

## SOGC COVID-19 Vaccination in Pregnancy FAQ for Patients

## How does COVID-19 infection affect a pregnant woman?

In most pregnant women, COVID-19 causes mild symptoms such as fever, cough, and muscle aches that will get better by themselves, similar to the symptoms in non-pregnant women. The majority of babies born to patients with COVID-19 are healthy and full term.

However, compared to non-pregnant women, pregnant women who have COVID-19 have a higher risk of requiring breathing support, and being admitted to intensive care. Compared to uninfected pregnant patients, COVID-19 infections increases the risk of delivering before the due date (at less than 37 weeks gestation). People who are older (over 35 years of age), obese (body mass index higher than 30), or have certain medical conditions (such as heart disease, diabetes, high blood pressure, or asthma) are at even higher risk of these complications.

### How effective are the vaccines against COVID-19?

In the published research trials, the Pfizer-BioNTech vaccine was 94.1% effective and the Moderna vaccine was 95% effective, both after two doses. For AstraZeneca, the vaccine was 70.4% effective, while the Janssen vaccine was 66.9% effective. Some of this difference may be explained by the level of COVID-19 variants at the time of the study.

Even one dose reduces the risk. Recent studies show that one dose of the mRNA vaccine (Pfizer-BioNTech and Moderna) and AstraZeneca vaccines reduces infection rates by 60-80% and 58-68% respectively. **These vaccines are all over 80% effective in preventing hospitalizations and deaths, which are the most important outcomes.** 

## What are the side effects of the COVID-19 vaccine?

The most common side effects are mild and get better on their own. These include soreness, redness, pain at the injection site, headache, feeling tired, swollen lymph nodes, and fever. Most of these side effects are related to the immune system ramping up a response to develop protection from COVID-19 infection.

There were no clear associations with severe side effects noted in the trials of the four vaccines. The occurrence of severe allergic reactions (anaphylaxis) was 11.1 per 1 million injections, which is very low.

Canada has a surveillance system in which all adverse effects are reported. You can read about it here: <u>https://health-infobase.canada.ca/covid-19/vaccine-safety/</u>

## How much do we know about the COVID-19 vaccine in pregnancy?

Over 90,000 pregnant women have been vaccinated against COVID-19 in the United States. No major side effects have been identified at this point. There are no differences in miscarriage, preterm births, stillbirths or birth defects noted. Studies on pregnant animals were also completed with no safety concerns.

Pregnant women were excluded from the initial vaccine trials, however some participants found out they were pregnant after their first dose. There were no effects on them or their newborns. We are now awaiting trials of pregnant individuals, which began enrolling patients in early 2021.

If you have been vaccinated while pregnant or breastfeeding, you are invited to participate in the Canadian Vaccine Registry here: <u>https://ridprogram.</u> <u>med.ubc.ca/vaccine-surveillance/</u>

## What benefits do we expect to see from the COVID-19 vaccine in pregnancy?

We expect the effectiveness to be similar in pregnant and non-pregnant women. If you are pregnant and receive the COVID-19 vaccine, you should be at a lower risk of acquiring the infection and at a lower risk of having severe COVID illness (such as requiring breathing support, needing to be admitted to intensive care, and delivering before your due date).

In pregnant patients, studies have shown that antibodies from vaccines are present in the umbilical cord and breast milk, which can be transferred to your newborn. However, there are no studies to show how effective the antibodies are at protecting the newborn from COVID-19.

## What side effects do we expect to see from the COVID-19 vaccine in pregnancy?

The side effects of COVID-19 vaccines should not be significantly different between pregnant and nonpregnant women.

One recent study of 30,000 + participants showed that pregnant individuals have more injection-site pain, but fewer muscle pains, headaches, fevers and chills. No other safety concerns were identified in the study.

#### Should I get the COVID-19 vaccine?

All pregnant women should be offered the COVID-19 vaccine, if they are eligible (based on their provincial/ territorial and local policies) and they have no allergies to the vaccine ingredients.

