

SOGC COVID-19 Vaccination in Pregnancy FAQ for Health Care Providers



SOGC Consensus Statement: Women who are pregnant or breastfeeding should be offered vaccination at any time, if they are eligible and there are no contraindications.

COVID-19 and Current Vaccines

What are the increased risks related to COVID-19 in pregnancy? Who is at increased risk?^{1, 2}

- In most pregnant patients, COVID-19 infections lead to mild symptoms (fever, myalgia, and cough).
- The majority of babies born to patients who had COVID-19 during pregnancy are born healthy and at full term.
- While absolute risks remain low, pregnant patients with COVID-19 infection were more likely to:
 - Require admission to intensive care (compared to non-pregnant patients)
 - Require invasive ventilation (compared to non-pregnant patients)
 - Deliver prematurely (compared to uninfected patients)
- Risk factors for increased morbidity include:
 - Age \geq 35 years old
 - Asthma
 - Obesity (body mass index $>$ 30 kg/m²)
 - Pre-existing diabetes
 - Pre-existing hypertension
 - Heart disease

What are the data on efficacy of the available vaccines in the general public?^{3, 4}

- For the Pfizer-BioNTech vaccine, the vaccine efficacy was 95.0% in preventing COVID-19 infection, based on data starting 7 days after the second injection.
 - Infection rate was reported as 0.9% in the placebo group versus 0.05% in the vaccine group.
 - The efficacy rate after one dose was 52.4%.
- For the Moderna vaccine, the vaccine efficacy was 94.1% in preventing COVID-19 infection, based on data starting 14 days after the second injection.
 - Infection rate was reported as 1.3% in the placebo group versus 0.08% in the vaccine group.
- For the AstraZeneca vaccine, the efficacy was 70.4% in preventing COVID-19 infection, based on data starting 14 days after the second injection.⁵
 - Infection rate was reported as 1.6% in the placebo group versus 0.6% in the vaccine group.
- For the Janssen vaccine, the efficacy was 66.9% in preventing against moderate to severe COVID-19 infection, based on data starting 14 days after the second injection.⁶
 - Infection rate was reported as 1.8% in the placebo group versus 0.6% in the vaccine group.
 - Janssen's primary end-point was moderate to severe COVID-19 rather than all COVID-19 infections.

What are the data on safety of the available in the general public?^{3, 4, 7}

In the Pfizer-BioNTech trial, vaccines were administered to 18,860 individuals.

- Common side effects included the following (depending on dose and age of recipient). Most side effects started at 15 hours post-vaccination and resolved by the end of the second day.
 - Mild to moderate pain, redness, or swelling at injection site (66% to 83%)
 - Fatigue (51% to 59%)
 - Headache (39% to 52%)
 - Fever (11% to 16%)
 - Lymphadenopathy (0.3%)
- Only four individuals in the vaccination group reported serious adverse events (SAEs). Overall, the incidence of SAEs was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively).
- In the trial, 2 deaths were observed in the vaccination group, while 4 were observed in the placebo group. None of these deaths were considered to be related to the vaccination or placebo.
- A 2-year safety monitoring program is ongoing.

In the Moderna trial, vaccines were administered to 15,181 individuals.

- Common side effects included:
 - Mild to moderate pain, redness, or swelling at the injection site (up to 83%)
 - Fever/chills (up to 15.5%)
 - Headache (up to 58%)
 - Fatigue (up to 65%)
 - Myalgia (up to 58%)
 - Arthralgia (up to 42%)

- In the trial, 2 deaths were observed in the vaccination group, while 3 deaths were observed in the placebo group. These were not related to the vaccination.
- Overall, SAEs were similar between vaccine and placebo groups (0.6% in both groups).
- A 2-year safety-monitoring program is ongoing.

