



# **POGS**

## **PRACTICE BULLETIN**

**JANUARY 26, 2021**

**FIRST UPDATE APRIL 5, 2021**

**SECOND UPDATE AUGUST 1, 2021**

**THIRD UPDATE AUGUST 9, 2021**

### ***COVID-19***

# ***Vaccination of Pregnant and Breastfeeding Women***



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## PRACTICE BULLETIN

NUMBER 1, JANUARY 29, 2021 (for expedited release)

FIRST UPDATE APRIL 5, 2021

SECOND UPDATE AUGUST 1, 2021

**THIRD UPDATE AUGUST 9, 2021**

### COVID-19 Vaccination of Pregnant and Breastfeeding Women

The POGS Clinical Consensus Committee is tasked with developing Clinical Consensus documents, which provide up to date clinical guidance on emerging issues in Obstetrics and Gynecology. A careful examination of the best available scientific data on the topic is done. When evidence is limited, the consensus will be sought from the experts.

COVID-19 vaccine availability, FDA and EUA approval are issues that are evolving currently. The following vaccines, BNT162b2 or (Pfizer-BioNTech®) COVID-19 Vaccine, SARS-CoV-2 Vaccine Coronovac( Sinovac®), ChAdOx1-S (Astra Zeneca Vaxzevria®), Sputnik V Gam-COVID Vac®, Janssen Ad26.COVS-2 Vaccine (Johnson & Johnson), Whole Virion, Inactivated Corona Virus Vaccine (Covaxin®) and COVID-19 mRNA Vaccine (Moderna®) have been approved for Emergency Use Authorization by the Philippine Food and Drug Administration.

This Practice Bulletin is a consensus among the Board Members of the Philippine Obstetrical and Gynecological Society (POGS), the Philippine Infectious Disease Society for Obstetrics and Gynecology (PIDSOG), the Philippine Society of Maternal Fetal Medicine (PSMFM) and the POGS Committee on Clinical Consensus. This Practice Bulletin is intended to be an overview of existing guidelines on the COVID-19 vaccines and the guidance for use in pregnant and breastfeeding women in the Philippines.

This Bulletin will be updated as additional information becomes available from clinical trials and as information on vaccinated pregnant and breastfeeding women are made available.

This Practice Bulletin No. 1 is intended to provide the following information:

- Guidance for use in Pregnancy
- Guidance for use in Breastfeeding Mothers

Pregnant women were not included in the Phase 3 clinical trials of the COVID-19 vaccines, therefore safety and efficacy data in pregnancy were initially limited. An updated guidance, however, regarding COVID-19 vaccination of pregnant and breastfeeding women is necessary as more data are reported regarding the safety of COVID vaccination in pregnancy over the last several months and the increase in cases among pregnant women.

#### 1. Is COVID-19 Vaccination recommended for pregnant women?

**COVID-19 vaccination is recommended for pregnant women. There is no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals with the COVID-19 vaccine. Post-introduction surveillance data have not shown harmful effects in pregnancy.**

##### References:

1. Update on WHO interim Recommendations on COVID-19 Vaccination of Pregnant Women and Lactating Women, June 2, 2021
2. ACOG Practice Advisory: COVID-19 Vaccination Considerations for Obstetric-Gynecologic Care, July 30, 2021

#### 2. What information do you need to give to pregnant women on offering vaccination?

**Pregnant women should be given information about the**

- a. Risks of COVID-19 in pregnancy which includes higher rates of pregnancy-induced hypertension, preeclampsia-eclampsia, infections requiring antibiotics, greater risk of ICU admission, longer hospital stay, increased cesarean delivery rates, and premature birth.**
- b. The benefits of vaccination in the local epidemiologic context**
- c. Current limitations of safety data in pregnant women**

### **d. The COVID-19 vaccine does not cause COVID-19 disease**

References:

1. Update on WHO interim Recommendations on COVID-19 Vaccination of Pregnant Women and Lactating Women, June 2, 2021
2. Villar J, Ariff S, Gunier RB, et al. Maternal and Neonatal Morbidity and Mortality Among Pregnant Women with and Without COVID-19 Infection: The INTERCOVID Multinational Cohort Study. *JAMA Pediatr.* Published online April 22, 2021.

