COVID-19 IMMUNITY TASK FORCE

GROUPE DE TRAVAIL SUR L'IMMUNITÉ FACE À LA COVID-19

Summary report #3

The impact of COVID-19 disease & vaccination on pregnancy and newborns

Background

Pregnant and breastfeeding people are advised, by the Society of Obstetricians and Gynaecologists of Canada and by all provinces in Canada, to get vaccinated against COVID-19. This recommendation is based on Canadian and international research to date, including from four **COVID-19 Immunity Task Force (CITF)**-funded studies that are included in this summary.

Key findings to date

The findings in this summary are preliminary and unpublished, for the most part, and have therefore not been peer-reviewed.

COVID-19 is serious among pregnant people

- The number of pregnant people in Canada with COVID-19 has increased steadily between April 2020 and November 2021.
- Pregnant people with COVID-19 suffer more severe disease than do non-pregnant women of child-bearing age (i.e., between 20 and 49 years old).
- Although pregnant people are usually between 20 and 49-years-old, they have similar risks of COVID-19 complications as people between the ages of 55 and 59.

When pregnant people get COVID-19, there are higher chances of negative repercussions on the baby

- Pregnant people with COVID-19 are two times more likely to have a premature birth than those without the disease and four times more likely to have an extremely premature baby.

COVID-19 vaccines are effective in pregnant people

- The body of evidence to date suggests approved COVID-19 vaccines induce good immune responses in pregnant people.

COVID-19 vaccination during pregnancy was not associated with adverse outcomes around the time of birth

- Increased risk was not observed after a first or second dose of vaccine, nor was there increased risk when the vaccine was received in mid-pregnancy (second trimester) or later pregnancy (third trimester).
- Pregnant people experience similar side effects (e.g., sore arm, temporary muscle soreness) as non-pregnant people[1].

[1] Collier AY, et al. Immunogenicity of COVID-19 mRNA Vaccines in Pregnant and Lactating Women. JAMA. 2021;325(23):2370-2380.

- Evidence does not show that vaccination negatively impacts fertility: vaccinated people have the same incidence of pregnancy as do unvaccinated people[2].

COVID-19 vaccine coverage is lower among pregnant people compared to those who are not pregnant.

Human milk appears to be safe for infants

- SARS-CoV-2 is a virus that is unlikely to be transmitted into human milk.
- Antibodies to SARS-CoV-2 are frequently found in the milk of women following COVID-19; however they are infrequently observed six months after symptom onset.
- While the presence of anti-SARS-CoV-2 IgA appears to be associated with the capacity to neutralize the virus, milk samples without antibodies can also be neutralizing.
- Vaccine-induced antibodies do transmit into human milk.

[2] Hillson K, et al. Fertility rates and birth outcomes after ChAdOx1 nCoV-19 (AZD1222) vaccination. Lancet. Published online October 21, 2021. doi:10.1016/S0140-6736(21)02282-0

CITF-supported research studies included

Study	Lead researcher(s) and affiliation	Who is participating?	Where is the study taking place?
COVID-19 vaccination during pregnancy in Ontario: A province-wide evaluation	**Dr. Deshayne Fell** University of Ottawa and Children's Hospital of Eastern Ontario Research Institute	Pregnant people	Ontario
COVID-19 in Pregnancy: Epidemiology, maternal and infant outcomes (CANCOVID-Preg) and COVID-19 vaccines and pregnancy (COVERED)	**Dr. Deborah Money** University of British Columbia and Women's Health Research Institute, BC Women's Hospital	Pregnant people and infants	Canada-wide
Can COVID-19 and maternal antibodies to SARS-CoV-2 be transmitted through human milk? Implications for breastfeeding and human milk banking	**Dr. Deborah O'Connor** **Dr. Sharon Unger** **Dr. Susan Poutanen** University of Toronto, The Hospital for Sick Children, and Sinai Health	Lactating persons exposed to SARS-CoV-2 Donors to the Rogers Hixon Ontario Human Milk Bank Lactating persons vaccinated during pregnancy and/or lactation	Primarily Ontario

Latest results

Early in the COVID-19 pandemic, necessary data were lacking to determine the effects of either SARS-CoV-2 infection or vaccines on pregnant people and newborns. However, the evidence has evolved and is now clear that infection in pregnant people has more severe consequences than in the general population. There is also increasing evidence that COVID-19 vaccines are effective in pregnancy, and have not been associated with adverse pregnancy outcomes. The CITF has compiled results from four of its funded studies here, but these results are preliminary and unpublished, for the most part, and have therefore not been peer-reviewed.

