



**PHILIPPINE OBSTETRICAL AND GYNECOLOGICAL SOCIETY
PRACTICE BULLETIN NO.1
COVID-19 Vaccination of Pregnant and Breastfeeding Women
January 26, 2021 for expedited release**

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. One vaccine, BNT162b2 or Pfizer-BionTech COVID-19 Vaccine has been approved for Emergency Use Authorization by the Philippine Food and Drug Administration on January 14, 2021.

Pregnant women were not included in the Phase 3 clinical trials of the COVID-19 vaccines, therefore safety and efficacy data in pregnancy are limited. Guidance, however, regarding COVID-19 vaccination of pregnant and breastfeeding women is necessary.

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

1. Is it safe to administer the COVID-19 vaccine during pregnancy?

There are no studies at present on the safety of administration of COVID-19 vaccine among pregnant and breastfeeding women.

A. mRNA COVID-19 vaccines (Pfizer BioNtech® and Moderna®):

- These mRNA vaccines generate the coronavirus spike protein by using the host's cells. These vaccines are unlikely to pose a specific risk for people who are pregnant. However, the actual risks of mRNA vaccines to a pregnant person and her fetus are unknown .

B. Inactivated COVID-19 Vaccine (Sinovac®)

- These vaccines contain viruses whose genetic material has been destroyed by heat, chemicals or radiation so they cannot infect cells and replicate but can still trigger an immune response.
- Inactivated vaccines are safe for use in pregnancy. However, there are no data to prove the safety of the inactivated COVID-19 vaccine in pregnancy.

C. Viral Vector Vaccines (Oxford Astra Zeneca, Johnson and Johnson, Gamaleya Sputnik®)

- These vaccines do not contain antigens, but rather use the body's own cells to produce them. A modified virus (the vector) is used to deliver the genetic code for the antigen, *in the case of COVID-19 spike proteins found on the surface of the virus*, into human cells. By infecting cells and instructing them to make large amounts of antigen, which then trigger an immune response, the vaccine mimics what happens during natural infection with certain pathogens - especially viruses.
- There are no data specific to safety in pregnancy.

D. Protein Subunit Vaccines (Novavax®)

- Protein subunit vaccines contain fragments of protein and/or polysaccharide from the pathogen.
- There are no data yet to prove their use in pregnancy.

E. The vaccine, currently available under EUA in the Philippines, the BNT162b2 or Pfizer-BionTech COVID-19 vaccine, has not been tested in pregnant women. Therefore, there are no safety data specific to its use in pregnancy.²

References:

1. *US CDC: Vaccination Considerations for People who are Pregnant or Breastfeeding, January 7, 2021*

²*ACOG Vaccinating Pregnant and Lactating Patients Against COVID-19. Practice Advisory December 21, 2020*

The mRNA COVID-19 vaccines should be offered only to pregnant and breastfeeding women classified to be in the high-risk group recommended for priority vaccination.

A. The Philippine National Government identified the following Priority Eligible Population:

1. Frontline Health Workers: All health workers from the PRIVATE and PUBLIC sectors, currently on ACTIVE practice/service,

whether they are permanent, contractual, job-order and/or outsourced employees or staff

- Public and private health facilities
- Public health workers in public primary care facilities
- Barangay Health Workers including Barangay Health Emergency Response Teams
- Relevant Personnel in National Government Agencies (NGAs)

2. Uniformed Personnel: All enlisted uniformed personnel in active services under the:

- Armed Forces of the Philippines
- Philippine National Police
- Philippine Coast Guard
- Bureau of Fire Protection
- Citizen Armed Force Geographical Unit

B. The identification of eligible populations by the National Government was identified based on the WHO Strategic Advisory Group of Experts on Immunization (SAGE) Values Framework for the Allocation and Prioritization of COVID-19 Vaccination, taking into consideration the national context, the epidemiologic settings and the COVID-19 vaccine characteristics and supply.