2. Royal College of Obstetricians and Gynecologists. Updated advice in COVID-19 vaccination in pregnancy and women who are breastfeeding. December 30, 2020
3. American College of Obstetricians and Gynecologists. ACOG Practice Advisory: Vaccinating pregnant and lactating patients against COVID-19. December 2020.
4. ACOG Practice Advisory: COVID-19 Vaccination Considerations for obstetric-Gynecologic Care, July 30, 2021

### **3. Is COVID-19 vaccination recommended among breastfeeding women?**

**A. COVID-19 vaccination is recommended among breastfeeding women. There is no need to avoid initiation or discontinue breastfeeding in patients who receive the COVID-19 vaccine.**

**B. Vaccine-induced antibodies were found in breast milk samples among women given the Pfizer/BioNTech or Moderna mRNA COVID-19 vaccine, indicating the transfer of antibodies from mothers to infants.**

**1. Vaccination-induced antibody levels were significantly higher compared with antibody levels induced by natural COVID-19 infection in pregnancy.**

**2. The second dose of COVID-19 vaccine increased concentrations of coronavirus-specific immunoglobulin G (IgG) but not immunoglobulin A (IgA).**

**3. Levels of mucosal (IgA) antibodies generated by the second dose of the Moderna vaccine were higher than those induced by two doses of the Pfizer version.**

References:

1. Update on WHO interim Recommendations on COVID-19 Vaccination of Pregnant Women and Lactating Women, June 2, 2021
2. ACOG Practice Advisory: COVID-19 Vaccination Considerations for obstetric-Gynecologic Care, July 30, 2021
3. Gray KJ, Bordt EA, Atyeo C, Deriso E, Akinwunmi B, Young N, Medina Baez A, Shook LL, Cvrk D, James K, De Guzman R, Brigida S, Diouf K, Goldfarb I, Bebell LM, Yonker LM, Fasano A, Rabi SA, Elovitz MA, Alter G, Edlow AG. COVID-19 vaccine response in pregnant and lactating women: a cohort study. *American Journal of Obstetrics and Gynecology* (2021).

### **4. Should a pregnancy test be done before giving the COVID-19 vaccine?**

**A pregnancy test is not a requirement prior to COVID-19 vaccination.**

References:

1. Centers for Disease Control and Prevention. Vaccination considerations for people who are pregnant or breastfeeding. January 7, 2021.

### **5. Is it safe to administer the COVID-19 vaccine in the first trimester of pregnancy?**

**A. There is limited data on the safety of vaccine administration during the first trimester of pregnancy.**

**B. At present however, there is no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals with COVID-19 vaccine, and a growing body of data demonstrate the safety of such use. Therefore, individuals who are or will be pregnant may receive the COVID-19 vaccine. Vaccination during the first trimester should be a shared decision between the obstetrician and the patient after careful consideration of the risks and benefits.**

References:

1. Centers for Disease Control and Prevention. Vaccination considerations for people who are pregnant or breastfeeding. January 7, 2021.
2. Royal College of Obstetricians and Gynecologists. Updated advice in COVID-19 vaccination in pregnancy and women who are breastfeeding. December 30, 2020
3. American College of Obstetricians and Gynecologists. ACOG Practice Advisory: Vaccinating pregnant and lactating patients against COVID-19. December 2020.
4. Update on WHO interim Recommendations on COVID-19 Vaccination of Pregnant Women and Lactating Women, June 2, 2021.
5. ACOG Practice Advisory: COVID-19 Vaccination Considerations for obstetric-Gynecologic Care, July 30, 2021

### **6. Which COVID vaccine brands or types are recommended for pregnant women?**

**The following are recommended by the US CDC and the WHO:**

**a. Messenger RNA vaccines or mRNA vaccines (Pfizer BioNTech Comirnaty®, Moderna mRNA-1273®)**

**b. Inactivated vaccines (Sinovac-CoronaVac®, Covaxin®)**

**c. Viral vector vaccines (Oxford/AstraZeneca AZD1222 Vaxzevria®, J&J Janssen COVID-19 Vaccine®)**

References:

