

Ministry of Health

COVID-19 Vaccine Obtaining Informed Consent - Script for Health Care Providers

Version 2.0 – December 30, 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.

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.

The following script is intended for health care providers who will be administering the [Pfizer-BioNTech](#) or [Moderna](#) COVID-19 vaccine.

Note: Informed consent must be obtained prior to administration of the vaccine.

Before Vaccination

1. *Confirm patient information (e.g. name, date of birth, contact information).*
2. *Confirm that patient is seeking to receive a COVID-19 vaccine.*
3. Is this **your first or second dose** of the vaccine?
 - a. If second, ask for the date of the first dose (and skip ahead) and if experienced any side effects after the first dose.

It is strongly recommended that you receive a vaccine to protect yourself against the COVID-19 virus. The vaccine has been authorized for use by Health Canada.

Before we get started, I would like to go over some important details with you about the vaccine that we are giving you today.

- *For Pfizer-BioNTech vaccine:* The vaccine we are offering today is called Pfizer-BioNTech COVID-19 vaccine. This vaccine has been shown to help the body protect itself from becoming sick against the new coronavirus, COVID-19. In order for your body to build up protection against the virus, you will need to receive TWO DOSES of this vaccine, 21 days apart. In the research done to test this vaccine, over 40,000 doses were administered, and no serious side effects associated with this vaccine have been reported to date. However, you may experience some mild side effects in the day or two after receiving the vaccine that often get better on their own. Common side effects with the vaccine can include pain, redness and swelling where the needle was given, tiredness, headache, muscle pain, joint pain, chills, mild fever, and/or swollen glands. As with any treatment, allergic reactions are rare, but can occur after receiving a vaccine. You cannot get COVID-19 from the vaccine.
- *For Moderna vaccine:* The vaccine we are offering today is called Moderna COVID-19 vaccine. This vaccine has been shown to help the body protect itself from becoming sick against the new coronavirus, COVID-19. In order for your body to build up protection against the virus, you will need to receive TWO DOSES of this vaccine, 28 days apart. In the research done to test this vaccine, over 30,000 doses were administered, and no serious side effects associated with this vaccine have been reported to date. However, you may experience some mild side effects in the day or two after receiving the vaccine that often get better on their own. Common side effects with the vaccine can include pain, redness and swelling where the needle was given, tiredness, headache, muscle pain, joint pain, chills, mild fever, and/or swollen glands. As with any treatment, allergic reactions are rare, but can occur after receiving a vaccine. You cannot get COVID-19 from the vaccine.

Check to see if the patient has any questions at this time.

I need to ask you a few questions about your medical history to see if you can receive the COVID-19 vaccine today.

1. Do you have symptoms of COVID-19, for example fever, new onset of cough or worsening of a 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?
 - a. If you are over 70 years of age, have you experienced an unexplained or increased number of falls, acute functional decline, worsening of chronic conditions or delirium?
2. Are you or could you be pregnant?
3. Are you currently breastfeeding?
4. Do you have a bleeding disorder or are taking medications that could affect blood clotting?
5. Are you immunosuppressed due to disease or treatment of an autoimmune disorder?
6. Are you allergic to polyethylene glycol which is contained in the vaccines? *(It can be found in some cosmetics, skin care products, medications including laxatives and cough syrups, and some food and drinks.)*
7. **For Pfizer-BioNTech:** Have you previously had an allergic reaction to any vaccine or any component of the Pfizer-BioNTech vaccine? OR
For Moderna: Have you previously had an allergic reaction to any vaccine or any component of the Moderna vaccine?
8. Have you previously experienced a serious allergic reaction, including anaphylaxis, to another vaccines, drugs (medications) or foods?
9. Have you ever fainted after receiving a vaccine or medical procedures before?
10. Have you received any other vaccines (not a COVID-19 vaccine) in the past 14 days?
11. Do you have any questions?

Would you like to receive your COVID-19 vaccine today?

Have patient read and sign the consent form.

SECOND DOSE

1. Did you have any side effects after you received the first COVID-19 vaccine?
 - a. *If yes and minor side effects, provide advice about how to manage similar side effects, (e.g., You can take pain or fever medication, such as acetaminophen (Tylenol) or ibuprofen (Advil or Motrin), or apply a cool damp cloth where the vaccine was given. If you have any questions or concerns, please contact your health care provider.)*
 - b. *If yes and symptoms of anaphylaxis or other severe side effect(s), confirm if they have already consulted with a health care provider on whether it is safe to receive a second dose, specifically allergist if anaphylaxis. If no, then they cannot receive vaccine.*

Similar to your first dose, I need to ask you a few questions about your medical history to see if you can receive the COVID-19 vaccine today.

2. Do you have symptoms of COVID-19, for example fever, new onset of cough or worsening of a 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?
 - a. If you are over 70 years of age, have you experienced an unexplained or increased number of falls, acute functional decline, worsening of chronic conditions or delirium?
3. Are you or could you be pregnant?
4. Are you currently breastfeeding?
5. Do you have a bleeding disorder or are taking medications that could affect blood clotting?
6. Are you immunosuppressed due to disease or treatment of an autoimmune disorder?
7. Are you allergic to polyethylene glycol which is contained in the vaccines? *(It can be found in some cosmetics, skin care products, medications including laxatives and cough syrups, and some food and drinks.)*

8. **For Pfizer-BioNTech:** Have you previously had an allergic reaction to any vaccine or any component of the Pfizer-BioNTech vaccine? OR
For Moderna: Have you previously had an allergic reaction to any vaccine or any component of the Moderna vaccine?
9. Have you previously experienced a serious allergic reaction, including anaphylaxis, to another vaccine, drugs (medications) or foods?
10. Have you ever fainted after receiving a vaccine or medical procedures before?
11. Have you received any other vaccines (not a COVID-19 vaccine) in the past 14 days?
12. Do you have any questions?

Would you like to receive your COVID-19 vaccine today?

Have patient read and sign the consent form.

After vaccination

Please **wait for 15 minutes** after receiving your vaccine. If you feel unwell while waiting, please let one of the clinic staff know. Longer waiting times of 30 minutes may be recommended if there is a concern about a possible vaccine allergy.

While waiting inside the clinic, please keep your mask on (unless you are unable to wear a mask due to a medical condition) and continue to practice physical distancing (2 meters) from others.

You may experience **some mild side effects** that are common with vaccinations in the day or two after receiving the vaccine. These usually go away on their own. You can take pain or fever medication, such as acetaminophen (Tylenol) or ibuprofen (Advil or Motrin), or apply a cool damp cloth where the vaccine was given. If you have any questions or concerns, please contact your health care provider.

Keep this sheet or other immunization record in a safe place.

It is very important that, even after you receive the vaccine, that you continue to follow the recommendations of local public health officials to prevent the spread of COVID-19. This includes wearing a mask, staying at least 2 metres from others and limiting/avoiding contact with others outside your immediate household. This is because while we are confident that the vaccine reduces your risk of becoming sick with COVID-19, we do not know yet if it stops transmission.

If you got your first dose today of the Pfizer-BioNTech vaccine: Return for your second dose of the Pfizer -BioNTech vaccine in 21 days. Bring this sheet or other immunization record with you for your second dose of vaccine.

If you got your first dose today of the Moderna vaccine: Return for your second dose of the Moderna vaccine in 28 days. Bring this sheet or other immunization record with you for your second dose of vaccine.

Make an appointment now to ensure you receive the second vaccine dose at the right time. Protection offered by the first dose is lower than the efficacy achieved after the second dose.

When you return for your second dose of the vaccine, tell your health care provider if you develop any side effects after today.