COVID- 19 Protocol for Patients Update 06-14-2020

Dear Patients,

Due to the unprecedented nature of the current Coronavirus epidemic, our facility will abide by recommendations from the Maryland state Department of Health, the Centers for Disease Control, as well as the American Society of Reproductive Medicine.
Due to the current coronavirus pandemic all elective procedures had been previously halted as per the instruction of the Governor of the State of Maryland. Furthermore, the American Society of Reproductive Medicine recommends that fertility services do not resume practices until such a time as there is a sustained decrease in the number of new cases in the local state of the practice.
Due to the recent amendment by the Governor of Maryland some elective procedures may resume. We will proceed with mostly Telemedicine consultations.

The following will be the protocols that will be followed.

- Direct patient contact in the office will be strictly limited.
- All new patients must have been initial consultation by Telemedicine. Co-pays will be collected prior to the office visit.
- To address asymptomatic and pre-symptomatic transmission, we have implemented source control for everyone entering of our facility (e.g., healthcare personnel, patients, visitors), regardless of symptoms. **Everyone MUST wear a face mask that fully covers their nose and mouth.**
- **You WILL NOT BE ADMITTED WITH A BANDANA OR IF YOU HAVE NO MASK.**
- **IF we provide you with a mask you will be charged $25. Please note this is not to make money on our part but to prevent our facility from running out of masks for staff.**
- You will be asked screening questions before you are allowed in.
- There will be no waiting in the facility. When you arrive please call to let us know you are here. You will be told to WAIT in your car till you are called up.
- For patients undergoing procedures, their partner or other support person will be asked to wait in their cars.
- We ask that you check your temperature **before** entering the clinic. If your temperature exceeds 99.5 F, please DO NOT COME.
- Upon entering, **your temperature will be checked, and you must wash your hands**.
- After all examinations and ultrasounds, you will be asked to wash your hands again after you dress up.

- We are requiring that all patient be tested for COVID -19 before being starting fertility treatment. Patients that are positive will be asked to self-quarantine themselves and follow the instructions of their physician till such a time as they are deemed negative. For patients that start treatment repeat testing will be required every 2 weeks.
- There will be no visitors or support persons allowed in with patients. That means if interpretation services are needed this will be conducted via Telemedicine.
- Partners will not be allowed in the office.
- Semen analysis samples will no longer be collected in the office. Instead patients will be given a collection container as well as identification forms to fill. The forms must be completed before the appointment and faxed back to the office along with a copy of their driver's license for identification purposes. Please call the office before specimen drop-off by appointment only.
- Office visits will be reserved for only examinations as needed such as monitoring visits and or ultrasounds. The results of such evaluations WILL NOT be discussed during that visit but instead a follow-up Telemedicine visits will be scheduled to discuss this.
- Patients may be instructed to have their blood drawn at LabCorp or Quest prior to coming for monitoring visits.
- Follow-up consultation after the initial consult and evaluation will be done by Telemedicine.
- Medication teaching will be done via Telemedicine.

Due to the unprecedented nature of this pandemic we have instituted **very rigorous protocols for enhanced safety** of staff and patients. These protocols mostly compliment the exacting standards that we have always used.

1. All high touch surfaces are cleaned constantly throughout the day. This includes doorknobs, light switches, tabletops, phones, chairs, computer keyboards and mouse.
2. All BP cuffs, cables, iv poles, contact-less thermometers, pens are sanitized after each use.
3. All rooms undergo deep cleaning after each patient.
4. Hand sanitizers are located throughout the facility.
5. Hand washing stations are readily available outside exam rooms and throughout the facility.
6. High use corridor carpets and flooring are sprayed with hospital-grade disinfectant after patient visits and every 2 hours
7. We already had a high-grade air purifier in the Embryology lab, but we acquired an additional unit to be placed in patient care area.
    a. **The IQAir GC MultiGas Air Purifier Medical Grade.** The GC MultiGas combines HyperHEPA particle filtration with powerful gas and odor filtration. The IQAir GCMultiGas features HyperHEPA filtration technology for superior airborne particle removal. IQAir's HyperHEPA filtration is tested and certified by an independent third-party lab to effectively filter ≥ 99% of harmful ultrafine pollution particles down to ≥ 0.3 microns. This is 100 times smaller than what is achieved with ordinary air filtration technology and 10 times smaller than a virus. The GC MultiGas packs the chemical removal power of more than 100 gas masks, featuring 12 lbs. (5.4 kg.)

of premium activated carbon from high-quality bituminous coal provides the maximum number of micropores. Alumina pellets impregnated with potassium permanganate remove formaldehyde from the air, and post filters wrap each cylinder to further filter the air.

