is a molecule that provides cells with instructions						
	for making proteins. Messenger RNA (mRNA) vaccines contain the genetic instructions for						
	making the SARS-CoV-2 spike protein. This protein is found on the surface of the virus that causes COVID-19.						
	When a person is given the vaccine, their cells will read the genetic instructions like a						
	recipe and produce the spike protein. After the protein piece is made, the cell breaks down						
	the instructions and gets rid of them. The cell then displays the protein piece on its						
	surface. Our immune system recognizes that the protein doesn't belong there and begins						
	building an immune response and making antibodies.						
Can the mRNA	No. mRNA is not able to alter or modify a person's genetic makeup (DNA). The mRNA from						
vaccine alter a	a COVID-19 vaccine never enters the nucleus of the cell, which is where our DNA are kept.						
person's DNA?	This means the mRNA does not affect or interact with our DNA in any way. Instead, COVID-						
person's DNA:	19 vaccines that use mRNA work with the body's natural defenses to safely develop						
	protection (immunity) to disease.						
How is the	The vaccine is given by an injection into the muscle of the arm.						
vaccine given?	For the vaccine to work best, everyone needs to get 2 doses: a single dose and then a						
	second dose 21 days later. (although there has been discussion amongst the medical						
	community that the time between doses may be longer). CLNB would follow the						
	recommendations of the Public Health Unit.						
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## Why are 2 doses required?

Receiving only one dose of the vaccine is not recommended. Some studies have shown that the first dose is only 54% effective in preventing COVID-19 and it is unclear how long the protection will last. It is only after the second dose that the vaccine becomes 94% effective and long lasting.

Think of the first dose as the one that "primes" the immune system to identify the virus and begin producing antibodies. The body will produce some antibodies after the first injection, but not many and they are not that strong. After the second dose the body gets a "wake up call" and starts to produce stronger antibodies that provide long-term protection.

# How fast does the vaccine protect against COVID-19?

The Pfizer-BioNTech COVID-19 vaccine was 95% effective in preventing COVID-19 beginning 1 week after the second dose (based on studies in about 44,000 participants). This means that people may not be fully protected against COVID-19 until at least 7 days after the second dose.

The Moderna COVID-19 vaccine was 94.1% effective in preventing COVID-19 beginning 2 weeks after the second dose (based on studies in about 30,000 participants). This means that people may not be fully protected against COVID-19 until at least 14 days after the second dose.

## What are the possible side effects?

The most frequent side effects are:

- injection site pain,
- fatigue and headache.

Some people receiving the vaccine in trials also reported:

- muscle pain,
- chills, joint
- pain and fever.

These symptoms were usually mild or moderate in intensity and resolved within a few days after vaccination. These are all expected reactions to vaccines because of the immune

response and are very similar to those reported following the seasonal influenza vaccination.

As with all vaccines, there is a chance that there will be a serious side effect, such as an allergic reaction, but these are rare. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness.

We will be beginning to contact each family physician to determine if any of the people supported should not get the vaccine due to health issues or history of reactions. We will not allow vaccination until we have received your consent and the ok from the doctor or nurse practitioner.

# Can the COVID-19 vaccine cause a COVID-19 infection?

No. None of the COVID-19 vaccines currently in development use the live virus that causes COVID-19. The goal of each of the vaccines is to teach the immune system how to recognize and fight the virus that causes COVID-19. Sometimes this process can cause symptoms, such as fever. These symptoms are normal and are a sign of the immune response to vaccine.

It usually takes the body a few weeks to build immunity after receiving a vaccine. It is possible that someone could become infected with the COVID-19 virus before or just after getting the vaccine and get sick. This happens because the vaccine has not had enough time to provide protection in the body.

# Does getting the vaccine mean that staff will no longer have to wear masks and eye protection?

All staff must still wear personal protective equipment (PPE) even after they have been vaccinated. We will continue to following the safety measures in place.

During clinical trials it was determined that the vaccine provides protection to the individual that has been vaccinated. It has not yet been proven to prevent the spread of Covid-19 from a person that is immunized to someone that is not. Therefore, it is important for us to continue all current health measures.

Once a resident receives both doses of the vaccine, will they be able to resume visits, outings, and other activities?

It will take time for health officials to evaluate how the vaccine is impacting the infection rate and severity of the virus to determine at what point things can start to go back to normal. All health measures and restrictions will likely stay in place for many months as they vaccinate more of the general population. We will follow the recommendations from Health Unit and MCCSS as to when outings and other programs can resume.

## What happens between the first and second dose of the vaccine?

All health measures and current safety procedures will continue. If an individual does get COVID-19 before receiving the second dose, the second dose may be delayed until they have recovered.