Pregnancy is **not** a reason to be excluded from vaccination. With recent severe COVID-19 infections seen in pregnant women in Canada, pregnancy should be a reason to be prioritized for COVID-19 vaccination.

The decision to get vaccinated depends on each person's risk profile and personal choice. Each individual has different factors that may influence decision including:

- Age (over 35)
- Body mass index (over 30)
- Existing medical conditions
- COVID-19 infection rates in their local area
- Workplace exposures
- Own beliefs regarding vaccination

Your health care providers are available to explore this topic with you. However, you do not need to see a health care provider before vaccination, if you are eligible and have no allergies to the vaccine or its ingredients. You are the ultimate decision-maker about whether you receive the COVID-19 vaccine.

## When will we know more about the COVID-19 vaccine in pregnancy?

Since some pregnant women are choosing to get vaccinated, public health agencies across the world are also conducting surveillance programs involving these individuals. In the United States, over 90,000 pregnant women have been vaccinated, and over 4,000 are enrolled in a study registry. There is also a concurrent Canadian vaccine registry for pregnant and lactating individuals.

Pharmaceutical companies began enrolling pregnant women in new trials in early 2021.

## Certain vaccines are not given during pregnancy. Why is this one different?

The vaccines that are not recommended in pregnancy contain weakened, but live viruses that can cause a form of weak infection. These vaccines are not recommended during pregnancy. However, pregnant women who were vaccinated with weakened viruses before they realized they were pregnant have had no consequences (both for the pregnant person and the newborn).

The Pfizer-BioNTech and Moderna COVID-19 vaccines do not contain a live or weakened virus. Instead, they are based on mRNA, the recipe for the spike protein on the surface of the COVID-19 virus. This allows your body to make only this surface protein (not the virus itself), which will then trigger your immune system to make antibodies to protect you from anything with that protein (such as the COVID-19 virus).

The Janssen and AstraZeneca COVID-19 vaccines also do not contain weakened viruses. Instead of mRNA, these vaccines use a modified virus that cannot cause infections in humans to carry the recipe for the spike protein. This allows your body to make the spike protein (not the virus itself), which will then trigger your immune system to make antibodies to protect you from anything with that protein (such as the COVID-19 virus). At this time, the age eligibility for the AstraZeneca vaccine is provincially dependent. Please refer to your provincial government's guidelines for further information. If eligible, all vaccines are appropriate to be given in pregnancy in every trimester.

## What are the chances of severe allergic reactions in pregnancy?

There are limited data on allergic reactions to COVID-19 vaccines in pregnancy. However, in the general population, the risk of a severe reaction (anaphylaxis) is extremely low: 11.1 per 1 million vaccinations. The risk is expected to be similar in pregnant women.

You cannot receive the COVID-19 vaccine if you have allergies to the vaccine (as discovered after the first dose) or to the vaccine ingredients (including polyethylene glycol [PEG]).

You can receive the vaccine if you have other allergies, including nuts, eggs, seafood, latex, or other drugs. We don't expect these allergies to affect your risk of allergic reactions to the COVID-19 vaccine.



### How long will I be protected from COVID-19 infections if I get the vaccine?

Since the original studies took place over a 2-month period, we do not have a definitive answer beyond this time period. However, in these studies, patients' immunity was stable to the end of the 2-month period. Recent follow-up studies suggest immunity may reach six months.

We will know more as the clinical trials and vaccine rollout continue.

#### I've had COVID-19 in the past and I'm currently pregnant. Should I get the vaccine?

There is little known about COVID-19 vaccines in previously infected individuals. The duration of natural immunity is also currently uncertain. It appears that reinfection is rare, especially in the 90 days after illness.

Your local public health unit or provincial/territorial government may set restrictions on whether you can get a vaccine if you have had a previous COVID-19 infection. Please check with your local health authority to determine whether you are eligible for vaccination.

