

# Alberta COVID-19 Immunization in Pregnancy Factsheet for Practitioners – Update

*\*This summary is based on information available up to September 21, 2021. Contents are subject to change as new information becomes available.*

SOGC Statement on COVID-19 Vaccination in Pregnancy (Updated May 25, 2021) and SOGC Statement on the COVID-19 Vaccines and Rare Adverse Outcomes of Thrombosis Associated with Low Platelets (Updated April 20, 2021)

## CONSENSUS STATEMENTS:

- 1. Pregnant individuals are urged to get immunized at any time during pregnancy or while breastfeeding, in light of increased maternal morbidity and rates of preterm birth associated with COVID-19 infection (original variant and VOC) and evidence of mRNA vaccine safety, if no contraindications exist.**
- 2. The National Advisory Committee on Immunization (NACI) guidelines recommend the mRNA vaccine preferentially for pregnant individuals due to reassuring published safety data from post-marketing surveillance including 156,658 pregnant individuals (5,104 enrolled in CDC’s v-safe COVID-19 Pregnancy Registry).**
- 3. The decision to be immunized 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 immunized during pregnancy or while breastfeeding. Individuals should not be precluded from immunization based on pregnancy status or breastfeeding.**
- 4. Given that pregnant people are at increased risk of morbidity from COVID-19 infection, all pregnant persons are eligible to receive a COVID-19 vaccination.**

## Key Messages

- The now predominant Delta variant is associated with a higher risk of maternal hospital admission, ICU admission and preterm birth than that observed with prior variants.
- Pregnant patients with COVID-19 infection are at a higher risk of hospitalization, admission to the ICU, and preterm birth than non-pregnant patients of the same age.<sup>1-4</sup>
- Prior to the emergence of the SARS-Co-V-2 Delta VOC, the risk of severe morbidity from COVID-19 in pregnant women appeared to be associated with risk factors including age >35 year old, asthma, obesity, pre-existing diabetes, pre-existing hypertension and heart disease.<sup>2,3</sup>



## Alberta COVID-19 Immunization in Pregnancy Factsheet for Practitioners • 2

- mRNA vaccines do **not** increase the baseline risk of miscarriage inherent to any pregnancy, and do **not** increase the risk of congenital heart defects. This is based in international registry and surveillance data.<sup>5, 14-17</sup>
- mRNA vaccines are well tolerated among individuals who are pregnant, lactating, or planning pregnancy (based on a sample of 17,000 individuals self-reporting their post-vaccination symptoms and events).<sup>18</sup>
  - **Pregnant individuals tolerate mRNA vaccine better than non-pregnant individuals** (less frequency of fever)<sup>18</sup>
- mRNA vaccines do not cause infertility. Clinical trials for mRNA and adenoviral vector COVID vaccines did not report any evidence on infertility.<sup>19</sup> There is no change in sperm parameters before and after COVID-19 mRNA vaccination.<sup>20</sup>
- Emerging evidence suggests passive antibody transfer to the fetus in utero and to the infant through breastmilk.<sup>6,7</sup>
- Individuals who may be pregnant, are pregnant or are breastfeeding have the right to receive the vaccine, should they choose to do so.<sup>8</sup>
- Individual counselling with a clinician regarding immunization in pregnancy is recommended. However, this is not a requirement before immunization.
- Immunization is recommended regardless of prior symptomatic or asymptomatic COVID-19 infection because:
  - Prior COVID-19 infection does NOT protect from recurrent COVID-19 infection in pregnancy
  - Protective Antibodies from COVID-19 immunization are present in higher concentrations in breast milk and cord-blood compared to antibodies arising from natural infection<sup>6</sup>
- COVID-19 Immunization can be scheduled 4-weeks or more after their COVID-19 diagnoses.
- Immunization within 30-days of conception with mRNA vaccines is safe<sup>5,9</sup>
- COVID-19 vaccinations can be administered simultaneously during pregnancy with other inactivated vaccinations like Influenza or Tdap.
- Live vaccines including MMR/MMRV require 14 day spacing between administration of the COVID-19 vaccine.

### Scientific Data – mRNA COVID-19 Vaccines

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 COVID-19 vaccine (non-replicating viral vector vaccine) and Janssen (non-replicating viral vector vaccine). Information provided below is limited to mRNA vaccines because NACIs preferential recommendation for their use in pregnancy.

