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



SOGC Consensus Statement: Women who are pregnant or breastfeeding should be offered vaccination at any time during pregnancy, if they are eligible and there are no contraindications.

COVID-19 and Current Vaccines

What are the increased risks related to COVID-19 in pregnancy? Who is at increased risk?^{1, 2}

- Pregnant patients with COVID-19 infection were more likely
 - to:
- Require admission to intensive care (compared to non-pregnant patients)
- Require invasive ventilation (compared to nonpregnant patients)
- Deliver prematurely (compared to uninfected patients)
- Maternal death (compared to uninfected patients)
- Risk factors for increased morbidity include:
 - Age \geq 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 are the data on efficacy of the available vaccines in the general public?^{3, 4}

• For the Pfizer-BioNTech vaccine, the vaccine efficacy was 95.0% in preventing COVID-19 infection, based on data starting 7 days after the second injection.

- Infection rate was reported as 0.9% in the placebo group versus 0.05% in the vaccine group.
- An interim analysis by Pfizer-BioNTech six months after the second dose demonstrated a 91.3% efficacy.⁵
 - At the six month interval, the vaccine demonstrated a 95.3-100% efficacy against severe disease.
- For the Moderna vaccine, the vaccine efficacy was 94.1% in preventing COVID-19 infection, based on data starting 14 days after the second injection.
 - Infection rate was reported as 1.3% in the placebo group versus 0.08% in the vaccine group.
- For the AstraZeneca vaccine, the efficacy was 70.4% in preventing COVID-19 infection, based on data starting 14 days after the second injection.⁵
 - Infection rate was reported as 1.6% in the placebo group versus 0.6% in the vaccine group.
- For the Janssen vaccine, the efficacy was 66.9% in preventing against moderate to severe COVID-19 infection, based on data starting 14 days after the second injection.⁶
 - Infection rate was reported as 1.8% in the placebo group versus 0.6% in the vaccine group.
 - Janssen's primary end-point was moderate to severe COVID-19 rather than all COVID-19 infections.

What is the real world data on the effectiveness of the available vaccines?⁷

- Due to a need to vaccinate the largest number of people, many jurisdictions around the world are extending the interval to the second dose of the vaccine.
- Observational data on the effectiveness of the available vaccines are as follow:
 - For mRNA vaccines, the one-dose effectiveness ranged from 60 80% against any COVID-19 infections
 - For the AstraZeneca vaccine, the one-dose effectiveness ranges from 58 68% against any COVID-19 infections
- One dose of the mRNA vaccine and AstraZeneca appears to be at least 80% protective against hospitalizations and deaths, which is the most important outcome.

What are the data on safety of the available in the general public? $^{\rm 3,\ 4,\ 7}$

In the Pfizer-BioNTech trial, vaccines were administered to 18,860 individuals.

- Common side effects included the following (depending on dose and age of recipient). Most side effects started at 15 hours post-vaccination and resolved by the end of the second day.
 - Mild to moderate pain, redness, or swelling at injection site (66% to 83%)
 - Fatigue (51% to 59%)
 - Headache (39% to 52%)
 - Fever (11% to 16%)
 - Lymphadenopathy (0.3%)
- Only four individuals in the vaccination group reported serious adverse events (SAEs). Overall, the incidence of SAEs was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively).
- In the trial, 2 deaths were observed in the vaccination group, while 4 were observed in the placebo group. None of these deaths were considered to be related to the vaccination or placebo.

In the Moderna trial, vaccines were administered to 15,181 individuals.

- Common side effects included:
 - Mild to moderate pain, redness, or swelling at the injection site (up to 83%)
 - Fever/chills (up to 15.5%)
 - Headache (up to 58%)
 - Fatigue (up to 65%)
 - Myalgia (up to 58%)
 - Arthralgia (up to 42%)
- In the trial, 2 deaths were observed in the vaccination group, while 3 deaths were observed in the placebo group. These were not related to the vaccination.
- Overall, SAEs were similar between vaccine and placebo groups (0.6% in both groups).