Pregnant people have a greater chance of severe outcomes from COVID-19 than the general population

- 100% of pregnant people hospitalized with COVID-19 were unvaccinated or incompletely vaccinated, according to information from early analysis to the end of September 2021[3].
- Pregnant people with COVID were **three times more likely to be hospitalized** and nearly **seven times more likely to be admitted to the ICU** than non-pregnant women of child-bearing age with COVID[4]:
    - 7.6% of pregnant people with COVID-19 had to be hospitalized, compared to 2.6% of females between the ages of 20 and 49 (generally, child-bearing age) who were not pregnant.
    - 2% of pregnant people with COVID-19 were admitted to the ICU, whereas only 0.3% of the non-pregnant group were admitted to the ICU.
- Adverse effects from COVID-19 experienced by pregnant people include abnormal X-ray pneumonia, the need for ventilation, and oxygen therapy[5].
- Pregnant people have a similar risk of COVID-19 complications as the general population between the ages of 55 and 59, despite being, on average, significantly younger[6].

[3] Dr. Deborah Money, COVID-19 in Pregnancy: Epidemiology, Maternal and Infant Outcomes (CANCOVID-Preg) and COVID-19 vaccines and pregnancy (COVERED).
[4] Ibid.
[5] Ibid.
[6] Ibid.

When pregnant people get COVID-19, there are higher chances of negative repercussions for the baby

- Pregnant people with COVID-19 have a **higher risk of a preterm birth** than pregnant people without COVID-19[7]:
    - More than double the percentage of preterm births (less than 37 weeks), 13.6% compared to 6.8% among non-COVID-19 affected pregnancies.
    - Four times the percentage of extremely preterm births (20 to 27 weeks), 1.6% as opposed to 0.4%
    - Double the percentage of very preterm births (28 to 31 weeks), 1.0% compared to 0.5%
    - Double the percentage of moderate preterm births (32-33 weeks), 1.4% compared to 0.7%
    - Nearly double the percentage of late preterm births (34 to 36 weeks), 9.6% compared to 5.4%

COVID-19 vaccines during pregnancy were not associated with adverse outcomes

Compared with those who were vaccinated following delivery, pregnant people who received at least one dose of COVID-19 vaccine during pregnancy did not have any increase in a range of pregnancy and birth outcomes investigated[8]:

- Post-partum hemorrhage;
- Chorioamnionitis (an infection of the membranes that surround the fetus or the amniotic fluid);
- Cesarean and emergency Cesarean birth (15.3% of those who were vaccinated vs. 16.4% of those vaccinated following pregnancy);
- Newborn intensive care unit admissions (11% of admissions for babies of people who were vaccinated vs. 13.3% of people vaccinated following delivery);
- A slightly higher percentage of babies from people who were vaccinated during pregnancy had APGAR[9] scores over 7 (10 being the highest).

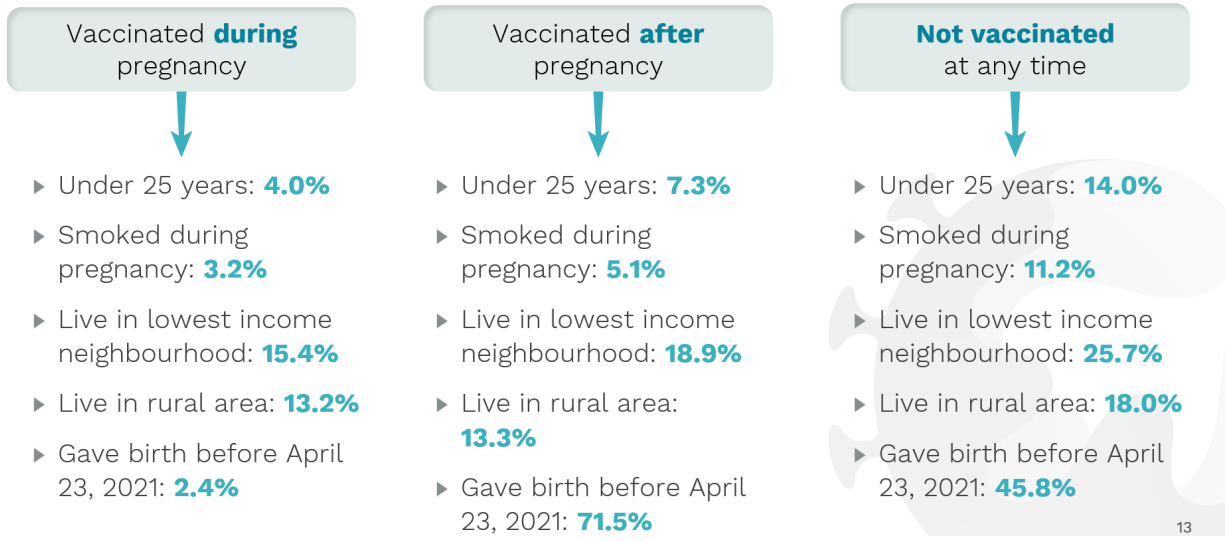
[7] Ibid.

