

ACOG and SMFM Joint Statement on WHO Recommendations Regarding COVID-19 Vaccines and Pregnant Individuals

January 27, 2021, Washington, DC – The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) are aware of the World Health Organization's (WHO) recommendation to withhold COVID-19 vaccines from pregnant individuals unless they are at high risk of exposure. ACOG and SMFM continue to stress that both COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration should not be withheld from pregnant individuals who choose to receive the vaccine. ACOG's and SMFM's current guidance on the COVID-19 vaccine in pregnant patients remains in place.

Despite efforts by ACOG and SMFM to advocate for their inclusion, clinical trials that informed the emergency use authorization (EUA) of the vaccines did not include pregnant individuals. However, preliminary developmental and reproductive toxicity (DART) studies for both the Pfizer-BioNtech and Moderna vaccines are encouraging, with no safety signals reported. DART animal studies provide the first safety data to help inform the use of these vaccines in pregnancy until there are more data in this specific population. These studies do not indicate any adverse effects on female reproduction or fetal/embryonal development. ACOG and SMFM strongly urge manufacturers and federal agencies to collect and report data regarding the use of these vaccines in pregnancy.

Data have demonstrated that symptomatic pregnant individuals with COVID-19 are at increased risk of more severe illness and death compared with nonpregnant peers. Many pregnant individuals have medical conditions known to put them at further increased risk of severe illness and complications. Therefore, given clear evidence of the dangers of COVID-19 in pregnancy, an absence of data demonstrating adverse effects associated with the vaccine in pregnancy, and in the interest of patient autonomy, ACOG and SMFM recommend that pregnant individuals be free to make their own informed decisions regarding COVID-19 vaccination. This decision should consider a number of factors, including the available information about the safety and efficacy of the vaccine and considerations include the level of activity of the pandemic in the community, the potential efficacy of the vaccine, and the potential risk and severity of maternal disease. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.

As physicians who care for pregnant individuals, and as vaccine rollout expands to other eligible populations, ACOG and SMFM continue to firmly assert that pregnant individuals should be given the opportunity to make their own decision as to whether to receive the COVID-19

vaccine and that barriers should not be put in place to prevent access and hinder the ability of pregnant people to protect themselves from a virus that could potentially be life-threatening.

For more information <u>ACOG Practice Advisory: Novel Coronavirus 2019 (COVID-19)</u> <u>ACOG Practice Advisory: Vaccinating Pregnant and Lactating Patients Against COVID-19</u> <u>SMFM's COVID Resources</u>