- **We understand that this are incredibly stressful times. If you need help with coping you may call Neuroscientific insights 3202 Tower Oaks Blvd Ste 100, Rockville, MD 20852 Phone: (301) 468-1001 Dr. Amita Jha (adult Psychiatry) and Dr. Naveena Hemanth (Child, Adolescent Psychiatry)**
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The following is excerpted from the CDC. Additional information including SSL videos can be found at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html

We do not currently know if pregnant people have a greater chance of getting sick from COVID-19 than the general public nor whether they are more likely to have serious illness as a result. Based on available information, **pregnant people seem to have the same risk as adults who are not pregnant**.

However, we do know that

- Pregnant people have changes in their bodies that may increase their risk of some infections.
- Pregnant people have had a higher risk of severe illness when infected with viruses from the same family as COVID-19 and other viral respiratory infections, such as influenza.

Pregnant people should protect themselves from COVID-19

- Avoid people who are sick or who have been exposed to the virus.
- Clean your hands often using soap and water or alcohol-based hand sanitizer.
- Clean and disinfect frequently touched surfaces daily.

Risks to the pregnancy and to the baby

- Pregnant people have had a higher risk of severe illness when infected with viruses from the same family as COVID-19 and other viral respiratory infections, such as influenza.
- It is always important for pregnant people to protect themselves from illnesses.

Mother-to-child transmission

- Mother-to-child **transmission of coronavirus during pregnancy is unlikely, but after birth a newborn is susceptible to person-to-person spread.**

- A very small number of babies have tested positive for the virus shortly after birth. However, it is unknown if these babies got the virus before or after birth.
- The virus has not been detected in amniotic fluid, breastmilk, or other maternal samples.

Breastfeeding if you have COVID-19

- **Breast milk provides protection against many illnesses** and is the best source of nutrition for most infants.
- You, along with your family and healthcare providers, should decide whether and how to start or continue breastfeeding
- **In limited studies, COVID-19 has not been detected in breast milk**; however we do not know for sure whether mothers with COVID-19 can spread the virus via breast milk.
- If you are sick and choose to **direct breastfeed**:
    - Wear a facemask and wash your hands before each feeding.
- If you are sick and choose to **express breast milk**:
    - Express breast milk to establish and maintain milk supply.
    - A dedicated breast pump should be provided.
    - Wash hands before touching any pump or bottle parts and before expressing breast milk.
    - Follow recommendations for proper pump cleaning (Español) after each use, cleaning all parts that come into contact with breast milk.
    - If possible, consider having someone who is well feed the expressed breast milk to the infant.

The following is excerpted from the American Society of Reproductive

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

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

The world has been suffering a pandemic of a proportion not previously experienced in this century, with higher infectivity and mortality than previous epidemics. While acknowledging that infertility is a serious disease that requires treatment in a timely manner, in its recommendations of March 17, 2020 and in the subsequent Updates, No. 1 and No. 2, the ASRM Coronavirus/COVID19 Task Force (the "Task Force") recognized the need to delay any but the most urgent of reproductive care cases. This was necessary as the extent of the COVID-19 pandemic, its viral transmission rate, its impact on reproductive well-being and pregnancy, and the ability of health systems to cope were yet unknown, at least in the U.S.

Over the past several months, significant knowledge has been gained regarding the virus and its impact on patients and the medical system. However, the associated delay in care resulted in an increasing number of patients whose situation had become more urgent. In Update No. 3 (American Society for Reproductive Medicine (ASRM) Patient Management and Clinical Recommendations during the Coronavirus (COVID-19) Pandemic - Update No. 3, April 24,

2020) the Task Force issued recommendations for gradually and judiciously resuming the delivery of reproductive care, which were elaborated upon further in Update No. 4.

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

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

• To date, there have been almost 6.5 million confirmed cases and over 380,000 deaths due to COVID-19 worldwide, the disease produced by the virus SARS-CoV-2, with more than 1.9 million confirmed cases and 110,500 deaths in the United States (U.S.) alone.

• While no community is unaffected, the prevalence of the disease varies widely throughout the U.S. (1).

