

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

UPDATE #5 (June 8, 2020 through July 6, 2020)

The world has been suffering a pandemic of a proportion not previously experienced in this century, with higher infectivity and mortality than previous epidemics. While acknowledging that infertility is a serious disease that requires treatment in a timely manner, in its recommendations of March 17, 2020 and in the subsequent Updates, No. 1 and No. 2, the ASRM Coronavirus/COVID-19 Task Force (the "Task Force") recognized the need to delay any but the most urgent of reproductive care cases. This was necessary as the extent of the COVID-19 pandemic, its viral transmission rate, its impact on reproductive well-being and pregnancy, and the ability of health systems to cope were yet unknown, at least in the U.S.

Over the past several months, significant knowledge has been gained regarding the virus and its impact on patients and the medical system. However, the associated delay in care resulted in an increasing number of patients whose situation had become more urgent. In Update No. 3 (American Society for Reproductive Medicine (ASRM) Patient Management and Clinical Recommendations during the Coronavirus (COVID-19) Pandemic - Update No. 3, April 24, 2020) the Task Force issued recommendations for gradually and judiciously resuming the delivery of reproductive care, which were elaborated upon further in Update No. 4.

Since then, it has become clear that we will need to be practicing in a COVID-19 environment at least until an effective and safe vaccine or broadly effective treatment become widely available. Consequently, the Task Force continues to support the measured resumption of care. In the current update (Update No. 5), additional clarification and information is provided regarding third-party reproduction, fertility services for health care workers, having partners present when providing care, travel restrictions, and resumption of reproductive surgery. The next update from the Task Force will be in four weeks (on or about July 6, 2020), unless conditions warrant greater frequency.

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, Samantha Pfeifer MD, Catherine Racowsky PhD, Laura Riley MD, Enrique Schisterman PhD, James Segars MD, Peter Schlegel MD, Hugh Taylor MD, and Shane Zozula BS, in consultation with other experts.

Since the last update, the Task Force has observed and re-affirmed the following:

- To date, there have been almost 6.5 million confirmed cases and over 380,000 deaths due to COVID-19 worldwide, the disease produced by the virus SARS-CoV-2, with more than 1.9 million confirmed cases and 110,500 deaths in the United States (U.S.) alone.
- While no community is unaffected, the prevalence of the disease varies widely throughout the U.S. (1).
- COVID-19 disproportionally impacts racial and ethnic minorities. Data from 580 patients hospitalized with lab-confirmed COVID-19 found that 45% of individuals for whom race or ethnicity data were available were white, compared to 59% of individuals who were white in the surrounding community; however, 33% of hospitalized patients were black, compared to 18% in the community, and 8% were Hispanic, compared to 14% in the community (2). A recent (as yet not peer-reviewed) study conducted a cross-sectional analysis using publicly reported COVID-19 mortality data from 28 states and New York City and estimated age-adjusted disparities; the study showed that black people are more than 3.5 times and Latino people nearly 2.0 times as likely to die of the virus as are white people (3).
- No vaccine yet exists to prevent infection with COVID-19 and, at this time, few medications have shown benefit in decreasing morbidity and mortality.
- Given current gaps in knowledge regarding the impact of COVID-19 on both patient response to fertility treatment and on early pregnancy, prospective research is critically needed as fertility centers reinitiate care.
- Infertility patients should be counseled regarding the risks and benefits of initiating fertility treatment during this pandemic. This counseling should convey that those with certain medical conditions (e.g. hypertension, diabetes, obesity) may face an increased risk of complications if they become infected.
- Due to the stress involved in returning to reproductive care while the pandemic is still ongoing, as well as the potential for risks associated with reproduction during the COVID-19 pandemic, practices are advised to ensure that every patient is provided with a list of resources for support and counseling including, but not limited to, a referral list of mental health professionals who specialize in fertility/infertility counseling in reproductive medicine.