In the AstraZeneca trial, vaccines were administered to 12,021 individuals $^{8}\,$

- Common side effects included:
 - Tenderness (75.3%) or pain (54.2%) at the injection site
 - Fatigue (62.3%)
 - Headache (57.5%)
 - Myalgia (48.6%)
- In the trial, 1 death was observed in the vaccination group, while 4 deaths were noted in the placebo arm.
- Non-fatal serious adverse events were similar between groups (0.7% vaccination group vs 0.8% placebo group)
- Thrombosis related to the AstraZeneca vaccine is estimated to be between 1 in 50,000 and 1 in 100,000.⁹

In the Janssen trial, vaccines were administered to 21,895 individuals

- Common side effects included:
 - Injection site pain (48.6%),
 - Headache (38.9%),
 - Fatigue (38.2%)
 - Myalgia (33.2%)
- In the trial, 3 deaths were observed in the vaccination group, while 16 deaths were observed in the placebo group. None of the deaths were related to the vaccine.
- Thrombosis related to the Janssen vaccine has been described in 8 people among 7 million recipients,¹⁰ primarily in women under the age of 60.
- Non-fatal serious adverse events were similar between the groups (0.4% each).

From a Canadian perspective, there is an ongoing national surveillance program for COVID-19 vaccinations.

- As of April 18, 2021, 3738 adverse events (0.039%) following immunization were reported from 9,525,732 total vaccinations.
 - 529 events (0.006%) were deemed serious.
 - The reported Canadian adverse events related to immunization included vaccination-site reactions, paresthesia, pruritis, urticaria, headache, hypoesthesia, nausea, and anaphylaxis.
- For up-to-date information, please refer to: <u>https://health-infobase.canada.ca/covid-19/vaccine-safety/</u>

What are the proven benefits of COVID-19 vaccination in pregnancy?^{11, 12}

- Pregnant patients were excluded from all current available trials. However, there were 65 women, who found out they were pregnant after their first dose
 - 23 women in the Pfizer-BioNTech vaccine trial (12 in the vaccine arm and 11 in the placebo arm)
 - 13 women in the Moderna vaccine trial (6 in the vaccine arm and 7 in the placebo arm)
 - 21 women in the AstraZeneca vaccine trial (12 in the vaccine arm and 9 in the placebo arm)

- 8 women in the Janssen vaccine trial (4 in the vaccine arm and 4 in the placebo arm)
- In a study on 131 people who have received the vaccine, vaccine-induced antibody is equivalent between pregnant and non-pregnant participants.¹³
 - Vaccine-induced antibodies were at higher titres than COVID-19 infection induced antibodies
 - Vaccine-induced antibodies were present in umbilical cord and breastmilk

What are benefits of COVID-19 vaccination in pregnancy expected (but not proven yet) for the pregnant patient?¹⁴

- COVID-19 vaccines should have similar efficacy in pregnancy to prevent COVID-19.
 - In other vaccine studies, pregnant patients consistently produce antibody titres equivalent to those in non-pregnant individuals.
 - 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) as well.

What are benefits of COVID-19 vaccination in pregnancy expected (but not proven yet) for the neonate?

- 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 patients¹⁵
 - However, it is unclear whether oral ingestion of breast milk antibodies would confer any protection to an infant.

