

## KEY POINTS

### What we know:

- Pregnancy is a high-risk condition for severe COVID-19, hospitalization, and mortality.
- Pregnant and lactating people were excluded from participation in vaccine trials.
- Moderna’s mRNA-1273 and Pfizer’s BNT162b2 both use novel vaccine platforms (mRNA based) that have not been studied in pregnant or lactating people.
  - The Pfizer vaccine will be administered in 2 doses 21 days apart and is 95% effective in preventing COVID-19.
  - The Moderna vaccine will be administered in 2 doses and is 94.1% effective in preventing COVID-19.
  - Common side effects include headache (55.1%), mild fever (up to 15%), fatigue (62.9%), joint pain (23.6%), muscle pain (38.3%), and pain at the injection site (84%) which may last several days and were more common following the 2nd dose of the vaccine.
  - Pregnant mouse models utilizing mRNA based vaccine platforms against Zika virus and Cytomegalovirus have not demonstrated evidence of harm.
  - The Pfizer vaccine trial reported 23 pregnancies - 12 in the vaccine arm and 11 in the placebo arm. Vaccination occurred prior to LMP, within 30 days of LMP and in unknown relation to LMP. There was one miscarriage and one instance of retained products of conception, both in the placebo arm. Pregnancy outcomes are otherwise unknown at this time according to the Vaccines and Related Biological Products Advisory Committee Meeting.
  - The FDAs Vaccines and Related Biological Products Advisory Committee endorsed the Pfizer-BioNtech vaccine on 12/10/2020 and on 12/11/2020 the FDA issued an emergency use authorization (EUA) for the Pfizer-BioNtech vaccine for individuals 16 and older.
- AstraZeneca AZD1222 uses a viral-vector similar to the Ebola vaccine (only regulated vaccine using next-generation platforms).
  - The Ebola vaccine (live-attenuated recombinant vesicular stomatitis virus rVSV vaccine) was inadvertently administered to 84 pregnant women with no evidence of unacceptable adverse pregnancy outcomes.

### What we do not know:

- Safety or efficacy in large groups of pregnant and lactating people.
- Unknown, if any, fetal or neonatal impact of COVID-19 vaccination.
- Whether mRNA crosses the placenta.
- How long the vaccine will provide protection.
- Whether or not the vaccine can prevent person to person transmission of SARS-CoV-2.

### Current opinions:

- In its EUA - the FDA acknowledged the lack of clinical data about the vaccine use in pregnant individuals but indicated that pregnant individuals make their own decision about vaccination after having a conversation with their medical provider.
- Some vaccine experts have stated: “FDA-approved COVID-19 vaccines should not be withheld from women solely based on their pregnancy or lactation status, when they otherwise meet criteria for vaccination” calling this unethical (Craig et al).
- The American College of Obstetrics and Gynecologists (ACOG) and the Advisory Committee on Immunization Practices (ACIP) echo this language advising all pregnant patients in prioritized groups may choose to receive the Pfizer-BioNtech’s COVID-19 vaccine.
- The Society for Maternal-Fetal-Medicine (SMFM) also strongly recommends that pregnant women have access to COVID-19 vaccines and that pregnant healthcare workers should be offered the vaccine as part of prioritizing vaccination in front-line healthcare workers.



## UNIVERSITY OF MN MFM RECOMMENDATIONS

**We agree with national societal recommendations that pregnant and lactating people should have access to COVID-19 vaccines.** The decision of each individual to be vaccinated will need to be centered around the unknown risks of this vaccination in pregnancy and lactation but also taking into account the known risks of COVID-19 in pregnancy and considering the risks of failing to intervene. The decision will ultimately be up to each patient. A conversation with their clinical team may assist individuals in making their decision **but is not required** prior to vaccination.

Specifically for lactating people, the theoretical safety concerns of receiving the vaccination while lactating do not outweigh the potential benefits of the vaccine and thus lactating individuals who otherwise meet criteria for the vaccine should receive it similar to nonlactating individuals.

Non-pregnant individuals actively contemplating pregnancy should receive the vaccine as indicated and do not need to delay pregnancy after completion of both doses. Individuals becoming pregnant between doses or within 30 day of receipt of the vaccine should participate in the CDC's V-SAFE program.

Finally, we, as a profession, continue to advocate for the inclusion of pregnant and lactating women in phase II/III vaccine trials and recommend pregnant women who receive the vaccine be monitored through a vaccine registry, when this becomes available, so we can continue to monitor the safety for this vulnerable population. We will continue to update our recommendations regarding the COVID-19 vaccine as further safety data emerges as we anticipate emerging data may identify some vaccines are more suitable than others for pregnant women.

