



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

UPDATE #4 (May 11, 2020 through June 8, 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 to reproductive well-being and in pregnancy, and the ability of health systems to cope were yet unknown, at least for the U.S.

With the passage of time, significant knowledge was gained as an increasing number of patients whose care had been delayed were in a situation that had become more urgent. Therefore, 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.

The Task Force continues to support the measured resumption of care. In the current update (Update No. 4), additional clarification and information is provided with regards to testing, pregnancy, and third-party reproduction, and the specifics around its recommendations for the use of Personal Protective Equipment (PPE) to mitigate risk of infection during the delivery of reproductive care.¹

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.

While it is unclear how long the pandemic will last, it is highly probable that we will need to be operating in a COVID-19 environment for several months, at least until an effective and safe vaccine becomes widely available. Consistent with this long-term view, moving forward, the Task Force now plans to release updates to its recommendations every four weeks, unless conditions warrant greater frequency.

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

- To date, worldwide, there have been almost four million confirmed cases of COVID-19, the disease produced by the virus SARS-CoV-2, with more than 1.3 million confirmed cases and more than 79,000 deaths in the United States (U.S.) alone.
- While no community is unaffected, the prevalence of the disease varies widely throughout the U.S. In some areas, mitigation strategies have led to a “flattening of the curve” or a sustained decrease, while other areas are still seeing an increase in the rate of new cases and deaths over time.
- Many parts of the country are now in the process of loosening mitigation strategies. At the same time, viral testing capacity is increasing and contact tracing algorithms are being developed. The impact of these measures on COVID-19 prevalence is not yet known. While peak resource utilization resulting from COVID-19 disease has severely burdened healthcare systems in some communities, other parts of the country have not seen similar stress to their healthcare safety net. Overall, these developments suggest that most patients currently falling ill with COVID-19 will be able to access the care they need.
- Over time, it has become apparent that the ebb and flow of COVID-19 is not accurately predictable despite the use of multiple models. It is not clear, for example, whether a sustained plateau might be followed by a gradual resolution or by a resurgence of new viral cases. Given this, decisions regarding patient care must remain flexible.
- No vaccine yet exists to prevent infection with COVID-19, and at this time, few medications have shown benefit in decreasing morbidity and mortality. Until we achieve better outcomes – whether via vaccine, medication, or management – efforts to mitigate disease spread will remain a core strategy for fighting the virus.
- Data suggest that COVID-19 will remain a factor to be managed in our lives and practices for a prolonged period of time. Scientific data should continue to guide disease treatment and optimization of the response to the pandemic.
- 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 reinstate care. ASRM encourages fertility providers and their patients to participate in studies that will help our understanding of these issues. To this end, the ASRM affiliate, Society for Assisted Reproductive Technologies (SART), is adding COVID-19 related questions to the SART Clinic Outcome Reporting System (CORS) registry in an effort to better understand the impact of the disease on reproductive outcomes following the use of assisted reproductive technologies (ART).
- Infertility patients, whose underlying medical conditions place them at increased risk of complications if infected with SARS-CoV-2, should be counseled regarding the risks and benefits of initiating fertility treatment during this pandemic. Such informed consent discussions should be individualized to each patient's unique situation (e.g. [see SART](#)

[COVID toolkit](#)). Considerations regarding whether or not to perform viral testing on patients, including the consequences of such testing, are discussed in more detail below.

- 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.

TESTING FOR SARS-COV-2 AND COVID-19

Scientists continue to learn more about the SARS-CoV-2 virus and its transmission dynamics. The timeline of test positivity after infection has recently been published (Sethuraman et al, 2020). For example, in most individuals with symptomatic COVID-19 infection, viral RNA in the nasopharyngeal swab becomes detectable as early as day 1 of symptoms and peaks within the first week of symptom onset. This positivity starts to decline by week 3 and subsequently becomes undetectable. However, in severely ill hospitalized patients, PCR positivity may persist beyond 3 weeks after illness onset when most mild cases will yield a negative result.

