

Joint IFS-ISAR-ACE Recommendations on Resuming/Opening up Assisted Reproductive Technology Services

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ABSTRACT

COVID-19 – A Global challenge on a scale not previously seen. Reproductive care is essential for the well-being of society and therefore the treatment needs to be completely re-thought and individualised. Infectivity and mortality rates are higher than previous pandemics and the disease is present in almost every country. Propagation and containment have varied widely by location and, at present, the timeline to complete resolution is unknown. With successful mitigation strategies in some areas and emergence of additional data, the societies have sanctioned gradual and judicious resumption of delivery of full reproductive care. When we resume, monitor local conditions, including prevalence of disease, status of government or state regulations, and availability of resource. It is important to implement proactive risk assessment within their practices prior to restarting services. One needs to develop clear and modified plans to ensure the ability to provide care while maximizing the safety of their patients and staff. One should also remain informed and stay current regarding new medical findings. These recommendations provide resources for restarting ART practice again.

KEYWORDS: *Assisted reproductive technology, COVID-19, precautions, resumption*

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INTRODUCTION

The novel coronavirus pandemic globally has created an unprecedented situation with major challenges that will continue as we understand the pattern of this disease. Besides effects on the health systems, the illness has made a major impact on the economic and social framework of our societies. In keeping with the lockdown since March 23, 2020, imposed by the Government of India, wherein only emergency services were permitted, all assisted conception units across the country stopped work. However, as the situation unfolds, the government at the center relaxes the lockdown permitting nonessential services in a gradual manner; it is time to consider reassuming infertility services in keeping with the guidelines set by the Ministry of Health and Family Welfare. This document is drafted to provide centers across the country a guidance as to how should they restart the services. The recommendations, however, are to be practiced in keeping with the prevailing regulations set up by the health services of their state. These are based on the understanding of the COVID-19 disease as of today and shall change with evolving scientific, political, and economic situations.

FUNDAMENTAL PRINCIPLE

The fundamental principle guiding all units is to implement all the measures to protect their patients and staff on priority and minimize the chance of spread of COVID-19. Units providing infertility services should be willing and prepared to modify their services in terms of available framework and human resource to meet the demanding situation. This shall involve triage of patients while commencing and continuing the treatment cycle, besides regular triage of the staff. Further, all units should have their standard operating procedure (SOP) in place and a code of conduct, for both the patients and staff. The key areas that need guidance include:

Units to reassume

All units can restart (stand-alone unit, chain of fertility units, corporate set up units, or ones in institutions) their services provided they take into consideration:

- a. Willing to start services in a phased manner beginning with diagnostic services, controlled ovarian hyperstimulation, and timed intercourse intra-uterine insemination (TI/IUI), and subsequently with *in vitro* fertilization (IVF) over 2–3 weeks
- b. Sufficient clinical staff, in-house embryologists, and nurses that can work in shifts and a back-up team in case any need quarantining if suspected or tested COVID positive

- c. Sufficient facilities for separate cryostorage of gametes and embryos from cycles undertaken during this period
- d. Have clear policy on the number of cycles/patients the clinic can handle and not violate the government's policy that demand adequate interval between attending patients and have means to implement the same^[1]
- e. Unit that has adequate supply of personal-protective equipment (PPE) for staff, drugs and media and consumables for committed patients
- f. Fair and scientific approach on making their policies on education and training of staff
- g. Willing to triage patients and undertake only patients tested negative for COVID-19
- h. Have a close liaison with another clinic so that they can transfer patients in times of unintended critical situation so that the clinic can undertake trouble shooting to reopen at the earliest
- i. Have a written code of conduct for patients and staff that explains need of physical distancing, and maintaining etiquettes that mitigate the disease in the clinic
- j. All patients to have the Arogya Setu app downloaded on their mobile phones before start of the treatment.

Diagnostic services

These can be resumed as part of the initial phase of re-opening.^[2] Only start with couples that are triage negative.

- a. Semen analysis
 - i. Ensure husband is negative for COVID with reverse transcription polymerase chain reaction (RT-PCR) (preferable)
 - ii. This may be done taking precautions with adequate PPE, as preliminary data suggests the presence of virus in semen, with 15.8% men confirming positive for severe acute respiratory syndrome (SARS)-COV-2 in semen collected from men with positive RT-PCR on nasopharyngeal swabs.^[3]
- b. Hormone assays
- c. Saline sonography
- d. HSG – Mostly done at radiology suites. However, in institutions to be done with all precautions and adequate PPE
- e. Office hysteroscopy.
 - i. Office diagnostic hysteroscopy may be done with local para or intracervical block (2).^[4] Total intravenous anesthesia may be another choice
 - ii. For hysteroscopic resection of intracavitary lesion regional anesthesia to be preferred, safeguarding the risks to anesthetist from GA.

