Guidelines for Recommencing ART Services during COVID-19 Pandemic

Indian Council of Medical Research
Department of Health Research
Ministry of Health and Family Welfare, Govt. of India
Ansari Nagar, New Delhi-110029

2020
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Department of Health Research
Ministry of Health and Family Welfare
Government of India
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2020
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<td>Members of the Drafting Committee for formulating the “Guidelines for Recommencing ART Services during COVID-19 Pandemic”</td>
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Preface

The novel Corona virus pandemic has created an unprecedented situation which has presented major challenges for the health care systems worldwide along with the social and economic framework of our societies. Arising in China in late 2019, the novel corona virus has swept the globe leading to worldwide national lockdowns. In India, the Prime Minister announced a National Lockdown from 23rd March 2020 to contain the spread of the virus. Subsequently, only emergency medical services were functioning and all the ART clinics were shut down which had an enormous impact on the patients already undergoing infertility treatment economically as well as mentally. But, as the ongoing coronavirus pandemic situation is stabilising, it becomes essential to resume the ART services in a gradual manner. However, strict vigilance and stepwise approach to the treatment is required to minimise the risks related to SARS CoV-2 infection to patients and healthcare staff.

In the current scenario, living and working with coronavirus has become a ground reality for us. Data suggest that Covid-19 will remain a factor to be managed in our lives and practices for a prolonged period of time. Until the development of an effective vaccine, SARS CoV-2 testing and contact tracing are the key strategies for limiting the spread of the virus. ART services are an essential health care service considering the time sensitive nature of infertility. So, the worsening prognosis of ART treatments with passage of time must be weighed against the decreased access to ART services that occurs with further delays in recommencing these services.

This document has been drafted with the intent of guiding all the ART clinics across the country to resume their services in a stepwise manner keeping in mind the risks of Covid-19 infection to be balanced against the benefits of the patients who need infertility treatment. However, these recommendations must be followed in keeping with the local and national guidelines at the prevailing time and these are subject to change in the face of ever evolving scientific and economic situations.

(Dr. Balram Bhargava)
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# Abbreviations

<table>
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<tr>
<td>SARS-CoV-2</td>
<td>Severe acute respiratory syndrome coronavirus 2</td>
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<td>ART</td>
<td>Assisted Reproductive Techniques</td>
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<td>IVF</td>
<td>In Vitro Fertilization</td>
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<td>IUI</td>
<td>Intra Uterine Insemination</td>
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<td>PPE</td>
<td>Personal Protective Equipment</td>
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<td>OPD</td>
<td>Outpatient Department</td>
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<td>RTPCR</td>
<td>Reverse Transcription Polymerase Chain Reaction</td>
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<td>SSG</td>
<td>Saline Sonosalpingography</td>
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<td>HSG</td>
<td>Hysterosalpingography</td>
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<tr>
<td>FSH</td>
<td>Follicle Stimulating Hormone</td>
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<td>LH</td>
<td>Luteinizing Hormone</td>
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<td>ICMR</td>
<td>Indian Council of Medical Research</td>
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<td>BBIL</td>
<td>Bharat Biotech International Limited</td>
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<td>NIV</td>
<td>National Institute of Virology</td>
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<td>ET</td>
<td>Embryo Transfer</td>
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<td>OHSS</td>
<td>Ovarian Hyperstimulation Syndrome</td>
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<td>OD</td>
<td>Oocyte Donation</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>Operation Theatre</td>
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Guidelines for recommencing ART services during COVID-19 Pandemic

1.0 Introduction

The spread of novel corona virus SARS-CoV-2 (COVID-19) across the globe has brought into existence an unparalleled situation with significant path-breaking changes that have terribly influenced not only the health systems but also the economic and social systems of the country. Considering this pandemic situation nationwide emergencies were announced and lockdowns were imposed and only essential services were permitted. The COVID-19 pandemic caused fertility clinic closures worldwide. These closures were abrupt and sudden, patients undergoing treatment lost access to services, the cycles that were in progress were abandoned which led to freezing of all embryos in an IVF cycle without a fresh embryo transfer. Nations worldwide are attempting to stop the outbreak of the disease escalation into a worldwide health crisis. Gradually as the situation is unfolding the Governments have relaxed the lockdown conditions allowing the non-essential services following various National and local guidelines.