1. Update on WHO interim Recommendations on COVID-19 Vaccination of Pregnant Women and Lactating Women, June 2, 2021

2. ACOG Practice Advisory: COVID-19 Vaccination Considerations for obstetric-Gynecologic Care, July 30, 2021

3. Philippine Food and Drug Administration (FDA) List of COVID-19 Vaccines Authorized by the FDA, July 25, 2021.

## **7. Which COVID vaccine brands or types are recommended for lactating women?**

The following are recommended by the US CDC and the WHO:

- a. Messenger RNA vaccines or mRNA vaccines (Pfizer BioNTech a.Comirnaty®, Moderna mRNA-1273®)
- b. Inactivated vaccines (Sinovac-CoronaVac®, Covaxin®)
- c. Viral vector vaccines (Oxford/AstraZeneca AZD1222 Vaxzevria®, J&J Janssen COVID-19 Vaccine®)

### References:

1. Update on WHO interim Recommendations on COVID-19 Vaccination of Pregnant Women and Lactating Women, June 2, 2021
2. ACOG Practice Advisory: COVID-19 Vaccination Considerations for obstetric-Gynecologic Care, July 30, 2021
3. Philippine Food and Drug Administration (FDA) List of COVID-19 Vaccines Authorized by the FDA, July 25, 2021.

## **8. What are the important considerations in the decision to administer the COVID-19 vaccine in the Philippines?**

1. A pregnant or breastfeeding woman should be given the COVID-19 vaccine.
2. A pregnant woman may be classified according to the current DOH Prioritization Framework
  - a. A1 workers in Frontline Health Services
  - b. A3 persons with comorbidities
  - c. A4 Frontline personnel in essential sectors, including uniformed personnel
  - d. A5 Indigent population
3. A pregnant woman without a comorbidity may now be classified under expanded A3.
4. An informed consent should be signed after a thorough pre-vaccination counselling.
5. Factors to be considered in the pre-vaccination counselling include the potential efficacy of the vaccine in the general population, the rate of transmission of COVID-

19 infection in the community, the benefits of vaccination in the local epidemiologic context, the limited data on pregnancy, and the known side effects of the vaccine in the general population. Currently, documented local symptoms include pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm. Most common systemic symptoms are fatigue, headache, chills, myalgia, arthralgia, diarrhea, nausea, and fever. They should be advised that majority of these side effects are mild and transient.

6. The counselling should be an opportunity to emphasize the importance of infection control measures such as handwashing, use of face masks and face shields and physical distancing.
7. For patients who do not receive the vaccine, the discussion should be documented in the patient's medical record. During subsequent office visits, obstetrician-gynecologists should address ongoing questions and concerns and offer vaccination again.

### References:

1. Centers for Disease Control and Prevention. Vaccination considerations for people who are pregnant or breastfeeding. January 7, 2021.
2. Royal College of Obstetricians and Gynecologists. Updated advice in COVID-19 vaccination in pregnancy and women who are breastfeeding. December 30, 2020
3. American College of Obstetricians and Gynecologists. ACOG Practice Advisory: Vaccinating pregnant and lactating patients against COVID-19. December 2020.
4. Guidelines on the Issuance of Emergency Use of Authorization for Drugs and Vaccines for COVID-19. Department of Health, Food and Drug Administration Circular No. 2020-036. Dec 14, 2020
5. Vaccination Considerations for People who are Pregnant or Breastfeeding/CDC Updated Jan 7, 2021)
6. Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States | Vaccines & Immunizations /CDC Updated Jan 6, 2021
7. University of Massachusetts: Shared Decision-Making: COVID Vaccination in Pregnancy working group) experts in the fields of OB/GYN, Maternal-Fetal Medicine, Shared Decision-Making and risk communication, Emergency Medicine, and current COVID-19 research group. Updated Dec 28, 2020
8. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/948518/Information\\_for\\_UK\\_recipients\\_on\\_PfizerBioNTech.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948518/Information_for_UK_recipients_on_PfizerBioNTech.pdf)
9. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/950661/Moderna\\_Information\\_HCP.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950661/Moderna_Information_HCP.pdf)
10. <https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-uk-recipients-on-covid-19-vaccine-astrazeneca>
11. Republic of the Philippines Department of Health FAQs: Vaccines July 2021



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