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

Should I recommend the COVID-19 vaccination for pregnant patients, patients planning conception or lactating patient?[1]

- **YES!** COVID-19 vaccination is recommended during pregnancy in any trimester and while breastfeeding.[2]
- 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 if pregnant
    - 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 risks of vaccination are very low (see the section on safety data for details).

What are the increased risks related to COVID-19 in pregnancy? Who is at increased risk?

- Pregnant patients with COVID-19 infection were more likely to:[3, 4]
    - Require admission to intensive care (compared to non-pregnant patients)
    - Require invasive ventilation (compared to non-pregnant patients)
    - Deliver prematurely (compared to uninfected patients)
    - Experience maternal death (compared to uninfected patients)
- Risk factors for increased morbidity include:[3, 4]
    - Age ≥ 35 years old
    - Asthma
    - Obesity (body mass index > 30 kg/m2)
    - Pre-existing diabetes
    - Pre-existing hypertension
    - Heart disease
- While the risks are higher, most pregnant patients with COVID-19 infections lead to mild symptoms (fever, myalgia, and cough) with babies born at term.

What is the efficacy data for the vaccines available for pregnant women?

- The efficacy of mRNA vaccines has been demonstrated for adults 16 years and older in Phase II and Phase III trials involving the randomization of >70,000 individuals.[5] These trials demonstrated a vaccine efficacy ≥94% for preventing symptomatic COVID-19 cases at least 7 to 14 days following the second dose.[5, 6]
- Since the initial clinical trials, numerous population-based studies have reported on real-world vaccine efficacy. Canadian data from Quebec and British Columbia have demonstrated vaccine efficacy greater than 80-90% for infection for at least 4 months after the 2nd dose and including against infections with Delta variant.[7, 8]
- Data specific to pregnant women suggest that COVID-19 mRNA vaccine efficacy is comparable to the vaccine efficacy observed in non-pregnant persons,[9, 10] as it is for the other vaccines.[11, 12, 13]

How effective are the approved COVID-19 vaccines against the emerging variants?

- There is some evidence that mRNA vaccines offer a good protection against the most severe forms of COVID due to variant, even if slightly less effective to prevent the infection due to some variants.[14, 15, 16]
- This is a rapidly changing area of virology and clinicians may wish to consult the NACI website[2] for more detail and as evidence emerges.
- 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.

What are the contraindications to the COVID-19 vaccines?

- The only contraindications to the mRNA 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.

What are the proven benefits of COVID-19 vaccination in pregnancy?

- COVID-19 vaccination in pregnant and lactating individuals is effective in preventing COVID-19 disease.[12, 13]
- 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).
- Antibodies against COVID-19 are found in cord blood and infant serum after delivery in vaccinated patient.
    - The protective benefits of the antibodies for the neonate remain uncertain.
    - It is biologically plausible that fetal vaccination in pregnancy confers protective benefits for the neonates.
- Antibodies against COVID-19 are found in breast milk of vaccinated patients.[17]
    - However, it is unclear whether oral ingestion of breast milk antibodies would confer any protection to an infant.

What are the data on safety of the vaccines?

- In the mRNA trials, common side effects included the following:[5, 18, 19, 20]
    - Mild to moderate pain, redness, or swelling at injection site (up to 83%)
    - Fatigue (up to 59%)
    - Headache (up to 58%)
    - Fever (up to 16%)
    - Lymphadenopathy (0.3%)
    - Myalgia (up to 58%)
    - Arthralgia (up to 42%)

Overall, the incidence of SAEs was similar in the vaccine and placebo groups (up to 0.6%). Most side effects started at 15 hours post-vaccination and resolved by the end of the second day. There is no sign of association with Bell's palsy.