As we all are battling the COVID-19 pandemic together, our return to normal daily activities will also need our healthcare system to restart the ART services. There are many repercussions regarding recommencing the ART procedure during COVID-19 pandemic as it's still unclear what impact COVID-19 has on a pregnant woman or her fetus. Patients might worry about the risks of getting infected with COVID-19 and whether it’s safe to embark on pregnancy through ART services right now. The impact of COVID-19 is still not clear and these ART procedures tax the patients financially and emotionally, it is therefore necessary for all the ART clinics to undertake ART procedures in a way that must ensure high-quality patient care and make strategies that will minimize individual exposure risk. At present, a total of 1866 ART clinics and banks have been identified under the National Registry of ART clinics and banks in India. This calls for strict vigilance of ART services in the country and it is imperative that meticulous steps are taken to promote safe practices so that the risks related to SARS-CoV-2/COVID-19 are minimised, both for the patients and the ART clinic staff. Thus, there is a need to formulate guidelines on a National level to avoid any sort of disparity between protocols to be followed by ART Clinics all over the country. Although the services
are now recommencing, but uncertainty still remains as to how treatment services will be resumed, prioritized and delivered, whether there will be a re-closure of clinics due to a second wave or localised lockdowns. Considering such conditions, ICMR recommends that ART clinics should follow these guidelines in accordance with local and national Governments advice related to COVID-19 pandemic.

2.0 Key Principles

The following principles were kept in mind while developing this guidance:

- Assisted reproductive facilities should be recommenced in a stepwise manner to minimise the chances of transmission of COVID-19 infection to patients and ART clinic staff.
- Patients must be fully informed about the nature of the Covid-19 pandemic and its effect on their treatment and future pregnancy outcome(s).
- Patients should acknowledge all the facts and give informed consent for the fertility treatment at this particular time.
- The ART clinics should modify their layout and working practices in accordance with National and local guidelines for Covid-19 which will also help our health care system against any future rise in the spread of COVID-19 in the community.

3.0 Step-wise Module for ART Clinics:

The following steps must be followed while restarting ART clinic practices:

3.1 Patient information and counselling
3.2 Consent to start the treatment
3.3 Patient and ART Clinic staff risk assessment triage
3.4 Modification of ART clinic layout and services
3.5 Planning treatment specific to individual

3.1 Patient information and counselling:

It should be recognised that patients are likely to be anxious about coronavirus infection and its potential effects on pregnancy. It must be explained to the patient that, since it is a new disease the clinical knowledge about this disease is limited and so far, there are no reasons to believe that disease is
more severe during a pregnancy. At present, the studies do not reflect any evidence of an increased risk of congenital anomalies or adverse pregnancy outcomes. They should be made aware that it is likely that virus may persist in the local community for longer time. The counselling should wherever necessary be individualised based on individual clinical profile and risk factors. It is necessary that before the treatment is agreed upon, the patient is educated about the risks with respect to COVID-19 and strategies for their prevention.

Patient education should essentially include:

- The symptoms of SARS-CoV2/COVID-19
- Importance of continued social distancing
- Importance of minimising human physical contact
- Situations where personal protective equipment (PPE) may be required.
- Correct method to use the personal protective equipment when required.
- Possibility that treatment may need to be discontinued if a high-risk clinical situation arises during treatment

3.2 Consent to start the treatment:

The patient's decision whether to proceed with fertility treatment should be documented in the medical record. The consent for starting the treatment should be taken (Appendix 2) and following points must be discussed with the patient:

- Patients with high-risk characteristics like hypertension, diabetes, chronic pulmonary renal or hepatic diseases or patients who have undergone a transplant or are receiving immunosuppressant or multiple medical therapies should be advised to consult respective specialists. For such patients ART treatment should only be started after they have been considered safe by the concerned specialists
- All patients should be allowed to take an informed decision whether they want to pursue the ART treatment or would prefer to postpone it. Clear documentation should be made about the patients’ choices.
- Patients must be comprehensively made to clearly understand the risks related to COVID-19 disease and acknowledge the increased risks in case
of infection during pregnancy. Patients must also be informed on how to reduce the risk of infection in general.

3.3 Patient and ART Clinic staff risk assessment triage

ICMR provides an ART risk assessment triage questionnaire which can be used for the triage of patients and ART clinic staff (Appendix 1).

3.3.1 Patient Workup:

(i) Patients who are planning to start fertility treatment should undergo ART risk assessment triage questionnaire assessment two weeks before commencing treatment.

(ii) ART risk assessment triage questionnaire should be filled at every OPD clinic visit by the patient.

