



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

UPDATE #7 (August 10, 2020 through September 7, 2020)

The current update by the ASRM Coronavirus/COVID-19 Task Force (the “Task Force”)¹ affirms the recommendations presented in Update No. 3 ([American Society for Reproductive Medicine Patient Management and Clinical Recommendations during the Coronavirus \(COVID-19\) Pandemic - Update No. 3, April 24, 2020](#)), which issued recommendations for gradually and judiciously resuming the delivery of reproductive care, and which were further elaborated in Updates Nos. 4-6. Given the resurgence of COVID-19 cases in much of the United States, the aforementioned strategies continue to be critical in managing this ongoing pandemic.

Since the last update, the Task Force has observed the following:

- As of August 9, 2020, COVID-19 cases have exceeded five million in the U.S. with more than 160,000 deaths, an increase of nearly 1.7 million cases since the last ASRM update on July 10th. Because deaths follow case diagnoses, deaths may reach the 175,000 mark by the end of August and are predicted to exceed [295,000 by December 1st](#) if further mitigation measures are not taken.
- In the past four weeks, the virus has spread throughout most of the U.S. and cases have increased 3.4-fold from the levels of disease present in late May. Increases in viral infection within states and locales have followed relaxation of measures to control the contagion, such as wearing of

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.

masks, social distancing, isolation and limiting group size. There appears to be no difference in the spread of disease in urban vs. rural environments.

- Now more than ever, it is critical to do everything possible to maximize adherence to scientifically grounded guidelines from the U.S. Centers for Diseases Prevention and Control (CDC) and World Health Organization (WHO). These include proven mitigation strategies, such as social distancing, hand washing and face mask usage, all of which should be strongly emphasized during this watershed moment in the spread of the virus.
- The percentage of tested individuals with a positive result for COVID-19 in the U.S. was lowest in June at 4%, but now is 8%. In some locales, positive testing rates have increased to 12-22%. This high disease prevalence has overwhelmed the capabilities of many local public health resources to effectively test, trace, and isolate, and has strained healthcare resources. Adequate capacity point of care testing and timely result reporting for COVID-19 remain elusive, thus significantly hampering contact tracing and subsequent quarantine. Due to the increased prevalence and these limitations, some states and locales have reversed course regarding reopening measures.
- Phase III trials of COVID-19 vaccines have begun but widespread vaccination remains at least several months away. Notably, pregnant women or women planning pregnancy have not been included in most trials. No curative medication exists, though improved treatments have led to overall better survival rates.
- The prevalence of disease continues to disproportionately affect Latinx and African American individuals and infections continue to increase in younger adults and children.
- Though the use of Personal Protective Equipment (PPE) is highly effective, emerging data demonstrate an increased risk of disease for health care workers, at least in some settings. The reemergence of disease following relaxation of measures to control spread emphasizes that reproductive medicine providers need to practice in a COVID-19 environ for the foreseeable future. Recognition of this challenge is critical to avoid the risk of a renewed shutdown in reproductive services.

In the current revision, updated information is provided concerning: testing, treatments, and vaccines for COVID-19; managing mental health and COVID-19; counseling of patients seeking care during the pandemic; the risk of aerosolization; and updated recommendations for PPE use in the reproductive care setting. The next update from the Task Force will be in four weeks (on or about September 7, 2020), unless conditions warrant earlier release.

UPDATE ON TESTING FOR SARS-COV-2

Ideally, testing for the SARS-CoV-2 virus should be performed on a widespread basis to track disease and reduce the spread by quarantine strategies. ASRM continues to support testing when available prior to surgical procedures including oocyte retrievals (see [The Society for Reproductive Surgeons \(SRS\) Recommendations Regarding Reproductive Surgery During The Covid-19 Pandemic. Update #1 published May 4, 2020](#)). However, six months into the pandemic in the U.S., the lack of widely available testing persists.

Several issues have hampered our ability to broadly test the reproductive care population, including:

- Slow turnaround of test results.

