

SOGC Statement on COVID-19 Vaccination in Pregnancy

POLIQVIN, V; CASTILLO, E; BOUCOIRAN, I; WONG, J; WATSON, H; YUDIN, M; MONEY, D; VAN SCHALKWYK, J; ELWOOD, C on behalf of the Infectious Disease Committee of the Society of Obstetricians and Gynaecologists of Canada

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Preamble

The SOGC acknowledges the need for guidance related to the COVID-19 vaccine and pregnancy and during lactation. We recognize the difficulty facing women and their health care providers at this time, due to the absence of clinical trials that can support evidence-informed recommendations about the COVID-19 vaccine for pregnant and breastfeeding populations. Information related to COVID-19, the impact of the disease on pregnancy and data related to COVID-19 vaccines in development are rapidly evolving. The information contained herein is subject to change as further evidence becomes available.

CONSENSUS STATEMENTS:

- 1. Pregnant individuals should be offered vaccination at any time during pregnancy or while breastfeeding if no contraindications exist.**
- 2. All available COVID-19 vaccines approved in Canada can be used during pregnancy and breastfeeding, but the SOGC recommends following provincial and territorial guidelines on type of vaccine to prioritize for pregnant and breastfeeding individuals.**
- 3. The decision to be vaccinated is based on the individual's personal values, as well as 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. Individuals should not be precluded from vaccination based on pregnancy status or breastfeeding.**
- 4. Given that pregnant people are at increased risk of morbidity from COVID-19 infection, all pregnant persons should be eligible to receive a COVID-19 vaccination.**

SUPPORTING EVIDENCE:

SARS-CoV-2 and the impact on pregnancy

Most pregnant individuals who become infected with SARS-CoV-2 will have mild-to-moderate symptoms and many can be asymptomatic.¹ However, both Canadian and international data from large studies spanning multiple jurisdictions demonstrate that approximately 7-11% of pregnant women will require hospitalization for COVID-related morbidity and between 1-4% of pregnant women require admission to an intensive care unit (ICU).^{2,3,4} Compared to non-pregnant women with COVID-19, pregnant women are at increased risk of admission to hospital, critical care and invasive ventilation compared to age-matched peers.^{2,4} The risk of severe morbidity from COVID-

19 in pregnant women appears to be associated with risk factors including age ≥ 35 years old, asthma, obesity, preexisting diabetes, preexisting hypertension and heart disease.^{2,4} In addition, both Canadian and US data^{2,3,4} show an increased risk of preterm birth associated with COVID-19 infection in pregnancy which will cause consequent morbidity to the infant related to prematurity.

COVID-19 vaccines approved for use in Canada

There are currently four COVID-19 vaccines licensed for use in Canada: Pfizer-BioNTech COVID-19 vaccine (mRNA vaccine), Moderna COVID-19 vaccine (mRNA vaccine), AstraZeneca/COVISHIELD COVID-19 vaccine (non-replicating viral vector vaccine) and Janssen (non-replicating viral vector vaccine).

1. mRNA Vaccine Platforms

This model consists of messenger RNA (mRNA) encapsulated by a lipid nanoparticle (LNP), which allows the mRNA entrance into host (human) cells. The mRNA in the vaccine codes for the SARS-CoV-2 spike protein utilized by the virus to bind to human receptors and promote viral replication. The vaccine provides the host cell instructions to manufacture only this spike protein and express it on its surface. Recognizing the spike protein as a foreign antigen, the host immune system is then activated to produce an immune response.⁵ The mRNA does not enter the nucleus or alter human DNA and human cells do not have the machinery to allow it to do so.

The Pfizer-BioNTech and Moderna COVID-19 vaccines were originally evaluated in licensure trials as a series of two intramuscular injections given 21-28 days apart.⁶ However, since then, considerable data has been generated on different dosing intervals.⁷ The efficacy of the 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.⁸ These trials demonstrated a vaccine efficacy of 94.6% for preventing symptomatic COVID-19 cases at least 7 days following the second dose.⁸ In Phase III trials for the Moderna COVID-19 vaccine involving the randomization of 30,000 individuals, the vaccine was reported to have 94.1% efficacy against symptomatic COVID-19 with no serious safety concerns identified during the initial 2 month follow-up period.⁹ Since the initial clinical trials, numerous population-based studies have reported on real-world vaccine efficacy. Among these, Canadian data from Quebec and British Columbia have demonstrated vaccine efficacy of 71-89% for symptomatic and asymptomatic COVID-19 infection.⁷ Immunogenicity data specific to pregnant women are emerging and suggest that COVID-19 mRNA vaccines generate humoral immune responses in pregnant and lactating persons that are similar to that observed in non-pregnant persons.¹⁰

