



AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM)
PATIENT MANAGEMENT AND CLINICAL RECOMMENDATIONS DURING THE
CORONAVIRUS (COVID-19) PANDEMIC

UPDATE No. 11 – COVID-19 Vaccination
December 16, 2020

The ASRM Coronavirus/COVID-19 Task Force (the “Task Force”)¹ is issuing this update to the reproductive care community in response to the U.S. Food & Drug Administration (FDA) Emergency Use Authorization (EUA) of the Pfizer-BioNTech SARS-COV-2 vaccine on Dec. 11th, 2020.

- As of December 15th, COVID-19 infections and hospitalizations in the U.S. have reached record levels, resulting in more than 300,000 COVID-19-related deaths. **At the present time, mitigation strategies for controlling the pandemic continue to rely heavily on universal masking, physical distancing, limiting social interactions, and frequent sanitizing measures.** It is hoped that widespread vaccination will further limit viral spread and shorten the length of the pandemic and its impact on morbidity and mortality.
- **On December 11th, 2020, the FDA issued the first EUA approval of a SARS-COV-2 vaccine in the U.S. for the Pfizer-BioNTech COVID-19 vaccine to be distributed in the U.S. for individuals age 16 and older.** The Vaccine and Related Biological Products Advisory Committee (VRPAC) to the FDA is meeting again on December 17th to evaluate the safety and effectiveness data submitted by Moderna in anticipation of its EUA approval.
- **The Pfizer and Moderna vaccines are both mRNA vaccines that do not contain live virus.** Both these vaccines require a two-injection series at 21-day (Pfizer-BioNTech) or 28-day (Moderna) intervals. The vaccines deliver mRNA into cells near the injection site. This mRNA instructs the body’s own cells to

¹ This guidance document was developed under the direction of the Coronavirus/COVID-19 Task Force of the American Society for Reproductive Medicine. These recommendations are being provided as a service to its members, other practicing clinicians, and to the patients they care for, during the coronavirus pandemic. While this document reflects the views of members of the Task Force, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Clinicians should always use their best clinical judgment in determining a course of action and be guided by the needs of the individual patient, available resources, and institutional or clinical practice limitations. The Executive Committee of the American Society for Reproductive Medicine has approved this guidance document.

The ASRM Coronavirus/COVID-19 Task Force members for this update included Ricardo Azziz MD, MPH, MBA, Natan Bar-Chama MD, Marcelle Cedars MD, Christos Coutifaris MD, PhD, Mark Cozzi MBA, Jodie Dionne-Odom MD, Kevin Doody MD, Eve Feinberg MD, Elizabeth Hern MBA, Jennifer Kawwass MD, Sigal Klipstein MD, Paul Lin MD, Anne Malave PhD, Alan Penzias MD, John Petrozza MD, Samantha Pfeifer MD, Catherine Racowsky PhD, Enrique Schisterman PhD, James Segars MD, Peter Schlegel MD, Hugh Taylor MD, and Shane Zozula BS, in consultation with other experts.

replicate the coronavirus's spike (S) protein. This protein, in turn, is recognized by the body as foreign, generating protective antibodies. The mRNA itself is rapidly degraded and does not enter the cell's nucleus. Specifically, the Pfizer-BioNTech COVID-19 vaccine is a lipid nanoparticle-formulated, nucleoside-modified mRNA vaccine. The lipid coating of the nanoparticles binds to the cell membrane, facilitating entry of the mRNA segment into the cell. Rarely, some individuals could be allergic to a part of the lipid nanoparticle known as polyethylene glycol (PEG), a common component in other injectable medicines. Consequently, caution is advised when administering the vaccine to those individuals who have experienced severe allergic reactions to prior vaccines or injectable drugs.

- **All mitigation measures as outlined in the Task Force's [Update #3](#) should remain firmly in place while vaccination efforts get underway**, as: 1) it is not yet known whether a vaccinated individual can spread the virus if they become infected with SARS-COV-2; 2) protective immunity against COVID-19 takes time to develop; and 3) although a two-dose regimen of the Pfizer-BioNTech vaccine is 95% effective against the development of COVID-19, it does not confer 100% immunity.
- **The Task Force does not recommend withholding the vaccine from patients who are planning to conceive, who are currently pregnant, or who are lactating (1,2,3).** These recommendations are in line with those of the Advisory Committee for Immunization Practices (ACIP) of the U.S. Centers for Disease Prevention and Control (CDC), the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal-Fetal Medicine (SMFM).
- **Patients undergoing fertility treatment and pregnant patients should be encouraged to receive vaccination based on eligibility criteria.** Since the vaccine is not a live virus, there is no reason to delay pregnancy attempts because of vaccination administration or to defer treatment until the second dose has been administered.
- **A shared decision-making model between patients and providers should be used when considering vaccination and should take into consideration the ethical principles of autonomy, beneficence, and non-maleficence.** Consideration of local COVID-19 transmission and risk of acquisition, personal risk of contracting COVID-19, risks of COVID-19 to the patient and potential risks to a fetus, efficacy of the vaccine and known side effects, and the lack of data about the vaccine during pregnancy should all be taken into consideration as patients make decisions regarding vaccination. Some individuals may elect to defer conception attempts until both doses of vaccine have been administered.
- **Recent studies have suggested that pregnancy is a risk factor for severe COVID-19 disease (4-8).** Furthermore, many women who are pregnant or contemplating pregnancy have additional risk factors such as obesity, hypertension or diabetes which may further increase the chance of severe disease from COVID-19 infection. These considerations should be included in decisions regarding vaccination.
- **Because COVID-19 mRNA vaccines are not composed of live virus, they are not thought to cause an increased risk of infertility, first or second trimester loss, stillbirth, or congenital anomalies.** It should be noted that pregnant and lactating women were excluded from the initial phase III trials of these two vaccines, so specific safety data in these populations are not yet available and further studies are planned. However, the mechanism of action of mRNA vaccines and existing safety data provide reassurance regarding the safety of COVID-19 mRNA vaccines during pregnancy. The FDA EUA letter permits the vaccination of pregnant and breastfeeding individuals with a requirement that the company engage in post-authorization observational studies in pregnancy (9).

- **While COVID-19 vaccination can cause fever in some patients (up to 16% of those vaccinated and mostly after the second dose), this risk should not be a concern when deciding whether to vaccinate a pregnant individual or a patient desiring pregnancy.** While fever in pregnancy (particularly the 1st trimester) has been associated with an increased risk of neural tube defects, a recent study demonstrated the association no longer remained significant if the patient is taking >400 mcg of folic acid daily (10). Another large Danish cohort study did not demonstrate any increased risk of congenital anomalies of those who reported fever in the first trimester (11). Additionally, the most common symptom of COVID-19 infection itself is fever (83-99% of affected patients). Patients who experience fever following vaccination should take an antipyretic medication, like acetaminophen (12).
- **Patients who conceive in the window between the first and second dose of the vaccine should be offered the second dose of the vaccine at the appropriate interval.**
- **Physicians should promote vaccination to patients, their communities, and to the public.** Preliminary data suggests that those populations at greatest risk of severe disease from COVID-19 may also be the most hesitant to be vaccinated, and specific efforts to increase vaccine uptake in these communities should be undertaken.

Additional COVID-19 vaccines using different platforms are in development. The ASRM COVID-19 Task Force will continue to provide updates on these vaccines as they obtain approval.

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