



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

### UPDATE No. 10 (November 17, 2020\*)

The current update by the ASRM Coronavirus/COVID-19 Task Force (the “Task Force”)<sup>1</sup> continues to affirm 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 were further elaborated upon in Updates No. 4-9. Collectively, these updates recommend the judicious resumption of the delivery of reproductive care, with the use of careful preventive measures, such as the use of Personal Protective Equipment (PPE), including masks, frequent hand washing, and social distancing measures. Given the continued presence, and more recently the marked upsurge, of COVID-19 cases in much of the United States (U.S.), these strategies continue to be critical in managing this ongoing pandemic. Since the last update published on October 6, 2020, the Task Force has observed the following:

- As of November 15, 2020, the U.S. continues to lead the world in COVID-19 deaths and cases. COVID-19 cases now exceed 10.9 million in the U.S. with more than 245,000 deaths. With respect to excess deaths in the U.S. largely attributable to COVID-19, the largest percentage increases are now being seen among younger adults aged 25–44 years and among Hispanic/Latino persons (1).
- At the time Update No. 9 was published, daily cases in the U.S. exceeded 54,000. As of this update the daily case rate has risen to >180,000, confirming another wave of contagion in the U.S. Every state, except Hawaii, has seen a [recent increase in their positive rate](#).

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<sup>1</sup> 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.

- Statewide viral spread, population positivity rates by age demographic and ethnic distribution, and weekly case accrual rates continue to differ widely across the U.S. Even within a state, county level data may differ significantly. Reproductive medicine practices should monitor disease prevalence and spread in their local community and region for trends that may impact their patients and staff.

Accurate current data is available through a variety of sources including the World Health Organization (WHO), U.S. Centers for Disease Prevention and Control (CDC), and individual U.S. state Departments of Public Health (see table below).

#### RELIABLE SOURCES FOR DATA ON COVID-19 INCIDENCE

Resource	Description
<a href="#">WHO COVID-19 Dashboard</a>	Global overview of new cases and deaths, including cumulative totals
<a href="#">CDC Weekly Surveillance Summary</a>	A data-rich resource, with features for easy data visualization and links to a wide array of epidemiologic data on COVID-19
<a href="#">CDC COVID Data Tracker</a>	U.S. county level data with cumulative case rates and total deaths. With additional links to individual state Public Health Department
<a href="#">Johns Hopkins Coronavirus Resource Center</a>	International, and U.S. national and state level data

In the current revision, the Task Force continues to support the judicious delivery of fertility care with strict adherence to recommended measures for disease prevention, including implementation of travel restrictions and quarantines when appropriate. This update provides new information on patient counseling, clinic management, advocacy for telehealth, COVID-19 and pregnancy, vaccines, and mental health.

#### PATIENT COUNSELING

The significant escalation of the COVID-19 pandemic is resulting in unprecedented daily case rates, hospitalizations, and deaths. We once again face the real risk of overwhelming our health care resources and manpower, which may affect the ability of all providers, including reproductive care practitioners, to serve their patients. This situation mandates reinforcing with patients and staff their responsibilities in minimizing the transmission of this disease via adherence to proven and effective mitigation strategies. The Task Force strongly encourages all ASRM members to use their platform not only as healers and researchers, but also as leaders to educate their staff, patients, and the broader community about the now well-established recommendations to slow the spread of the virus and keep themselves and their families safe.

- With a disease surge evident, continued vigilance is warranted with emphasis on risk mitigation efforts using hand washing, social distancing measures, and PPE, including masks. In the last update, issued [November 10, 2020](#), the Task Force noted that the CDC stated that *“Experimental and epidemiological data support community masking to reduce the spread of SARS-CoV-2. The prevention benefit of masking is derived from the combination of source control and personal protection for the mask wearer.”* For the first time, this report emphasized two independent and synergistic roles for this mitigation strategy. In addition to the documented "source control," whereby mask-wearing reduces the emission of virus-laden droplets, especially relevant for asymptomatic or pre-symptomatic infected wearers, the new development centered on the

wearer. New evidence suggests that masks function as a method of “filtration for personal protection” reducing inhalation of viral droplets by the wearer. We know more than 50% of transmission arises from spread from asymptomatic persons, who carry the virus, and that mask wearing protects those around the wearer. Now the CDC acknowledges that mask-wearing protects the wearer from infection as well. Thus, the community benefit of masking for SARS-CoV-2 control is due to the combination of these effects.