Testing could be used to guide patient management and inform the use of appropriate PPE in order to protect patients and staff against infection. Both viral and serologic testing platforms and strategies for SARS-CoV-2 are rapidly evolving. However, although testing capacity is increasing in the U.S., both the efficacy and the availability of testing vary widely. Importantly, there is insufficient information at this time to recommend a specific algorithm or testing program for patients, providers and staff engaged in reproductive care.

Nonetheless, incorporating testing as part of patient and staff management strategies, when these are accurate and available, is recommended. In addition, such testing may be required by some hospitals or centers where fertility care is provided. Therefore, the ASRM encourages its members to stay current with available tests and testing strategies, as they continue to develop. Detailed testing guidelines for patients and providers are available and are regularly updated by the [U.S. Centers for Disease Prevention and Control \(CDC\)](#) and the [Infectious Diseases Society of America \(IDSA\)](#).

Currently, COVID-19 testing relies on the detection of the virus (either nucleic acid or protein antigen) or immunity (antibody serology). Each test type will be discussed briefly below.

1. **Nucleic acid testing:** Detecting the presence of SARS-CoV-2 can rely on the direct detection of the novel coronavirus' RNA using Polymerase Chain Reaction (PCR). There are a variety of manufacturers of SARS-CoV-2 PCR tests with variable performance characteristics (sensitivity and specificity). Some PCR testing in diagnostic laboratories have documented excellent performance but other PCR testing is less accurate, particularly for rapid tests. The turnaround time for PCR testing generally ranges from 24-48 hours, but rapid testing is available with results in less than 60 minutes.
 - a. The use of high-performance PCR testing is essential to guide clinical decision-making regarding COVID-19. The [CDC recommends](#) the use of a viral test (nucleic acid, or antigen – see below) to diagnose acute infection. It is anticipated that PCR testing for SARS-CoV-2 will likely become essential for guiding patient care in reproductive practices, although at this time, algorithms for use and interpretation are not yet fully established.

- b. False-positive SARS-CoV-2 testing is rare, but false-negative results can occur with inadequate sample collection or if the sample is collected early in the disease course. Proper sample collection from a trained staff member is needed for accurate results. [According to the CDC](#), acceptable specimens include nasopharyngeal, oropharyngeal, nasal mid-turbinate, or anterior nares swabs, or nasopharyngeal or nasal washes or aspirates, collected by a trained healthcare professional. For all testing personnel, wearing appropriate PPE, including a facial shield, is important since nasopharyngeal sample collection can lead to coughing and droplet production by the subject being tested.
 - c. PCR positivity often persists for 3-4 weeks after initial diagnosis of infection, but persistence as long as 6 weeks has been documented. Studies suggest that adults with SARS-CoV-2 are infectious for about 9 days after the onset of symptoms, but it is not yet clear whether those who continue to test positive for the virus by PCR remain infectious throughout the period of positivity or if infectivity dissipates over time. However, we should note that a positive PCR result reflects only the detection of viral RNA and does not necessarily indicate the presence of viable virus (Wölfel et al, 2020).
2. **Antigen testing:** The U.S. Food and Drug Administration (FDA) [recently issued](#) the first emergency use authorization (EUA) for a COVID-19 antigen test, a new category of tests that quickly detect fragments of proteins found on or within the virus when testing samples collected from the nasal cavity using swabs. Negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative. Overall, experience with these tests to detect the SARS-CoV-2 virus is currently limited.
3. **Antibody (serologic) testing:** Serologic testing relies upon the production of antibodies by the host in response to infection. Most, but not all individuals with SARS-CoV-2 infection produce antibodies and *antibody testing is not recommended for the diagnosis of acute infection*. The presence of immunoglobulin M (IgM) antibodies indicates a more recent infection and immunoglobulin G (IgG) antibodies tend to last long after infection. ELISA-based IgM and IgG serologic tests have >95% specificity for disease diagnosis, but sensitivity ranges from 60-98%. In general, rapid point-of-care (POC) serologic tests provide qualitative results with lower sensitivity and specificity compared to standard serologic testing. There is considerable [variability among commercial tests](#); practices should use a well-validated test, preferably one of the FDA-approved tests, and be aware of their limitations.

