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

Update #3 (April 24, 2020 through May 11, 2020)

Infertility is a serious disease that requires treatment in a timely manner. With the passage of time, an increasing number of patients whose care has been delayed are now in a situation that has become more urgent. Since the publication of Update No. 2 of the "American Society for Reproductive Medicine (ASRM) Patient Management and Clinical Recommendations During the Coronavirus (COVID-19) Pandemic" on April 13, 2020, the ASRM Coronavirus/COVID-19 Task Force ("the Task Force") has observed that:

- There have been 2.7 million confirmed cases worldwide so far, with more than 880,000 confirmed cases and more than 50,000 deaths in the U.S. alone.
- It has now become more apparent that there are regional differences in both case numbers and timing of the apex of disease incidence.
- While no community is unaffected, measures taken in many states and cities across the U.S. are leading to a decrease in the number of new cases per day. In some localities, we are seeing evidence of a "flattened" transmission curve. The predicted peak demands on the resources of local healthcare systems have been reached in some communities, while in others demand is rapidly increasing toward their apex.
- While not lessening concerns for the severity of the disease, these developments across the U.S. cautiously suggest that most patients falling ill with COVID-19 will be able to access the care that they need in the context of a healthcare system that is not overburdened.
- Over time, both the modes of disease transmission and the impact of mitigation strategies have become better understood. Effective strategies include the use of non-medical grade face masks in public, physical distancing, frequent handwashing, contact tracing, and the rapid response to testing and isolation in individuals who have been exposed to COVID-19 or who are under investigation for infection.
- Living and operating in a society where COVID-19 exists is becoming a reality for many. Data suggest that COVID-19 will remain a factor to be managed in our lives and practices for a prolonged period of time. The ultimate response to this pandemic may rely on the development of a vaccine that prevents COVID-19, or of effective treatments, or both. Until then, detailed contact tracing and ready access to SARS-CoV-2 testing will remain key components of an effective public health response. Such data will continue to guide quarantine and isolation procedures, and community mitigation strategies, at the local level.

The Task Force[1] reaffirms that fertility care is an essential health service. Nonetheless, the Task Force recognizes the need to minimize the spread of COVID-19 and preserve critically needed local healthcare resources to address the pandemic, while simultaneously acknowledging the essential timeliness and importance of access to fertility treatment.

In the early stages of the U.S. COVID-19 pandemic, the Task Force recommended implementing a moratorium on non-urgent care until the conditions on the ground, the ability of healthcare systems to deal with disease surge, and the transmission rates could be better defined and managed. As the pandemic has progressed in the U.S., the Task Force observes that there are clear regional differences in cases and healthcare system capacity, that some localities have reached their apparent apex of transmission, and that the disease will be with us for some time. Consequently, this update to the Task Force recommendations identifies the elements required or recommended to allow for a carefully considered and gradual resumption of patient care.

In considering when and how to provide reproductive care, the risk of viral transmission to patients, physicians, and staff, and the utilization of critically needed healthcare resources must be weighed against the time sensitive nature of infertility. This calculation includes understanding the worsening prognosis of treatments with the passage of time, and the threat of decreased access to care that occurs with further delays.

The Task Force notes that while the *approaches* to responsibly resuming care of patients do not vary across communities, the *resources and expertise* required to execute them may. This update also provides suggestions for general resources that practices may wish to utilize or reference. Practices with the necessary internal expertise and resources may choose to develop their own tools and resources to meet the needs outlined.

WHEN TO RESUME CARE

- National, regional, state, and municipal regulations produced by authoritative health organizations and agencies dictate what is and is not permitted within their jurisdiction based on their analysis of disease transmission and hospital capacity data.

- However, individual programs, physicians, and other healthcare providers need to be flexible and fully prepared to recognize and address the status of their local coronavirus transmission rate, medical conditions, and the impact that resuming operations would have on their community's risk and resources, even when clinical activities are permitted by law.

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[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, including Peter Klatsky, Lora Shahine, and Richard Scott.

- Before reproductive care practices can safely resume, several milestones should be considered, including a sustained reduction in cases in their area (e.g. for at least 14 days) and the ability of their local hospitals to safely treat all patients without resorting to crisis standards of care.