#### *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

## Alberta COVID-19 Immunization in Pregnancy Factsheet for Practitioners • 3

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.<sup>9</sup> 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 efficacy of the Pfizer-BioNTech COVID-19 vaccine has been demonstrated for adults 12 years and older in Phase II and Phase III trials involving the randomization of approximately 44,000 individuals.<sup>6</sup> These trials demonstrated a vaccine efficacy of 94.6% for preventing symptomatic COVID-19 cases at least 7 days following the second dose.<sup>10</sup> 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.<sup>11</sup>

Pregnant and breastfeeding women were excluded from the available Phase II and Phase III studies for the PfizerBioNTech and Moderna COVID-19 vaccines. Real-life data (post-marketing surveillance) from the US CDC reporting on nearly 156,658 pregnant individuals (5,104 enrolled in CDC's v-safe COVID-19 Pregnancy Registry) shows that 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.<sup>5,21</sup> Data from the 36 reported pregnancies that happened during the Phase II and Phase III studies was reassuring as well.<sup>4</sup>

### **Considerations for COVID-19 Immunization 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. There are no red flags or hypothesized mechanisms for potential harm associated with the administration of an mRNA vaccine during pregnancy. A non-immunized 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 both maternal, fetal and neonatal health. Owing to maternal age or underlying comorbidities, some pregnant women are at high risk of severe COVID-related morbidity.

NACI has advised “that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about emerging evidence on the safety of mRNA COVID-19 vaccines in this population. (*Strong NACI Recommendation*)”.<sup>9</sup>

It is recommended that pregnant and breastfeeding women make an informed decision by having access to up-to-date information about the safety and efficacy of the vaccine, theoretical risk of harm,

## Alberta COVID-19 Immunization in Pregnancy Factsheet for Practitioners • 4

and potential benefits to the fetus. During an epidemic, the default should be to offer vaccines to pregnant women alongside other affected populations.<sup>4,12,13</sup> Pregnant and breastfeeding women will likely look to their prenatal care provider to assist in making decisions weighing 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
- Available data related to the safety of the vaccine during pregnancy and lactation
- Individual beliefs and personal risk assessment of the available data

### Individuals who proceed with immunization

Individuals should be informed of the expected side effects following immunization. While pain at the injection site, fatigue and headache are the most commonly reported symptoms following immunization, pregnant patients report fever frequently than 16% reported by non-pregnant individuals.<sup>7</sup> Pregnant women can be counselled to treat mild post vaccination fevers with antipyretics (e.g., acetaminophen). Please encourage your patient to enroll in<sup>18</sup> COVERED the Canadian Registry for COVID-19 Vaccination in Pregnancy or Lactation.

### Timing of immunization during pregnancy and vaccine interval

Immunization of a pregnant woman can confer benefit to a newborn infant through a mechanism of maternal immunization similar to what is seen for pertussis and influenza immunization during pregnancy. Emerging data shows maternal antibodies to SARS-CoV-2 cross the placenta after infection or immunization. This preliminary data also suggests vaccine-generated antibody titers are higher compared to those seen following COVID-19 infection in pregnancy. Antibodies were found in umbilical cord blood and breastmilk, suggesting it is possible for maternal antibodies to transfer through the placenta and confer protection against COVID-19 infection to the fetus in utero and the neonate during lactation.<sup>13</sup>

All pregnant individuals are encouraged to consider COVID-19 immunization in pregnancy, even if the patient has had a symptomatic or asymptomatic COVID-19 infection. Immunization can be given after 4-weeks from diagnoses. COVID-19 vaccinations can be administered simultaneously during pregnancy with other inactivated vaccinations like Influenza or Tdap. Live vaccines including MMR/MMRV require 14 day spacing between the administration of the COVID-19 vaccine.

## Alberta COVID-19 Immunization in Pregnancy Factsheet for Practitioners • 5

Rhogam and Betamethasone should be given as indicated for obstetrical reasons. Vaccination (COVID-19, pertussis, or flu vaccines) can be administered simultaneously or at any time before or after these treatments.

If contemplating pregnancy, ideally individuals will complete a full course of COVID-19 vaccination (2 doses) prior to becoming pregnant to gain the most benefit from vaccination throughout the whole pregnancy.

As per most recent NACI guidance, those who are trying to become pregnant do not need to avoid pregnancy after immunization with an mRNA vaccine,<sup>9</sup> because US safety data suggests mRNA vaccine administration within 30 days of vaccine administration is safe.<sup>5</sup> Consequently, **inadvertent pregnancy between doses or shortly after receiving the COVID-19 vaccine is not an indication for pregnancy termination.**

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## Alberta COVID-19 Immunization in Pregnancy Factsheet for Practitioners • 7

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