Emerging evidence suggests that positive serologic testing for SARS-CoV-2 may confer immunity or reduced risk of reinfection. However, this is not well established, and a positive test should not lead individuals to disregard recommended COVID-19 precautions. Currently, the implications of serologic antibody testing remain unclear with regards to both accuracy and immunity. Based on current evidence, serologic antibody testing should not be used for patient or provider decision-making at this time and should not change adherence to guidelines for PPE use.

PREGNANCY AND COVID-19

A significant concern when managing reproductive care during the COVID-19 pandemic is how the disease, and the virus that causes it, may impact the pregnant patients and/or pregnancy outcome. We summarize below what we know and do not know about the impact of COVID-19 on the fetus and neonate.

1. What we know about the impact of COVID-19 on the fetus and neonate:

- Full term newborns delivered from mothers with active COVID-19 infections have done well overall (Shalish et al, 2020)
- Severe illness, including COVID-19, may precipitate premature labor or lead to early delivery with resultant neonatal complications of prematurity (Liu et al, 2020; Zhu et al, 2020)
- A case series of 9 women affected with COVID-19 that delivered via cesarean section showed no viral RNA in the amniotic fluid, cord blood, or breastmilk (Chen et al, 2020).

2. What we don't know about the impact of COVID-19 on the fetus and neonate:

- No data yet exist regarding the impact of SARS-CoV-2 infection on the fetus during the first or second trimesters of pregnancy. It should be noted that other maternal viral infections have been shown to impact the fetus even in the absence of direct fetal infection.
- Adverse perinatal outcomes have been reported (Mehan et al, 2020), but it is unclear whether these outcomes are directly related to COVID-19.
- Evidence of vertical transmission of COVID-19/SARS-CoV-2 is still unclear but possible, although data should be interpreted with caution:
 - Neonatal COVID-19 is uncommon and respiratory outcomes are favorable (Shalish et al, 2020). The outcomes of 217 neonates born to mothers with positive SARS-CoV-2 testing demonstrated no strong evidence for vertical transmission when delivery was via cesarean section (Shalish et al, 2020). Alternatively, a recent case report in JAMA (Dong et al, 2020) described the presence of IgM antibodies in the neonate at birth and suggested that vertical transmission may be possible.
 - Three other case reports suggested the potential for intrauterine infection. One described a 19-week pregnancy loss in a patient with active COVID-19 infection (Baud et al, 2020). The second reported the case of a woman at 22 weeks of gestation who elected to terminate; examination of the placenta and umbilical cord, but not the fetus, demonstrated the presence of SARS-CoV-2 (RNA) infection with macrophage infiltration (Hosier et al, 2020). The third report is of a patient with COVID-19 at 28 weeks gestation and rapid deterioration. The placenta was visualized using electron microscopy and coronavirus virions were seen invading into syncytiotrophoblasts in placental villi (Algarroba et al, 2020).
 - Another case report documented birth of an asymptomatic neonate born to a woman with COVID-19 who tested negative at birth and at 3 days of life, but tested positive after 14 days of life, suggesting that infection may have been acquired postnatally (Buonsenso et al, 2020).
- Data are emerging on a form of coagulopathy associated with COVID-19 (DiRienzo et al, 2020). Whether this is directly related to the viral infection or is associated with hypertensive disorders of pregnancy, or with fetal growth restriction, is yet to be determined.

Determining the effect of COVID-19 and SARS-CoV-2 on pregnancy and the optimal management of pregnant patients is critical not just for this pandemic, but for those that will occur in the future. Consequently, ASRM encourages reproductive care providers and their patients to participate in studies that will help our understanding of these issues. For example, the ASRM COVID-19 Task Force encourages SART member clinics to recruit patients who achieve pregnancy

between April 30, 2020 to December 31, 2020 for the [ASPIRE \(Assessing the Safety of Pregnancy in the Coronavirus Pandemic\) trial²](#).

