

# FREQUENTLY ASKED QUESTIONS ABOUT THE NEW COVID-19 mRNA VACCINES

From the Centre for Effective Practice (January 8, 2021)

## 1. COVID-19 risk and transmission

### *I am not at risk/COVID-19 isn't that bad*

- COVID-19 is much more serious than the flu. In Canada, the flu kills roughly 3,500 patients per year. In less than a year, COVID-19 has killed 4 times that many.
- COVID-19 is very contagious and can cause serious illness. More than 14,000 Canadians and close to 300,000 Americans have died of COVID-19.
- Even if a young and healthy person does not die of COVID-19 infection, they may have long term complications from COVID-19, affecting multiple organ systems. Long-term effects include memory loss, fatigue, body aches, unexplained breathing difficulties, and damage to the lungs and heart. Clinics have already been set up to support the many COVID-19 patients who, although they are no longer infected, cannot go back to work or live a normal life.
- Even if a young and healthy person does not develop severe COVID-19 infection, you may still pass on the virus to someone who will. If you are vaccinated, you're helping protect the people around you.
- Vaccination is the only way to end this pandemic. We and all the members of the healthcare team around you have gotten/will be getting immunized. You can protect yourself, your loved ones, and your community by getting vaccinated.

### *I already had COVID-19. Do I still need a vaccine?*

- Even if you had COVID-19 in the past, it is uncertain how long the antibodies will last. You should still get the vaccine to protect yourself and others, but priority may be given to people who have never been infected.

### *Am I still contagious even if I get vaccinated?*

- The information on this is still developing. Right now, we know that the vaccines protect most vaccinated people from getting sick with COVID-19. For those who still get sick, they appear to get a milder case. However, studies are ongoing as to how the vaccine affects how contagious infected people are. It is important to continue public health measures of distancing and masking even after vaccination, until scientific experts say it is safe to stop.

## 2. Vaccine availability

### *There are not enough vaccines to go around/I want to see what happens to others who have received it*

- The pandemic – and the lockdowns and public health measures – will not end until the majority of Canadians are vaccinated. To ensure we can vaccinate everyone as quickly as possible, it is important that people access the vaccine the first time it is offered to them.
- Canada has ordered more than enough vaccines – we have purchased more shots per person than any other country in the world! We will be getting those vaccines delivered over time. The implementation plan of those vaccines is designed to most efficiently end this pandemic. You can feel confident that when you are offered one, it is because it is the right time for you to get it. This is your chance to do your part to end the pandemic and get back to normalcy quickly.
- If you wait to get vaccinated and get infected in the meantime, you may end up in hospital – which would put more strain on the system than getting the vaccine.
- If Canadians wait to get the vaccine, the pandemic will keep going – and that includes the restrictions, inability to see family and friends, send your kids to school, travel.
- If Canadians wait to get the vaccine, more people will die.

## 6. Religious beliefs

### *I don't know if my religious beliefs allow me to take the vaccine*

Some patients may have questions regarding their religion and receiving COVID-19 vaccines.

The approved COVID-19 vaccines do not contain any food products or gelatin and are considered recommended or permissible by many religious organizations (South Asian Covid Task Force and COVID-19 Made Simple, 2021).

Many religious organizations have issued statements that encourage COVID-19 vaccination for the health and safety of individuals and their communities, following the advice of patients' healthcare providers.

These organizations include:

- The Vatican and the Canadian Conference of Catholic Bishops
- Muslim American Society
- World Jewish Congress and World Council of Churches
- Orthodox Union and Rabbinical Council of America

#### 4. Special populations and contraindications

##### *I'm pregnant/breastfeeding, or planning to become pregnant. Should I receive a COVID-19 vaccine?*

Neither the Pfizer-BioNTech vaccine or the Moderna vaccine has been tested in pregnant women, so more studies are needed. There is no known mechanism to suggest that it could affect fertility negatively, just that evidence is limited. The women who were included in the Pfizer study and found out were pregnant after having had the vaccine, have not had any known adverse events so far. However, the potential harm of COVID-19 is well-established. Let's discuss the benefits and risks and come to a decision together.

##### *Can the Pfizer-BioNTech vaccine be given to children?*

- The Pfizer-BioNTech vaccine has not been tested in children. The clinical trial included people aged 16 and over.
- Currently, it is not recommended that the vaccine be administered to children under 16, as children often need a different dose than adults and may show stronger immune reactions. More data are expected in 2021.

##### *Can the Moderna vaccine be given to children?*

- The Moderna vaccine has not been tested in children. The clinical trial included people aged 18 and over.
- Currently, it is not recommended that the vaccine be administered to children under 18, as children often need a different dose than adults and may show stronger immune reactions.

##### *Does the Pfizer-BioNTech work in older people?*

- The Pfizer-BioNTech vaccine trials included patients aged over 65, and the efficacy was very similar to the younger age group, with older patients experiencing slightly fewer side effects like local reactions, headaches and body aches.

##### *Does the Moderna vaccine work in older people?*

- The Moderna vaccine trials included patients aged over 65, and the efficacy was 86.4% – similar to the younger age group.
- Older patients experienced slightly fewer side effects like local reactions, headaches and body aches.