(iii) Patient and the partner should undergo further triage again before starting ovarian stimulation treatment.

(iv) After triage, those patients or partners suspected of infection should be advised to get RT-PCR test done.

(v) The patients who have recovered from COVID-19 infection should provide medical certificate in order to be eligible for fertility treatment. If patients have recovered from severe COVID-19 disease and were on respiratory support during the treatment, they should additionally provide evidence of recovery and a medical clearance report from the specialist or treating physician/ local Registered Medical officer (RMO).

3.3.2 Before starting ART treatment: ART triage questionnaire (Appendix 1) should be completed before starting the treatment. All patients and partners should be advised to get COVID RT-PCR test done before commencing the treatment and also before any ART procedure, preferably within a week before starting treatment or any ART procedure. Patients and donors with a diagnosis of COVID-19 infection should not start treatment until they have recovered and are not considered infectious. The National and local guidelines must be followed in this regard. The patients, partners and potential donors are
advised to self-isolate themselves from the start of ovarian stimulation treatment until the planned ART procedure is completed.

3.3.3 During ART treatment: ART triage questionnaire should be administered prior to every clinic visit. Patients, partners and donors with a negative RT-PCR test at the start of treatment, and who remain negative on questionnaire screening throughout, should be allowed to complete the treatment.

3.3.4 Action in the event of suspected COVID-19: If a patient or donor develops symptoms suggestive of corona virus or screens positive on the questionnaire during treatment, RTPCR test should be done and treatment should not proceed unless the patient screens negative as defined by national guidelines. Patients who become symptomatic after oocyte retrieval but prior to embryo transfer should be advised to freeze all their embryos for future use.

3.3.5 Patient assessment:

Group I:
- Both partners are triaged as low risk (negative clinical history, lifestyle compatible with low/minimal risk of contact with potentially infected individuals)
- Both partners are asymptomatic.
  RTPCR test should be done before starting ART treatment and before oocyte retrieval or hcg trigger.
  If RTPCR negative: Continue the treatment
  If RTPCR positive: Postpone the treatment

Group II:
- Patients who have recovered from a previous COVID-19 infection, proven by certified medical evidence of clearance, should have RTPCR test done prior to starting ART treatment and before oocyte retrieval or hcg trigger.
  If RTPCR negative: Continue the treatment
  If RTPCR positive: Postpone the treatment
**Group III:**

- Presence of symptoms related to Covid 19 infection in one of the partners before starting ovarian stimulation for IUI/IVF:
  
  Repeat the triage at the beginning of ovarian stimulation cycle.

  RTPCR test should be done prior to starting ART treatment

  If RTPCR negative: Continue the treatment

  If RTPCR positive: Postpone the treatment

**Group IV:**

- Presence of Covid -19 symptoms arising during ovarian stimulation in IUI/IVF cycle:

  Perform RTPCR test before further treatment like oocyte retrieval or hcg trigger.

  If RTPCR negative: Continue the treatment

  If RTPCR positive: Postpone the treatment

Patients who become Covid positive during ovarian stimulation should be advised to postpone the treatment and cancel the ovarian stimulation cycle.

**Group V:**

- If patients and/or partners are symptomatic after oocyte retrieval in IVF cycle:

  Perform RTPCR test before further treatment.

  If RTPCR negative: Continue the treatment

  If RTPCR positive: Postpone the treatment

Patients who become Covid positive after oocyte retrieval but prior to embryo transfer should be advised to postpone the treatment and freeze all their embryos for future use.
3.3.6 Procedure for staff

(i) Triage information regarding health status, symptoms and lifestyle of the clinic team members and of individual(s) living in the same household should start at least two weeks before the beginning of clinical activities at the centre.

(ii) Staff, suspected of infection after triage, should undergo SARS-CoV-2 RTPCR test.

(iii) All staff members who test positive for SARS-CoV-2 RTPCR, should receive occupational health advice and go into self-quarantine

(iv) Staff who is symptomatic should be referred for medical advice and testing and should not re-attend work until the infection is cleared and documented by negative RT-PCR test.

(v) Contact tracing and testing should be routine if a staff member is diagnosed with COVID-19 infection.

(vi) Depending on the size of the unit, staff should be subdivided in “mini-teams” with minimum interactions among them and they should work according to a rotating schedule.

3.4 Modification of ART clinic layout and services

Resumption of fertility services must take place in a manner that minimises the spread of COVID-19 infection to patients and fertility clinic staff, areas of the clinic may require reconfiguration to enable safe physical distancing.