- Lack of testing availability.
- Inconsistent accuracy of testing, i.e. variable false negative rates along the timeline from asymptomatic carrier state to manifest disease.

Most infected individuals no longer shed live virus that can be cultured after 10 days from the onset of illness or, if not symptomatic, from the date of their first positive test, although very severely ill or severely immunocompromised patients may shed replication competent virus in respiratory tract samples for up to 20 days. However, a surprising number of individuals demonstrate detectable RNA in upper respiratory specimens after recovery, some for up to 12 weeks. If viral testing is performed and noted to be persistently positive more than 10 days from symptom onset or first positive result, the findings most likely reflect the presence of viral RNA, but not infectious risk. See related [CDC statement](#).

When accurate and timely testing for the presence of the SARS-CoV-2 virus remains unavailable, the following clinical practice alternatives may be considered:

- Universal patient screening using questionnaire for symptoms and temperature assessment.
- Cancellation of the procedure or appropriate use of PPE in an operating room equipped to minimize transmission of disease via aerosolized droplets when patients present with fever or with COVID-19 symptoms. If planned, embryo transfers should be delayed until patients are symptom free for at least 10 days.
- Use of appropriate PPE by all medical personnel caring for all patients undergoing surgical procedures (see Table below: *Risk assessment and mitigation for reproductive care procedures and activities*).
- Use of masks and appropriate PPE by all patients undergoing surgical procedures (see Table below: *Risk assessment and mitigation for reproductive care procedures and activities*).

UPDATE ON TREATMENTS FOR COVID-19

The therapeutic landscape for COVID-19 treatment continues to evolve. Currently, high-quality data from randomized clinical trials with two medical treatments, dexamethasone steroid therapy and remdesivir antiviral therapy, suggest improved health outcomes in hospitalized patients. Both medications are recommended for inpatients with severe COVID-19 infection according to national treatment guidelines issued by the [National Institutes of Health \(NIH\)](#) and the [Infectious Diseases Society of America \(IDSA\)](#). Remdesivir is FDA-approved under an emergency use authorization with aggressive efforts being made to increase the drug supply. More than 200 clinical trials are active or about to start enrolling participants in studies designed to test a variety of medications and convalescent plasma for efficacy and safety. Studies will test for potential activity in terms of COVID-19 treatment and prevention.

Patients may have questions about hydroxychloroquine or other unproven medications for COVID-19 treatment or prevention. Of note:

- There are insufficient data to support the empiric use of hydroxychloroquine with or without azithromycin, doxycycline, or zinc, as prophylaxis or in patients with mild symptoms of COVID-19 (Siemieniuk et al., 2020).
- Providers can play an important role in explaining the importance of clinical trials to gather efficacy and safety data in patient populations that are impacted by COVID-19. Patients who are

interested in supporting efforts to identify new treatment options during the global pandemic should be encouraged to participate in clinical trials, such as those [listed on the CDC website](#).

Multiple trials are ongoing in the hope of identifying new therapeutic options for COVID-19.

UPDATE ON THE AVAILABILITY OF A COVID-19 VACCINE

Intense global scientific efforts over the past eight months have led to incredible and rapid progress toward the development of a COVID-19 vaccine. Many experts cite vaccine availability as the best hope for an effective public health response to the current pandemic. At the time of this update, [26 candidate vaccines for COVID-19 are undergoing rigorous clinical evaluation for safety and efficacy](#). Many others are in preclinical phases. Large phase III multicenter clinical trials have been activated with a goal of enrolling 30,000 participants to evaluate some of the most promising vaccine candidates.

Mass production of different vaccines is already underway as a key strategy towards expediting the wide-scale availability of vaccines as soon as clinical trials demonstrate that they are both safe and efficacious. This is critical to the rapid deployment of recommended vaccines. However, such redundancies may pose supply chain issues due to production bottlenecks that might affect the availability of syringes, medication vials and other components necessary for fertility treatments. As such, access to pharmaceuticals and adjuncts necessary for effectively caring for infertile patients may be limited. Providers should maintain ongoing communication with pharmacies to help ensure a consistent supply of necessary medications and supplies.