In the AstraZeneca trial, vaccines were administered to 12,021 individuals⁸

- Common side effects included:
 - Tenderness (75.3%) or pain (54.2%) at the injection site
 - Fatigue (62.3%)
 - Headache (57.5%)
 - Myalgia (48.6%)
- In the trial, 1 death was observed in the vaccination group, while 4 deaths were noted in the placebo arm.
- Non-fatal serious adverse events were similar between groups (0.7% vaccination group vs 0.8% placebo group)
- Safety monitoring program is ongoing

In the Janssen trial, vaccines were administered to 21,895 individuals⁶

- Common side effects included:
 - Injection site pain (48.6%)
 - Headache (38.9%)
 - Fatigue (38.2%)
 - Myalgia (33.2%)
- In the trial, 3 deaths were observed in the vaccination group, while 16 deaths were observed in the placebo group. None of the deaths were related to the vaccine.
- Non-fatal serious adverse events were similar between the groups (0.4% each)

From a Canadian perspective, there is an ongoing national surveillance program for COVID-19 vaccinations.

- As of March 12, 2021, 2209 adverse events (0.078%) following immunization were reported from 2,830,164 total vaccinations
 - 287 events (0.01%) were deemed serious.
 - The reported Canadian adverse events related to immunization included vaccination-site reactions, paresthesia, pruritis, urticaria, headache, hypoesthesia, nausea, and anaphylaxis.
- For up-to-date information, please refer to: <https://health-infobase.canada.ca/covid-19/vaccine-safety/>

What is the current state of evidence regarding the benefits of COVID-19 vaccination in pregnancy?^{9, 10}

- Pregnant patients were excluded from all current available trials. However, there were 65 women, who found out they were pregnant after their first dose
 - 23 women in the Pfizer-BioNTech vaccine trial (12 in the vaccine arm and 11 in the placebo arm)
 - 13 women in the Moderna vaccine trial (6 in the vaccine arm and 7 in the placebo arm)
 - 21 women in the AstraZeneca vaccine trial (12 in the vaccine arm and 9 in the placebo arm)¹¹
 - 8 women in the Janssen vaccine trial (4 in the vaccine arm and 4 in the placebo arm)¹²
- While no adverse outcomes have been reported, these numbers are far too few to make generalizations.

What benefits of COVID-19 vaccination are expected in pregnancy?¹³

- COVID-19 vaccines should have similar efficacy in pregnancy to prevent COVID-19.
 - In vaccine studies, pregnant patients consistently produce antibody titers equivalent to those in non-pregnant individuals.
 - By preventing cases of COVID-19, vaccination is expected to reduce the morbidity related to the disease (intensive care admissions, invasive ventilation, preterm delivery, and death) as well.

- There is evidence, based on detection in cord blood that maternally derived IgG antibodies cross the placenta, particularly if infection precedes delivery by at least 17 days. It is biologically plausible that fetal IgG acquisition from vaccination in pregnancy may be transferred to the neonate. However, the protective benefits of the antibodies for the neonate remain uncertain.

What is the current state of evidence regarding the risks of COVID-19 vaccination in pregnancy?^{9, 10}

- In the Pfizer-BioNTech and Moderna trials, 12 and 6 participants, respectively, who received the vaccine reported pregnancies during the trial and did not show adverse outcomes, based on current analysis. However, the numbers are far too few to make generalizations.
- Development and reproductive toxicity (DART) trials of the vaccines are ongoing:
 - Both Pfizer-BioNTech and Moderna vaccines administered to female pregnant rats at clinically relevant doses did not show any adverse effects.

What risks of COVID-19 vaccination are expected in pregnancy?¹⁴

- Similar side effect profiles would be expected in pregnant and non-pregnant patients (e.g., mild to moderate pain, redness, swelling, fever, fatigue, and headache).
- Studies of influenza vaccines have shown that pregnant individuals experience fewer side effects than their non-pregnant counterparts. Given the slightly decreased inflammatory response in pregnancy, there may be fewer side effects following COVID-19 vaccinations for pregnant than for non-pregnant patients.

What ongoing studies will help improve the evidence for COVID-19 vaccination in pregnancy?

- As the DART studies conclude, pharmaceutical companies are beginning human trials in pregnant subjects. Pfizer-BioNTech states that its trials in pregnancy will start in the first three months of 2021.
- Health care providers should remain informed about the results of these ongoing trials to provide patients with the most up-to-date information.