- It is incumbent upon all people, especially healthcare practitioners, to encourage responsible and beneficial social and ethical behavior. The trajectory of this crisis is not inevitable if individual actions are implemented. Overall prevention benefits increase with the increase in the numbers of individuals appropriately using masks, hand washing, social distancing consistently and correctly. Furthermore, emphasis on the power of asymptomatic spread to drive this pandemic should be a priority. As such, adopting universal masking policies can help avert future lockdowns, especially if combined with other non-pharmaceutical interventions, such as social distancing, frequent hand hygiene, and adequate ventilation. Such adoption is a social and civic responsibility.
- With the beginning of the winter months in the northern hemisphere, combined with the inadequate availability of rapid and reliable testing, PPE supplies, and specific and effective therapeutics or vaccines, the implementation of mitigation strategies is even more critical. As noted above, it is abundantly clear that mask wearing is both protective to the user as well as to those around them. Social distancing and limiting crowd size, requires even more effort, focus, and sacrifice as the weather gets colder and gathering outdoors is less viable. This becomes even more difficult as we approach the holiday season, when family and friend gatherings are the norm. But this year is not the norm and safety must take priority.

We must re-emphasize that at this juncture mask-wearing, social-distancing and frequent handwashing are even more urgently needed to enable patients to continue to have access to those fertility therapies that we all desire to provide. This message is unfortunately confounded by increasing fatigue and contradictory or confusing information. Consequently, the Task Force requests that all reproductive care practitioners use their position and influence to encourage patients to take responsibility and help maintain the health and safety of their communities and practices. And that they appeal to their staff and patients to continue to be engaged in promoting disease mitigation tactics and in combating the trajectory of the pandemic.

## **CLINIC MANAGEMENT**

In [Update No. 3](#), the ASRM COVID-19 Task Force emphasized the importance of each clinic performing a thorough risk assessment to facilitate the implementation of COVID-19 risk mitigation strategies. This was intended to be an ongoing and iterative process consistent with the need to provide reproductive medicine services within the context of a prolonged pandemic, and the fact that the transmission of the virus has impacted many regions differently at different times.

In the face of rapidly rising transmission in nearly all states, it would be prudent at this time for each practice to carefully re-evaluate risk and mitigation strategies. The recent surge in cases will inevitably lead to new challenges. Importantly, our understanding of the epidemiology and transmission of SARS-CoV-2 has evolved. The primary goal currently is to minimize risk of transmission and disease to staff and patients. An important secondary goal is to avoid interruption of fertility services.

Over the last several months, testing has become more widely available and plays a larger role in the management of both patients and staff. Additionally, the CDC’s guidelines have evolved for handling of

healthcare staff with exposures or infection. It is important to be familiar with these recommendations, which are described in some detail below:

- **Isolation and quarantine:**
  - For most persons with COVID-19 illness, the CDC recommends that [isolation](#) and [quarantine](#) precautions can generally be discontinued 10 days *after symptom onset* and resolution of fever for at least 24 hours without the use of fever-reducing medications, and with improvement of other symptoms. Exceptions to this are those with severe illness, who may be contagious for longer. Consider consultation with infection control experts for patients with severe illness.
  - For persons who never develop symptoms, isolation and other precautions can be discontinued 10 days *after the date of their first positive RT-PCR test for SARS-CoV-2 RNA*.
- **Definition of “close contact”:**
  - On October 21<sup>st</sup>, [the CDC updated its guidance on what constitutes “close contact”](#) with a person who has tested positive for COVID-19 for the purpose of isolation. “Close contact” has been revised to be within six feet for a total of 15 minutes or more over a 24-hour period. The timeframe for having contact with an individual includes the period 48 hours before the individual became symptomatic. A distinction has been made regarding close contact of healthcare personnel to COVID-19 positive individuals in the workplace. In the workplace, if appropriate PPE is worn, close proximity to an infected individual for an extended amount of time is not considered a relevant exposure.
  - Of note, [cloth masks are not considered PPE](#). It is important that the current definition does not recommend differential determination of close contact for healthcare personnel using fabric face coverings. Fabric masks are not relevant for the determination of “close contact”.
- **Isolation following “close contact”:**
  - In general, employees who have been exposed to a “close contact” who has tested positive should isolate and may return to work if symptom-free for 14 days following the exposure. The CDC, however, makes an important distinction in how close contacts should be handled depending on occupation. To ensure continuity of operations of essential functions, [CDC advises that ‘critical infrastructure’ workers may be permitted to continue to work following potential exposure to COVID-19](#), provided they remain asymptomatic and additional precautions are implemented to protect them and the community. Healthcare is one of the sixteen sectors of work categorized as “critical infrastructure”. When a 14-day isolation is not practical, asymptomatic staff should adhere to the following practices prior to and during their work shift.
    - *Pre-Screen:* Employers should measure the employee’s temperature and assess symptoms prior to them starting work.
    - *Regular Monitoring:* As long as the employee does not have a temperature or symptoms, they should self-monitor under the supervision of their employer’s occupational health program.
    - *Wear a mask:* The employee should always wear a face mask while in the workplace for 14 days after last exposure. Employers can issue facemasks or can approve employees’ supplied cloth face coverings in the event of shortages.
    - *Maintain social distancing:* The employee should practice at least six feet social distancing as work duties permit in the workplace.

