

Alberta COVID-19 Vaccination in Pregnancy Factsheet for Practitioners

**This summary is based on information available up to January 11, 2021. Contents are subject to change as new information becomes available.*

SOGC Statement on COVID-19 Vaccination in Pregnancy (Updated January 11, 2021)

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

This decision is based on the women's personal values and an understanding that the risk of infection and/or morbidity from COVID-19 outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding. Women should not be precluded from vaccination based on pregnancy status or breastfeeding.

Key Messages

- Expert opinion suggests mRNA vaccines are unlikely to pose a risk to patients who may be pregnant, are pregnant or breastfeeding, or to their unborn babies or breastfed infants. This is because mRNA vaccines are not live virus vaccines, nor are they genetic therapy.
- Vaccines currently available have not been tested on individuals who may be pregnant, are pregnant, or are breastfeeding.
- Pregnant patients with COVID-19 infection are at higher risk of hospitalization and admission to the ICU than non-pregnant patients of the same age.
- Individuals who may be pregnant, are pregnant or are breastfeeding have the **right to receive the vaccine**, should they choose to do so when it is offered in the overall vaccine sequencing.
- Individual counselling with a clinician regarding vaccination in pregnancy is recommended. However, this is not a requirement before vaccination.

Scientific Data

- Pfizer BioNTech and Moderna vaccines use a messenger RNA (mRNA) vaccine platform.
 - The mRNA contains the Sars-CoV-2 "spike protein" genetic information encapsulated by a lipid nanoparticle for delivery into the human cells.
 - Once the mRNA gets into the ribosomes -cell protein factories- the host cell manufactures the SARS-CoV-2 spike protein and expresses it on its surface.
 - The host immune system is then activated to produce antibodies against SARS-CoV-2.
 - The mRNA vaccines cannot cause genetic changes: the vaccines do not enter the nucleus and therefore do not alter human DNA.
- **Developmental and reproductive toxicity studies (DART) studies for Moderna vaccine trials show no teratogenic effects in rats or postnatal development.**
- Safety and efficacy trials were conducted in adults >16 yo (Pfizer > 44, 000 individuals, Moderna > 30,000)
- **COVID-19 vaccine efficacy after two doses was ~95%.** COVID-19 vaccine efficacy after a single dose is lower than 95%; if the second dose of a COVID-19 vaccine is delayed, the second dose should be provided as soon as possible.

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There was total 46 unintended pregnancies in both Pfizer and Moderna as follows

- Pfizer BioNTech vaccine trials included 23 patients with unintended pregnancies: 12 in the vaccine arm / 11 in the placebo arm.
- Moderna vaccine trials included 13 patients with unintended pregnancies: 6 in the vaccine arm / 7 in the placebo arm
- No adverse effects noted to date.
- Lactating patients were excluded from clinical COVID-19 vaccine trials. Therefore there is no data on the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion.
 - It is unlikely the vaccine lipid would enter the bloodstream and reach breast tissue.
 - If this were to happen, it is even less likely that an intact nanoparticle or mRNA would transfer into the breastmilk.
- **There is a biologically plausible benefit to breastfeeding after vaccination:** IgG antibodies can be detected in breastmilk within 5-7 days. The maternal antibodies and T-cells stimulated by the vaccine could transfer into the breastmilk providing passive immunity to the infant against COVID-19 infection.

Patient Counselling

- Individual counselling with a clinician regarding vaccination in pregnancy is recommended. However, this is not a requirement before vaccination.
- Considerations when counselling may include:
 - Level of exposure risk in the patient's home and work environment
 - Local virus activity and current outbreak status
 - Co-morbidities such as immunosuppressive conditions, HTN, diabetes, obesity, chronic respiratory conditions, advanced maternal age
 - Gestational age at the time of vaccination
- **When planning conception, complete both doses of vaccination before pregnancy.**
- If pregnancy occurs between the two vaccine doses and no contraindications exist, then it is reasonable to proceed with the second dose of the vaccine.
- Patients with an inadvertent pregnancy following vaccination should not be counselled to terminate the pregnancy based on having received the vaccine.
- Patients should be encouraged to initiate or continue breastfeeding if they receive the COVID-19 vaccine.

Vaccination – the basics

- COVID-19 vaccination consists of TWO Intramuscular injections, up to 42 days apart
- Most common side effects include:
 - Pain at the injection site, fatigue, headache
 - Fever noted in 11-16% after the second dose
 - Acetaminophen can be used as needed to treat side effects

References

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