Consideration should be given to the layout of each area including:

- Patient reception
- Patient waiting areas
- Consultation and counselling rooms
- Clinical rooms used for ultrasonography
- Procedure rooms for oocyte retrieval or embryo transfer
- Embryology Lab Complex
- Administration offices
- Communal staff areas (e.g. canteen, staff room)
The following measures, relating to clinic layout, should be considered:

- Physical barriers between staff and patients, and/or appropriate PPE for the activity being undertaken.
- Spacing of furniture to ensure social distancing is maintained (e.g. waiting area chairs, workstations in administrative offices).
- Thermal scanning before entry of staff and patients inside the ART clinic.

3.4.1 Social distancing

Social distancing should be adhered to at all times, in line with National guidelines. Centres should consider each type of patient and staff interaction and put measures in place to minimise the risk of COVID-19 infection.

Consideration should be given to the following interactions and processes, in terms of social distancing. (This list is not exhaustive and centres should undertake assessment of all areas within their licensed facility):

(i) Patient arrival and checking in process at the clinic
(ii) Patient consultation
(iii) Patient consent taking
(iv) Ultrasonography
(v) Counselling
(vi) Semen collection
(vii) Oocyte or Surgical sperm recovery
(viii) Embryo transfer
(ix) Staff meetings
(x) Use of corridors, communal areas, lifts and stairways

The following measures should be considered to ensure social distancing wherever possible:

(i) Reconfiguration of areas of the clinic
(ii) Implementation of restrictions to the use of communal (social) areas, such as the staff room
(iii) Staff working from home should be encouraged wherever possible
(iv) Production and delivery of semen samples from home, following guidelines to avoid compromising the sample
(v) Implementation of virtual meetings wherever possible, minimising face to face appointments. (e.g. consultation and counselling)
(vi) Use of approved electronic communications and messaging systems wherever possible
(vii) Implementation of restrictions on partners and companions for appointments, wherever possible and appropriate
(viii) Limiting staff and patient numbers permitted in each clinic area

The treatment of each patient should be completely thought over and individualised. In order to reduce unnecessary visits and staff-patient contact, telemedicine should be used to minimise the physical presence of patients at the centre.

3.4.2. Recommendations on modification of services in the ART clinics

(i) Routine sanitization of all areas should be performed according to local protocols.
(ii) Specific COVID-19 sanitisation procedures should be implemented in case of COVID-19 positive patients or staff members.
(iii) COVID-19-specific training for staff
(iv) COVID-19-specific standard operating procedures
(v) Adjusted work shifts
(vi) Limitation of the number of persons simultaneously present in the centre
(vii) Provision of protective screens for staff
(viii) Provision of personal protective equipment and sanitation devices for patients and staff
(ix) Restriction of access for partners and accompanying persons
(x) Redesign of waiting rooms and working spaces to guarantee appropriate social distancing
(xi) Management of appointments according to specific timetables, also for scans and blood tests

(xii) Subdivision of staff into mini-teams to reduce unnecessary exposure of patients and staff members

(xiii) Follow-up of patients two weeks after oocyte retrieval and/or embryo transfer in IVF cycle, in order to identify potential COVID-19 positive patients and implement necessary measures (i.e. contact tracing and sanitization)

(xiv) Telephone and video consultations should replace face-to-face interactions in most situations, depending on the patient profile.

(xv) In case of any emergency or closure due to positive COVID cases where the clinic might not be able to perform its services, the clinic should have association with some other clinic in proximity where it can refer their patients.

(xvi) Use of Aarogya setu app should be mandatory for all staff and patients.

3.5 Treatment planning:

3.5.1 Diagnostic Procedures:

The diagnostic procedures for infertility should be done in couples who are negative on ART triage questionnaire. RTPCR test for COVID should be done before any invasive diagnostic procedure requiring regional/general anesthesia.

(i) Hormonal assays
   Blood tests for hormones like FSH, LH, Prolactin etc. can be done in patients who are negative on ART triage questionnaire.

(ii) Semen analysis
   It should be ensured that the husband/donor is negative on ART triage questionnaire. It is preferable that husband/donor should be tested for COVID with RTPCR test and further treatment to continue only if they test negative for COVID RTPCR.

   Adequate precautions should be taken for semen collection with appropriate PPE as preliminary research data is suggestive of the
presence of virus in semen. Research data suggested that 15.8% of men were confirmed positive for SARS-COV-2 in the semen sample specimens collected from men who tested positive for RT-PCR on nasopharyngeal swabs.