- *Disinfect and clean workspaces:* Clean and disinfect all areas such as offices, bathrooms, common areas, and shared electronic equipment routinely.
    - If the employee becomes sick during the day, they should be sent home immediately. Surfaces in their workspace should be cleaned and disinfected. Information on persons who had contact with the ill employee during the time the employee had symptoms and two days prior should be compiled. Others at the facility with close contact within six feet of the employee during this time should be considered exposed unless adequate PPE was worn.
- **“Return to work” guidelines for healthcare providers (HCPs) following COVID-19 infection:** The CDC has issued interim guidance for [criteria for return to work for healthcare personnel with SARS-CoV-2 Infection](#). Below we summarize these criteria.
  - **Symptom-based Strategy:** HCPs with mild to moderate illness, and without immunocompromise, can return to work if:
    - At least 10 days have passed since symptoms first appeared, and
    - At least 24 hours have passed since last fever, and
    - Symptoms (e.g. cough, shortness of breath) have improved.
  - **Test-based Strategy:** In some instances, a test-based strategy could be considered to allow critically needed HCPs to return to work earlier than if a symptom-based strategy were used. However, many individuals will have prolonged viral shedding, limiting the utility of this approach. The criteria for the test-based strategy are based on presence or absence of symptoms:
    - *HCPs who are symptomatic should have:*
      - Resolution of fever, and
      - Improvement of symptoms (e.g. cough, shortness of breath, and
      - Test results that are negative from at least two consecutive respiratory specimens collected > 24 hours apart tested using a U.S. Food and Drug Administration (FDA)-approved molecular assay for SARS-CoV-2 RNA.
    - *HCPs who are not symptomatic should have:*
      - Test results that are negative from at least two consecutive respiratory specimens collected >24 hour apart tested using an FDA-approved molecular assay for SARS-CoV-2 RNA.
- **Travel restrictions for staff:**
  - Local governments and institutions may provide rules or guidance related to travel restrictions. In the absence of these restrictions, it still might be appropriate to consider non-essential / recreational travel restrictions for staff to and from areas with differing prevalence of infection. In any case, it is advised that staff be requested to keep management and their colleagues informed of travel plans (or if they plan to participate in large gatherings), and staff that travel should strive to use precautions to keep safe during travel.
- **Keeping up to date with occupational health recommendations:**
  - Clinics associated with academic or hospital institutions can generally rely on specialists in occupational health to keep them up to date with [the recommendations of the CDC](#) and other authoritative agencies for handling of workplace questions related to personnel with COVID-19 exposure or infection.

- Because guidelines will likely continue to evolve, freestanding practices should designate at least one individual to make staffing decisions related to exposure or infection. These “COVID-19 evaluators” should be notified immediately of all circumstances where patients, visitors, or personnel report signs and symptoms of COVID-19, test positive for COVID-19, or report exposure to a person known to have COVID-19. These COVID-19 evaluators should gather information regarding the circumstances of the situation including, but are not limited to, determining what cleaning measures should be taken, and what contact tracing needs to be done to inform/mitigate risk to others.
- **Management of PPE:**
  - As COVID-19 cases are on the rise in many areas, follow all [CDC](#) and local guidelines for PPE usage. Remind patients and staff to not only follow mask precautions when entering the clinic but also outside of the clinic to mitigate the spread of COVID-19. With some PPE supplies in high demand, new cycles should only be started once confirmation of all necessary PPE supplies are in hand. Clinics should also have contingency products and suppliers in place for PPE should usual sources be out of stock.

## ADVOCACY FOR TELEHEALTH

- In the midst of the COVID-19 pandemic, increased telehealth has emerged as an important method to allow patients to obtain needed consultations and care in a safe, convenient manner. ASRM has strenuously supported actions to eliminate restrictions on the provision and coverage of telehealth services, efforts that the COVID-19 Task Force has strongly supported. To that end, ASRM has vocally supported efforts by the U.S. Congress, the Executive Administration, many state legislatures, and private payers to implement significant changes intended to make it easier for individuals to receive treatment remotely in order to mitigate risk of exposure for both patients and healthcare workers. Such measures will also reduce pressure on an increasingly strained healthcare infrastructure. ASRM is committed to supporting its members and their patients as they seek to maintain access to this important modality.