Based on the available evidence, should I recommend the COVID-19 vaccination for pregnant patients or patients planning conception?¹⁵

- All pregnant patients should be offered the opportunity to be vaccinated¹⁶ when they are eligible, based on the local and/or provincial/territorial allocation of vaccines. Pregnant patients do not take priority in vaccination; they will receive the vaccine according to other eligibility criteria.
- Patients have the right to make informed decisions based on the risks of vaccination versus the risks of remaining unvaccinated
- The risks of remaining unvaccinated depend on certain patient characteristics:
 - Gestational age of the fetus
 - Risk of exposure to COVID-19 (home and work environments)
 - Local prevalence of COVID-19 infections
 - Comorbidities such as age, hypertension, diabetes, and asthma
- The risk of vaccination is associated with the understudied nature of vaccines in pregnancy; this is not immaterial. Other medications (such as thalidomide) have shown serious unintended fetal harms in the past. Exercising caution is a valid patient choice.
- Health care providers should remain informed about the most recent state of evidence and recommendations to provide appropriate counselling to their patients.

What are the contraindications to the COVID-19 vaccines?

- The only contraindications to the COVID-19 vaccines are immediate or anaphylactic hypersensitivity reactions to the vaccine ingredients (including polyethylene glycol [PEG]) or to a previous COVID-19 vaccine.
 - If patients have other allergies (e.g., seafood, nuts, latex, other drug allergies), they remain eligible for the COVID-19 vaccination.

Common Patient Concerns About COVID-19 Vaccinations

What are the chances of serious allergic reactions in pregnancy?^{3, 4, 16, 17}

- In the Moderna trial, 1.5% in the vaccination group versus 1.1% in the placebo group developed hypersensitivity reactions.
 - Only one case of an anaphylactic reaction (< 0.01%) was found in each group.
- After administration of 1,893,360 doses of the Pfizer-BioNTech vaccine in the United States, 21 cases of anaphylaxis were identified.
 - Seventeen cases were treated in the emergency department and discharged, and only 4 were hospitalized. All have recovered, and no deaths were reported.
 - This equates to 11.1 cases per 1 million vaccinations (0.001%).
- There is no evidence that pregnancy increases hypersensitivity reactions.

How long does immunity last following COVID-19 vaccination?

- The studies conducted by Pfizer-BioNTech and Moderna were completed over a study period of 2 months, so the long-term immunity due to the COVID-19 vaccine is still unknown. Immunity did not appear to wane toward the end of the 2-month study period.
- As the vaccine is distributed, ongoing studies will allow us to determine the duration of immunity over a longer time period.

If my patient has had COVID-19 in the past, should they receive the COVID-19 vaccination?¹⁸

- There are reports of reinfection with COVID-19, and we are still determining the duration of immunity after natural infection.
- Studies have shown that patients who have acquired COVID-19 infection are unlikely to be reinfected within 90 days of the original infection.
- Each provincial/territorial jurisdiction may have guidelines for the period between COVID-19 infection and eligibility for the vaccination. Please refer to your local guidelines.
- If your patient is eligible, we continue to recommend the vaccine.
 - A discussion between you and your patient to balance the risks and benefits of vaccination versus remaining unvaccinated may be helpful, but is not necessarily required.
 - In this discussion, if the patient has had a previous COVID-19 infection, the duration of natural immunity may affect the risk-benefit balance, particularly if the patient is in the third trimester, when a 90-day interval may exceed the duration of remaining pregnancy.

If my patient has received an influenza, RhoGAM, or Tdap vaccination in pregnancy, how long should they wait to receive the COVID-19 vaccination?¹⁹

- The influenza vaccine (during influenza season) and the Tdap vaccine are still recommended in all pregnancies during the COVID-19 pandemic.
- Based on Public Health Agency of Canada Recommendations:

- If your patients have received another vaccine recently, the COVID vaccine should be delayed by 14 days based on limited data on safety and effectiveness of receiving concurrent vaccinations.

- If your patients have received the COVID-19 vaccine recently, other vaccinations should be delayed by 28 days except in the case of post-exposure prophylaxis (Hepatitis B)

- In the case of RhoGAM, neither RhoGAM nor COVID-19 vaccine should be delayed.

