

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 Pfizer-BioNTech and Moderna 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. This means the vaccine reduces the rate of developing COVID-19 infection by 95% when compared to no vaccine. Even one dose reduces the risk. The effectiveness of the Pfizer-BioNTech vaccine was 52% one week after the first dose. The effectiveness of the Moderna vaccine was 80.2% after one dose, but we don't know about the effectiveness of one dose beyond 28 days.

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 two 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: <https://health-infobase.canada.ca/covid-19/vaccine-safety/>



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

Pregnant women were excluded from the initial vaccine trials. Data for pregnant women are limited to 36 participants (23 in the Pfizer-BioNTech vaccine trial and 13 in the Moderna vaccine trial) who found out they were pregnant after their first dose. There were no effects on the pregnant women or their newborns, and these individuals are being followed by the research team. However, these numbers are too few to reach any conclusions.

Studies of pregnant animals for both vaccines are now completed, and there were no safety concerns. There were no changes in the rate of miscarriage, and no adverse effects on fetal development or newborn function. We are now awaiting trials with pregnant women, which are planned for early 2021.

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. The level of protection should remain high in pregnant women. If you are pregnant and receive the COVID-19 vaccine, you should be at a lower risk of acquiring the infection and therefore 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).

Studies have recently shown that pregnant women who recover from a COVID-19 infection transfer protective antibodies to their newborn. However, we do not know whether the antibodies from a COVID-19 vaccine would also be transferred to the newborn. 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 non-pregnant women. This means that we expect side effects to be mild, short-lasting, and get better on their own. Some other vaccines actually have fewer side effects in pregnant patients, because a pregnant patient's immune system is slightly different from normal. In order to protect the newborn, which the body recognizes as a 'foreign' object, the pregnant immune system is less reactive.

Should I get the COVID-19 vaccine?

We believe that 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. On the other hand, pregnant women do not take priority for 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 > 35 years
- Body mass index > 30
- Existing medical conditions
- COVID-19 infection rates in local area
- Workplace exposures
- Own beliefs regarding vaccination
- The level of risk you are willing to accept (of vaccination or of remaining unvaccinated)

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?

Studies of pregnant animals were recently completed and were reassuring. Pharmaceutical companies will begin enrolling pregnant women in new trials in early 2021. Since some pregnant women are choosing to get vaccinated, public health agencies across the world are also conducting surveillance programs involving these individuals.

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

The vaccines that are not recommended in pregnancy contain weakened viruses. Since pregnant women are considered to have a weaker immune system, we do not give them vaccines containing weakened viruses, to be extra cautious about causing harm to the fetus. However, pregnant women who were inadvertently vaccinated with weakened viruses before they realized they were pregnant have had no poor outcomes, for either the patient or the newborn.

The Pfizer-BioNTech and Moderna COVID-19 vaccines do not contain a 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).

At this time, there are no restrictions on giving COVID-19 mRNA vaccines in pregnancy. If additional vaccine options become available that include a weakened virus, these options will be addressed separately.

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 the studies, patients' immunity was stable to the end of the 2-month period.

We will know more as the research continues, since there is a planned 2-year surveillance period for both the Pfizer-BioNTech and Moderna vaccine trials.

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.

If you are eligible to be vaccinated, we recommend that you weigh the risk and benefits of vaccination versus remaining unvaccinated. You may have a degree of natural immunity from a previous COVID-19 infection, but its effects in future protection are unclear.

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 higher risks associated with COVID-19 in pregnancy. There is no evidence to require a delay between the date you complete your vaccine series and your attempt to get 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 entirely 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 the pregnant women included in the vaccine trials. 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. We don't yet know if the antibodies from vaccination will protect your newborn. Other ingredients in the vaccine are safe with breastfeeding.

If you are eligible for the COVID-19 vaccine, we recommend that you weigh the risks and benefits of vaccination versus remaining unvaccinated.

Does the mRNA vaccine 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 the vaccine. 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 strong 95% protection was measured 1 week after the second dose was given. While it provides exceptional protection from illness, it is not 100%, 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?

No, there are no fetal cells used in the development of the Pfizer-BioNTech or Moderna COVID-19 vaccines. This has been confirmed by lobby groups who monitor pharmaceutical companies for this practice.

As well, the Vatican has recently published a statement stating that, if "ethically irreproachable COVID-19 vaccines are not available, it is morally acceptable to receive COVID-19 vaccines that have used cell lines from aborted fetuses in their research and production process."

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

No, there are no animal products (including pork) in the 2 COVID-19 mRNA 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.

Pathogens mutate (change) to evade host defenses. Fortunately, mRNA vaccine technology is adaptable and pharmaceutical companies are exploring modified vaccines to better match the different variants.

Additional research is needed for each specific vaccine to determine how well they work against each variant. This will need to be determined for individually due to the different mechanisms of achieving immunity.

Some manufacturers have reported that the COVID-19 vaccine may be less effective against certain variants of the virus. 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.

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