- f. Laparoscopy
Elective laparoscopic procedure should be based on the principle of prioritization based on the urgency of fertility treatment. However, emergency laparoscopies for ectopic pregnancy and adnexal torsion should be performed in view of the underlying urgency. During laparoscopy aerosolization can take place during anesthesia and pneumoperitoneum. The anesthetist should use a box, video-laryngoscope and a triple filter for safety purposes (if available). Regional anesthesia may be preferred for the safety of anesthetist if unsure of COVID status in the emergency situation.^[5] The pneumoperitoneum and the smoke generated during laparoscopic surgery should be evacuated using filter at suction and outflow trocars going through specially designed smoke evacuators and ultra-low-pressure apparatus.^[6] Both ultrasonic and electrosurgical devices have the propensity to create large surgical plumes thus potentially increasing the risks of viral transmission.^[7] Ultrasonic devices are high-frequency oscillating devices which may hypothetically add to the potential risk although the magnitude of any such risks are unknown.^[8] Bipolar energy sources are to be preferred to ultrasonic devices.

Consent including information and discussion on diagnostic and treatment services

A thorough counseling should be done about all issues related to treatment including:^[1]

- a. The potential risks involved in proceeding with fertility testing and treatment during the COVID-19 pandemic
- b. That the decision of couple to proceed or postpone the treatment cycle is entirely theirs and they are in agreement of the same^[9]
- c. The clinic shall have a policy on selecting and prioritizing patients which they shall agree to
- d. The clinic shall follow all measures as per the Government's guidance on COVID^[10]
- e. The couple should be informed on the need of triage and screening for COVID-19 infection, through the approved testing method (as per the local health policy of that area/region) at the commencement and during the treatment cycle. The clinic shall have a policy in place to cancel cycle in case the patient or her husband/partner turns positive, on testing at any point during the treatment cycle^[1,9]
- f. Inform patients that available tests have limited sensitivity and specificity and in eventuality of false negative or positive, cancellation will be done in keeping with safety of patient and staff, at any time during cycle. The clinic shall provide all possible medical guidance in such situation^[1,9]
- g. The additional costs involved in testing shall be borne by the patient
- h. That information on the effects of COVID-19 infection on fertility treatment and early pregnancy are limited. However, there is no evidence that infection increases risk of fetal malformations or miscarriage at present^[1,2,9,11]
- i. In case the staff at the hospital tests positive for COVID-19, during treatment cycle, patient will be shifted to another unit for completing the cycle.

See website of IFS/ISAR/ACE for consent forms at www.isarindia.net/www.indianfertilitysociety.org

Patient selection and prioritization for fertility services

- a. High risk patients (those with hypertension, diabetes, on immunosuppressants or transplant patients, with renal, liver, lung disease, or medical conditions) should be unfit for treatment during this period^[1,9,11,12]
- b. All patients should be offered a choice to proceed with or postpone their assisted reproductive technology (ART) treatment. In both cases, patient preference should be clearly documented^[1,9,11,12]
- c. Third party reproduction, including donor and surrogate cycles, may be avoided for now
- d. ART cycles for fertility preservation in cancer survivors to be started at the earliest
- e. Low-risk cases that would require the minimum visits to the clinic to be taken
- f. Patient prioritization to be based on:^[1,9]
 - i. The impact of delay on the patient prognosis due to medical factors, such as age, ovarian reserve, or endometriosis
 - ii. The impact of treatment delay on the mental and emotional well-being of patients.^[9]

Triaging screening and testing of patients

Triaging and screening should be done for all patients with a questionnaire and followed by testing as suggested^[9,11,12] (attached in appendix). The patient and husband, both have to agree to the following strategies which include:

- a. Detailed history of travel, symptoms, and contact history
- b. Temperature recording and SpO₂ (preferable) for screening
- c. Testing
 - i. Diagnostic evaluation will be done using RT-PCR, or depending on the regional/local protocol as well as availability of the test^[1,9]
 - ii. Use of ELISA antibody testing for triage may not be reliable at this time.^[1,9]
- d. Testing shall be done at the commencement of treatment that is day 2 of IVF/ICSI cycle.^[11] Those with a positive test will not be allowed to initiate cycle