# Who should NOT get the vaccine before consulting with their doctor:

Currently the vaccine is not recommended for the following individuals without approval from the primary care provider (Medical Doctor or Nurse Practitioner):

- anyone unwell (fever or any signs or symptoms of COVID-19 that day),
- under the age of 16.
- allergy or sensitivity to a component of the COVID-19 vaccine,
- history of severe allergic reaction (including anaphylaxis),
- have an autoimmune disorder,
- weakened immune system due to illness or treatment,
- pregnant or breastfeeding.
- anyone with a bleeding disorder or on blood thinner medications. We will obtain clearance from a medical practitioner first.

How did they develop the COVID-19 vaccine so fast?	Creating a vaccine in under one year is no small feat. Considering that the fastest vaccine development in history, the mumps vaccine, took 4 years to develop, it is natural to have some apprehension over the safety and effectiveness of a vaccine that has come out so fast.  The coronavirus pandemic spurred global cooperation for vaccine research and distribution. Researchers quickly mobilized to share their coronavirus data with other scientists. Researchers were also not starting from scratch when they learned about SARS-
	CoV-2, the virus that causes COVID-19. Scientists have been studying coronaviruses for over 50 years. This meant scientists had existing data on the structure, genome, and life cycle of this type of virus. Also, in Canada and other parts of the world, a vaccine for SARs had already begun after the SARs outbreak and this provided a tremendous head start in developing this vaccine since the virus is in the same family.  Due to advances in genomic sequencing, researchers successfully uncovered the viral sequence of SARS-CoV-2 in January 2020, roughly 10 days after the first reported pneumonia cases in Wuhan, China. The ability to fast-track research and clinical trials was a direct result of worldwide cooperation as well as the historical evidence that already existed on coronaviruses.
How was Health Canada able to approve the COVID-19 vaccine so quickly?	The reason the COVID-19 vaccine was approved quickly is not because safety standards have changed, it is because Health Canada shortened the administrative and organizational process of vaccine authorization. The safety requirements in clinical trials for the COVID-19 vaccine were just as strict as the regular process for any other vaccine.
CLNB Consent Process	<ul> <li>We are currently reviewing requirements and processes for consent. Information will be sent out as it becomes available. You can start the consent process by:</li> <li>1. Please read this information package, videos, as well as the attached product information sheets provided by the government. If you have any questions please reach out to the medical professional or health unit. There are also other resources available on line that you are encouraged to research.</li> <li>2. Where appropriate, we will provide vaccine education to people supported using</li> </ul>

- a tool developed by the HCARDD team (Health Care Access and Developmental Disabilities). They have published easy to read information booklets which can be found at this website: <a href="https://www.hcarddcovid.com/info#vaccine">https://www.hcarddcovid.com/info#vaccine</a>. There are also a number of videos that will be used to assist in education from other reliable sources.
- 3. The current Ministry Of Health COVID-19 Vaccine Screening and Consent Form has been included for your review. (Please do not fill in this consent form, as the form may change prior to vaccination and thus not be valid). It has been provided to give you information as to what is included on the consent form.
- 4. Consultations with physicians will also be part of the consent process, and more information will follow.



#### **Ministry of Health**

#### **COVID-19 About Vaccines**

**Version 2.0 - December 30, 2020 (amended January 6, 2021)** 

#### **Highlights of changes**

- Updated to include Moderna vaccine (throughout)
- Removal of clinical trial details chart
- Question added to FAQs around interchangeability of COVID-19 vaccines

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) <u>COVID-19 website</u> 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 and Moderna COVID-19 mRNA vaccines. 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 in Canada.



- Canadians will have easy access to detailed information on the vaccine and the evidence behind the vaccine approval process through the <u>Government</u> of <u>Canada's website</u>.
- 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, these vaccines are the first mRNA vaccines 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 altera 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 coronavirus to generate an immune response in the body.
Inactivated or weakened virus vaccines	Use an inactivated or weakened form of the virus that does not cause disease but still generates an immune response in the body.



#### The Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

The Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines are highly efficacious in the short-term against laboratory-confirmed symptomatic COVID-19 disease; medium and long-term trials are ongoing. The Pfizer-BioNTech and Moderna mRNA vaccines are indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2. Clinical trial details are available in the <a href="Pfizer-BioNTech monograph">Pfizer-BioNTech monograph</a> and the <a href="Moderna monograph">Moderna monograph</a>. Additional information on the use of COVID-19 vaccines is available in <a href="statements and publications by the National Advisory">Statements and publications by the National Advisory</a> Committee on Immunization (NACI).

#### Side effects

Similar to medications and other vaccines, the Pfizer-BioNTech and Moderna COVID-19 vaccines can cause side effects. During the clinical trials, common side effects similar to other vaccines were reported (e.g., redness and pain at the injection site). These side effects 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.