As COVID-19 vaccine trials have started to enroll participants, it is important to remind investigators to include people of reproductive age as they design studies to gather information about the relative risks and benefits of vaccination for all populations at risk of COVID-19 infection. This includes both women and men undergoing workup for infertility, and women who are contemplating pregnancy, or who are pregnant or breastfeeding. Study eligibility criteria will vary. The informed consent process is an effective mechanism to allow women and men to take part in the decision-making process about potential risks and benefits of participating in COVID-19 vaccine trials. Providers may be able to help address patient concerns about study participation as it relates to reproductive health.

Once a safe and effective COVID-19 vaccine is available, some patients will have questions or hesitancy about vaccination. Trusted healthcare providers are often in an ideal position to lay the groundwork to support vaccination by addressing these patient concerns even before a vaccine becomes available.

AN UPDATE ON MENTAL HEALTH AND THE COVID-19 PANDEMIC

The mental health of many individuals is being profoundly and negatively affected as the COVID-19 pandemic continues to spread. Fertility clinics need to be aware of this risk and implement mitigation factors for patients, physicians, and healthcare workers, and provide resources and referrals for psychological and/or psychiatric treatment, counseling, and coping. There has been an exponential increase in the number of [studies assessing the effects of the COVID-19 pandemic on mental health outcomes](#). The information below is intended to provide a thumbnail sketch of the psychological impact of COVID-19.

Experts anticipate that the impact of this pandemic on mental health will have extremely negative long-term effects. In March 2020, [the WHO](#) recognized that mental health would be negatively affected by the

COVID-19 pandemic. As the pandemic has developed it has been variously described as a “public health crisis” (Dong and Bouey, 2020), as another pandemic of mental and behavioral illness (Galea et al., 2020), and as a “parallel epidemic” of fear, anxiety, and depression that may increase the risk of infection (Yao et al., 2020). Research is demonstrating that COVID-19 may negatively impact mental health through the virus itself, as well as through the psychosocial impact of fear, uncertainty, social isolation, financial stress, stigma, comorbidity, and other factors. Below, we briefly highlight emerging data, as well as approaches to address the impact of the COVID-19 pandemic on the mental health of patients and providers in the reproductive medicine setting.

- In the first study to investigate psychopathology in a sample of COVID-19 survivors after hospital treatment, more than half of patients treated in hospital for COVID-19 were found to have a psychiatric disorder one month later (Mazz et al., 2020). Women were more likely to be affected than men, patients with previously diagnosed psychiatric disorders were at a higher risk, and young people showed higher levels of depression and sleep disturbances consistent with other studies (Vindegard et al., 2020; Ozamiz-Etxebarria et al., 2020; Pappa et al., 2020; Wang et al., 2020a). The investigators reported that these psychiatric outcomes could be caused by the virus itself, or by psychological stressors such as social isolation, the psychological impact of having the virus, concerns about infecting others, and stigma. They concluded that there is a need to diagnose and treat the psychiatric sequelae in COVID-19 survivors.
- Psychosocial factors have clearly contributed to increased stress during the pandemic. Early studies from China found evidence that social isolation was associated with feelings of anxiety and depression (Wang et al., 2020b). A review of the psychological impact of quarantine findings found evidence of post-traumatic stress symptoms, confusion, and anger amongst other stressors (Turocy et al., 2020).
- The [American Psychological Association is conducting an ongoing “pulse check” survey](#) through The Harris Poll to monitor increases in stress related to COVID-19. Current findings show that while average reported stress levels related to the coronavirus have remained generally consistent over the past three months (April-July), the proportion of respondents reporting certain negative feelings as a result of the coronavirus has increased significantly. Results show that individuals are more likely to report feeling frustrated, scared and angry than they were three months ago, and that more than half of U.S. adults (58%) wish they had more information about how to keep themselves and/or their family healthy as the U.S. reopens.
- [A recent tracking poll](#) showed an increase of 14 percentage points since May in public health concerns about mental health and that currently 53% of all respondents believe that the pandemic is taking a toll on their mental health. The poll found that younger adults, women, and people experiencing financial difficulties are at higher risk. COVID-19 related stress has led to problems with sleep (36%), eating (32%), headaches and stomach aches (18%), difficulty controlling temper (18%), increased use of alcohol and drugs (12%), and most U.S. adults feel the worst effects of the pandemic are yet to come.
- In the field of reproductive medicine, both patients and healthcare workers are at a greater risk for psychological distress and mental health disorders. Infertility patients are already at risk for psychological distress and mental health vulnerability (Lawson, 2019). Recent research showed a negative impact on the mental health of patients whose treatment cycles were canceled based on the recommendations set forth by the ASRM COVID-19 Task Force. In one study, 85% of respondents found it to be moderately to extremely upsetting, with 22% rating it to be equivalent to the loss of a child (Turocy et al., 2020). Another study found psychological distress for all