- e. Repeat test to be done at-least 48 h before human chorionic gonadotropin (hCG) trigger (some laboratories may take 24–48 h to report RT-PCR). Cycle will be cancelled in case the test is positive^[11]
- f. The husband also needs testing, at least once during the cycle, preferably at the start of cycle
- g. In case either partner turns positive on tests, they should help contact tracing in keeping with the national policy.^[9,11]

Triaging screening and testing of staff

- a. All staff at the clinic will undergo triaging and screening as for patients (questionnaire and daily temperature/pulse oximetry checks)^[1,9,12]
- b. Those suspected to have symptoms will be subjected to RT-PCR test (as per ICMR guidelines of 18.05.2020) and should be asked to quarantine^[1]
- c. In case any staff turns positive on tests, he/she will cooperate for contact tracing.^[1,11] In case any staff member found positive for COVID-19, only those in direct contact (face to face with less than a meter/ having unprotected direct contact with infectious secretions or excretions of the person with confirmed COVID-19) shall be quarantined.^[1]

Rearrangements/modifications of the assisted reproductive technology services

- a. Infrastructure
 - i. Triaging of patients and staff should be outside the reception area
 - ii. Reception, patient waiting area, scan rooms should be rearranged, so as to maintain physical distancing. May need to do away with extrafurniture to provide adequate space for physical distancing^[1,11]
 - iii. Physical distancing (at least 2 m/6 ft) to be maintained between individuals including staff and patients^[1,11]
 - iv. Sanitization should be performed routinely as per the local protocols^[1,12]
 - v. Sanitization of the ultrasound probe, ultrasound couch, blood collection, and semen collection area should be done after each patient. Similarly, outpatient's area should be sanitized on frequent basis^[1,12]
 - vi. In case there is a COVID-positive individual (staff/patient/husband) at the clinic, then complete sanitization to be done after informing the local authority. Closure of the facility will be required as per the regional guidelines for 24–48 h. In such an eventuality, the clinic will have to shift patients with ongoing cycles to a back-up facility with a close liaison as informed to patients before the start. This has to be consented from every patient before the start of the cycle.^[1]

- b. Patient management
 - i. Limit the number of individuals present at the facility at a given time^[1,9,12]
 - ii. Patient have to be scheduled for visits (consultations, consenting, scans, blood tests, procedures, and semen collection) keeping in mind sufficient interval in-between two patients^[1,9,12]
 - iii. To restrict the appointments on individual basis. Husbands to come on the day a of consenting and IUI/ovum pick-up (OPU)/semen analysis/freezing and when required. This is to ensure the safety of staff and patients^[12]
 - iv. All patients including husbands to wear masks at all times. Follow hand hygiene and follow all rules to prevent disease spread as per the guidelines from the Ministry of Health and Family Welfare.^[1,9,12]
- c. Staff management.
 - i. Staff roster to be planned in a manner with minimal working at a time. To work in shifts considering longer hours to maintain physical distancing. Concept of “Mini-teams” or “Back-up teams” to be kept in mind for doctors, embryologists, nursing staff to avoid unnecessary exposure and preparedness for trouble shooting, respectively^[1,9,11]
 - ii. All individuals including staff to wear masks at all times. Follow hand hygiene and follow all rules to prevent disease spread as per the guidelines from the Ministry of Health and Family Welfare^[1,9]
 - iii. Also maintain physical distancing for staff discussion. To keep discussion meetings over zoom or similar virtual platforms^[1,11]
 - iv. Staff to avoid meals/tea breaks together.

Treatment cycle (intra-uterine insemination and *in vitro*-fertilization)

Pre *in-vitro* fertilization/intrauterine insemination

- a. Only those with triage negative and confirmed negative tests for COVID to commence IUI or IVF cycle. Ideal to have tests by day 2 of cycle
- b. All discussions and planning to be completed 2 weeks in advance (ideally over teleconsultations) and consents and agreements to be done on the day of starting
- c. Couples to be advised social isolation for 2 weeks before reduce risks of infections
- d. Stimulation protocols planned in a manner that involves minimal visits for scans and blood samples^[11,12]
 - i. Consider utilizing fixed antagonist protocol for IVF cycles, where antagonist is started on day 7 of cycle rather than follicle size criteria, to reduce visits for ultrasound monitoring^[1,9,11]