(iii) Saline sonography (SSG)

(iv) Hysterosalpingography (HSG)
HSG should be carried out to with all precautions and adequate PPE in patients negative on ART triage questionnaire.

(v) Office hysteroscopy
It must be ensured that patient/partner/donor is negative on ART triage questionnaire and RTPCR test for COVID should be done before undertaking the procedure. If RTPCR test is negative, then only further procedure should be carried out in the patient/donor. Office hysteroscopic procedures may be done under local paracervical block or total intravenous anesthesia. For any operative hysteroscopic procedure (e.g. resection of intracavitary lesions), regional anesthesia is to be preferred for safeguarding the anesthetist from aerosol generating risks of general anesthesia.

(vi) Laparoscopy
The patients should be prioritized according to the urgency of fertility treatment for elective laparoscopic procedures. However, emergency laparoscopic procedures (e.g. adnexal torsion, ectopic pregnancy etc.) should be performed on urgent basis as they are life threatening situations. Regional anesthesia should be preferred for the safety of anesthetist in the emergency situations, if COVID status of the patient is not known.

Laparoscopic procedures can lead to aerosolization during anesthesia and pneumo-peritoneum so, the anesthetist should use a box, video-laryngoscope and a triple filter for safety purposes (if available). The smoke generated during laparoscopic procedures should be evacuated using filter at suction and outflow trocars going through specially designed smoke evacuators and ultra-low-
pressure apparatus in OT. The ultrasonic and electrosurgical devices used during laparoscopy create large surgical plumes which potentially increases the risks of viral transmission. Bipolar energy sources should be preferred to ultrasonic devices as ultrasonic devices are high-frequency oscillating devices which may hypothetically add to the potential risk of viral transmission although the magnitude of any such risks is unknown.

3.5.2 Ovarian stimulation monitoring during IUI/IVF cycles

During this phase the following specific precautions should be taken:

(i) Minimal exposure for both staff and patients.
(ii) Isolation of staff showing symptoms of infection
(iii) Use of personal protective equipment (PPE) by staff
(iv) Minimal number of visits and optimised number of blood tests
(v) Vaginal probe hygiene to be maintained
(vi) Re-triage and action depending on pre-triage results or new non-specific symptoms.
(vii) All measures should be taken to avoid risks of ovarian hyperstimulation syndrome (OHSS)

3.5.3 Oocyte Retrieval in IVF cycle

If patients and/or partners become symptomatic after oocyte retrieval in IVF cycle but prior to embryo transfer, they should be advised to undergo RTPCR test before further treatment.

If RTPCR is negative, they can continue the treatment but if RTPCR is positive then they should be advised to postpone the treatment and freeze all their embryos for future use.

3.5.4 Embryo transfer in IVF cycle

(i) Limit the number of staff members in the embryo transfer (ET) room
(ii) Restrict access for accompanying person(s)
(iii) Perform transfer only in cases of low risk/asymptomatic patients and partners
(iv) Apply a freeze-all policy for all patients and/or partners who become symptomatic after the oocyte retrieval.

3.5.5 Cryopreservation

Currently available evidence indicates that the cryopreservation of gametes and embryos during the pandemic may be performed using routine practices, although centres are advised to risk assess and consider similar practices and storage to that used for seropositive infectious diseases such as HIV, as a precaution for known COVID-19 positive patients only (e.g. high security straws or vials, vapour phase or separate liquid phase storage). Separate cryo-containers and closed system vitrification process should be used for COVID-19 positive patients.

3.5.6 Laboratory Practices

Evidence to date suggests that the respiratory virus responsible for COVID-19 is not present in follicular fluid or seminal plasma, nor associated with gametes or embryos. Standard infection control procedures and good laboratory practices are, therefore, considered appropriate in the IVF laboratory during this time. This includes standard IVF laboratory PPE and the use of biological safety cabinets. Laboratory staff should aim to minimise handling and sharing of pipette handles, pens and keyboards etc. and clean down equipment, such as microscope controls and eyepieces between operators.

Recommendations for embryology lab complexes:

(i) Routine good laboratory practice should be followed and laboratory staff should wear masks and gloves.
(ii) Staff should be organised in mini-teams.
(iii) 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.
(iv) If a patient becomes suspect or positive for COVID-19 during embryo culture, a freeze-all policy should be adopted.
(v) Since most of the IVF labs use controlled lab conditions with centralized conditioning and closed air systems, this may lead to the increase in the spread of virus from potential asymptomatic patients. Therefore, adequate provisions should be made to control the air quality with proper filtration systems.