- Ultimately, as we consider offering services to our patients, local conditions and government regulations should ultimately guide what an individual practice, and physicians and other healthcare providers involved in reproductive care can and should offer their patients.

- Prior to resuming, practices must ensure that they are adequately prepared to provide patient care in a manner that limits risk to patients, staff, and physicians and other healthcare providers**.** This includes substantial self-education and staying up to date, as new information emerges, on the risk of disease transmission by symptomatic and asymptomatic individuals. Additionally, practices must ensure that they are prepared to perform a *formal risk assessment* of practice activities and the physical plant by the practice leadership team using publicly available resources or with the assistance of experts. Practices should create or adapt existing written risk mitigation policies and procedures that include having an adequate supply of necessary resources and training for all staff.

- Formal risk assessment includes identifying and categorizing the predictable risks associated with each procedure the clinic plans to offer (see section on Risk Assessment below).

- Consequently:
    - When:
        - education and staff training are achieved and certified,
        - a documented risk mitigation strategy is in place for the operation of the clinic as a whole, and
        - a documented risk mitigation plan is in place for each procedure.
    - Then:
        - the clinic may select the tests and or treatments to resume,
        - consider reinitiating a limited number of services when initially resuming care,
        - begin at a pace that allows new policies and procedures to be operationally observed to ensure that they are working as designed, and
        - monitor, reassess and modify clinic operations as community conditions change, knowledge of the disease increases, and additional resources to mitigate, test for, and combat the disease become available.

PREPARING TO RESUME CARE: RISK ASSESSMENT

Practices should perform a ***formal documented risk assessment*** to determine what activities, if any, are feasible at this time, accounting for local prevalence and trends, availability of Personal Protective Equipment (PPE) for all patients, staff, and physicians and other healthcare providers, and availability and type of selective testing, facility physical plant factors, and staff training (**Table 1**). It should be recognized that this will require an iterative cycle of surveillance and ongoing risk assessment. In simple terms, the elements of a COVID-19 Formal Risk Assessment could include:

- An assessment of who might be harmed and how.
- An evaluation of actions that are currently being taken to control the risks.
- A plan for further actions required to control the risks.
- A determination of who should carry out these actions.
- A timeline for the implementation of these actions.

The U.S. Occupational Safety and Health Administration (OHSA) and the CDC, among others, provide more detailed risk assessments (**Table 1**).
Considerations **FOR** offering evaluation and/or treatment:

- Delaying treatment may have permanent negative consequences to:
    - Treatment outcome
    - Mental health (e.g. patient's clinical depression, severe anxiety)
    - Access to care (e.g. loss of employment, loss of health insurance, and harm to practices leading to fewer services being available in a community)
- The ability to mitigate risk to patients and staff with carefully considered policies and procedures.

Considerations **AGAINST** offering evaluation and/or treatment:

- To avoid complications arising from assisted reproduction treatment (ART) and/or pregnancy (e.g. ovarian hyperstimulation syndrome, ectopic pregnancy, spontaneous abortion) that may further burden local healthcare facilities at a time when significant resources are required for the care of critically ill COVID-19 patients.
- The potential risk of exposure and transmission to patients, physicians and other healthcare providers and staff.
- A requirement for local reallocation of healthcare resources (e.g. PPE, nursing and anesthesia staff, ventilators, and testing).
- When delaying treatment will not significantly impact treatment outcome and time is required for cases of COVID-19 to decrease within a given community prior to initiating infertility care.

Practices and providers should familiarize themselves and their staff with resources produced by authoritative health organizations and agencies and with local or institutional guidance and regulations. It is important to check these resources regularly and frequently for updates and revisions on the full spectrum of topics necessary to care for patients in the era of COVID-19. Examples of such sources are listed in **Tables 1 and 2**.