What are the risks of COVID-19 vaccination in pregnancy?^{11, 12}

- Among all randomized-control vaccine trials, less than 50 vaccinated participants reported pregnancies. No adverse outcomes were identified, based on current analysis.
- Development and reproductive toxicity (DART) trials of all approved Canadian vaccines did not identify any adverse effects.¹⁶
- The U.S. v-safe pregnancy registry recently published safety data on the use of Pfizer-BioNTech and Moderna vaccines in pregnancy:
 - 35,691 participants were identified to be pregnant, when obtaining their vaccination
 - Injection pain is more frequent in pregnant patients (84%)
 - Fatigue (26%), headache (16%), myalgia (9%), chills (3%), fever (3%) were less frequent in pregnant patients.
 - 3,958 participants agreed to be followed during pregnancy and post-pregnancy
 - At the time of publication, 827 of the participants completed their pregnancy with the following findings
 - Spontaneous abortion: 12.6% (expected rate: 10-26%)
 - Preterm delivery rate: 9.4% (expected rate: 8-15%)
 - Small for gestational age: 3.2% (expected rate: 3.5%)
 - Congenital anomalies: 2.2% (expected rate: 3%)
 - Stillbirth: 0.1% (expected rate: <1%)
 - Neonatal deaths: 0% (expected rate: <1%)
 - Conclusion: No obvious safety signals among pregnant persons who received the mRNA vaccines

What ongoing studies will help improve the evidence for COVID-19 vaccination in pregnancy?

• Pharmaceutical companies have started their trials in pregnant subject in early 2021.

- The U.S. Centre for Disease Control (CDC) has a Vaccine Safety in Pregnancy Monitoring system and data will continue to be published as follow up continues.
- There is a Canada-wide vaccine registry for pregnant women being established for women who have or have not received the vaccine to complete survey information to understand Canadian specific outcomes for pregnant women during this vaccination roll out.
 - Click here for more details: <u>https://ridprogram.</u> med.ubc.ca/vaccine-surveillance/
- Health care providers should remain informed about the results of these ongoing trials to provide patients with the most up-to-date information.

Based on the available evidence, should I recommend the COVID-19 vaccination for pregnant patients or patients planning conception?¹⁷

- All pregnant patients should be offered the opportunity to be vaccinated18 when they are eligible, based on the local and/ or provincial/territorial allocation of vaccines.
- Given the recent rise of severe COVID-19 infections in pregnant patients, pregnancy should be prioritized in the vaccination rollout.
- 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
 - 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 risk of vaccination is associated with the understudied nature of vaccines in pregnancy; this is not immaterial. Exercising caution is a valid patient choice.
- Health care providers should remain informed about the most recent state of evidence and recommendations to provide appropriate counselling to their patients.

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.
- The indications/contraindications administering the Janssen and AstraZeneca vaccines may vary by regional jurisdiction.
 Please refer to your regional guidelines.

Common Patient Concerns About COVID-19 Vaccinations

What are the chances of serious allergic reactions in pregnancy?^{3, 4, 18, 19}

- In the Moderna trial, 1.5% in the vaccination group versus 1.1% in the placebo group developed hypersensitivity reactions.
 - Only one case of an anaphylactic reaction (< 0.01%) was found in each group.
- After administration of 1 893 360 doses of the Pfizer-BioNTech vaccine in the United States, 21 cases of anaphylaxis were identified.
 - Seventeen cases were treated in the emergency department and discharged, and only 4 were hospitalized. All have recovered, and no deaths were reported.
 - This equates to 11.1 cases per 1 million vaccinations (0.001%).
- There is no evidence that pregnancy increases hypersensitivity reactions.

How long does immunity last following COVID-19 vaccination?

- The studies conducted by the pharmaceutical companies were completed over a study period of 2 months, so the longterm immunity due to the COVID-19 vaccine is still under investigation. Immunity did not appear to wane toward the end of the 2-month study period.
 - An update at the 6 month mark for the Pfizer-BioNTech vaccine continues to show efficacy of 91.3%⁵

• As the vaccine is distributed, ongoing studies will allow us to

determine the duration of immunity over a longer time period.

- Current evidence supports protection from one dose of mRNA vaccines and the AstraZeneca vaccine extend to at least 8 weeks and 90 days respectively⁷
- Antibody persistence for the Moderna vaccine has been described up to 6 months²⁰

If my patient has had COVID-19 in the past, should they receive the COVID-19 vaccination?²¹

- There are reports of reinfection with COVID-19, and we are still determining the duration of immunity after natural infection.
- Studies have shown that patients who have acquired COVID-19 infection are unlikely to be reinfected within 90 days of the original infection.
- 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, we continue to recommend the vaccine.
 - A discussion between you and your patient to balance the risks and benefits of vaccination versus remaining unvaccinated may be helpful, but is not necessarily required.



