

COVID-19 Vaccination for Pregnant and Breastfeeding Women

Although the absolute risk of severe COVID-19 in pregnancy remains low, it is now established that pregnant women are at increased risk of severe COVID-19-associated illness compared with non-pregnant women.^{1,2,3,4} Such illness can require hospitalisation, intensive care unit admission, mechanical ventilation and even cause death. Thus, preventing critical COVID-19 infection is of paramount importance for both the mother and her fetus.

Most countries have availability of COVID-19 vaccines and are offering them to priority groups. Existing COVID-19 vaccines use different technologies, including messenger RNA (mRNA), viral vectors, or recombinant proteins manufactured in a baculovirus system that are co-formulated with adjuvants.⁵ Clear guidance is needed on whether pregnant and breastfeeding women should receive a COVID-19 vaccine.

FIGO position

Given that clinical trials of COVID-19 vaccines specifically in pregnant women have not yet been conducted (some are underway or planned soon⁶), limited data are available on their efficacy and safety during pregnancy. Hence, there is not sufficient evidence to recommend the routine use of COVID-19 vaccines for pregnant or breastfeeding women. Limited data from animal studies are reassuring and do not indicate direct or indirect harmful effects on embryo/fetal development or pregnancy.⁷ Additional reassuring data come from a statement, released in the USA in the first week of February, that 20,000 pregnant women had been vaccinated with no alarming signs reported.⁸

FIGO, therefore, considers that there are no risks – actual or theoretical – that would outweigh the potential benefits of vaccination for pregnant women. We support offering COVID-19 vaccination to pregnant and breastfeeding women.

Empower women to make informed choices

FIGO urges health care providers to support pregnant women to make an informed decision regarding COVID-19 vaccination in consultation with their obstetrician. Important considerations when offering the vaccine should include the:

- level of activity of the virus in the local community
- potential efficacy of the vaccine
- lack of safety data specific to its use in pregnancy
- risk and potential severity of maternal disease, including the possible effects of the disease on the fetus (preterm birth) and newborn
- timing of vaccination during pregnancy.

Counselling should also address the expected side effects that are considered a normal part of the body's reaction to the vaccine, which is more prevalent among younger people due to overreaction of the immune system. Fever, one of the most common side effects reported with COVID-19 vaccines,⁹ can be managed by acetaminophen, which is considered safe during pregnancy and should not theoretically impact the antibody response to COVID-19 vaccines.¹⁰ Women should be particularly reassured that the existing COVID-19 vaccines are not live virus vaccines and that the mRNA vaccines do not cause any genetic changes since they do not alter human DNA.

Following a risk-based approach may put pregnant women at a disadvantage

It is important to highlight that following a risk-based approach – whereby the vaccination is restricted to pregnant women who are at high risk of exposure to SARS-CoV-2 (e.g. health care workers) or those with co-morbidities (e.g. diabetes and heart disease) – might put pregnant women, who are by definition considered at increased risk for severe COVID-19 illness,¹¹ at a disadvantage due to limited access to the vaccine.

Vaccine administration in pregnant women

There is currently no preference for the use of a particular COVID-19 vaccine, but pregnant women who agree to be vaccinated should be advised to complete their two-dose series (where applicable) with the same vaccine product.¹² It is advisable that a COVID-19 vaccine series should be administered without any other vaccine, with a minimum interval of 14 days before or after administration of any other vaccine.¹² Hence, vaccines including Tdap (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis) and influenza, which are routinely and safely offered during pregnancy,¹³ should be deferred for 14 days from the administration of COVID-19 vaccines.

Health care providers are urged to continue to advise their pregnant patients that vaccination against influenza is safe throughout pregnancy and is recommended during the influenza season to protect both the woman and fetus from the adverse effects of becoming seriously ill with flu during pregnancy, particularly so during the COVID-19 pandemic.¹³ The practice of offering Tdap vaccine between the 27th and 36th weeks of pregnancy in each pregnancy should also continue to be followed.¹³ Pregnant women who decline vaccination against COVID-19 should be supported in their decision and should be updated with new evidence when it becomes available.

Women planning their pregnancy can take the COVID-19 vaccine if they choose to do so. Routine testing for pregnancy before COVID-19 vaccination is not recommended. Women who are trying to become pregnant do not need to postpone pregnancy after receiving a COVID-19 vaccine.