**The following script is provided as a launching point to these conversations with your patient:**

*As you may have heard there is a COVID-19 vaccine now available. The way this vaccine works is by using messenger RNA (mRNA) which acts like an instruction booklet for your cells. This vaccine provides instructions on how to make a small, harmless piece of the spike protein found on SARS-CoV-2 virus. The spike protein that is made is seen as foreign and our body's response is to make antibodies against it. Then, when we are exposed to COVID-19, our body has a readied defense system that prevents us from getting sick. This vaccine has proven to be highly effective with minimal side effects (fever, chills, headache, body aches, injection site pain) however it has not been specifically studied in pregnant or lactating people. We know that pregnant women who contract COVID-19 are at increased risk of developing severe infection, requiring hospitalization, and needing ventilatory support. The risk of fetal harm is theoretical for any untested medical treatment and this vaccine would be no different. We support pregnant women being offered and receiving the COVID-19 vaccine to help reduce the risk of adverse outcomes for you but ultimately that decision is up to you.*

*Regardless of whether or not you receive the vaccine we support your decision and would recommend continuing to follow CDC guidelines with regards to mask wearing, hand hygiene, and social distancing as we do not yet know how long the vaccine will provide protection against COVID-19 and whether or not it prevents person to person transmission of the virus.*

**References:**

1. Zambrano LD, Ellington S, Strid P, Galang RR, Oduyebo T, Tong VT, et al. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(44):1641–7.
2. Legardy-Williams J, Carter R, Goldstein S, Jarrett O, Szefer E, Fombah A, et al. Pregnancy Outcomes among Women Receiving rVSVΔ-ZEBOV-GP Ebola Vaccine during the Sierra Leone Trial to Introduce a Vaccine against Ebola. *Emerg Infect Dis.* 2020;26(3):541.
3. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>.
4. Jagger BW, Dowd KA, Chen RE, et al. Protective Efficacy of Nucleic Acid Vaccines Against Transmission of Zika Virus During Pregnancy in Mice. *J Infect Dis.* 2019; 220(10):1577-1588. doi:10.1093/infdis/jiz338
5. Richner JM, Jagger BW, Shan C, et al. Vaccine Mediated Protection Against Zika Virus-Induced Congenital Disease. *Cell.* 2017;170(2):273-283.e12. doi:10.1016/j.cell.2017.06.040.
6. Nelson CS, Jenks JA, Pardi N, Goodwin M, Roark H, Edwards W, McLellan JS, Pollara J, Weissman D, Permar SR. Human Cytomegalovirus Glycoprotein B Nucleoside-Modified mRNA Vaccine Elicits Antibody Responses with Greater Durability and Breadth than MF59-Adjuvanted gB Protein Immunization. *J Virol.* 2020 Apr 16;94(9):e00186-20. doi: 10.1128/JVI.00186-20. PMID: 32051265; PMCID: PMC7163130.
7. Society for Maternal-Fetal Medicine (2020, December 1) Society for Maternal-Fetal Medicine (SMFM) Statement: SARS-CoV-2 Vaccination in Pregnancy. (Press Release). Retrieved from [https://s3.amazonaws.com/cdn.smfm.org/media/2591/SMFM\\_Vaccine\\_Statement\\_12-1-20\\_\(final\).pdf](https://s3.amazonaws.com/cdn.smfm.org/media/2591/SMFM_Vaccine_Statement_12-1-20_(final).pdf).
8. Centers for Disease Control and Prevention. Local reactions, systemic reactions, adverse events, and serious adverse events: Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/pfizer/reactogenicity.html>. Retrieved December 13, 2020.
9. Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020. FDA Briefing Document. Pfizer-BioNTech COVID-19 Vaccine. Retrieved from <https://www.fda.gov/media/144245/download>. Accessed on 12/11/2020.
10. Craig AM, Hughes BL, Swamy GK. COVID-19 Vaccines in Pregnancy. *MFM AJOG* in press.
11. U.S. Food and Drug Administration. Fact Sheet for Recipients and Caregivers. Emergency Use Authorization (EUA) of the Pfizer-Biontech COVID-19 vaccine to prevent Coronavirus Disease 2019 (COVID-19) in individuals 16 years of age and older. Available at: <https://www.fda.gov/media/144414/download>. Retrieved December 13, 2020
12. Vaccinating pregnant and lactating patients against COVID-19. American College of Obstetricians and Gynecologists. Practice Advisory. December 13 2020. <https://www.acog.org/en/clinical/clinicalguidance/practice-advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Patients-Against-COVID-19>

**COVID-19 WORKGROUP FOR THE OB/GYN CLINICAL PRACTICE COUNCIL**

*This team represents expertise in Obstetrics. If you would like further information, please contact the work group lead, Todd Stanhope, MD - [Todd.Stanhope@NorthMemorial.com](mailto:Todd.Stanhope@NorthMemorial.com).*

**MEMBERS:**

Jessica Nyholm, MD

Todd Stanhope, MD

*If you would like further information about Clinical Programs and Integration, please contact the Medical Director of Quality,*

Jeffrey Vespa, MD— [Jeffrey.Vespa@NorthMemorial.com](mailto:Jeffrey.Vespa@NorthMemorial.com) or Anna Rees, Manager— [Anna.Rees@NorthMemorial.com](mailto:Anna.Rees@NorthMemorial.com)

**Revision History**

This document is active and further recommendations are forthcoming. It will be updated as additions develop.

Revision	Description of Changes	Approvals	Date
1.0	Initial Document	OB/GYN Clinical Practice Council	01-12-2021