##### *Is a previous history of allergies a contraindication to the Pfizer-BioNTech vaccine?*

- Health Canada has not made a recommendation that anyone with a history of severe allergic reactions should avoid the Pfizer-BioNTech vaccine. There is no evidence that people with allergies to non-vaccine ingredients are at higher risk of allergy to the vaccine.
- However, those with a known allergy to a component of the vaccine is a contraindication should not get this vaccine.
- The Pfizer-BioNTech vaccine is contraindicated in those with a known diagnosis of anaphylaxis to polyethylene glycol.

- It is always advised to wait 15-20 minutes after receiving a vaccine, since an allergic reaction or anaphylaxis is always a possible reaction to any medication or vaccination.
- There are many vaccines currently under development. Some patients may be allergic to an ingredient in one, but not another. Health Canada has purchase agreements with six other vaccines that are different from the Pfizer-BioNTech vaccine.

### Have the vaccines been tested in people of colour or other minority groups?

- In both the Pfizer-BioNTech and Moderna trials, between 35-40% of the participants were Black or African American, Latinx and Hispanic.

## 5. Vaccine Ingredients and Efficacy

### What are the Pfizer-BioNTech vaccine ingredients? Does it contain mercury, formaldehyde, aluminum, or fetal cells?

- **No. It does not contain mercury, formaldehyde, aluminum, or fetal cells.**
- The ingredients of the vaccine are:
  - Medicinal ingredient: BNT162b2 (mRNA)
  - Non-medicinal ingredients:
    - 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

### What are the Moderna vaccine ingredients? Does it contain mercury, formaldehyde, aluminum, or fetal cells?

- **No. It does not contain mercury, formaldehyde, aluminum, or fetal cells.**
- The ingredients of the vaccine are:
  - Medicinal ingredient: mRNA-1273 SARS-CoV-2
  - Non-medicinal ingredients:
    - 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
    - acetic acid
    - cholesterol
    - PEG2000 DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol)
    - lipid SM-102
    - sodium acetate
    - sucrose
    - tromethamine
    - tromethamine hydrochloride
    - water for injection

### If the vaccines are 94-95% effective, does that mean I cannot get COVID-19?

- **No. Vaccinated individuals can still be infected, but vaccination greatly reduces the risk of infection, and reduces the risk of an infection progressing to the more severe form of the disease.**

## 6. Side effects

### Can the vaccines cause COVID-19 disease?

- The vaccine cannot give you COVID-19 or any other infectious disease. None of the licensed vaccines so far use the live virus that causes COVID-19.
- It is still possible to contract COVID-19 after you have been vaccinated. Like with other vaccinations, it takes a few weeks for the body to build immunity after vaccination. Someone could be infected with the virus just before or just after vaccination and get sick, because the vaccine didn't have enough time to provide protection.

### What are the side effects of the Pfizer-BioNTech vaccine?

- Most people can expect to feel a sore arm, a bit of tiredness and a mild headache as the vaccine starts to work. Some people will feel muscle aches, chills, or a mild fever. Reactions at the injection site will improve by 48-72 hours.
- Around 1 in 10 people will feel like they want to take acetaminophen or ibuprofen.
- Less often, people may experience enlarged lymph nodes (1 in 100). Other rare side effects include anaphylaxis, especially if someone has a history of a severe allergy.

#### **Very common side effects** (may affect more than 1 in 10 people)

- Pain at injection site (84.1%\*)
- Fatigue (62.9%\*)
- Headache (55.1%\*)
- Muscle pain (38.3%\*)
- Chills (31.9%\*)
- Joint pain (23.6%\*)
- Fever (14.2%\*)

#### **Uncommon side effects** (may affect up to 1 in 100 people)

- Enlarged lymph nodes (0.008%\*\*)

\*subset (n=8183)

\*\*subset (n=7960)

### What are the side effects of the Moderna vaccine?

- Most people can expect to feel a sore arm, a bit of tiredness and a mild headache as the vaccine starts to work. Some people will feel muscle aches, chills, or a mild fever.
- The majority of local and systemic adverse reactions had a median duration of 1 to 3 days.

#### **Most frequently reported side effects**

- Pain at injection site (92%)
- Fatigue (70%)
- Headache (64.7%)
- Muscle pain (61.5%)
- Chills (5%)

### Is Bell's Palsy a possible side effect of the Pfizer-BioNTech vaccine?

- Among the almost 22,000 vaccinated with the Pfizer-BioNTech COVID-19 vaccine, there were 4 cases of Bell's palsy. This number of Bell's palsy cases is consistent with the expected rate in the general population and did not suggest it was caused by the vaccine. Three cases occurred within one month after both doses were completed, and one case occurred later than one month after both doses were completed, and all four patients recovered.
- More research will be conducted as this was the only "imbalanced" occurrence that happened more in the vaccine arm of the study than the placebo arm.
- Those with previous history of Bell's palsy may still take this vaccine.

### Should I receive the second shot of the vaccine if I experience mild side effects?

- Yes. Mild side effects are common for all vaccines.