If my patient received the COVID-19 vaccine, how long should they delay pregnancy or fertility treatments?^{15, 20}

- Since the data from the DART studies do not suggest that the available vaccines carry any risks, there is no recommended delay between vaccination and conception.
 - We do recommend completing the vaccine series before conception to ensure adequate protection from the vaccine.
- If your patient is planning a pregnancy, completing the COVID-19 vaccination series is likely to reduce the increased risks associated with COVID-19 infections in pregnancy.
 - Planning a pregnancy does not affect your patient's eligibility for COVID-19 vaccination, which is based on their local and/or provincial/territorial allocation of vaccines. Pregnant patients do not take priority in vaccination; they will receive the vaccine according to other eligibility criteria.
 - Patients have the autonomy to make an informed decision concerning whether to delay pregnancy while awaiting COVID-19 vaccination.

In the case of inadvertent pregnancies after vaccination, what should I recommend to patients?¹⁵

- Individuals should not be counselled to terminate pregnancy due to the vaccination.
- If pregnancy is detected between vaccine doses, you should discuss the risks and benefits of completing the vaccination series with your patient.
- Routine prenatal visits are recommended for the patient as per guidelines.

Should my patient who is breastfeeding receive the COVID-19 vaccination?¹⁵

- Lactating patients should be offered the COVID-19 vaccination, if they are eligible and there are no contraindications.
- Since breastfeeding individuals were excluded from the original vaccine trials, there are no safety data for COVID-19 vaccination in lactating patients for effects on their neonate and breastmilk.
 - Vaccination should have efficacy in breastfeeding patients similar to that in the general population. There is limited theoretical risk anticipated with the COVID-19 vaccinations, as they are not live vaccines.
 - You should have an informed discussion with your patient to balance the risks and benefits of vaccination with those of remaining unvaccinated.
- If the breastfeeding patient has been vaccinated, there is no need to discontinue or delay breastfeeding because of the COVID-19 vaccine.

Does the mRNA vaccine (BioNTech-Pfizer, Moderna) alter your DNA? What could mRNA vaccines do to a growing fetus?²¹

- No, it does not alter your DNA. The mRNA vaccine encodes the spike protein found in the SARS-CoV-2 virus that causes COVID-19. This triggers our cells to produce the spike protein, which will be recognized by our immune system as foreign, leading our cells to develop antibodies. Once the mRNA is used to produce the spike protein, the mRNA is degraded.
 - Our cells do not take up the mRNA into the nucleus, where genes are stored.
- If fetal cells are exposed to mRNA vaccines, the vaccines may cause fetal cells to produce similar proteins. Studies have shown that vaccinated patients secrete antibodies in the umbilical cord and breast milk.²² The protection to the newborn is still unknown at this point.
- Until further information about the benefits of maternal vaccination for the infant is available, the risk-benefit discussion related to the COVID-19 vaccine in pregnancy should be focused on potential maternal benefits.

Does the viral vector vaccines (AstraZeneca, Janssen) alter your DNA? What could viral vector vaccines do to a growing fetus?²³

- No. The viral vector vaccines uses a non-pathogenic virus to produce SARS-CoV-2 spike proteins. After the body recognizes the protein, it will trigger the immune system to produce antibodies against SARS-CoV-2 spike proteins.
- If fetal cells are exposed to viral vector vaccines, the vaccines may cause fetal cells to produce similar proteins.
- At this time, there is no data on the transfer of antibodies derived from viral vector vaccines from mother to newborn.

Certain vaccinations are contraindicated in pregnancy. Why isn't the COVID-19 vaccine contraindicated?¹⁵

- A few specific diseases, like polio and rubella, are prevented using live-attenuated vaccines. This means they use the virus itself, in a form that prevents it from replicating, to train the immune response. There is a theoretical risk that these "attenuated" viruses could cross the placenta and harm the fetus, whose own immune system is not mature enough to defend against them.
- To date, in clinical practice, there are patients who were treated with live-attenuated vaccine before they knew they were pregnant, and no adverse obstetrical or neonatal outcomes were observed.
 - Given herd immunity and low prevalence of the diseases that are preventable by live-attenuated vaccines, the risk-benefit balance is toward avoiding the vaccines in pregnancy.
- In the case of the COVID-19 vaccine, there is limited theoretical risk from the vaccine and many expected benefits from avoiding the proven harms in pregnant patients affected by COVID-19 infections. In all cases, women should choose what is right for them.
 - There is documented risk to pregnant individuals (especially those with risk factors) of harm associated with COVID-19 infection if they are not vaccinated.