References:

1. *US CDC: Vaccination Considerations for People who are Pregnant or Breastfeeding, January 7, 2021*
2. *World Health Organization: Who can take the Pfizer BioNTech COVID-19 Vaccine? January 8, 2021*
3. *The Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines . Interim Plan January 2021.*

2.Is it safe to administer the COVID-19 vaccine to breastfeeding women?

There are no data on the safety of COVID-19 vaccines in breastfeeding women or on the effects of mRNA vaccines on the breastfed infant or on milk production/excretion.

A. A woman who is breastfeeding and is part of the Priority Eligible Population group recommended to receive a COVID-19 vaccine, such as a frontline healthcare worker or a frontline essential care worker with an unavoidable high risk of exposure, may choose to be vaccinated.

- B. For women administered with the Pfizer BioNTech COVID-19 vaccine, the World Health Organization (WHO) does not recommend discontinuing breastfeeding after vaccination.

References:

1. *US CDC: Vaccination Considerations for People who are Pregnant or Breastfeeding, January 7, 2021*
2. *World Health Organization: Who can take the Pfizer BioNTech COVID-19 Vaccine? January 8, 2021*
3. *The Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines . Interim Plan January 2021.*

3. Should a pregnancy test be done before giving the COVID-19 vaccine?

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

- A. A routine pregnancy test is not a requirement prior to vaccination.
- B. Among patients who are suspected to be pregnant (with missed menses, or unsure of menses), a pregnancy test may be done.
- C. This also applies to women who have already received the first dose of the COVID-19 vaccine. If the patient signifies uncertainty in her menses or a possibility of pregnancy, a pregnancy test should be done before giving the next dose of the vaccine

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

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

- Immunization should be avoided in most patients during the first trimester to avoid a coincidental association with spontaneous abortion, which is common in the first trimester

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. *ACIP workgroup on the use of vaccines during pregnancy and breastfeeding. Guiding principles for development of ACIP recommendations for vaccination during breastfeeding and pregnancy p5 April 2008*
5. *Sur, Denise, et al. Vaccinations in Pregnancy. Am Fam Physician. 2003 Jul 15;68(2):299-309 <https://www.aafp.org/afp/2003/0715/p299.html>*

5. When should the vaccination be scheduled in consideration of Tdap, flu and other vaccines?

COVID-19 vaccines should not be administered within 14 days of receipt of another vaccine. For pregnant individuals, vaccines including Tdap and influenza should be deferred for 14 days after the administration of COVID-19 vaccines

Reference:

1. *American College of Obstetricians and Gynecologists. ACOG Practice Advisory: Vaccinating pregnant and lactating patients against COVID-19. December 2020.*

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

- A. If a pregnant or breastfeeding woman is in the Priority Eligible Population Group, the COVID-19 vaccine should not be withheld from her.
- B. An informed consent should be signed after a thorough pre-vaccination counselling.
- C. 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 lack of data on pregnancy, and the known side effects of the vaccine in the general population.
- D. 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 and fever.
- E. Before administering the vaccine, full information regarding vaccine phase status, available data regarding benefits, risks, safety and efficacy and risk management plan in cases where adverse events following immunization may arise must be disclosed, informed and documented to the vaccine recipient

- F. If a pregnant or breastfeeding woman refuses to get the vaccine, she should still be supported in her decision.
- G. 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.

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
9. 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>


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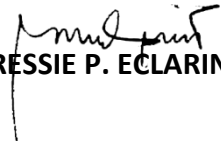

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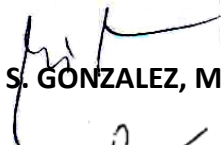
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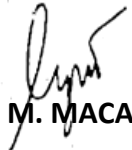
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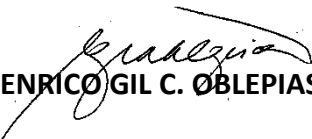
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