In Phase III trials for both Pfizer-BionNTech and Moderna COVID-19 vaccines, there were no clinically meaningful differences in adverse events or severe adverse events in the vaccine group compared to control except for lymphadenopathy which occurred in approximately 0.3% of the vaccine group compared to <0.1% of the placebo group for the Pfizer-BioNTech COVID-19 vaccine. The most commonly reported side effects from the mRNA COVID-19 vaccines were pain at the injection site, fatigue and headache. Fever was reported in 11-16% of patients, particularly following the second dose.⁸ Data from the US v-safe pregnancy registry demonstrates that pregnant women are more likely than non-pregnant women to report injection site pain following administration of COVID-19 mRNA vaccines, but are less likely to report headache, myalgia, chills and fever.¹¹

Pregnant and breastfeeding individuals were excluded from the available Phase II and Phase III studies for the Pfizer-BioNTech and Moderna COVID-19 vaccines. However, for Pfizer-BioNTech, there were 23 individuals (12 in

the vaccine arm and 11 in the placebo arm) who reported pregnancies during the trial and are being followed for pregnancy outcomes with no reports of adverse effects to date. For the Moderna trials, there were 13 women (6 in the vaccine and 7 in the placebo group) who reported pregnancies during the trial without reports of adverse effects to date. US data reporting on nearly 4,000 pregnant women who received either the Pfizer-BioNTech vaccine or the Moderna vaccine reported no differences in the rates of adverse pregnancy and neonatal outcomes for those women who were pregnant and compared to pre-pandemic rates.¹¹ The Developmental and Reproductive Toxicity (DART) animal studies for the Moderna and Pfizer-BioNTech vaccines are ongoing. According to the World Health Organization (WHO) and the American College of Obstetricians & Gynecologists (ACOG), no major safety signals have been identified.¹²

Similarly, breastfeeding individuals 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.¹³

2. *Non-replicating Viral Vector Vaccines*

The Oxford-AstraZeneca ChAdOx1 nCoV-19 vaccine and the Janssen Ad26.COV2.S vaccine both utilize adenovirus non-replicating vector vaccine platforms. The adenovirus does not cause disease in humans, but is used to carry a small part of the pathogen's DNA into human cells where it causes the human cells to make viral proteins (in this case the spike protein of SARS-CoV-2). The viral DNA does not alter human DNA. Less restrictive storage and handling requirements may facilitate logistics for widespread administration of this vaccine platform.

The AstraZeneca COVID-19 vaccine was initially evaluated as a series of two intramuscular injections given 4-12 weeks apart; however, similar to the mRNA vaccines, considerable data on different dosing intervals has accrued.⁷ Phase III data from 32,449 participants in the United States demonstrates an overall vaccine efficacy of 79% against symptomatic COVID-19 disease with comparable efficacy across ethnicity and age groups.^{14, 15} Pregnant and breastfeeding individuals were excluded from the Phase III AstraZeneca Trials, however 21 inadvertent pregnancies (12 in the vaccine arm and 9 in the placebo arm) were reported without adverse effects to date. Preclinical trials did not demonstrate adverse effects on fertility, pregnancy, fetal or postnatal outcomes.

The Janssen Ad26.COV2.S vaccine was initially evaluated as a single-dose of an intramuscular injection. Phase III data from 43,783 international participants demonstrated a 65.5% vaccine efficacy against asymptomatic COVID-19 and 85.4% vaccine efficacy against severe/critical at 28 days post-administration with early onset of protection beginning at 7-14 days post vaccination. Vaccine efficacy was comparable among age groups and co-morbidity status.¹⁶ The specific efficacy in the US (primarily WUhan-H1 strain) was 72.0%, in Brazil was 68.1% (predominantly V2 variant) and in South Africa was 64.0% (predominantly 20H/501Y variant) at 28 days post vaccination.^{16, 17}

In Phase III trials for the viral vector COVID-19 vaccine platforms (AstraZeneca/COVIDSHIELD and Janssen), there were no clinically meaningful differences in adverse events or severe adverse events in the vaccine group compared to control. Side effects following these vaccines were reported as mild to moderate and commonly included: pain at the site of injection, fatigue, myalgias and feeling feverish.