If my patient has received an influenza, Rh-Immune Globulin, or Tdap vaccination in pregnancy, how long should they wait to receive the COVID-19 vaccination?²²

- The influenza vaccine (during influenza season) and the Tdap vaccine are still recommended in all pregnancies during the COVID-19 pandemic.
- Based on Public Health Agency of Canada Recommendations:
 - If your patients have received another vaccine recently, the COVID vaccine should be delayed by 14 day based on limited data on safety and effectiveness of receiving concurrent vaccinations.
 - If your patients have received the COVID-19 vaccine recently, other vaccinations should be delayed by 28 days except in the case of post-exposure prophylaxis (Hepatitis B)
- In the case of RhoGAM, neither RhoGAM nor COVID-19 vaccine should be delayed.

If my patient received the COVID-19 vaccine, how long should they delay pregnancy or fertility treatments?^{17, 23}

- Since the data from the DART studies do not suggest that the available vaccines carry any risks, there is no recommended delay between vaccination and conception.
 - We do recommend completing the vaccine series (if feasible) before conception to ensure adequate protection from the vaccine.
- If your patient is planning a pregnancy, completing the COVID-19 vaccination series is likely to reduce the increased risks associated with COVID-19 infections in pregnancy.
- Patients have the autonomy to make an informed decision concerning whether to delay pregnancy while awaiting COVID-19 vaccination.

In the case of inadvertent pregnancies after vaccination, what should I recommend to patients?¹⁷

- Individuals should **not** be counselled to terminate pregnancy due to the vaccination.
 - There has been no teratogenicity identified with any of the vaccines.

- If pregnancy is detected between vaccine doses, we continue to offer patients the opportunity to complete their vaccine series.
- Routine prenatal visits and testing are recommended for the patient as per usual guidelines.

Should my patient who is breastfeeding receive the COVID-19 vaccination?¹⁷

- Lactating patients should be offered the COVID-19 vaccination, if they are eligible and there are no contraindications.
- Breastfeeding individuals were excluded from the original vaccine trials.
 - Vaccination should have efficacy in breastfeeding patients similar to that in the general population.
 - Vaccine-induced antibodies have been consistently found in lactating individuals:
 - In a study of 84 lactating participants, vaccine-induced antibodies were present in breast milk in 97% of women by week 5/6.¹⁵
 - You should have an informed discussion with your patient to balance the risks and benefits of vaccination with those of remaining unvaccinated.
- If the breastfeeding patient has been vaccinated, there is no need to discontinue or delay breastfeeding because of the COVID-19 vaccine.

Does the viral vector vaccines (AstraZeneca, Janssen) alter your DNA? What could viral vector vaccines do to a growing fetus?

- No. The viral vector vaccines uses a non-pathogenic virus to produce SARS-CoV-2 spike proteins. After the body recognizes the protein, it will trigger the immune system to produce antibodies against SARS-CoV-2 spike proteins.
- If fetal cells are exposed to viral vector vaccines, the vaccines may cause fetal cells to produce similar proteins.
- At this time, there is no data on the transfer of antibodies derived from viral vector vaccines from mother to newborn.

Does the mRNA vaccine (BioNTech-Pfizer, Moderna) alter your DNA? What could mRNA vaccines do to a growing fetus?²⁴

- No, it does not alter your DNA. 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.
 - Our cells **do not** take up the mRNA into the nucleus, where genes are stored.
- If fetal cells are exposed to mRNA vaccines, the vaccines may cause fetal cells to produce similar proteins.
 - Until further conclusive information about the benefits of maternal vaccination for the infant is available, the risk-benefit discussion related to the COVID-19 vaccine in pregnancy should be focused on potential maternal benefits.