Third-party reproduction

The task Force reaffirms the 'Third Party Reproduction Recommendations' provided in <u>Update 4.</u> Given the continued restrictions on international travel, we recommend against initiating cycles in which the intended parents do not live in the same country as the gestational carrier.

Fertility services for health care workers

Fertility services for health care workers should be provided with usual precautions. There are no data to support avoidance of either infertility treatment or pregnancy for health care workers, especially since universal masking for all staff has been advised (4).

Having partners present when providing care

ASRM recognizes the psychological and emotional benefits of having partners present during fertility procedures and supports the involvement and inclusion of all partners during fertility treatment and family building planning, whenever possible. However, during the COVID-19 pandemic, safety considerations necessitate limiting the number of people in the clinical suite.

Ideally, only the person undergoing the procedure should be present, taking into consideration hospital or practice guidelines regarding the number of allowed persons. Patients should also be encouraged to use alternative methods for partner participation when not able to be physically present, such as use of phone or video.

Travel restrictions

One of the main strategies to mitigate transmission of the SARS-Cov-2 virus is physical distancing. Given that a vaccine is not yet available, and no curative treatment exists, avoidance of infection remains the most effective way to circumvent the potential risks of COVID-19 in women who are or will become pregnant. While local and state officials across the United States are beginning to loosen restrictions on social movement, public gatherings and business closures, the prevalence of COVID-19 and the incidence of new cases waxes and wanes in different localities. Additionally, the risks of infection are not equal for all those in the community. Specifically, the effects of COVID-19 on pregnant women and pregnancy is not yet fully understood.

Consequently, individuals seeking pregnancy, and the clinic staff that care for them, should continue to avoid infection to the extent possible. This includes, for example, avoiding air, bus, or train travel, and the use of public transportation, when feasible. When considering urgent travel, it is beneficial to be aware of the rates of new infections both locally and at the destination site. Additionally, self-quarantining, if potentially exposed, is a strategy that should continue to be practiced to the extent possible. Remote ART care in areas where local options are limited can be considered when patients and provider(s) adhere to the Taskforce recommendations and follow locally recommended quarantine guidelines.

Resumption of reproductive surgery

The resumption of reproductive surgery, including oocyte retrievals, should follow the recommendations outlined by the Society for Reproductive Surgeons update #1 (5,6). Ideally, disease prevalence should be low (less than 2%) in areas where reproductive surgery has resumed. The Task Force recommends that, prior to any procedure that requires anesthesia, the patient is screened for COVID-19 symptoms. Preoperative viral testing (for SARS-CoV-2) should also be strongly considered.

One of the benefits of viral testing is to help mitigate disease exposure and help anticipate staff Personal Protective Equipment (PPE) need (e.g. standard vs. full respiratory PPE), especially in parts of the country where PPE availability may be limited. However, there is legitimate concern that validated RT-PCR COVID-19 testing can have significant false negative rates, especially early and late in the disease process. Hence, if a preoperative test is done and is negative, the test should be considered as a supplement to risk mitigation to the spread of COVID-19 and not in lieu of current recommended mitigation strategies. Serial viral testing can help reduce the possibility of a false negative test, but for many localities, test availability is limited and turn-around time long (7).

Foregoing viral testing could be considered for asymptomatic patients who are preoperatively determined to be candidates for intravenous sedation and therefore are at low risk of aerosolization during surgery. Alternatively, testing has been suggested prior to procedures that have the potential to generate aerosols (see below) (8).

If a patient scheduled for a non-urgent procedure is exposed to someone with confirmed COVID-19, the patient should be tested, quarantined for 14 days, and the procedure rescheduled for a date later than the 14 days of quarantine. If the viral test is positive during the preoperative assessment, the patient should be quarantined for 14 days and the procedure rescheduled.

Surgical staff should follow the recommendations for PPE use outlined in the Task Force's update <a href="mailto:the-task Force's update <a href="mailto:the-t

With all cases, high-touch surfaces, including the ultrasound and anesthesia machines, should be sanitized with a U.S. Environmental Protection Agency (EPA)-approved hospital disinfectant after the procedure is complete.