THIRD-PARTY REPRODUCTION

Third-party reproduction is an important therapeutic intervention to build families for a number of individuals and couples. As we plan for resumption of care to treat infertility, we must also address the concerns of, and support, those intending to embark on this journey. Third-party reproduction during the COVID-19 pandemic is complex, as one must consider the risks and benefits of the process for all parties involved including the egg donor, the sperm donor, the gestational carrier, the fetus, and the intended parents. The cornerstone to determine the eligibility of donors and recipients of human cells and tissues is to test for relevant communicable disease agents and diseases. This is particularly challenging with SARS-CoV-2 (see section on testing above). In addition, the various potential modes of transmission are poorly understood. FDA guidance on donor/recipient eligibility for SARS-CoV-2 is not yet available. [FDA guidance for the related SARS-CoV screening](#) relied primarily on symptoms and quarantine of potential donors/recipients who had come into contact with infected individuals or who had traveled to endemic areas. However, this is not a realistic strategy for SARS-CoV-2 given the widespread prevalence of disease.

The risk of COVID-19 infection presents unique challenges to patient care when utilizing third-party reproduction. Consideration of the safety of oocyte donors and gestational carriers should be a priority, particularly in areas of high disease prevalence.

- 1. Clinics should weigh the benefits and risks of proceeding for the involved individual(s).** In addition to the ability of the clinic to adhere to safe practices to reduce the spread of COVID-19, factors to consider include:
 - Urgency to proceed (for example, due to age of donor, recipient, or intended parents, or availability of donor or gestational carrier).
 - Understanding that the disease prevalence varies by region, the prevalence of COVID-19 in the home state of the clinic, the intended parent(s), the donor and/or the gestational carrier must be weighed.
 - The need for travel for the intended parents, the donor and/or gestational carrier.
 - The unknown impact of COVID-19 on pregnancy and the fetus (see above section).
 - Compliance with national, regional, state, and municipal regulations produced by authoritative health organizations and agencies regarding clinical activities and travel.
 - International travel restrictions: new cases of third-party reproduction across international borders should not be pursued at this time.

- 2. Enhanced FDA and donor / recipient eligibility**
 - Recommend adding screening for SARS-CoV-2 to the [current FDA recommendations for third-party reproduction](#) by documentation of absence of symptoms associated with COVID-19 infection such as fever, cough, shortness of breath, sore throat, anosmia and lack of taste, as well as documentation of temperature in the physical exam.
 - Testing availability for SARS-CoV-2 remains limited and screening methodologies vary in sensitivity and specificity. Nevertheless, PCR testing is the recommended approach for the detection of SARS-CoV-2 RNA (see above section).

² The University of California-San Francisco's ASPIRE research study related to COVID-19 is not affiliated with Aspire Fertility Institute or Inception Fertility Ventures, LLC. Any reference to ASPIRE does not constitute or imply affiliation, sponsorship, endorsement, or connection between the University of California and either Aspire Fertility Institute or Inception Fertility Ventures, LLC.

3. Oocyte donors

- Clinics should consider incorporating additional counseling and documentation regarding screening for SARS-CoV-2 during ovarian stimulation.
- Clinics should consider cancellation if the donor has a positive test for SARS-CoV-2 or develops COVID-19 during ovarian stimulation.
- *Currently*, the FDA does not recommend testing for SARS-COV-2 prior to obtaining oocytes for third-party reproduction. The most current FDA [guidance](#) regarding "The Coronavirus 2019 Disease Pandemic" from April 1, 2020 recommends using screening questions to defer potentially infected women.