participants and a moderate to extreme level for most participants (Lawson, 2019). Similar findings have been reported in the U.K. and Italy at the recent 2020 meeting of the European Society for Human Reproduction and Embryology (Bigg, 2020).

- Research on the psychological impact of the COVID-19 pandemic on infertility patients found that the stressor of the pandemic increased over time, but that infertility continued to be significant and comparable to the stressor of the pandemic itself (Vaughan et al., 2020). COVID-19 is exacerbating existing levels of stress, loss, grief, anxiety, and depression for all patients accessing fertility care, and is increasing risks for other psychiatric problems such as substance abuse and post-traumatic stress disorder (PTSD). Patients are facing increased uncertainty regarding factors including, but not limited to, fear of future delays of treatment, impact of past delays (backlogs), delays associated with current mitigation precautions (social distancing and spaced appointments), and travel restrictions. Patients pursuing third party reproduction (reliant on third parties who themselves may be less likely to participate due to their own fears for safety and challenging psychosocial circumstances) may be at a higher risk for being negatively affected. Patients, many who are desperately longing to become parents, are at risk for feeling more isolated, distressed, and psychologically “triggered” when confronted with emotionally laden topics in public discourse such as the current focus on parents, children and school re-openings.
- Physicians and healthcare workers are also at risk for psychological distress and mental health disorders as COVID-19 presents new stressors for all healthcare providers (Pappa et al., 2020). Sources of anxiety include risks of exposure, spreading infection to family members or patients, fear of illness in self or family members, poor access to testing, social isolation, and a lack of access to up-to-date information and communication (Shanafelt et al., 2020; Lai et al., 2020). Additionally, fear of financial loss adds an extra level of stress and anxiety. Besides an increased workload, many providers are experiencing increased demands at home due to school closures and increased childcare responsibility because many daycare centers and schools are closed, and childcare workers are hesitant to work in the homes of healthcare providers.
- Physician burnout and [moral injury](#) have serious consequences to the individual physician, to patients, and to healthcare institutions. While burnout is thought of as an individual issue, moral injury is a systemic problem.
- There is a great need for mental health support for both patients and physicians, and healthcare workers. ASRM continues to provide resources through webinars, podcasts, and updates. [Members within the Mental Health Professional Group](#) of ASRM provide psychiatric and counseling services. Fertility clinics can have a powerful positive impact on the mental health of patients, physicians, and healthcare providers by providing: 1) accurate information and education about mitigation and protection procedures; 2) a list of resources for support and coping; and 3) appropriate referrals for psychiatric and psychological services.

In some locales, mental health services are now being provided in person, while the recent transformation to telemental health has increased access to care. For challenges within clinics, effective leadership with good communication may decrease healthcare professionals’ anxiety (Shanafelt et al., 2020). Team based strategies such as de-briefing sessions and pairing healthcare workers with colleague partners to provide support have been shown to be effective in high stress environments (Smith, 2020).