### How should I deal with local reactions from the vaccines?

- There could be soreness and swelling which for some might be significant (sometimes from shoulder to elbow). In these cases:
  - Use cold compresses over the site.
  - Know that local reactions, even big ones, improve by 48-72 hours. If the reaction worsens at 72 hours or has not disappeared in 5 days, seek medical attention.
  - Even though sometimes this reaction can look like an infection, the risk of skin/local infection from a vaccine needle is very small. These reactions do not need any antibiotics in the first 72 hours.
  - If the swelling progresses rapidly, is associated with breathing problems, or makes you very concerned about an allergic reaction, seek urgent medical attention and/or call 9-1-1.

## 7. Vaccine safety and adverse events

### Other vaccines in the past were not safe. Why are these new ones safe?

- It is true that some vaccines in the past were associated with adverse events and then removed from the market. Those vaccines were not tested in nearly as many people as the COVID-19 vaccines. Normally, vaccine clinical trials need 6000-8000 people for the approval process. The Pfizer-BioNTech trial had over 45,000 people and the Moderna trial over 30,000.

### Is there long-term data on safety and immunogenicity?

- Since the vaccines are new, studies are ongoing to determine how long the immunity lasts or if there are long-term side effects. The long-term data we're still waiting for is more about long-term efficacy (how long immunity lasts) than long-term safety.
- Studies have been reassuring that there are no serious adverse effects for the duration of clinical trials in tens of thousands of people so far. It is very unlikely for long-term effects to develop, as these initial vaccines are not live vaccines and side effects most often present in the first few days after vaccination.

## 8. mRNA Vaccines

### How do mRNA vaccines work?

- The purpose of any vaccine is to mimic the infection, get the body to build immunity to the virus but not cause the illness. The vaccine will train the immune system to recognize COVID-19 and respond quickly if you are ever exposed to the actual COVID-19 virus.
- mRNA is something we already rely on in our bodies. On a regular basis, mRNA (messenger RNA) carries genetic messages from the DNA to the ribosomes – the “kitchen” of each cell, where the proteins we need for everyday life are made. mRNA is the recipe that carries information for protein production. Our immune system “reads” our proteins to develop antibodies.
- A COVID-19 mRNA vaccine contains the genetic material to make the “spike protein” that instructs the immune system to develop antibodies against COVID-19. This spike protein does not cause disease: rather, once our immune system sees the spike protein made, it builds antibodies to it. The vaccine does not stay in your body and does not change your own body in any way. After the protein is made, the cell breaks down the recipe instructions (mRNA).

### Can these vaccines mess with genes or change DNA?

- mRNA vaccines do not change your DNA. Human beings do not have the enzymes to convert RNA into DNA. In fact, our cells have enzymes that destroy the mRNA after the protein is made – which is why the vaccine doesn't stay in your body for long.

## 9. Vaccine development and approval process

### Did scientists and the government skip steps to rush vaccine production and approval?

- No steps were skipped in the process of developing, testing, approving, and producing the vaccines.
- Canada's best independent scientists have thoroughly reviewed all the data before approving the vaccines as safe and effective for Canadians.

- The vaccines were produced faster than before not because of skipped steps but because of never-before-seen levels of collaboration and funding around the world invested in this effort. Normally, vaccine clinical trials need 6000-8000 people for the approval process. The Pfizer-BioNTech trial had over 45,000 people and the Moderna trial over 30,000.
- Unlike with other vaccines that go one step at a time and then plan the next step, for the COVID-19 vaccines, governments invested in having companies plan all the steps at the beginning and build up their manufacturing capacity right away.
- [We have reviewed the steps taken and have full faith in it. We physicians, our colleagues, and our families will be taking or have taken the vaccine. Health Canada is known to have a rigorous and thorough approval process to ensure the safety of all Canadians.](#)

### *How can the vaccines have been developed so quickly?*

- [The use of mRNA for vaccines and treatment of disease has been around for a while – that's one of the reasons why these vaccines could be developed so quickly.](#) mRNA vaccines have been used in animal models for influenza, Zika, Rabies, CMV and others, and in humans for cancer treatment and cancer vaccine clinical trials.
- mRNA vaccines are like CD players that can play any kind of CD – classical music, rap or pop. The scientists had the CD player before COVID-19 hit. Once they figured out the Coronavirus CD, they could place it into the player and make the vaccine a lot faster than before, since they used what was known and built on it.

### *Who is involved in licensing and reviewing the safety of a vaccine? How much pharma involvement is there in the studies?*

- The pharmaceutical companies manufacture the vaccine and sponsor and conduct the clinical trials, but [all vaccine clinical trials must have an independent data and safety monitoring board review the vaccine efficacy and unblind the data.](#)
- [As the trial is completed, Health Canada reviews all safety and efficacy data before allowing the vaccine to be used in the Canadian population.](#)
- After a vaccine has been approved for use and made available, its safety is continuously monitored by healthcare providers and Canada-wide networks specifically designed for safety. Health Canada monitors national and international vaccine safety reports and will update information about the vaccine as it becomes available.