Vaccine	Very common side effects (may affect more than 1 in 10 people)	Uncommon side effects (may affect up to 1 in 100 people)
Pfizer- BioNTech	<ul> <li>Pain at injection site</li> <li>Fatigue</li> <li>Headache</li> <li>Muscle pain</li> <li>Chills</li> <li>Joint pain</li> <li>Fever</li> <li>Diarrhea</li> </ul>	Axillary swelling and tenderness (enlarged lymph nodes)



Vaccine	Very common side effects (may affect more than 1 in 10 people)	Uncommon side effects (may affect up to 1 in 100 people)
Moderna	<ul> <li>Pain at injection site</li> <li>Fatigue</li> <li>Headache</li> <li>Myalgia</li> <li>Chills</li> <li>Nausea/Vomiting</li> <li>Axillary swelling and tenderness (enlarged lymph nodes)</li> </ul>	• Fever

Note: Additional details on side effects are available in the Pfizer-BioNTech monograph and the Moderna monograph.

#### 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 alterthe 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.



- Will this vaccine alterthe 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.
- If the recipient received the Pfizer vaccine for their first dose, can they receive the Moderna vaccine for their second dose?
  - No. Currently, no data exist on the interchangeability of COVID-19 vaccines. Both doses should be given with the same vaccine (i.e., dose #1 Pfizer, dose #2 Pfizer or dose #1 Moderna, dose #2 Moderna).



#### **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 <u>Vaccination Recommendations for Special</u>
   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) <u>COVID-19 website</u> 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.
- <u>Symptoms of COVID-19</u> 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 <a href="Public Health Ontario">Public Health Ontario</a> (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 <u>symptoms that could be due to COVID-19</u>, 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 <u>Vaccination Recommendations for Special</u> <u>Populations</u> guidance document

#### Precautions during vaccination should be takenwith:

- 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 <u>Vaccination Recommendations for Special Populations</u> 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 <u>any COVID-19 symptoms</u> 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 othervaccines?

• 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.



Version 2.0 - January 23, 2021

#### **COVID-19 Vaccine Screening and Consent Form**

**SCREENING AND CONSENT FORM -COVID-19 Vaccine** 

Last Name		First	Name	9	Identification (e.g., health card number)		
Sex: ☐ Female☐ Male ☐ Non-Binary ☐				efer not to answer	Primary Care Clinician (Family		
Home Phone	Mobile Ph	ione	Ema	nil Address	Physician or Nurse Practitioner;		
Street Address				City	Province	Postal Code	
Date of Birth (month, day, year)	Age	ls this y	your <b>1</b>	<b>first or second dose</b> of the va	accine? ☐ First ☐ Second		
//				lease indicate the date of the (month, day, year)	e first dose: /		
Please answer all qu	ıestions b	elow:					
Do you have symptom	s of COVID	)-19 or	feel i	ill today*?,	If yes, please provide details		
□ No □ Yes							
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?					If yes, please provide details		
□ No □ Yes							
Do you have a suspect immediate allergic rea occurred within 4 hours including wheezing) to:	If yes, please	e provide details					
A previous dose of an mRNA COVID-19 vaccine     □ No □ Yes							
Any componen     polyethylene g     □ No □ Yes							
Polysorbate (c     hypersensitivi  □ 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.?	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)?	If yes, please provide details
Do you have an autoimmune disease?	If yes, please provide details
□ No □ Yes	
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?

If yes, please provide details

□ No □ Yes

- \* 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 ar	d understand the above stateme	nt.							
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 com  ☐ by email ☐ by text/SMS	nmunications:								
Consent to Being Contacted About R	lesearch Studies								
Many research studies will be conduc	ted in respect of COVID-19 vaccine	es.							
vaccine related research studies. If yo be used to determine which studies n will be disclosed to researchers. Cons you have consented to participate in t	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								
If you consent to be contacted about withdraw your consent at any time by	9								
I consent to be contacted about COV	/ID-19 vaccine related research s	tudies:							
□ by email □ by text/SMS □ by	phone 🛘 by mail								
☐ I do not consent to be contacted a	bout COVID-19 related research s	studies:							
Signature Print Name Date of Signature									
If signing for someone other than you	rself, indicate your relationship to t	hat other person:							
☐ If signing for someone other than n decision maker.	nyself, I confirm that I am the parer	nt / legal guardian or substitute							

#### 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	' '	oduct ame					Lot#				Dose	
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Date Give	n		/ d/yyyy)	/_		1.		am pm AEFI?			Yes □	l No	
Given By Designation	en By (Name, Loc					ocation Authorized By							
Retired Reason for □ LTC Immunization □ Oth				□ 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 Immuniza Given	unizations Not												
Your dose	/ (m/d/yy		_ /	<b>,</b>		 om							