[8] Dr. Deshayne Fell, COVID-19 vaccination in pregnancy: A province-wide epidemiological assessment of safety and effectiveness using the Better Outcomes Registry & Network (BORN) Ontario Registry.

[9] An APGAR score is a rating of newborn health taken within five minutes of birth.

Characteristics of pregnant people according to their COVID-19 vaccination status

The following chart shows the characteristics of pregnant people in Ontario according to their COVID-19 vaccination status:



Comparison by vaccine, number of doses and timing of vaccination

There was no increase in risk of any adverse outcomes in sub-group analyses where the following groups were compared[10]:

- Pfizer-BioNTech vs. Moderna for dose 1
- One vs. two doses during pregnancy
- Dose 1 in 1st/2nd trimester vs. dose 1 in 3rd trimester

Human milk remains safe for newborns[11]

- The SARS-CoV-2 virus is unlikely to be transmitted into human milk.
    - Studying two cohorts – COVID-19+ or presumptive COVID-19+ mothers and donors to the Rogers Hixon Ontario Human Milk Bank – **no milk sample tested positive** for SARS-CoV-2 using PCR testing.
- Antibodies to SARS-CoV-2 are frequently (52.7%) found in milk of women following COVID-19; however, they are infrequently observed six months after symptom onset.
- While the presence of anti-SARS-CoV-2 IgA appears to be associated with capacity to neutralize the virus, milk samples without antibodies can also be

[10] Ibid.
[11] Dr. Deborah O'Connor and Dr. Sharon Unger, Impact of COVID-19 disease and vaccination on human milk antibodies.

neutralizing. This is thought to be due to the presence of other components in milk, such as lactoferrin, human milk oligosaccharides, that have anti-viral activities.
    - 39% of samples that tested positive for IgA were neutralizing.
    - 25% of samples that were negative for IgA were neutralizing.

Vaccine-induced antibodies do transmit through human milk

- IgA and IgG antibodies against SARS-CoV-2 have been detected in human milk following vaccination with mRNA vaccines, predominantly following the second dose.
- Antibody levels appear to be dependent on which vaccine product is administered and the interval between vaccine doses.
- Research examining the neutralization capacity of vaccine-induced SARS-CoV-2-specific antibodies in human milk is underway.

Policy implications to date

- Since June 2021, all provinces in Canada have recommended vaccination for pregnant people.
- CanCOVID-Preg[12] has produced four reports (a fifth is currently in preparation) and has shared them with the Public Health Agency of Canada (PHAC), the Canadian Perinatal Surveillance Program, the Canadian Neonatal Network, and the Canadian Congenital Anomalies Surveillance Program.
- The Canadian Pediatric Society recommends that people with COVID-19 continue to breastfeed as there is no apparent risk of viral transmission to the infant[13].

Report #1 December 2, 2020	Society of Obstetricians and Gynecologists of Canada (SOGC) **recommends vaccination** for all pregnant individuals due to risk of COVID-19 in pregnancy
Report #2 January 15, 2021	COVID-19 in pregnancy guideline for clinical care – February 15, 2021
Report #3 February 25, 2021	SOGC calls for a Canada-wide policy change to **prioritize pregnant individuals** for vaccination **Vaccination policies updated** in: ON, BC, NL, NB, SK, MB
Report #4 June 3, 2021	Pregnant persons at risk of COVID complications similar to age 55-59 year olds

[12] Dr. Money's pan-Canadian surveillance project dedicated to collecting and analyzing data on COVID-19 in pregnancy in support of optimal clinical care and public policy.
[13] https://cps.ca/en/documents/position/breastfeeding-when-mothers-have-suspected-or-proven-covid-19

Policy implications moving forward

- Prioritize third doses (booster) in pregnant people, particularly as we face fast-spreading variants such as Delta and Omicron.
- Reinforce vaccine confidence among pregnant people, primary caregivers, and other birthing professionals.
- Tailor vaccine confidence campaigns to reach out particularly to those who are least likely to be vaccinated (under 25, from lower-income neighbourhoods, in rural areas, and who smoke).
- Strengthen vaccine confidence in individuals who wish to become pregnant in the future by amplifying evidence-informed messaging and by refuting erroneous disinformation linking infertility to COVID-19 vaccines. Use social media platforms to effectively engage in this dialogue.
- Pay particular attention to design vaccine campaigns for pregnant people in households with young children who are not yet eligible to be vaccinated and are likely to be participating in congregate settings with unvaccinated children (daycare, school, etc.)
- Reinforce campaigns regarding the safety of breastfeeding, as the evidence indicates that this remains a safe and healthy choice for infants. Pasteurized donor human milk remains the the most suitable option for hospitalized very low birth weight infants when their mother's milk is unavailable.

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