Certain vaccinations are contraindicated in pregnancy. Why isn't the COVID-19 vaccine contraindicated?¹⁷

- A few specific diseases, like polio and rubella, are prevented using live-attenuated vaccines. This means they use the virus itself, in a form that prevents it from replicating, to train the immune response. There is a theoretical risk that these "attenuated" viruses could cross the placenta and harm the fetus, whose own immune system is not mature enough to defend against them.
- To date, in clinical practice, there are patients who were treated with live-attenuated vaccine before they knew they were pregnant, and no adverse obstetrical or neonatal outcomes were observed.
 - Given herd immunity and low prevalence of the diseases that are preventable by live-attenuated vaccines, the risk-benefit balance is toward avoiding the vaccines in pregnancy.
- In the case of the COVID-19 vaccine, there is limited theoretical risk from the vaccine and many expected benefits from avoiding the proven harms in pregnant patients affected by COVID-19 infections. There is limited herd immunity for COVID-19 currently. In all cases, women should choose what is right for them.

- There is documented risk to pregnant individuals (especially those with risk factors) of harm associated with COVID-19 infection if they are not vaccinated.
- For other non-live attenuated vaccines such as the influenza vaccine, large meta-analyses of over 180,000 pregnant patients demonstrating safety in pregnancy.²⁵

Can COVID-19 vaccine cause COVID-19 infections?²⁴

- No, it cannot cause COVID-19 infections because there is no live virus in the vaccine.
- Side effects that may mimic COVID-19 infections are related to the immune system response to the body producing the spike protein of the SARS-CoV-2 virus that causes COVID-19.

Could the COVID-19 vaccine cause infertility?²⁶

- There is no suggested impact of the COVID-19 vaccine on male or female fertility.
- 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. The antibodies produced against the SARS-CoV-2 spike protein would not have 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.

Can the COVID-19 vaccination cause Bell's palsy?^{3, 4}

- There is no conclusive association between Bell's palsy and the COVID-19 vaccine.
- In the Pfizer-BioNTech trial, four cases of Bell's palsy were noted in the vaccination group (none in the placebo group).
 In the Moderna trial, three cases were noted in the vaccination group (1 in the placebo group).
- This is deemed to be in line with the rate of Bell's palsy in the general population. Current surveillance has not identified any safety signals related to the vaccine and Bell's palsy.
- It is also important to note that COVID-19 infections have been associated with Bell's palsy in multiple case reports.

Are fetal cells used to develop the COVID-19 vaccines?²⁷

- The development of the Pfizer-BioNTech and Moderna vaccines did not involve any human fetal cell lines.
- The development of the AstraZeneca and Janssen vaccines required human cell lines derived from fetal cells from 1973 and 1985 respectively. These cells **are not** found in the vaccine itself.
- COVID-19 vaccination was deemed ethically acceptable by the Vatican in December 2020.
- On March 11, 2021, the Canadian Conference of Catholic Bishops stated:
- "Catholics in good conscience, may receive the vaccine that is available and offered to them."²⁸

Is there pork or other animal by-products in the COVID-19 vaccines?²⁹

 There are no animal products (including pork) in the 4 available COVID-19 vaccines

Are there microchips in the COVID-19 vaccine?

 No, there are no radio-frequency identification (RFID) microchips in the COVID-19 vaccine. There is a social media misinformation movement regarding the presence of a microchip engineered by Bill Gates, a businessman who formerly headed Microsoft Corporation. This rumour has been publicly refuted multiple times by Gates himself.

• There is no microchip in existence that would be small enough to be injected via the syringes used for COVID-19 vaccination.

If my patient did not have significant side effects from the vaccine, does this mean the vaccine did not work?

- From the published data, not everyone who receives the vaccine gets significant side effects. Everyone's immune system reacts differently to vaccines.
- For example, while a significant number of people who receive the second dose of the Moderna vaccine had side effects such as fatigue (65%), muscle aches (58%) and fevers (15%) – many did not have any side effects.
 - The occurrence of side effects does not impact the effectiveness of the vaccines.