#### I've just received other vaccines recommended in pregnancy. How long should I wait to receive the COVID-19 vaccine?

It is recommended that you receive both influenza (depending on the season) and Tdap (tetanus, diphtheria, and pertussis) vaccines in pregnancy. If you have recently received your COVID-19 vaccine, please wait 28 days from your last dose before receiving other vaccine.

If you have received another vaccine, please wait 14 days before receiving your COVID-19 vaccines.

### I am trying to get pregnant. How long should I wait to try after getting my vaccine?

If you have recently received your COVID-19 vaccination, we would recommend completing the full series before trying to get pregnant. This will protect you and your newborn from the risks associated with COVID-19 in pregnancy. There is no evidence to delay attempts in becoming pregnant. If you choose to delay your pregnancy based on personal choice, delaying for one month would be enough to remove theoretical risks.

If you are still waiting for your turn to be vaccinated, whether to delay conception until you are vaccinated is ultimately up to you.

# I just received the COVID-19 vaccine and found out I was already pregnant. What should I do?

There were no safety issues with the vaccine in pregnant women. At this time, we recommend routine prenatal visits with your health care providers. No additional visits, tests or ultrasounds are required.

## If I am currently breastfeeding, should I receive the COVID-19 vaccination?

All breastfeeding individuals should be offered the COVID-19 vaccine, if they are eligible (based on their provincial/territorial and local policies) and they have no allergies to the vaccine or vaccine ingredients.

Individuals who were breastfeeding were excluded from the original vaccine trials. However, we do not expect that effectiveness or side effects will be any different in breastfeeding individuals than in the general population. Recently, studies showed that breastmilk produced by vaccinated breastfeeding women contained the COVID-19 antibody. However, we don't yet know if the antibodies from vaccination will protect your newborn. Other ingredients in the vaccine are safe with breastfeeding.

### Does the mRNA vaccine (BioNTech-Pfizer, Moderna) alter my DNA or my baby's DNA?

No. The mRNA vaccine is the recipe for the spike protein on the surface of the COVID-19 virus. This allows your body to make only this surface protein (not the virus itself), which will then trigger your immune system to make antibodies to protect you from anything with that protein. The mRNA is then destroyed, and the cells that converted the vaccine into surface proteins naturally die over a couple of weeks.

The mRNA does not enter the cell's nucleus, where our DNA and genes are stored. Similarly, the vaccine does not enter the nucleus of fetal cells and has no way to affect the DNA or genes of a developing baby.

### Does the COVID-19 vaccine cause COVID-19 infections?

No, there is no evidence to support this claim. There is no live virus in any vaccines. The side effects such as fevers, muscle aches, and fatigue are part of the process your body goes through to make protective antibodies.

Keep in mind that you can acquire COVID-19 infection from other people while you are receiving your vaccines. The protection was measured 2 weeks after the second dose was given. While it provides great protection from illness, it is not 100% effective, so safety measures like physical distancing, handwashing, and mask wearing still apply.

## Does the COVID-19 vaccine cause male or female infertility?

No, there is no evidence to support this claim. This rumour stems from an incorrect assumption that the spike protein is similar to a protein in the placenta used for implantation. Since the spike protein and the placenta-related protein are actually quite different, the antibody produced by the COVID-19 vaccine does not react with the placenta-related protein. At this time, COVID-19 infections have reached over 100 million cases. If the antibody produced by the COVID-19 vaccine reacted with the placenta-related protein, the individuals who recovered from the infection (who developed natural antibodies) would have high rates of infertility. But this is not the case.

## Does the COVID-19 vaccine cause Bell's palsy?

There is no conclusive association between the COVID-19 vaccines and Bell's palsy, according to the American Academy of Otolaryngology – Head and Neck Surgery. There were a small number of cases of this condition seen in the trials (6 cases in more than 33,000 vaccinations).

