

The European Network of Teratology Information Services, ENTIS: position statement on COVID-19 vaccines during pregnancy & lactation.

Position adopted by ENTIS as of April 14th, 2021.

ENTIS holds the position that vaccination is the currently most effective measure to reduce the risks associated with COVID-19 disease in pregnant women. Current safety data are reassuring, and ENTIS endorses a favorable benefit-risk ratio for COVID-19 vaccination in pregnancy

General considerations

The issue of COVID-19 vaccination during pregnancy (and lactation) is currently subject to some controversies as opinions and practices differ across Nations, Regulatory Agencies, health care professionals and patients. We acknowledge that regulatory entities may differ with respect to labelling (as defined by “Indications” and “Contraindications” in the respective Summaries of Product Characteristics, SmPC’s), and in guidelines from health authorities. This may influence clinical practice and decision making. Additionally, the amount of safety data for each specific vaccine varies substantially with most pregnancy data currently accumulated for the Pfizer-BioNTech and Moderna vaccines.

The above factors notwithstanding, ENTIS supports the following points to consider on COVID-19 vaccines in pregnancy and lactation given the current level of evidence and benefit-risk assessments:

Specific points to consider

Considerations for the pregnant woman

- Pregnancy, especially in its third trimester, poses an increased risk for severe COVID-19 disease, compared to women with similar characteristics who are not pregnant. Severe maternal COVID-19 disease appears associated with an elevated risk of stillbirth and preterm delivery.
- We currently hold the position that the benefit-risk assessment favors COVID-19 vaccines during pregnancy. This is especially true for women
 - at increased risk for acquiring COVID-19, such as health care providers or those who reside in high morbidity outbreak areas
 - who carry risk factors associated with more severe COVID-disease e.g. diabetes, BMI>30, or hypertension
- World-wide, a very large number of pregnant women have been vaccinated with no signs of untoward effects to the pregnant woman or the fetus. There are documented post-marketing data on more than 40.000 pregnant women receiving COVID-19 vaccines with no signs of excess risk of morbidity or mortality.
- There should be no contraindication for women – regardless of individual risk status - who received their first vaccine dose before pregnancy to complete the

vaccination with the second dose according to the original recommended schedule, even after conception.

Considerations for women contemplating pregnancy

- Women planning a pregnancy and women during ART are at an optimal window of opportunities, to complete their vaccination before pregnancy, in countries where vaccination is available.

Considerations for the fetus

- To date, there is no evidence of risk to the embryo or fetus from COVID vaccination in pregnancy.
- Actual documented data on liveborn children exposed to COVID-19 vaccines in utero are sparse (about 250) but reassuring.

Considerations for the nursing infant

- Vaccination appears safe for the nursing infant. Generally, all non-live vaccines are considered safe for nursing.

On behalf of the ENTIS Organization

For the Board: Orna-Diav Citrin (chair)

For the Scientific Committee: Per Damkier (chair)

References

1. COVID-19 Vaccination in Pregnant and Lactating Women. Adhikari EH, Spong CY. JAMA. 2021 Mar 16;325(11):1039-1040. doi: 10.1001/jama.2021.1658.
2. The coronavirus disease 2019 vaccine in pregnancy: risks, benefits, and recommendations. Stafford IA, Parchem JG, Sibai BM. Am J Obstet Gynecol. 2021 Jan 30:S0002-9378(21)00077-6. doi: 10.1016/j.ajog.2021.01.022. Online ahead of print.
3. Pregnant people deserve the protection offered by SARS-CoV-2 vaccines. Maykin MM, Heuser C, Feltovich H; with the Society for Maternal-Fetal Medicine Health Policy Advocacy Committee. Vaccine. 2021 Jan 8;39(2):171-172. doi: 10.1016/j.vaccine.2020.12.007. Epub 2020 Dec 4.
4. Covid-19 safety update. Center for disease control. Available from: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf> (accessed March 16, 2021)
5. Young pregnant women are also at an increased risk of mortality and severe illness due to coronavirus disease 2019: analysis of the Mexican National Surveillance Program. Martinez-Portilla RJ et al. Am J Obstet Gynecol. 2021 Apr;224(4):404-407.