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

- There is no conclusive evidence on the level of protection of the approved COVID-19 vaccines against any new variants of the SARS-CoV-2 virus at the population level.
 - Additional in vitro and in vivo research is required for each specific vaccine to determine its efficacy against each variant.
 - This will need to be determined individually due to the different mechanisms of achieving immunity
- This is a rapidly changing area of virology and clinicians may wish to consult the CDC website for more detail and as evidence emerges: <u>https://www.cdc.gov/coronavirus/2019-</u> ncov/transmission/variant.html
- While some vaccine manufacturers have reported decreased efficacy against individual variants,30 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.

Should I receive the AstraZeneca and Janssen vaccine due to the clots related to the vaccine?

- There is an ongoing investigation in the thrombosis risks associated with the AstraZeneca and Janssen vaccine (approximate risk ranging from 1 in 50,000 to 1 in 100,000).⁹
- The discussion of rare thrombosis risks requires balancing the risks of COVID-19 infections on pregnancy (e.g. risk for severe disease, risk of preterm delivery, risk of maternal deaths). This is especially true in higher risk populations (age, asthma, preeclampsia, gestational diabetes, etc.), particularly if there are delays in obtaining alternative vaccines.
- As of April 23, 2021, NACI has concluded that the AstraZeneca vaccine may be offered to individuals 30 years of age and older.31
- The SOGC supports the use of all available COVID-19 vaccines approved in Canada in any trimester of pregnancy and during breastfeeding but we recommend following provincial and territorial guidelines on type of vaccine to prioritize for pregnant and breastfeeding individuals.

Since pregnancy is also associated with higher clot risk, would I be at higher risk of the vaccine-related clots?^{32, 33}

- The mechanism of action for thrombosis is different between pregnancy and the vaccines:
 - Pregnancy-related thromboses is largely due to a hypercoagulable state (changing fibrin and coagulation factors levels) in addition venous stasis (hormonally driven and from mechanical uterine obstruction)
 - The true mechanism of action for thromboses associated with the vaccine is still under investigation. Current hypotheses suggest an immune-mediated response, leading to thrombocytopenia, and atypical thromboses.
- The specific thromboses associated in pregnancy are mainly pulmonary embolisms and deep vein thrombosis, rather than central vein sinus thrombosis and splanchnic vein thrombosis associated with the viral vector vaccines.

 Since the mechanisms and manifestations are likely different, the risks of each thrombosis is expected to be independent of one another.

What is the rationale and evidence behind extending the vaccine dose interval in Canada?⁷

- Current evidence supports that one dose of mRNA vaccines and the AstraZeneca vaccine extends protection to at least 8 weeks and 90 days respectively
- Based on statistical modelling taking data on one- vs. twodose effectiveness and durability of protection, extending the interval between vaccines minimizes symptomatic cases, hospitalizations, and deaths while vaccine supply is constrained.³⁴
- Immunology principles suggest that extending vaccine intervals can provide increased efficacy and durability
 - Increased efficacy with increased vaccine interval has been demonstrated by the AstraZeneca Vaccine

Original date: February 16, 2021 Revision date: May 27, 2021

Dr. Jeffrey Man Hay Wong Dr. Heather Watson Dr. Chelsea Elwood Dr. Vanessa Poliquin

on behalf of the Infectious Disease Committee of the Society of Obstetricians and Gynaecologists of Canada



References

1. Canadian surveillance of covid-19 in pregnancy: Epidemiology, maternal and infant outcomes. Available at https://ridprogram.med.ubc.ca/cancovid-preg/.

2. Allotey J, Stallings E, Bonet M, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: Living systematic review and meta-analysis. BMJ. 2020;370:m3320. Available at <u>https://www.ncbi.nlm.nih.gov/pubmed/32873575</u>.

3. Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the bnt162b2 mrna covid-19 vaccine. N Engl J Med. 2020. Available at https://www.ncbi.nlm.nih.gov/pubmed/33301246.

4. Baden LR, El Sahly HM, Essink B, et al. Efficacy and safety of the mrna-1273 sars-cov-2 vaccine. N Engl J Med. 2021;384:403-16. Available at <u>https://www.ncbi.nlm.nih.gov/pubmed/33378609</u>.

