

SOGC guidelines on Covid19 vaccination.

Approximately 8-11% of pregnant women will require hospitalization for COVID related morbidity and between 2-4% of pregnant women will require admission to an intensive care unit (ICU).

Compared to non-pregnant individuals with COVID-19, pregnant individuals are at increased risk of invasive ventilation with an equivalent mortality to age-matched peers.

The risk of severe morbidity from COVID-19 in pregnant women appears to be associated with risk factors including age \geq 35 years old, asthma, obesity, preexisting diabetes, preexisting hypertension and heart disease.

Safety of the Vaccine

The safety and efficacy Pfizer-BioNTech COVID-19 vaccine has been demonstrated for adults 16 years and older in Phase II and Phase III trials involving the randomization of approximately 44,000 individuals. These trials demonstrated a vaccine efficacy of 94.6% for preventing symptomatic COVID-19 cases at least 7 days following the second dose

Currently, there are no other safety or efficacy data available for pregnant or breastfeeding women. Unfortunately, all the vaccines for which Phase III results are available excluded pregnant or breastfeeding women from their trials. Similarly, breastfeeding women were also excluded from the Phase III trials available at present. Therefore, there is no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or on milk production. Because mRNA vaccines are not considered live virus vaccines, they are not hypothesized to be a risk to the breastfeeding infant.

While there have been no red flags or hypothesized mechanisms for potential harm associated with administration of an mRNA vaccine during pregnancy, until more data is available, the potential risks of vaccination to a pregnant individual and fetus remain unknown.

What is known, however, is that an unvaccinated pregnant individual remains at risk of COVID-19 infection and remains at heightened risk of severe morbidity if infected compared to non-pregnant counterparts. Severe infection with COVID-19 carries risks to both maternal and fetal health.

While pregnancy itself does not appear to increase the risk of becoming infected with SARS-CoV-2, pregnant individuals may be in work-related (e.g., health care worker, front line workers etc.) or community situations (e.g., caregiver, indigenous communities, outbreak setting, etc.) where the risk of infection is considerable. Owing to maternal age or underlying comorbidities, some pregnant individuals are at high risk of severe COVID-related morbidity.

SOGC recommendation

Universal exclusion of pregnant women from receipt of the COVID-19 vaccine based on an undocumented and hypothetical risk to the fetus would leave pregnant women vulnerable to severe morbidity, which could also compromise fetal health. Conversely, lack of safety and efficacy data for this population precludes making a recommendation for routine COVID-19 vaccination for all pregnant and breastfeeding individuals

A discussion should prioritize patient autonomy and should include, but not be limited to assessment of:

1. Local epidemiology and risk of community acquisition of COVID-19

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2. Workplace situation and risk of work-related acquisition of COVID-19
3. Individual risk for COVID-related morbidity including consideration for comorbidities including advanced maternal age, immunosuppressive conditions, preexisting diabetes, preexisting hypertension, obesity or chronic respiratory conditions
4. Gestational age
5. Available data related to the safety of the vaccine during pregnancy and lactation
6. Data that is not yet available related to the safety and efficacy of the vaccine for pregnant and breastfeeding women
7. Individual beliefs and personal risk assessment of the available data.

Side effects of the Vaccine

The most commonly reported side effects from the vaccine were pain at the injection site (66-83%), fatigue (51-59%) and headache (39-52%). Fever was reported in 11-16% of patients, particularly following the second dose. 8

While pain at the injection site, fatigue and headache are the most commonly reported symptoms following vaccination, fever was reported 16% of the time for younger non-pregnant individuals. 8 Pregnant patients can be counselled to treat mild postvaccination fevers with antipyretics (e.g., acetaminophen)

Inadvertent pregnancy following vaccination

Inadvertent pregnancy following vaccination Individuals who are discovered to be pregnant during their vaccine series or shortly afterward should not be counselled to terminate pregnancy based on having received the vaccine. If conception is presumed to predate the first dose, it is recommended to follow the same procedures for active surveillance (as available) as would be activated if the pregnancy was known at the time of vaccination. Where pregnancy is detected during the vaccine series (i.e. following the first dose, but ahead of the second dose), the decision of whether to complete the vaccine series during pregnancy should be based on an assessment of the potential risks of not being completely vaccinated during pregnancy vs. the potential risks of receiving the vaccine during pregnancy (as discussed above)

Individuals contemplating pregnancy

For an individual planning a pregnancy, it is recommended to complete the entire COVID-19 vaccination series (where possible) to achieve maximal vaccine efficacy ahead of pregnancy. It is not known whether an individual should delay pregnancy following receipt of the vaccine and a risk-

Conclusion:

As the evidence evolves, it is becoming clear that pregnant and postpartum women may represent a population at increased risk of COVID-related morbidity. Severe COVID-19 infection during pregnancy has important implications for both maternal and fetal health. NACI acknowledges that people of reproductive age constitute a substantial proportion of the Canadian population, yet no data on the use of COVID-19 vaccine in pregnancy are available.