Vaccine administration for breastfeeding women

Breastfeeding confers many health benefits to mother and newborn. COVID-19 vaccines are believed to pose minimal to no potential risk to the newborn through breastmilk.¹⁴ Based on previously administered vaccines, there is the potential for direct neonatal benefit if the vaccine-stimulated immunoglobulin A prove to pass through breastmilk.¹⁴ For breastfeeding women, therefore, the COVID-19 vaccine can be offered if the mother meets the criteria based on prioritisation groups, such as a breastfeeding health care provider.

As additional data from clinical trials and vaccinated pregnant women become available, it will be imperative for obstetricians to keep up to date with that information.

FIGO commits to taking the following actions

- FIGO will encourage and support the publication and dissemination of all available data on vaccination in pregnant and breastfeeding women.
- We will advocate for the administration of the COVID-19 vaccination to all pregnant women.
- When more research data is available, FIGO will review this statement and any advice we have provided to ensure it is clear and accurate.

References

- ¹ Zambrano LD, Ellington S, Strid P, 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. CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team. MMWR Morb Mortal Wkly Rep 2020;69:1641-7.
- ² Delahoy MJ, Whitaker M, O'Halloran A, et al. Characteristics and maternal and birth outcomes of hospitalized pregnant women with laboratory-confirmed COVID-19 - COVID-NET, 13 states, March 1-August 22, 2020. COVID-NET Surveillance Team. MMWR Morb Mortal Wkly Rep 2020;69:1347-54.
- ³ Panagiotakopoulos L, Myers TR, Gee J, et al. SARS-CoV-2 infection among hospitalized pregnant women: reasons for admission and pregnancy characteristics - eight U.S. health care centers, March 1-May 30, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1355-9.
- ⁴ 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.
- ⁵ Rasmussen SA, Kelley CF, Horton JP, et al. Coronavirus Disease 2019 (COVID-19) Vaccines and pregnancy: What obstetricians need to know. Obstet Gynecol 2021 Mar 1;137(3):408-414.
- ⁶ Available at: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-commence-global-clinical-trial-evaluate>
- ⁷ U.S. Food and Drug Administration. Available at: <https://www.fda.gov/media/144434/download>
- ⁸ Address by Dr. Fauci. Available at: www.politico.com/video/2021/02/10/fauci-20-000-pregnant-women-vaccinated-with-no-red-flags-127024
- ⁹ 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>
- ¹⁰ Saleh E, Moody MA, Walter EB. [Effect of antipyretic analgesics on immune responses to vaccination](https://doi.org/10.1016/j.humvac.2016.09.002). Hum Vaccin Immunother 2016 Sep;12(9):2391-402.
- ¹¹ Centers for Disease Control and Prevention. People with Certain Medical Conditions. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>
- ¹² 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>
- ¹³ Nassar AH, Visser GHA, Nicholson WK, et al; FIGO Safe Motherhood, Newborn Health Committee. FIGO Statement: Vaccination in pregnancy. Int J Gynaecol Obstet 2021 Feb;152(2):139-143.
- ¹⁴ Dooling K, Marin M, Wallace M, et al. The Advisory Committee on Immunization Practices' updated interim recommendation for allocation of COVID-19 vaccine - United States, December 2020. MMWR Morb Mortal Wkly Rep 2021;69:1657-60.

About FIGO

FIGO is a professional organisation that brings together obstetrical and gynaecological associations from all over the world. FIGO's vision is that women of the world achieve the highest possible standards of physical, mental, reproductive and sexual health and wellbeing throughout their lives. We lead on global programme activities, with a particular focus on sub-Saharan Africa and South East Asia.

FIGO advocates on a global stage, especially in relation to the Sustainable Development Goals (SDGs) pertaining to reproductive, maternal, newborn, child and adolescent health and non-communicable diseases (SDG3). We also work to raise the status of women and enable their active participation to achieve their reproductive and sexual rights, including addressing female-genital mutilation (FGM) and gender-based violence (SDG5).

We also provide education and training for our Member Societies and build capacities of those from low-resource countries through strengthening leadership, good practice and promotion of policy dialogues.

FIGO is in official relations with the World Health Organization (WHO) and a consultative status with the United Nations (UN).

For enquiries Rob Hucker, Head of Communications and Engagement
rob@figo.org +44 (0) 7383 025 731