## UPDATE ON COVID-19 AND PREGNANCY

- **What have we learned about COVID-19 and pregnancy since the last [ASRM Task Force update that highlighted the topic](#)?**
  - Very little is still known regarding the impact of SARS-CoV-2 infection on gametes, embryos, and resultant pregnancies. Very generally, existing evidence suggests that the virus likely does not infect gametes (2,3) or embryos, however data remain scant. As with other viral illnesses, COVID-19 has been associated with an increased likelihood of severe disease among pregnant compared to non-pregnant women.
  - A recent meta-analysis (5) reported that pregnant and recently pregnant women are less likely to manifest COVID-19 related symptoms of fever and myalgia than non-pregnant women of reproductive age and are potentially more likely to need intensive care treatment for COVID-19. Pre-existing comorbidities, high maternal age, and high body mass index seem to be risk factors for severe COVID-19. Preterm birth rates are higher in pregnant women with COVID-19 than in pregnant women without the disease.
  - A recent Morbidity and Mortality Weekly Report (MMWR) [published by the CDC on November 6<sup>th</sup>](#) elaborates on these findings (4). Among more than 400,000 symptomatic

COVID-19 positive women aged 15-44 years, pregnant women were more likely to require admission to an intensive care unit (10.5 vs. 3.9 per 1,000 cases; adjusted relative rate [aRR] =3.0, Confidence Interval [CI] 2.6-3.4), invasive ventilation (2.9 vs. 1.1 per 1,000 cases; aRR 2.9, CI 2.2-3.8), and extracorporeal membrane oxygenation (ECMO) (0.7 vs. 0.3 per 1,000 cases; aRR 2.4, CI 1.5-4.0), compared to non-pregnant women, even after adjusting for age, race/ethnicity, and underlying medical conditions. The risk of death also was rare, but significantly increased among pregnant compared to non-pregnant women (1.5 vs. 1.2 per 1,000 cases; aRR 1.7; CI 1.2-2.4). Additionally, non-Hispanic Black women were disproportionately more likely to die, regardless of pregnancy status.

- **How can we improve patient counseling regarding COVID-19 and pregnancy?**
  - **Enrollment in Ongoing Studies:** Continued encouragement for *all* 1<sup>st</sup> trimester pregnant patients to enroll beginning at 4 to 10 weeks gestation in ongoing prospective studies with follow-up to pregnancy completion, such as [the University of California San Francisco ASPIRE trial](#), is crucial to obtaining data that can be used to better inform patient counseling. For pregnant or recently (<6 weeks) postpartum women who are suspected to have, are under investigation for exposure, or who have confirmed COVID-19, enrollment in the [PRIORITY Registry](#) should also be encouraged.
  - **Continued Counseling:** Continued emphasis should be made regarding the risks of COVID-19 infection in pregnancy and the need to comply with social distancing, masking, hand hygiene, and avoidance of high prevalence areas, if possible (see also [Patient Counseling](#) section above).
- **Will pregnant women be candidates for the COVID-19 vaccine?**
  - It remains unknown whether pregnant patients will be candidates for the COVID-19 vaccine. Inclusion of pregnant women in vaccine trials is encouraged to improve knowledge regarding safety and efficacy in pregnancy, especially as this population is potentially at risk for more severe disease (see above).
  - Inclusion of pregnant women in trials of vaccines that utilize an established technology shown to be safe in pregnancy minimizes the risks to the mother and child. However, pregnant women may not be ideal candidates for trials of vaccines that utilize unproven technology.

## VACCINES

- [There are currently twelve COVID-19 vaccine candidates](#) being studied in large scale phase III studies to assess safety and efficacy. These candidates are based on a variety of platforms, including RNA/DNA, viral vector, and protein subunit-based vaccines. Pfizer/BioNTech recently announced a >90% efficacy for their mRNA based COVID-19 vaccine compared to placebo based on an interim analysis of a trial that enrolled 44,000 adults. The scientific data has not yet been published and the company reports that it may file for an FDA Emergency Use Authorization (EUA) in late November once two months of safety data post-vaccination has been collected as recommended by the FDA. On November 16, Moderna announced a 94.5% efficacy of their mRNA based COVID-19 vaccine in a trial of 30,000. They will determine whether to request an EUA from the FDA depending on the safety results accrued after two months follow-up.
- The CDC and the CDC's Advisory Committee for Immunization Practices (ACIP) are [finalizing guidance](#) about prioritizing groups for vaccination when a vaccine is approved and available. The

four groups considered as high-priority are: healthcare workers, essential workers, adults age 65 and older, and people with underlying medical conditions that put them at risk of severe COVID-19 infection.