COUNSELING PATIENTS UNDERGOING TREATMENT DURING THE COVID-19 PANDEMIC

- Many patients undergoing fertility treatment are concerned about the potential risks of COVID-19 on early pregnancy. Many also fear that their treatment will be canceled should they develop symptoms of COVID-19 or test positive for it.
- Patients undergoing treatment during the COVID-19 pandemic should receive counseling regarding approaches to reduce the risk of exposure to SARS-CoV-2 at home, in the community, and in the work environment. These include:
 - Seeking care using telehealth whenever possible.
 - Reducing risk of exposure to potentially infected individuals.
 - Avoiding large gatherings of people.
 - Maintaining social distancing.
 - Ensuring universal masking.
 - Practicing frequent hand hygiene.
 - Ensuring surface decontamination.
 - Avoiding travel by air.
 - Avoiding travel to areas with high disease prevalence.
 - Working remotely to the extent possible.
- Patients and practices also can help by advocating for sufficient and timely testing for the virus, the availability of adequate PPE supplies for healthcare employees, and compliance by non-healthcare employers with current CDC guidelines and direction from local and state health departments with regard to the safety of their employees.
- Infection with SARS-CoV-2 can be particularly concerning for those who are pregnant, as they may be at higher risk for severe disease. Although the effects of SARS-CoV-2 infection during pregnancy have not yet been fully elucidated, including effects of infection in the first trimester of pregnancy, infection may precipitate premature labor and/or delivery although full term newborns delivered from mothers with active COVID-19 infections have done well.
- A recent [report from the CDC](#) suggests that pregnant women with COVID-19 appeared to be at increased risk of mechanical ventilation and admission to the intensive care unit (ICU) compared to nonpregnant peers, though the absolute rates were low. Pregnant women were not found to be at increased risk of death associated with COVID-19 compared with nonpregnant age-matched women.
- Hispanic and non-Hispanic black pregnant women appear to be [disproportionately affected](#) by SARS-CoV-2 infection during pregnancy.

VIRAL AEROSOLIZATION, AND THE USE OF PPE BY PATIENTS AND PROVIDERS IN THE HEALTHCARE SETTING

Contrary to early reports suggesting that [aerosolization](#), compared to droplets, was not a significant transmission route for the SARS-CoV-2 virus, newer data highlights the potential relevance of this mode of transmission, particularly in a closed and confined setting or when patients are undergoing aerosolization treatments for respiratory ailments (Jayaweer et al., 2020; Fears et al., 2020; Anderson et al., 2020). However, further studies are needed. As such, increased care and awareness of healthcare workers regarding the potential for viral transmission by aerosolization is warranted in the healthcare setting and selection of PPE to match assessed risk is advised.

Recently, some studies, but not all, have shown that healthcare workers are at increased risk of contracting COVID-19 as compared to the general population, even when appropriate PPE is utilized (Nguyen et al., 2020; Moscola et al., 2020). This was demonstrated in multiple studies, even after controlling for other risk factors. Healthcare workers reporting inadequate PPE or PPE reuse, and those working in inpatient settings and nursing homes, faced even higher risks of contracting COVID-19. Moreover, Black, Asian, and minority healthcare workers were found to have at least a fivefold increased risk of infection as compared to the non-Hispanic white general community.

All physicians and medical staff should remain diligent about strictly following the recommended PPE guidelines and ensure both availability and utilization of PPE for themselves, their healthcare team, and their patients. Following is the most updated table regarding risk assessment and mitigation for reproductive care procedures and activities.

Table. Risk assessment and mitigation methods for reproductive care procedures and activities (as of August 10, 2020)

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

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, glasses with solid side shields or face shields are advised; typical vision-related glasses would not qualify as protective.

** Conditional: Use of eye protection is recommended in areas with moderate to substantial community transmission (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html>) or if required by policy in hospital-based centers.

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