Postoperatively, the arrangements of the recovery bays must follow local and hospital guidelines, with patients at least six (8) feet apart and, ideally, with a curtain barrier or wall between beds/stretchers. Partners or family members should not be allowed in the recovery area if physical distancing requirements cannot be maintained.

Additional recommendations should be considered in the event of an aerosol generating procedure (AGPs), or when In vitro-fertilization (IVF) cycles, or urgent surgical procedures are performed.

• Aerosol generating procedures (AGPs): While there is no expert consensus of what are considered aerosol generating procedures (AGPs), for most reproductive centers these entail the use of nebulizer treatments, intubation, laryngeal mask placement, and open suctioning of airways (8,9). It is important to discuss the risk of aerosolization, whether intended or not, with the anesthesiologist before every case. The possibility of conversion to general anesthesia (due to obesity, GERD, prior difficult airway control, etc.), and hence an increased risk for aerosolization, should also be discussed. The Task Force recommends that testing be performed within 72 hours of a potential AGP, if testing is available and results can be obtained within that time frame.

If during a procedure an AGP must be urgently performed (e.g. immediate intubation), the surgical team, other than the anesthesiologist and a tech or circulating nurse, should consider exiting the room immediately. Staff should wait sufficient time to allow one or more complete room air exchanges before re-entering the room without enhanced PPE. Alternatively, the staff can don appropriate fully enhanced PPE, including an N95 mask or a powered air purifying respirator (PAPR), face shield or goggles, gowns, and gloves. These precautions should be taken regardless of whether the patient tested negative preoperatively, is asymptomatic, or was not tested at all.

• In vitro-fertilization (IVF) cycles: During oocyte retrievals, all patients should wear a medical grade surgical mask, as oxygen delivery by a nasal cannula or a facemask can still be delivered with it in place. The surgical mask reduces aerosol release if a patient begins coughing. The patient should continue to wear the mask even in the post-op recovery area if oxygenation is well-maintained.

In patients undergoing an IVF cycle and who test positive for SARS-CoV-2 preoperatively consideration should be given to cancelling the oocyte retrieval prior to triggering, in order to reduce the risk of ovarian hyperstimulation syndrome (OHSS). In centers who can safely manage an infected patient or if the procedure is urgent, as for medical fertility preservation, the retrieval can proceed, but with staff using full enhanced respiratory PPE. Any planned embryo transfer should be delayed until the patient is SARS-CoV-2 negative.

 Urgent surgical procedures: If a surgical procedure is urgently needed, such as a surgery for an ectopic, the procedure can proceed, but with staff using full enhanced respiratory PPE.

Update to recommendations for PPE use in the reproductive care setting

The Task Force continues to update the recommendations for PPE use in the reproductive care setting (see **Table**).

Table. Risk assessment and mitigation for reproductive care procedures and activities