PREPARING TO RESUME CARE: RISK MITIGATION

POLICIES AND PROCEDURES

A) Healthcare Staff

- Each practice should have written policies and procedures specific to the COVID-19 pandemic, including written documentation of risk mitigation procedures that must be acknowledged in writing and followed by every member of the staff, including physicians and other healthcare providers. OSHA and CDC recommendations are cited in resources listed in **Table 1**.
- Each practice should consider having policies and procedures to protect staff who are at higher risk for severe COVID-19 illness or live with a person who is at higher risk.
- Sick call policies should be in place for healthcare workers with symptoms or positive testing. Alternative and back-up scheduling may be useful to plan for potential staff absences due to COVID19.
- Authoritative health organizations and agencies have published procedures to return to the workplace after known or suspected infection. Providers should consider incorporating recommendations from these authoritative bodies in their own policies and procedures.
- Programs that are within larger institutions should follow and be in compliance with their institution's policies and procedures.

B) Patient Care

- Each practice should consider creating and providing educational materials for their patients regarding COVID-19 risk mitigation strategies as they apply to patient care (**Table 1**).

- It is important to provide information to patients regarding the potential risks of pursuing care during the COVID-19 pandemic. Elements may include:
    - Unknown impact of pregnancy on susceptibility to or severity of COVID-19.
    - Unknown impact of COVID-19 on pregnancy including maternal and fetal risks. Some warnings should be given related to general risk of febrile illness and experience with other viral infections.
    - Disclosure regarding limited access to or unknowns regarding COVID-19 testing.
    - Potential for treatment cancellation due to exposure, infection, unavailability of PPE, or changes in regulations. Statement of treatment cancellation should include some mention of financial consequences of cancellation.
    - Risk of exposure at clinic during treatment.
    - Option to postpone treatment.
    - Opportunity to have questions answered.
- Physicians are advised to document COVID-19 patient counseling and assent in the medical record.
- It is important to recognize that patients may interpret a physician's willingness to treat as an indication that their risk is minimal, and this may well not be the case. The issue of risk/benefit should be highlighted as a starting point for all patients treated in this environment.
- Anyone, patients or staff, who are considered to be infectious should not enter the clinic until they meet criteria for ending isolation after known or suspected infection.
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PHYSICAL DISTANCING, SANITIZING SURFACES, AND FREQUENT HANDWASHING

Studies of the COVID-19 show different durations of viral activity on a variety of materials under laboratory conditions. How this translates into actual infectious risk in the real world is unknown. Practices should:

- Screen patients and every member of the staff daily, including physicians and other healthcare providers, who enter the facility. This may include such elements as questioning regarding possible risk of exposure and/or the presence of signs and symptoms of COVID-19, and checking body temperature, before the individual enters the facility.
- Maintain physical distancing between individuals as recommended by the US CDC.
- Develop a face mask policy for patients and staff. CDC recommends wearing a face mask when in public spaces as a protective measure against asymptomatic viral transmission.
- Establish a frequency protocol and specific procedure for cleaning/decontaminating all surfaces touched by patients and staff during the ordinary course of operations.
- Consider posting public notices or signs for patients and staff, regarding avoiding touching one's face, mouth and eyes.
- Require frequent hand washing with soap and water for 20 seconds (or cleansing with a sanitizing gel) as a critical component of COVID-19 risk mitigation.

TESTING AND DOCUMENTING IMMUNITY

The landscape for testing for the novel coronavirus causing COVID-19 (i.e. SARS-CoV-2) for presence of the virus (e.g. by PCR) is evolving rapidly. Broad use of testing will allow for the early identification of infected individuals and is an important tool for minimizing viral transmission to patients and staff. For example, testing is currently recommended for all patients undergoing scheduled surgery who have the potential for intubation. However, as rapid testing is not yet widely available, the role of testing all patients and staff for viral presence in the provision of other forms of reproductive care is currently undefined. Nevertheless, as testing becomes more reliable and accessible, providers should develop and incorporate a testing strategy for patients and staff. Continuing consultation with authoritative sources, including the U.S. FDA, is strongly suggested. We also note that:

- The interpretation of SARS-CoV-2 tests is not straightforward. Up-to-date information on diagnostic testing is maintained and available on the FDA website.

- The sale of fraudulent COVID-19 test products is real and remains a threat to the public health. Practices can help mitigate this issue by reporting suspected fraud to the FDA.

Physicians and other healthcare providers should be aware of the limitations of serological tests to detect antibodies to SARS-CoV-2. The FDA warns against the use serological (antibody) tests as the sole basis to diagnose COVID-19, recommending that they be used primarily to provide information regarding whether a person may have been exposed.