International reports have emerged documenting rare events of arterial and venous thrombosis associated with low platelets following the adenovirus vector COVID-19 vaccines (AstraZeneca/COVISHIELD and Janssen COVID-19

vaccines), termed vaccine induced thrombotic thrombocytopenia (VITT). The risk of VITT is an immune phenomenon that occurs rarely, estimated to be between 1 in 50 000 and 1 in 100 000 vaccine doses.^{18, 19} Most cases have occurred in women <55 years of age, however, this may reflect a workforce gender bias due to the decision to prioritize front-line health care workers, most of whom identify as female. There is no known association between this syndrome and pregnancy and no physiologic basis to increase this risk in pregnancy. Importantly, the pathophysiologic mechanism underlying VITT and pregnancy-related venous thromboembolism are distinct and receipt of a COVID-19 vaccine does not compound a person's risk of venous thromboembolism during the antepartum and peripartum periods or while taking exogenous estrogens (e.g. oral contraceptive pill).²⁰

Considerations for COVID-19 vaccination during pregnancy and breastfeeding

Decades of experience with other vaccines administered during pregnancy would suggest that we could expect a similar efficacy for the COVID-19 vaccines in pregnant women compared to non-pregnant women. Vaccines in general are immunogenic, safe, and efficacious when delivered to pregnant women. While primary prospective clinical data on safety and efficacy of COVID-19 vaccines in pregnant populations is forthcoming, post-marketing surveillance has identified no signals for adverse pregnancy or neonatal outcomes associated with administration of COVID-19 vaccinations.

What *is* known, however, is that an unvaccinated pregnant woman 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 maternal, fetal and neonatal 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, underlying comorbidities, or social marginalization, some pregnant individuals are at higher risk of severe COVID-related morbidity.

NACI has advised “that a complete vaccine series with a COVID-19 vaccine may be offered to pregnant individuals in the authorized age group, without contraindications to the vaccine, if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population (Discretionary NACI Recommendation)”.⁵

Post-marketing surveillance data has not identified any pregnancy-related adverse outcomes related to *any* of the COVID-19 vaccines available in Canada. Published retrospective safety data in pregnancy is available for 827 completed pregnancies and nearly 4000 ongoing pregnancies following mRNA COVID-19 vaccines and, as such, mRNA COVID-19 are preferred, in general.¹¹ However, presented with the choice of a viral vector vaccine or no vaccine at all, prenatal providers and patients should be reassured that the risk of morbidity from COVID during pregnancy outweighs the rare risk of VITT following vaccination and that the viral vector vaccine can be administered in accordance with regional eligibility.

We recommend pregnant individuals should be offered vaccination against COVID-19 at any time during pregnancy or while breastfeeding if no contraindications exist. The concern around vaccination in the absence of evidence of safety in pregnancy has been debated in the literature. The [PREVENT](#) Working Group states, “the

absence of evidence and the mere theoretical or even documented risk of fetal harm is generally not sufficient to justify denying pregnant individuals access to a vaccine in an outbreak or epidemic.” During an epidemic, the default should be to offer vaccines to pregnant individuals alongside other affected populations.^{12, 21, 22} Universal exclusion of pregnant individuals from receiving the COVID-19 vaccine based on an undocumented and hypothetical risk to the fetus would leave pregnant individuals vulnerable to severe morbidity and their infants to preterm birth risk, which would also compromise fetal health.

Pregnant and breastfeeding individuals will likely look to their prenatal care provider to assist in making decisions, to help them weigh the risks and benefits so that they might arrive at a well informed and autonomous decision that is right for them as an individual.

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

- Local epidemiology and risk of community acquisition of COVID-19
- Workplace situation and risk of work-related acquisition of COVID-19
- Individual risk for COVID-related morbidity, including consideration for comorbidities such as advanced maternal age, immunosuppressive conditions, pre-existing diabetes, pre-existing hypertension, obesity or chronic respiratory/cardiac conditions
- Social marginalization that may confer greater risk for COVID-19 infection and severe morbidity, including racially and economically marginalized populations
- Available data related to the safety of the vaccine during pregnancy and lactation
- Data that is not yet available related to the safety and efficacy of the vaccine for pregnant and breastfeeding individuals
- Individual beliefs and personal risk assessment of the available data
- Current regional eligibility guidelines for available vaccines

Anticipatory guidance for vaccination during pregnancy

Individuals should be informed of the expected side effects following vaccination. 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.⁹ Pregnant individuals can be counselled to treat mild post-vaccination fevers with antipyretics (e.g. acetaminophen).

A registry to track pregnancy outcomes for those individuals that receive any vaccine doses in pregnancy is being planned for Canada. Pregnant individuals can get further information here: <https://covered.med.ubc.ca/>.