- ii. Stimulation for IUI cycles with lower doses of gonadotropins, monitoring as minimal as required based on follicular growth. Lower threshold to be kept for cycle cancellation if risk of OHSS.^[1,11]
- e. Dosages of gonadotropins to be decided judiciously. Whenever in doubt prefer agonist trigger or freeze all policy^[1,11]
- f. Husbands to undergo COVID testing (as per local/regional health policy) at least 48 h before hCG trigger (ideal to have it on day 2, when cycle to start)
- g. Cancellation policy strictly defined: for COVID positive (either partner)^[9] situation and also for OHSS.^[1,9]
- d. If either patient or husband has a direct contact (face to face, within <1 mt) with a COVID-positive case, then both need to go for quarantine justifying cancellation of cycle^[1]
- e. If any partner tests positive or develops the symptoms for COVID-19 on the day of embryo transfer, cancel fresh embryo transfer, and freezing of embryos is advised^[1]
- f. Keep low threshold to cancellation if risk of OHSS; earlier during the cycle if features of hyperresponse/features on ultrasound or hormone assay
- g. In case OHSS develops despite precautions (coasting/GnRh agonist trigger) then involve chest physicians and intensivists earlier. Repeat COVID-19 testing in such cases as picture may be confusing with the disease

Oocyte retrieval

- a. Ensure patient is COVID-19 negative (by prior testing), for safety of patient and staff. Cancel OPU if any patient tests positive for COVID-19
- b. Anesthesia— to prefer IV sedation/propofol or regional, avoiding GA, for safety to anesthetist
- c. PPE in OT-as per the hospital/prevaling protocol (ideal to have FFP2 masks) for surgeon and anesthesia team^[1,9,12]
- d. Handling spillage of follicular fluid, blood, stools should be as per infection control guidelines
- e. Avoid extra movement in and out of OT
- f. Interval between two cases should be minimum of 30 min to allow the disinfection of OT
- g. Disinfection of operating theater, transfer room, and IVF laboratory, including the equipment's such as incubators, aspiration pumps used for the procedure, after the procedure, as per the infection control guidelines.^[9,12]

Embryo transfer

- a. Limit the number of staff members in the transfer room^[12]
- b. Restrict access for accompanying person (s)^[12]
- c. Perform transfer only in cases of low risk/asymptomatic patients and partners^[12]
- d. Apply a freeze-all policy for all patients and/or partners who became symptomatic after the oocyte retrieval.^[12]

Cancellation/trouble shooting during art services

- a. If any partner tests positive or develops symptoms for COVID-19 at initiation, then do not commence the cycle^[1]
- b. If any partner tests positive or develops symptoms for COVID at day of trigger or OPU, consider cancelling cycle^[1]
- c. If husband test positive for COVID any time between start of cycle and day of OPU-go ahead with OPU if wife is negative and freeze all eggs with prior consenting in place^[1]

- d. If either patient or husband has a direct contact (face to face, within <1 mt) with a COVID-positive case, then both need to go for quarantine justifying cancellation of cycle^[1]
- e. If any partner tests positive or develops the symptoms for COVID-19 on the day of embryo transfer, cancel fresh embryo transfer, and freezing of embryos is advised^[1]
- f. Keep low threshold to cancellation if risk of OHSS; earlier during the cycle if features of hyperresponse/features on ultrasound or hormone assay
- g. In case OHSS develops despite precautions (coasting/GnRh agonist trigger) then involve chest physicians and intensivists earlier. Repeat COVID-19 testing in such cases as picture may be confusing with the disease
- h. In patients who have recovered from symptomatic/asymptomatic COVID-19 infection, commencing for an IVF cycle should be undertaken only after a thorough review.

Policies and procedures for embryology laboratory

General

- a. Deep cleaning of the ART laboratories to be carried out if the facility is shut down for quite sometime. Sanitize the environment, equipment and devices with appropriate nonembryotoxic disinfectants at the end of each procedure or after each access to the workplace
- b. IVF laboratory is one of the safer locations in the health care with its clean room components. Exposure concerns exists: Staff to staff (infection), patient to staff (infection), staff to patient (infection), sample to staff (infection), staff to samples (contamination), between samples (contamination)
- c. Universal Good laboratory practices should be followed by each staff^[12]
- d. Use proper PPE (eye protectors, face masks, gloves, shoe covers, and disposable laboratory coats)
- e. Based on staffing levels, whenever possible, facilities should arrange at least two teams that should alternate to limit the virus spread in the event of an operator being infected^[12]
- f. Restricted social life and interactions for all laboratory staff
- g. Train the internal personnel (clinicians, nurses, etc.) how to refill the cryo-tanks in order to safeguard the cryopreserved material in case of the lab staff being quarantined
- h. In the absence of electronic witnessing systems, outline lean protocols to conduct the clinical procedures, thereby minimizing the need for physical witnessing (external personnel properly equipped, telematic witnessing, etc.,)