If testing is not readily available or routinely used, practices should implement evidence-based infection prevention techniques including access control, workflow and distancing processes, and distribution of PPE appropriate for the clinical tasks to the clinical team, to create a safe environment in which fertility care can occur.

USING STANDARD OR UNIVERSAL VS. ENHANCED OR EXPANDED PRECAUTIONS IN REPRODUCTIVE MEDICINE

Universal or Standard precautions is an approach to the prevention of transmission of blood and human body fluid-borne pathogens. During the COVID-19 pandemic, Enhanced or Expanded precautions (transmission-based precautions) are recommended to provide additional protection to interrupt transmission by aerosolization or droplets, or contact with contaminated surfaces. Reproductive medicine practices typically offer both diagnostic and therapeutic procedures, each of which is associated with varying levels of invasiveness and disease transmission risk (see **Table 3**). Practices should evaluate the risks associated with each activity and procedure and determine whether their facility has the appropriate PPE, staffing level and staff training to safely proceed.

AVAILABILITY OF PPE AND OTHER RESOURCES

The demands of the COVID-19 pandemic on local healthcare systems vary in timing and magnitude by locality. As the transmission and disease rate peaks in a locality and the local incidence begins to decline, the strain on the healthcare system will ease, and PPE and other necessary resources will become more readily available.

Staff must be trained in the proper use of PPE, including proper donning and removing techniques. Providers should post reminder "how to" signs in areas where staff don and remove PPE.

- Providers must maintain sufficient PPE, potentially utilizing CDC recommended methods for preserving PPE, and other necessary supplies to ensure the safety of patients and staff.
- The type of PPE necessary for specific activities within the clinic setting will vary (**Table 3**).
- Providers must maintain adequate minimal staffing levels to meet the scope of services they offer.

Patients should wear cloth or surgical grade masks at all times when in the clinic, except when under anesthesia.

PRACTICE PATTERN CONSIDERATIONS

Altering practice patterns can help reduce disease transmission risk by minimizing the number of in-person interactions. Some approaches to do this may include:

- Having some staff members work remotely from home full or part-time where feasible.
- Continuing to use telehealth to the greatest extent possible to minimize number of patients in the office at one time.
- Minimizing the number of in-cycle monitoring visits to the fewest necessary, as determined by medical feasibility.
- Counseling and consenting patients electronically.

- Spreading out necessary appointments to limit the number of patients in the office at one time.

RESUMING CARE

With appropriate risk assessment, risk mitigation, consideration of resource availability, and thorough counseling, it is possible to resume providing reproductive services in an environment where COVID-19 exists. Newly established protocols, procedures, and systems to provide care in this environment should be monitored to ensure that they are functioning as intended as services resume and volume increases. Attention should be given to controlling the number of in-vitro fertilization (IVF) cycles to ensure that the capacity of the IVF laboratory is not exceeded.

It may not be possible to offer all patients access to care immediately upon resumption. The final decision on how to prioritize patient care is best handled at the local level, in consultation with patients, as physicians and other reproductive healthcare providers carefully assess local and regional conditions. Some considerations could include:

- The impact of delay on patient prognosis due to medical factors, such as age, ovarian reserve or endometriosis.
- The number of patient visits required (e.g. treatments that are associated with the fewest visits may be prioritized first).
- The impact of treatment delay on the mental and emotional well-being of patients.
- The impact of delay on patient ability to pursue or access treatment due to insurance coverage or employment status.

As practices begin to resume services, they should consider adapting or adopting strategies that can be found on the SART.org website: COVID-19 resources for professionals and providers.

Due to the impact of treatment delay, as well as the 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.

As conditions remain fluid, practices should strive to monitor, reassess and modify clinic operations as community conditions change, knowledge of the disease increases, and additional resources to mitigate, test for, and combat the disease become available.

We hope that the threat from the virus continues to fade and that all our patients will be able to receive the treatments they need without delay. However, it should be noted that progress in disease mitigation and containment with an eye toward effective medical treatment and vaccine prevention is by no means guaranteed. As such, conditions must be monitored closely as changes to implementation and expectations may be required.