Timing of vaccination during pregnancy, and vaccine interval

In theory, immunization of a pregnant woman may confer benefit to a newborn infant through a mechanism of maternal vaccination similar to what is seen for pertussis and influenza vaccination during pregnancy. Emerging evidence demonstrates that vaccine-generated antibodies are present in umbilical cord blood following maternal vaccination.¹⁰ However, until such time when a clinical benefit to the newborn is confirmed, the primary indication for administration of a COVID-19 vaccine to a pregnant individual remains for maternal protection. For now, there

is no data to guide administration at a particular gestational age and vaccination may be considered at any gestational age, including the first trimester.

There is no clear evidence to direct whether spacing of other vaccines is required, relative to the COVID-19 vaccine. In the absence of evidence, NACI recommends spacing any other vaccines 28 days from completion of the COVID-19 vaccines. However, other jurisdictions do not recommend any specific spacing and simultaneous administration of other vaccines can occur. The spacing recommendation is based on the theoretical risk of an increased inflammatory response, and the potential for confusion for any adverse events between different vaccines. The spacing recommendation is not based on data about impact on efficacy or adverse events, as such data is not available. Theoretically, administration of immunoglobulins is thought to interfere with vaccine efficacy due to circulating levels of antibody from live attenuated vaccines within the population. However, the rates of circulating antibodies to COVID-19 are low, and therefore the impact of this on vaccine efficacy for COVID-19 is unclear.

Given this, the following can be recommended:

- Wait 14 days after any other vaccine before receiving a COVID-19 vaccine. However, given the context of the global pandemic, simultaneous or closer interval of administration may be considered for individuals at higher risk.
- After receiving a COVID-19 vaccine dose, where possible wait 28 days before receiving any other vaccine, unless a vaccine is required urgently due to an exposure to a virus such as Hepatitis B. Again, given the global pandemic and condensed timelines of pregnancy this may not be possible.
- Time-sensitive interventions such as administration of anti-D immunoglobulin and blood products should not be delayed on account of recent COVID-19 vaccination and could be given simultaneously.

Vaccination of the pregnant patient in the context of limited vaccine supply

Certain jurisdictions may manage interruptions of the vaccine supply chain by delaying administration of the second dose of a COVID-19 vaccine. Vaccine effectiveness following a single dose of the mRNA and non-replicating viral vector vaccines has been thoroughly reviewed at a federal level to inform jurisdictional decisions to delay administration of second doses of a COVID-19.⁷ There are no physiologic reasons to anticipate that the effect of delaying the second dose of the COVID-19 vaccine would be different for a pregnant individual compared to a non-pregnant individual. Pregnant individuals may resume their vaccine series akin to the non-pregnant population in situations of supply chain interruptions.

In the context of limited vaccine supply, distribution of vaccination will be prioritized differently in each jurisdiction depending on local epidemiology and public health priorities. Decisions made regarding prioritization of pregnant individuals should reflect that pregnancy carries an increased risk for COVID-related hospitalization, ICU admission and mechanical ventilation. Additional factors in pregnancy such as advanced maternal age, immunosuppressive conditions, pre-existing diabetes, pre-existing hypertension, obesity or chronic cardiac and respiratory conditions may confer increased risk to pregnant individuals and could be considered for further prioritization in the context of limited vaccine supply.

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. A registry to track pregnancy outcomes for individuals receiving any vaccine doses during pregnancy is being planned for Canada. Pregnant individuals can get more information here: <http://med-fom-ridprogram.sites.olt.ubc.ca/vaccine-surveillance/>.

Where pregnancy is detected during the vaccine series (i.e. following the first dose, but ahead of the second dose), pregnant individuals should continue to be offered the opportunity to complete their vaccination series. 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, compared to the potential risks of receiving the vaccine during pregnancy (as discussed above). Pregnant individuals should not be precluded or forced to delay the vaccine series in any trimester.

Individuals contemplating pregnancy

Ideally, an individual would be immunized against COVID-19 ahead of pregnancy to benefit from maximal vaccine efficacy throughout the entire pregnancy. It is not known whether an individual should delay pregnancy following receipt of the vaccine, and a risk-benefit discussion for those planning pregnancy should occur similar to the discussion for vaccination of pregnant and breastfeeding individuals.

Future research

As the evidence evolves, it is becoming clear that pregnant and postpartum individuals 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 limited data on the use of COVID-19 vaccine in pregnancy are available. We support NACI's recommendation for the inclusion of pregnant individuals in clinical trials of COVID-19 vaccines. This will help to ensure that this population has equitable access to COVID-19 vaccine options, and that vaccination decisions can be informed by robust safety, immunogenicity, and efficacy data.²³

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