4. Sperm donors

- Data regarding presence of SARS-CoV-2 in semen is conflicting (Sun et al, 2020; Song et al, 2020; Li et al, 2020).
- Quarantine of all anonymous donor sperm specimens for 6 months is an existing FDA requirement.
- Quarantine of directed donor sperm specimens is not required by the FDA but may be considered at the discretion of the recipient and physician.
- *Currently*, the FDA does not recommend testing for SARS-COV-2 prior to obtaining sperm for third-party reproduction. The most current FDA [guidance](#) recommends using screening questions to defer potentially infected men.

5. Gestational carriers

- Clinics should consider incorporating additional counseling regarding the unknown risks of COVID-19 on pregnancy and on the developing fetus (see section above).
- Clinics should consider incorporating additional counseling and documentation regarding screening for SARS-CoV-2 and postponement of embryo transfer if the gestational carrier has a positive test for SARS-CoV-2 or develops COVID-19 symptoms prior to transfer.
- As always, FDA donor eligibility is required for both semen and oocytes for use in a gestational carrier (Practice Committee of the ASRM et al, 2017).

6. Intended parents

- Clinics should consider incorporating additional counseling regarding the unknown risks of COVID-19 on pregnancy and the developing fetus (see section above).
- Clinics should consider incorporating additional counseling and documentation regarding screening for SARS-CoV-2 and cancellation of oocyte donor retrieval or postponement of embryo transfer if either the oocyte donor or gestational carrier has a positive test or develops COVID-19 symptoms during stimulation or prior to transfer.
- Intended parents should work with reproductive attorneys and third-party agencies to create a contingency plan for alternate arrangements in the case of increasing travel restrictions and inability to receive their child born through third-party reproduction.

UPDATE TO RECOMMENDATIONS FOR USE OF PPE TO MITIGATE RISK OF INFECTION IN THE REPRODUCTIVE CARE SETTING

In Update No. 3, the Task Force provided recommendations for the use of PPE to mitigate risk of infection in the reproductive care setting (Table 3 in Update No. 3). This table has been further revised to remove the recommendation for the use of face shields for procedures or activities occurring in the clinic with no or limited risk for airway manipulation and aerosolization.

The updated table is displayed below.

Table. Risk assessment and mitigation for COVID-19 infection during reproductive care procedures and activities				
Procedure/Activity	Potential Risk	Mask Type Required for Staff	Other PPE Required for Staff	PPE Required for Patients
Clinic Entry Screening	Droplet	Medical Grade	Gloves	Cloth Mask
Patient Registration	Droplet	Medical Grade	---	Cloth Mask
Vital Sign Measurement	Droplet	Medical Grade	Gloves	Cloth Mask
In Office Consultation	Droplet	Medical Grade	---	Cloth Mask
Phlebotomy	Droplet	Medical Grade	Gloves	Cloth Mask
Ultrasound	Droplet	Medical Grade	Gloves	Cloth Mask
Saline Infusion Sonogram	Droplet	Medical Grade	Gloves	Cloth Mask
Hysterosalpingogram	Droplet	Medical Grade	Gloves	Cloth Mask
Office Hysteroscopy	Droplet	Medical Grade	Gloves	Cloth Mask
Endometrial Biopsy	Droplet	Medical Grade	Gloves	Cloth Mask
Specimen Handling (Blood, Semen, Follicular Fluid)		Medical Grade	Gloves	N/A
Intrauterine Insemination	Droplet	Medical Grade	Gloves	Cloth Mask
Embryo Transfer	Droplet	Medical Grade	Gloves	Cloth Mask
Pre-Op Holding Area	Droplet	Medical Grade	Gloves	Cloth Mask
IV Line Insertion	Droplet	Medical Grade	Gloves	Cloth Mask
Oocyte Retrieval	Droplet	Medical Grade	Gloves	N/A
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>)

Revision: This table has been revised to remove the recommendation for the use of eye coverage for clinic-based activities with brief patient contact and low or potential risk of exposure to droplets or aerosolization, in the absence of airway manipulation, from a patient with asymptomatic infection.

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

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