Table 1. Risk assessment and mitigation, practice consideration, and professional training & education resources	
What	Link
Risk Assessment	CDC Guidance for Healthcare Personnel with potential exposure to patients with COVID-19 Managing risks and risk assessment at work (includes downloadable Risk Assessment Template) People at Higher Risk of Severe Illness OSHA Hazard Recognition OSHA Guidance on Preparing Workplaces for COVID-19 College of Reproductive Biology (CRB) guidance
Risk Mitigation	Strategies to Mitigate Healthcare Personnel Staffing Shortages Social Distancing, Quarantine and Isolation Hand Washing Use of Face Masks How to protect yourself and others (Poster) Putting on and Removing PPE (Poster) How our facility is keeping patients safe from COVID-19 (CDC poster referencing outpatient dialysis but applicable content) Cleaning and Disinfecting Your Facility Evaluating and Testing Persons for COVID-19 Strategies to Optimize the Supply of PPE and Equipment Guide to Infection Prevention for Outpatient settings: Minimum expectation for safe care Universal and Transmission Based (enhanced or expanded) precautions FAQs on Diagnostic Testing for SARS-CoV-2 Report Suspected Fraudulent COVID-19 products The Use of Personal Protective Equipment by Anesthesia Professionals during the COVID-19 Pandemic

	Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission How to protect yourself and others (CDC patient education) ASRM COVID-19 Resources for Patients
Practice Consideration	SART.org COVID-19 Resources for Professionals and Providers Online Patient Screening Questionnaire (developed by Apple and the CDC) The Human Diagnosis Project COVID-19 self-assessment tool Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19 Surgical Mask and Gown Conservation Strategies Embryology Laboratory Suggestions for COVID-19 Transmission based precautions Ambulatory Care Clinical Tool Kit
Healthcare Professional Training & Education	CDC Healthcare Professional Training Site Managing Stress and Anxiety Guidance for the Selection and Use of PPE in the Healthcare Setting

Table 2. Links to authoritative health organizations and agencies regarding COVID-19		
Organization	**Website**	**Content**
World Health Organization	www.who.int	Advice for the public Advice for health workers Country and Technical Guidance Situation updates Research and development
US Centers for Disease Control and Prevention	www.cdc.gov	Advice for the public Advice for health workers Situation updates Research and development
US State and Territory Health Departments	www.cdc.gov/publichealthgateway/healthdirectories/healthdepartments.html	Link to health departments in all 50 states, 8 US territories and freely associated states, and the District of Columbia.
Massachusetts Medical Society	http://www.massmed.org/About/State-Medical-Societies-in-the-U-S-/#.XpyulS3MxBw	Links to the 50 State Medical Societies in the US
Johns Hopkins University & Medicine	https://coronavirus.jhu.edu/map.html	COVID-19 Dashboard
Institute for Health Metrics and Evaluation	http://www.healthdata.org	COVID-19 Projections

Table 3. Risk assessment and mitigation for 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	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	Face Shield, Gloves	Cloth Mask
Ultrasound	Droplet	Medical Grade	Gloves	Cloth Mask
Saline Infusion Sonogram	Droplet, Splash	Medical Grade	Face Shield, Gloves	Cloth Mask
Hysterosalpingogram	Droplet, Splash	Medical Grade	Face Shield, Gloves	Cloth Mask
Office Hysteroscopy	Droplet, Splash	Medical Grade	Face Shield, Gloves	Cloth Mask
Endometrial Biopsy	Droplet, Splash	Medical Grade	Face Shield, Gloves	Cloth Mask
Specimen Handling (Blood, Semen, Follicular Fluid)	Splash	Medical Grade	Face Shield, Gloves	N/A
Lab Procedures (ICSI, biopsy, specimen prep, etc.)	Droplet, Splash	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, Splash, Needle Stick	Medical Grade	Face Shield, Gloves	Cloth Mask
Airway Management	Droplet, Aerosolization	N95 or Equivalent	Face Shield, Gloves	N/A
Oocyte Retrieval	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves	N/A
Operative Hysteroscopy	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves, Gown	N/A
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	Face Shield, 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)