5. Pfizer and biontech confirm high efficacy and no serious safety concerns through up to six months following second dose in updated topline analysis of landmark covid-19 vaccine study pfizer and biontech confirm high efficacy and no serious safety concerns through up to six months following second dose in updated topline analysis of landmark covid-19 vaccine study. 2021. Available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious.

6. Folegatti PM, Ewer KJ, Aley PK, et al. Safety and immunogenicity of the chadox1 ncov-19 vaccine against sars-cov-2: A preliminary report of a phase 1/2, single-blind, randomised controlled trial. Lancet. 2020;396:467-78. Available at https://www.ncbi.nlm.nih.gov/pubmed/32702298.

7. Government of Canada. Extended dose intervals for covid-19 vaccines to optimize early vaccine rollout and population protection in canada in the context of limited vaccine supply. Available at https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/extended-dose-intervals-covid-19-vaccines-early-rollout-population-protection.html#a6.1.

8. Public Health Agency of Canada. Covid-19 vaccine safety in canada. Available at <u>https://health-infobase.canada.ca/</u> covid-19/vaccine-safety/.

9. European Medicines Agency. Astrazeneca's covid-19 vaccine: Ema finds possible link to very rare cases of unusual blood clots with low blood platelets. 2021. Available at https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood.

10. European Medicines Agency. Covid-19 vaccine janssen: Ema finds possible link to very rare cases of unusual blood clots with low blood platelets. 2021. Available at <u>https://www.ema.europa.eu/en/news/covid-19-vaccine-janssen-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood</u>.

11. World Health Organization. Mrna-1273 vaccine (moderna) against covid-19 background document (draft). 2021. Available at https://www.who.int/publications/i/item/mrna-1273-vaccine-(moderna)-against-covid-19-background-document-(draft).

12. World Health Organization. Background document on mrna vaccine bnt162b2 (pfizer-biontech) against covid-19. 2021. Available at https://www.who.int/publications/i/item/background-document-on-mrna-vaccine-bnt162b2-(pfizer-biontech)-against-covid-19.

13. Gray KJ, Bordt EA, Atyeo C, et al. Covid-19 vaccine response in pregnant and lactating women: A cohort study. medRxiv. 2021:2021.03.07.21253094. Available at http://medrxiv.org/content/early/2021/03/08/2021.03.07.21253094.

14. Flannery DD, Gouma S, Dhudasia MB, et al. Assessment of maternal and neonatal cord blood sars-cov-2 antibodies and placental transfer ratios. JAMA Pediatr. 2021. Available at <u>https://www.ncbi.nlm.nih.gov/pubmed/33512440</u>.

15. Perl SH, Uzan-Yulzari A, Klainer H, et al. Sars-cov-2–specific antibodies in breast milk after covid-19 vaccination of breastfeeding women. JAMA. 2021. Available at <u>https://doi.org/10.1001/jama.2021.5782</u>.

16. Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary findings of mrna covid-19 vaccine safety in pregnant persons. New England Journal of Medicine. 2021. Available at <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2104983</u>.

References

18. National Advisory Committee on Immunization. Recommendations on the use of covid-19 vaccines. 2021. Available at https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html.

19. Shimabukuro T, Nair N. Allergic reactions including anaphylaxis after receipt of the first dose of pfizer-biontech covid-19 vaccine. JAMA. 2021. Available at https://www.ncbi.nlm.nih.gov/pubmed/33475702.

20. Doria-Rose N, Suthar MS, Makowski M, et al. Antibody persistence through 6 months after the second dose of mrna-1273 vaccine for covid-19. New England Journal of Medicine. 2021. Available at https://www.nejm.org/doi/full/10.1056/NEJMc2103916.

21. Harvey RA, Rassen JA, Kabelac CA, et al. Real-world data suggest antibody positivity to sars-cov-2 is associated with a decreased risk of future infection. medRxiv. 2020. Available at <u>https://www.ncbi.nlm.nih.gov/pubmed/33354682</u>.