Can COVID-19 vaccine cause COVID-19 infections?²¹

- No, it cannot cause COVID-19 infections because there is no live virus in the vaccine.
- Side effects that may mimic COVID-19 infections are related to the immune system response to the body producing the spike protein of the SARS-CoV-2 virus that causes COVID-19.

Could the COVID-19 vaccine cause infertility?²⁴

- There is no suggested impact of the COVID-19 vaccine on male or female fertility.
- The widespread social media concern stems from misinformation about the similarities between syncytin-1 (used for placental implantation) and the SARS-CoV-2 spike protein.
 - While the 2 proteins have several similar amino acids, they remain vastly different. The antibodies produced against the SARS-CoV-2 spike protein would not have cross-reactivity with syncytin-1.
- If there were significant cross-reactivity, we would have seen high rates of miscarriage and worsening infertility rates due to anti-syncytium antibodies during the COVID-19 pandemic. This has not been observed.

Can the COVID-19 vaccination cause Bell's palsy?^{3, 4}

- There is no conclusive association between Bell's palsy and the COVID-19 vaccine.
- In the Pfizer-BioNTech trial, four cases of Bell's palsy were noted in the vaccination group (none in the placebo group). In the Moderna trial, three cases were noted in the vaccination group (1 in the placebo group).
- This is deemed to be in line with the rate of Bell's palsy in the general population. Current surveillance has not identified any safety signals related to the vaccine and Bell's palsy.
- It is also important to note that COVID-19 infections have been associated with Bell's palsy in multiple case reports.

Are fetal cells used to develop the COVID-19 vaccines?²⁵

- No. The potential use of fetal cells in medical research is controversial. In the U.S., several organizations provide surveillance to identify these practices. The American Conference of Catholic Bishops issued a statement on November 23, 2020, that "Neither the Pfizer nor Moderna vaccine involve the use of cell lines that originate in fetal tissue...at any level of design, development, or production." — Archbishop Joseph F. Naumann, head of the committee on pro-life activities.
- COVID-19 vaccination was deemed ethically acceptable by the Vatican in December 2020.

Is there pork or other animal by-products in the COVID-19 vaccines?²⁶

- There are no animal products (including pork) in the 2 available COVID-19 vaccines.

Are there microchips in the COVID-19 vaccine?

- No, there are no radio-frequency identification (RFID) microchips in the COVID-19 vaccine. There is a social media misinformation movement regarding the presence of a microchip engineered by Bill Gates, a businessman who formerly headed Microsoft Corporation. This rumour has been publicly refuted multiple times by Gates himself.
- There is no microchip in existence that would be small enough to be injected via the syringes used for COVID-19 vaccination.

If my patient did not have significant side effects from the vaccine, 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.
 - The occurrence of side effects does not impact the effectiveness of the vaccines.

How effective are the approved COVID-19 vaccines 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 at the population level.
 - Additional in vitro and in vivo research is required for each specific vaccine to determine its efficacy against each variant.
 - This will need to be determined individually due to the different mechanisms of achieving immunity
- This is a rapidly changing area of virology and clinicians may wish to consult the CDC website for more detail and as evidence emerges: <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html>
- When looking at approved vaccines in Canada, there is a small in vitro experiment, which demonstrated that the antibodies produced by the Pfizer-BioNTech vaccine have similar efficacy in neutralizing viruses with spike protein mutations as seen in some of the UK and South African variants.²⁷

- While some vaccine manufacturers have reported decreased efficacy against individual variants,²⁸ it is important to bear in mind that >90% efficacy is an exceptional baseline; even a 20% loss of efficacy results in a good vaccine which can meaningfully impact public health outcomes.

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