

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

UPDATE No. 19 – *December 17, 2021* Awareness of Complexity in Uncertain Times

Epidemiology

- The COVID-19 pandemic in the US has been severe with nearly 50 million cases and 800,000 deaths since 2020. Among women who are pregnant, there have been 150,000 cases and 248 deaths.¹
- The newest COVID-19 variant, Omicron (B.1.1529), was first identified in November 2021. As of mid-December, the omicron variant has spread to 63 countries with cases confirmed in 28 US states. Information about transmissibility and severity with Omicron continues to emerge but the new variant appears to be highly transmissible.
- At this time, the delta variant is still 99% of circulating COVID-19 virus in the US with more than 118,000 new cases reported daily and increasing infection rates over the past several weeks.

Erosion of the American Healthcare System

- An unanticipated consequence of the ongoing pandemic is a shrinking pool of healthcare providers and the adverse impact on the mental health of healthcare workers. COVID-19 hospitalizations remain primarily among the unvaccinated.
- Operating rooms are going unused, and the impact is borne by patients whose surgical treatment is being delayed.

Surgery in infertility patients

- Due to increases in COVID-19 admissions, or in some cases, limited resources, many hospitals are reducing non-essential elective cases.
- Delays in surgical treatment may lead to further downstream delay in access or pursuit to fertility treatment.
- Procedures being done in reproductive-aged women for infertility, pain or bleeding should not be considered elective and are essential and in accordance with the recommendations provided by a joint statement of the major gynecologic societies.²
- Cumulative delays in care may mean the difference between success and failure in patients with diminished ovarian reserve.

Prevention: COVID-19 Vaccination

- COVID-19 vaccination is safe and highly effective at preventing infection and severe outcomes of COVID-19 infection, including death. Vaccination continues to be highly recommended by ASRM, ACOG, SMFM, and CDC for all persons who are pregnant or considering pregnancy.
- As of December 17, 2021, the Advisory Committee on Immunization Practices (ACIP) made a new recommendation to favor mRNA vaccines over Johnson & Johnson vaccines.³
- The latest numbers show 61% of the US population and only **35% of pregnant persons** are fully vaccinated against COVID-19.⁴ A total of 27% of adults have received a vaccine booster dose.
- Pregnancy is a well-recognized risk factor for severe maternal and neonatal COVID-19 infection outcomes. Providers are encouraged to continue to recommend COVID-19 vaccination, and boosters, and to discuss directly any concerns that patients and partners may have regarding vaccination.
- COVID-19 booster doses (6 months after a completed mRNA series or 2 months after a Johnson & Johnson vaccine) are now recommended for all adults.⁵ Emerging data suggest the 3rd dose of an mRNA vaccine increases neutralizing antibody levels against the Omicron variant. CDC recommends receiving a booster dose with any of the COVID-19 vaccines authorized in the US: Pfizer/BioNTech, Moderna or Johnson & Johnson.⁵ Some studies suggest an mRNA booster is beneficial for people who received the Johnson & Johnson vaccine.

- Vaccines and boosters not only protect the individual and those around them, but also are one of the best ways to prevent viral mutation and the evolution of new and potentially more contagious variants.
- In light of the new Omicron variant, we ask that every member of the ASRM community (doctors, patients, lab personal and staff) continue to adhere to COVID-19 mitigation strategies, includingmasking, physical distancing, hand hygiene, cleaning /disinfection, and respiratory etiquette). These proven mitigation strategies are effective. For more information, please review these CDC guidelines.⁶

Treatment: Monoclonal antibodies and oral antiviral therapy

- Prevention of COVID-19 with vaccination is preferable to any COVID-19 treatment option.
- When administered early in adults with mild-moderate COVID-19 infection, monoclonal antibodies have up to 80% efficacy in preventing hospitalization and severe outcomes. Several small studies have shown safety with the administration of COVID-19 monoclonal antibody therapy in pregnancy. A number of monoclonal antibodies are currently available for IV and SQ administration in the outpatient setting. Studies are ongoing to test whether the efficacy of monoclonal antibody therapy will be maintained following infection with the Omicron variant. Of note, COVID-19 vaccination should not be given within 90 days of treatment with monoclonal antibodies.
- There are two new oral antiviral medications with efficacy in clinical trials when administered within 3-5 days of symptom onset. Molnupiravir is a five-day oral regimen that was recently approved by an FDA panel. It interferes with viral replication and has 30% efficacy in preventing disease progression. Safety with administration in pregnancy is not yet clear; ongoing data collected by Merck will assess safety endpoints. Paxlovid (nirmatrelvir/ritonavir) also has promising efficacy in early treatment studies to date, but is not yet available for use, and safety in pregnancy not available.

REFERENCES

- 1. CDC COVID Data Tracker: Pregnancy Outcomes Data: <u>https://covid.cdc.gov/covid-data-</u> <u>tracker/#pregnant-population</u>
- Joint Society Statement on Re-Introduction of Surgical Procedures in the Setting of Covid-19: <u>https://www.sgsonline.org/joint-statement-on-re-introduction-of-hospitaland-office-based-procedures-in-the-covid-19-climate</u>.
- 3. CDC Updated COVID-19 vaccine recommendations: https://www.cdc.gov/media/releases/2021/s1216-covid-19-vaccines.html
- 4. CDC Vaccine Safety Datalink Vaccination Coverage in Pregnancy: <u>https://covid.cdc.gov/covid-data-tracker/#vaccinations-pregnant-women</u>

- 5. CDC Vaccine Booster Guidance: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html?s_cid=11706:cdc%20covid%20booster%20dose:sem.ga:p:RG:GM:gen:PTN:FY22</u>
- 6. CDC Guideline Mitigation Measures: <u>https://www.cdc.gov/coronavirus/2019-ncov/global-covid-19/global-urban-areas.html#:~:text=</u>

The ASRM Coronavirus/COVID-19 Task Force members are Amanda Adeleye, MD, 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.

This guidance document was developed under the direction of the COVID-19 Task Force of the American Society for Reproductive Medicine. These recommendations are being provided as a service to ASRM 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.