22. Centers for Disease Control and Prevention. Interim clinical considerations for use of mrna covid-19 vaccines currently authorized in the united states. Available at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

23. Castillo E, Poliquin V. No. 357-immunization in pregnancy. J Obstet Gynaecol Can. 2018;40:478-89. Available at https://www.ncbi.nlm.nih.gov/pubmed/29503251.

24. Health Canada. Covid-19 mrna vaccines. Available at <u>https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/type-mrna.html</u>.

25. Giles ML, Krishnaswamy S, Macartney K, et al. The safety of inactivated influenza vaccines in pregnancy for birth outcomes: A systematic review. Human vaccines & immunotherapeutics. 2019;15:687-99. Available at https://pubmed.ncbi.nlm.nih.gov/30380986 / https://pubmed.ncbi.nlm.nih.gov/30380986 / https://pubmed.ncbi.nlm.nih.gov/pmc/articles/PMC6605784/.

26. Evans MB, Alexander C, Barnard E, et al. Covid-19 vaccine and infertility: Baseless claims and unfounded social media panic. 2021. Available at https://www.fertstertdialog.com/posts/covid-19-vaccine-and-infertility-baseless-claims-and-unfounded-social-media-panic.

27. The Vatican. Note on the morality of using some anti-covid-19 vaccines. 2021. Available at <u>https://www.vatican.va/roman_</u>curia/congregations/cfaith/documents/rc_con_cfaith_doc_20201221_nota-vaccini-anticovid_en.html.

28. Canadian Conference of Catholic Bishops. Cccb note on ethical concerns related to currently approved covid-19 vaccines. 2021. Available at <u>https://www.cccb.ca/wp-content/uploads/2021/03/CLARIFICATION-CCCB-Statement-on-COVID-19-Vaccine-Choice-9-March-2021-EN.pdf</u>.

29. Can vegans get a covid-19 vaccine? People for the Ethical Treatment of Animals UK. 2021. Available at https://www.peta.org.uk/blog/vegans-covid-19-vaccine/.

30. Mahase E. Covid-19: Novavax vaccine efficacy is 86% against uk variant and 60% against south african variant. BMJ. 2021;372:n296. Available at <u>https://www.ncbi.nlm.nih.gov/pubmed/33526412</u>.

31. Government of Canada. National advisory committee on immunization: Summary of updated vaccine statement of april 23, 2021. Available at https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/summary-updated-statement-april-23-2021.html.

32. Greinacher A, Thiele T, Warkentin TE, et al. Thrombotic thrombocytopenia after chadox1 ncov-19 vaccination. New England Journal of Medicine. 2021. Available at <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2104840</u>.

33. Devis P, Knuttinen MG. Deep venous thrombosis in pregnancy: Incidence, pathogenesis and endovascular management. Cardiovascular diagnosis and therapy. 2017;7:S309-S19. Available at https://www.ncbi.nlm.nih.gov/29399535/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nih.gov/2939953/https://www.ncbi.nlm.nlm.gov/2939953/https://www.ncbi.nlm.nlm.gov/2939953/https://www.ncbi.nlm.nlm.gov/2939953/https://www.ncbi.nlm.nlm.gov/2939953/https://www.ncbi.nlm.nlm.gov/20399753/https://www.ncbi.nlm.nlm.gov/20399753/https://www.ncbi.nlm.nl

34. Nam A, Ximenes R, Yeung MW, et al. Modelling the impact of extending dose intervals for covid-19 vaccines in canada. medRxiv. 2021:2021.04.07.21255094. Available at http://medrxiv.org/content/early/2021/04/10/2021.04.07.21255094. Available at http://medrxiv.org/content/early/2021/04/10/2021.04.07.21255094. Available at http://medrxiv.org/content/early/2021/04/10/2021.04.07.21255094. Available at http://medrxiv.org/content/early/2021/04/10/2021.04.07.21255094. Abstract.