The influenza vaccine (flu shot) once led to concern it might cause Bell's palsy, and further studies ultimately disproved this concern.

## Are fetal cells used to develop the COVID-19 vaccine?

Pfizer-BioNTech and Moderna vaccines did not involve fetal cells in their development.

Human cell lines derived from fetal cells were required for the development of the AstraZeneca and the Janssen vaccines, but they are thousands of generations removed.

In March 2021, the Canadian Conference of Catholic Bishops stated: "Catholics in good conscience, may receive the vaccine that is available and offered to them."

## Is there pork or other animal products in the COVID-19 vaccines?

No, there are no animal products (including pork) in the COVID-19 vaccines currently available.

## Are there microchips in the COVID-19 vaccine?

No, there are no radio-frequency identification (RFID) microchips in the COVID-19 vaccine. There is no RFID microchip that can fit into a syringe and be injected.

This social media misinformation accused Bill Gates, a businessman who formerly headed Microsoft Corporation, of adding microchips to vaccines, and he has said this rumour is not true on several occasions. Bill Gates is developing a technology to inject a dye under the skin as a way of vaccination recordkeeping. It is still under development and not being used in the COVID-19 pandemic.

## If I do not have side effects from the vaccines, does this mean the vaccine did not work?

From the published data, not everyone who receives the vaccine gets significant side effects. Everyone's immune system reacts differently to vaccines.

For example, while a significant number of people who receive the second dose of the Moderna vaccine had side effects such as fatigue (65%), muscle aches (58%) and fevers (15%) – many did not have any side effects. This is similar for the Pfizer-BioNTech vaccine. Your experience with the vaccines' side effects does not impact the effectiveness of the vaccine.

## Do the COVID-19 vaccines work against the emerging variants?

There is no conclusive evidence on the level of protection of the approved COVID-19 vaccines against any new variants of the SARS-CoV-2 virus.

Viruses mutate (change) to avoid our immune systems. The early evidence is mixed with some vaccines seem to be similarly effective while others are not. However, it is important to remember that the vaccine was over 90% effective to begin with. So, even a vaccine that is 20% less effective still offers good protection against COVID-19. Pharmaceutical companies are always trying to adapt their vaccines as the COVID virus changes.

Additional research is needed for each specific vaccine to determine how well they work against each variant. This will need to be determined for individual vaccines due to the different ways of protecting against COVID-19.

## Should I receive the AstraZeneca and Janssen vaccine due to the clotting risk?

There is an ongoing investigation on the observed blood clots following administration of the AstraZeneca and Janssen vaccinations. The risk of developing a clot related to the vaccines is estimated to be less than 1 in 100,000. The risks associated with getting COVID-19 infection in pregnancy are greater than the risk of a rare blood clot. Delays in vaccination puts you at risk of severe COVID-19 infections.

The eligibility criteria for receiving the AstraZeneca and Janssen vaccines are dependent on regional recommendations. We support the use of all available COVID-19 vaccines approved in Canada in any trimester of pregnancy and during breastfeeding in accordance with regional recommendations.

# Since pregnancy puts me at higher risk of clots, am I at higher risk of the vaccine-related clots?

The way that clots form in pregnancy is different from how experts believe that the blood clots are formed following some vaccines (AstraZeneca and Janssen). The clots related to pregnancy usually affect the lungs and legs. Meanwhile, the clots related to vaccines usually affect the brain and intestines.

As they are caused in different ways, there is no current evidence to suggest that pregnancy would increase the risk of clots related to the vaccine.

## Should I worry now that we're extending the interval between vaccine doses?

The decision to extend the time interval between doses is based on research that shows that one dose of the available vaccines is effective in preventing infections and their protection is sustained. Using this information, a mathematical model was created and showed significant benefits in reducing COVID-19 infections, hospitalizations and deaths when extending the interval between doses. Original date: February 16th, 2021 Revision date: April 30th, 2021

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More information: pregnancyinfo.ca