Procedure/Activity	Potential Risk	Mask Type	Other PPE	PPE Required
		Required for Staff	Required for Staff	for Patients
Clinic Entry Screening	Droplet	Medical Grade	Gloves	Cloth Mask
Patient Registration	Droplet	Cloth Mask		Cloth Mask
Vital Sign Measurement	Droplet	Medical Grade	Gloves	Cloth Mask
In Office Consultation	Droplet	Cloth Mask		Cloth Mask
Phlebotomy	Droplet, Splash, Needle Stick	Medical Grade	Gloves	Cloth Mask
Ultrasound	Droplet	Medical Grade	Gloves	Cloth Mask
Saline Infusion Sonogram	Droplet, Splash	Medical Grade	Gloves	Cloth Mask
Hysterosalpingogram	Droplet, Splash	Medical Grade	Gloves	Cloth Mask
Office Hysteroscopy	Droplet, Splash	Medical Grade	Gloves	Cloth Mask
Endometrial Biopsy	Droplet, Splash	Medical Grade	Gloves	Cloth Mask
Specimen Handling (Blood, Semen, Follicular Fluid)	Splash	Medical Grade	Gloves	N/A
Intrauterine Insemination	Droplet	Medical Grade	Gloves	Cloth Mask
Embryo Transfer	Droplet	Medical Grade	Gloves	Cloth Mask
IV Line Insertion	Droplet, Splash, Needle Stick	Medical Grade	Gloves	Cloth mask
Pre-Op Holding Area	Droplet	Medical Grade	Gloves	Medical Grade
Airway Management	Droplet, Aerosolization	N95 or equivalent	Face Shield, Gloves	Medical Grade
Oocyte Retrieval	Droplet, Splash, Needle Stick	Medical Grade	Gloves	Medical Grade
Operative Hysteroscopy	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves, Gown	Medical Grade
Operative Laparoscopy	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves, Gown	N/A
Open Reproductive Surgery	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves, Gown	N/A
Post Anesthesia Care Unit	Droplet, Splash	Medical Grade	Gloves	Medical grade

Based on CDC guidance for the selection and use of PPE in Healthcare Settings (https://www.cdc.gov/hai/pdfs/ppe/ppeslides6-29-04.pdf)

^{*}Note: Eye protection devices, such as goggles or glasses with solid side shields are advised; typical vision-related glasses would not qualify as protective.

References

- 1. Geographic Differences in COVID-19 Cases, Deaths, and Incidence United States, February 12–April 7, 2020. MMWR Morb Mortal Wkly Rep 2020;69:465-71 (doi: http://dx.doi.org/10.15585/mmwr.mm6915e4external.icon, accessed June 6, 2020).
- Garg S, Kim L, Whitaker M, et al. Hospitalization Rates and Characteristics of Patients Hospitalized with Laboratory-Confirmed Coronavirus Disease 2019 — COVID-NET, 14 States, March 1–30, 2020. MMWR Morb Mortal Wkly Rep 2020;69:458–464 (https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6915e3-H.pdf, accessed June 8, 2020).
- 3. Gross CP, Essien UR, Pasha S, Gross JR, Wang S, Nunez-Smith M. Racial and Ethnic Disparities in Population Level Covid-19 Mortality. medRxiv (doi: https://doi.org/10.1101/2020.05.07.20094250, accessed June 8, 2020).
- 4. Chou R, Dana T, Buckley D, et al. Epidemiology of and Risk Factors for Coronavirus Infection in Health Care Workers Ann Internal Med. May 25, 2020, 1-50 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7240841/, accessed June 6, 2020).
- 5. SRS Recommendations Regarding Reproductive Surgery During the COVID-19 Pandemic: Update #1 (https://www.asrm.org/news-and-publications/covid-19/statements/the-society-for-reproductive-surgeons-srs-recommendations-regarding-reproductive-surgery-during-the-covid-19-pandemic--update-1/, accessed June 6, 2020).
- 6. Joint Statement on Re-introduction of Hospital and Office-based Procedures in the COVID-19 Climate for the Practicing Gynecologist (https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/covid-19/joint-statement-on-re-introduction-of-hospital-and-office-based-procedures-in-thecovid-19-climate.pdf, accessed June 6, 2020).
- 7. Kucrika LM, et al. Variation in False-Negative Rate of Reverse Transcriptase Polymerase Chain Reaction-Based SARS-CoV-2 Tests by Time Since Exposure. Ann Internal Med, 13 May 2020 (https://doi.org/10.7326/M20-1495, accessed June 6, 2020).
- 8. Centers for Disease Control, Healthcare Infection Prevention and Control FAQs for COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html, May 29, 2020).
- 9. American Society of Anesthesiologists, COVID-19 FAQs (https://www.asahq.org/about-asa/governance-and-committees/asa-committees/committee-on-occupational-health/coronavirus/clinical-faqs, May 7, 2020).