- From a Canadian perspective, there is an ongoing national surveillance program for COVID-19 vaccinations.
    - As of November 5, 2021, 22,231 adverse events (0.038%) following immunization were reported from >58,000,000 total doses administered.
        - This included vaccination-site reactions, paresthesia, pruritis, urticaria, headache, hypoesthesia, nausea, and anaphylaxis.
        - 5,653 events (0.01%) were deemed serious.
    - For up-to-date information, please refer to: https://health-infobase.canada.ca/covid-19/vaccine-safety/

What are the risks of COVID-19 vaccination in pregnancy?[21, 22]

- Among all randomized-control vaccine trials, less than 50 vaccinated participants reported pregnancies. No adverse outcomes were identified.
- Development and reproductive toxicity (DART) trials of all approved Canadian vaccines did not identify any adverse effects.[23]
- A growing body of data demonstrates no difference in rates of spontaneous abortion, stillbirth, preterm birth nor other pregnancy complications.
    - The V-Safe registry in the US has reported on over 7,000 vaccinated pregnant women received either the Pfizer-BioNtech vaccine or the Moderna vaccine and identified no differences in the rates of adverse pregnancy and neonatal outcomes for those women who were pregnant and compared to pre-pandemic rates.[9, 23]
    - Two case-controlled studies from Norway[24] and the US[25] have found no increased risk for early pregnancy loss after COVID-19 vaccination
    - Additional US data from the University of Washington does not raise significant vaccine-related adverse events or obstetrical and neonatal outcomes.[12, 13]
    - The UK data on the safety of COVID-19 vaccines during pregnancy and while breastfeeding collected through passive surveillance shows no sign of adverse events occurring more often than in the general population.[20]
    - 2 online reports from Ontario on 39,985 women who received at least one dose of COVID-19 vaccine during pregnancy show no evidence of any pregnancy specific increase in any risks associated with vaccine uptake.[26]

Data from the Canadian COVID-19 Vaccine Registry for Pregnant & Lactating Individuals (COVERED) will soon be available (registration: https://covered.med.ubc.ca/).

How long does immunity last following COVID-19 vaccination? Is a booster dose recommended for pregnant women?

- An update at the 6 month mark for the Pfizer-BioNTech vaccine continues to show efficacy of 91.3%[27]
- Antibody persistence for the Moderna vaccine has been described up to 6 months[28]
- However, antibodies have been shown to wane: at six months after 2 doses of Pfizer mRNA vaccine, IgG levels were from 2 to 25% (median 7%) of their peak levels, detected at one week after the second dose.[29] The cellular immune response is expected to last longer, and clinical implication is still debated.
- Pregnant women mount immune responses to COVID vaccines comparable to the non-pregnant population. While timing and criteria for booster doses may vary by jurisdiction, **pregnant women should receive a booster dose when recommended.**

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

- Studies have shown that patients who have acquired COVID-19 infection are unlikely to be reinfected within 90 days of the original infection.[30]
- 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, vaccination should be recommended.[2]

Is it recommended to have a delay between COVID-19 vaccination in pregnancy and influenza, Rh-Immune Globulin, or Tdap vaccination?

- Based on Public Health Agency of Canada Recommendations [2], COVID-19 vaccines may be given concomitantly with, or at any time before or after, other vaccines.
- There is no concern of interaction between Rh-Immune Globulin and COVID-19 vaccines and therefore no delay between the 2 is recommended.

If a patient received the COVID-19 vaccine, should she delay pregnancy or fertility treatments?

- There is no recommended delay between vaccination and conception. [1, 31]
    - We do recommend completing the vaccine series (if feasible) before conception to ensure adequate protection from the vaccine.

Does the mRNA vaccine (BioNTech-Pfizer, Moderna) alter the DNA?

- No, it does not alter DNA[32]. 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. It is never integrated into the DNA nor in the nucleus.

Could the COVID-19 vaccine cause infertility?[33]

- There is no suggested impact of the COVID-19 vaccine on male or female fertility:
    - Although pregnant people were not included in the first round of trials, and participants were asked to avoid becoming pregnant, nonetheless a number of people became pregnant by accident. The accidental pregnancies occurred equally across the vaccinated and the non-vaccinated groups.[34, 35]
    - In IVF patients, vaccination against COVID-19 does not affect ovarian function, egg quality, fertilization or clinical pregnancy rate.[36, 37, 38, 39]
- 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.[40, 41] The antibodies produced against the SARS-CoV-2 spike protein has not cross-reactivity with syncitin-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.
- Some transient menstrual disorder following vaccination have been reported and are currently monitored.[20] We need to keep in mind that whilst uncomfortable or distressing, period problems are extremely common and any stressful life event can disrupt menstrual periods.

Is there pork or other animal by-products in the COVID-19 vaccines?[42]

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

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Original date: February 16, 2021

Reaffirmed: April 7, 2022

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