• COVID-19 disproportionally impacts racial and ethnic minorities. Data from 580 patients hospitalized with lab-confirmed COVID-19 found that 45% of individuals for whom race or ethnicity data were available were white, compared to 59% of individuals who were white in the surrounding community; however, 33% of hospitalized patients were black, compared to 18% in the community, and 8% were Hispanic, compared to 14% in the community (2). A recent (as yet not peer-reviewed) study conducted a cross-sectional analysis using publicly reported COVID-19 mortality data from 28 states and New York City and estimated age-adjusted disparities; the study showed that black people are more than 3.5 times and Latino people nearly 2.0 times as likely to die of the virus as are white people (3).

• No vaccine yet exists to prevent infection with COVID-19 and, at this time, few medications have shown benefit in decreasing morbidity and mortality.

• Infertility patients should be counseled regarding the risks and benefits of initiating fertility treatment during this pandemic. This counseling should convey that those with certain medical conditions (e.g. hypertension, diabetes, obesity) may face an increased risk of complications if they become infected.

Third-party reproduction

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

Fertility services for health care workers

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

Having partners present when providing care

ASRM recognizes the psychological and emotional benefits of having partners present during fertility procedures and supports the involvement and inclusion of all partners during fertility treatment and family building planning,

whenever possible. However, during the COVID-19 pandemic, safety considerations necessitate limiting the number of people in the clinical suite. Ideally, only the person undergoing the procedure should be present, taking into consideration hospital or practice guidelines regarding the number of allowed persons. Patients should also be encouraged to use alternative methods for partner participation when not able to be physically present, such as use of phone or video. **Travel restrictions**

One of the main strategies to mitigate transmission of the SARS-Cov-2 virus is physical distancing. Given that a vaccine is not yet available, and no curative treatment exists, avoidance of infection remains the most effective way to circumvent the potential risks of COVID-19 in women who are or will become pregnant. While local and state officials across the United States are beginning to loosen restrictions on social movement, public gatherings and business closures, the prevalence of COVID-19 and the incidence of new cases waxes and wanes in different localities. Additionally, the risks of infection are not equal for all those in the community. Specifically, the effects of COVID19 on pregnant women and pregnancy is not yet fully understood.

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

Resumption of reproductive surgery

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

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

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

If a patient scheduled for a non-urgent procedure is exposed to someone with confirmed COVID19, the patient should be tested, quarantined for 14 days, and the procedure rescheduled for a date later than the 14 days of

quarantine. If the viral test is positive during the preoperative assessment, the patient should be quarantined for 14 days and the procedure rescheduled.

Surgical staff should follow the recommendations for PPE use outlined in the Task Force's update #4 and in table below. The recommendation for PPE use by patients has been modified in the table below. Page 4 of 6 With all cases, high-touch surfaces, including the ultrasound and anesthesia machines, should be sanitized with a U.S. Environmental Protection Agency (EPA)-approved hospital disinfectant after the procedure is complete.

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

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

• **Aerosol generating procedures (AGPs):** While there is no expert consensus of what are considered aerosol generating procedures (AGPs), for most reproductive centers these entail the use of nebulizer treatments, intubation, laryngeal mask placement, and open suctioning of airways (8,9). It is important to discuss the risk of aerosolization, whether intended or not, with the anesthesiologist before every case. The possibility of conversion to general anesthesia (due to obesity, GERD, prior difficult airway control, etc.), and hence an increased risk for aerosolization, should also be discussed. The Task Force recommends that testing be performed within 72 hours of a potential AGP, if testing is available and results can be obtained within that time frame.
If during a procedure an AGP must be urgently performed (e.g. immediate intubation), the surgical team, other than the anesthesiologist and a tech or circulating nurse, should consider exiting the room immediately. Staff should wait sufficient time to allow one or more complete room air exchanges before re-entering the room without enhanced PPE. Alternatively, the staff can don appropriate fully enhanced PPE, including an N95 mask or a powered air purifying respirator (PAPR), face shield or goggles, gowns, and gloves. These precautions should be taken regardless of whether the patient tested negative preoperatively, is asymptomatic, or was not tested at all.

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

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

• **Urgent surgical procedures**: If a surgical procedure is urgently needed, such as a surgery for an ectopic, the procedure can proceed, but with staff using full enhanced respiratory PPE. Page 5 of 6 Update to

recommendations for PPE use in the reproductive care setting The Task Force continues to update the recommendations for PPE use in the reproductive care setting.