- i. Minimize or avoid the practice of counselling by laboratory staff to patients. If it is unavoidable use the tele communication devices
- j. Extra care should be taken to reduce exposure to native follicular fluid and sperm by dilution and safe disposal of fluids in individual closed containers, as quickly as possible
- k. Diligently disinfect the outside of the shipments received including all the disposables and culture media bottles with nonembryo-toxic disinfectants
- l. Ultraviolet C light has the most energy and destroys the genetic material inside viruses and other microbes. Therefore, UVC light is used for disinfection. Other visible lights should be switched off while ultraviolet (UV) light is on. This type of disinfection may be useful for any IVF laboratory spaces. Exposure to UVC light is dangerous for people. Precautions are necessary as UVC sanitizers can damage your eyes and skin. UVC should only be used once the day's work is over and all gametes/embryos are in incubators. Sufficient air exchanges are needed to flush away the ozone generated by UV irradiation.

Semen testing/processing laboratory

- a. Semen freezing to be advised only in indicated cases and not as a regular back up for all OPU
- b. Use a tray to receive the semen container from the patient including any paper documents or use the gloves while receiving the containers
- c. Wipe exterior of container with suitable disinfectant when the sample is received before it is brought to the andrology laboratory
- d. Use the sterile type II hoods for semen testing and processing for IUI/IVF
- e. All body fluids including follicular fluid and semen should be handled/processed as potential source of SARS CoV-2. Appropriate sperm processing techniques should be adapted to reduce viral load (if present in the semen) as much as possible
- f. Diligently clean the laboratory surfaces and collection rooms (after each visits) with nonembryo-toxic disinfectants. Detergent and alcohol-based disinfectants may be used to disinfect semen collection room if it is away from the laboratory
- g. Off-site sample collection may be considered to minimize the partner/staff and other patients' exposure to each other. Clinics should consider the possibility of sample deterioration during commuting/transporting such a specimen from patient's place to the laboratory. Clinics that can manage in-house semen collection without compromising the staff and other patient's safety, may continue with the existing policy
- h. The sperm counting chambers must be properly cleaned and disinfected after every use. The usage of disposable counting slides could be an alternative.

Cryopreservation

- a. High-security straws and/or vapor phase storage tanks should be used for cryopreservation of samples from COVID-19 positive patients^[12]
- b. Gametes/embryos generated after the ART labs restart are desirable to store in Separate cryotanks
- c. Appropriate precautions should be taken during freezing.

Levels of personal protective equipment for staff

- a. For procedures (OPU) – to use FFP2 or N-95 mask. Protection of eyes using goggles or face shield, cap, impermeable gown, double gloves, and shoe covers is recommended
- b. In embryology laboratory -use of FFP2 masks
- c. For OPD—to use FFP2 or N-95 mask and face shield for safety.

Visits after ET

- a. To check for pregnancy (beta hCG at home and to be intimated over telephone)
- b. To be called for viability scan 4–5 weeks after ET.

Training of staff

- a. All efforts to be made by the clinic staff (including clinicians, embryologists, nurses and nursing orderly, receptionist, clerical staff, counselors and OT attendants, technicians) for training on PPE and are updated on the regular basis
- b. Have read the SOP which are in place
- c. All consenting to be done in a manner that does not emotionally stress the couple yet sensitizes them to the demanding situation.

Code of conduct for patient and staff

- a. That they shall share all information truthfully to the clinic when filling questionnaire for triage
- b. Staff and patients to restrict social life and interactions beyond clinic to reduce the risk of infection at the work place
- c. Staff to read and abide by SOPs
- d. All patients/husbands/family to be patient and cooperate in maintaining the SOPs.

DISCLAIMER

These recommendations represents the views of IFS/ISAR/ACE, which were put together after careful consideration of the scientific evidence available at the time of preparation after discussion with the task force committee. IFS/ISAR/ACE, are not liable for damages related to the use of the information contained herein. We cannot guarantee correctness, completeness, or accuracy

of the recommendations in the every respect. The advice expressed herein is not binding on professionals working in the field of human reproduction and embryology; however, it represents the best practice in the view of IFS/ISAR/ACE.

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