## MENTAL HEALTH AND COVID-19

- As the COVID-19 pandemic continues, more Americans are reporting symptoms of prolonged and acute stress. Although we know that the virus presents a universal threat and that there is an increased risk to groups such as the elderly, people with pre-existing medical and psychiatric conditions and the socially isolated, we are learning new information about other vulnerable groups. Furthermore, the pandemic is having both a direct and a compounding impact on existing social tensions in areas such as political polarization, racial injustice, and economic inequality. These findings have important implications for reproductive care facilities who aim to provide the best care for patients and to be protective of providers and clinic staff.
- A [recent national survey by the American Psychological Association \(APA\) regarding Stress in America](#) concluded that, *“We are facing a national mental health crisis that could yield serious health and social consequences for years to come... We need to act right now to help those who need it [care], and to prevent a much more serious and widespread mental health crisis.”* The survey findings include the following:
  - The COVID-19 pandemic has had a substantial impact on the lives of all Americans, and it will continue to do so.
  - It has disrupted work, education, health care, the economy, and relationships, with some groups more negatively impacted than others.
  - Nearly 8 in 10 adults (78%) say the coronavirus pandemic is a significant source of stress in their life.
  - Nearly half of all adults (47%) report negative effects on their relationships due to the coronavirus pandemic.
  - Generation Z adults (18-23) report the highest stress level, significantly higher than all other generations.
  - Most Generation Z teens (13-17) who are in school (81%) report they have been negatively impacted due to school closures as a result of the pandemic.
  - Seven in 10 parents (70%) say family responsibilities are a significant source of stress in their life.
  - Of employed adults, 68% report their job or employment has been negatively impacted by the coronavirus pandemic.
  - Nearly two in three adults (64%) say that money is a significant source of stress in their life, and around half of adults (52%) say they have experienced negative financial impacts due to the pandemic.
  - Discrimination rises as a source of stress, particularly for people of color.
  - One of the key approaches to maintaining strong mental health in times of adversity is by remaining hopeful: around seven in 10 (71%) surveyed say they feel hopeful about their future. By generation, millennials (76%) are the most likely to agree with this sentiment, followed by boomers (72%), Gen X (71%), older adults (69%), and Gen Z adults (64%).

- These findings, together with the other information included in this document, suggest the following stressors and suggestions for support:
  - **For patients:**
    - Fear of a possible shutdown of fertility services and frustration when seeing family, friends and/or society in general engaging in risky, non-essential behaviors that could lead to a shutdown.
    - Concerns about continuity of insurance coverage and ability to pay for fertility treatment.
    - Increased risk for single prospective parents (socially isolated).
    - Increased risk for members of economically and racially marginalized groups.
    - Patients with secondary infertility face challenges related to having children (home-schooling, no childcare, Generation Z, etc.).
    - Patients experiencing infertility/fertility challenges (not yet parents) may feel distress about the public emphasis on parents' problems (childcare, schools, etc.) and social media talk about "quarantine pregnancies".
    - Patients may experience a painful wait for treatments associated with third parties such as gestational carriers or gamete donors who may be reluctant or unavailable due to multiple COVID-19 related factors (e.g. restrictions on travel, caring for family members, childcare problems, etc.).
    - Fertility clinics can provide accurate health information about mitigation and safe practices.
    - Members within the [Mental Health Professional Group of ASRM](#) provide psychiatric and counseling services.
  - **For healthcare providers and clinic staff:**
    - Healthcare providers and clinic staff face a number of potential challenges and stressors including those related to having children (home-schooling, no childcare, Generation Z, etc.), anxiety about being infected and/or infecting family members, and concerns about losing their employment.
    - The APA survey recommends the following for employers to support workers:
      - Provide flexibility to employees...to allow people to do their jobs while still being able to handle new stressors and responsibilities in their lives, such as a child's education.
      - Provide support... emotional support through one-on-one check-ins or by reducing someone's workload to just essential tasks. This also applies to co-workers, who can support each other by checking in and approaching each other with empathy.
      - Provide clear communication to employees and supervisors about expectations, support resources and new policies that respond directly to impacts created by the pandemic. This reduces uncertainty at work, which is a major contributor to employee stress.
      - Supervisors should not expect work to continue at the same level as before. This can lead to employee burnout. Instead, employers should help employees prioritize what work is critical and what can wait.

\*The next update from the Task Force will be published as conditions warrant a release.

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