3.5.7 Equipments

ART clinics should ensure that equipment is fit for purpose and has been maintained appropriately during any period of lock down. All equipment should be validated for use. Up-to-date validation documentation should be maintained at resumption of services.

Staff should minimise sharing of any equipment wherever possible and equipment should be cleaned between different operators (e.g. microscope eye pieces or keyboards).

Emergency plans should be made by the clinics for managing supply chain of equipments and unintended exposure of the staff to COVID-19.

3.5.8 Personal Protective Equipment (PPE)

Centres should consider asking all visitors to the centre to use a face covering, and masks may be provided for those who need them. Provision must be made for safe disposal of PPE used by visitors. ART clinic staff should also be provided with appropriate PPE kit in accordance with National and local guidelines.

It is recommended that clinics should maintain a record confirming that all relevant members of staff have undergone training in the proper donning and doffing of PPE.

3.5.9 Third-Party Reproduction

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 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. The patient, partner, donor or surrogate, all should undergo COVID RTPCR testing prior to starting treatment and before any ART procedure.

Clinics should weigh the benefits and risks of proceeding for the involved individuals. In addition to the ability of the clinic to adhere to safe practices to reduce the spread of COVID-19, factors to consider include:

(i) Urgency to proceed (for example, due to age of donor, recipient, or intended parents, or availability of donor or gestational carrier)
(ii) 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
(iii) The need for travel for the intended parents, the donor and/or gestational carrier
(iv) The unknown impact of COVID-19 on pregnancy and the fetus
(v) Compliance with national, regional, state, and municipal regulations produced by authoritative health organizations and agencies regarding clinical activities and travel

3.5.10 Additional eligibility criteria for donor / recipient

(i) 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.
(ii) RTPCR testing is the recommended approach for the detection of SARS-CoV-2 RNA.

3.5.11 Oocyte donors

(i) Clinics should consider incorporating additional counselling and documentation regarding screening for SARS-CoV-2 during ovarian stimulation for oocyte donation (OD)
(ii) Oocyte donors should be screened with ART triage questionnaire and RTPCR test done before starting the treatment

(iii) Clinics should consider cancellation if the donor has a positive RTPCR test for SARS-CoV-2 or develops COVID-19 during ovarian stimulation

3.5.12 Sperm donors

(i) Data regarding presence of SARS-CoV-2 in semen is conflicting

(ii) Quarantine of all anonymous donor sperm specimens for 6 months is an existing FDA requirement

(iii) Quarantine of directed donor sperm specimens is not required by the FDA but may be considered at the discretion of the recipient and physician

4.0 Mental Health and COVID-19 Disease

As the corona pandemic continues to spread, the patients and the physician are at increased risk of psychological distress, mental health and behavioural disorders. The psychological well-being of patients, physicians and healthcare workers has been significantly and adversely influenced as the COVID-19 pandemic keeps on spreading. The major sources of anxiety among these individuals involve:

• Cessation of treatment due to COVID-19
• Anticipatory grief
• Uncertainty about the attainment of their parenthood goals
• Emotional distress
• Risks of self-exposure
• Spreading infection to family members
• Fear of illness in self or family members
• Fear of death
• Social isolation
• Job and financial losses
• Loss of coping mechanisms
• Poor access to testing
• Lack of adequate reliable information and communication
Fertility clinics can have a powerful positive impact on the psychological and emotional wellbeing of patients, physicians, and healthcare providers by:

- Appropriate counselling (patient centred care and structured psychological interventions)
- Educating about the accurate information and mitigation and protection procedures
- Providing a list of resources for support and coping up strategies
- Providing referrals for psychiatric and psychological services
- Communicating the strategies optimised for uncertain and unpredictable situations

5.0 Availability of COVID-19 vaccine

To battle the surge of corona virus pandemic, intense scientific efforts are being made globally for rapid progress towards the development of COVID-19 vaccine. As the race around vaccine development kicks up a notch globally, Indian scientists are no step behind to present a prototype of a novel COVID-19 vaccine to battle this pandemic. Amongst the strongest competitors is COVAXIN, which has been developed by Bharat Biotech International Limited (BBIL) in collaboration with ICMR (Indian Council of Medical Research) and NIV (National Institute of Virology), Pune. Clinical trials are going underway. Mass production of different vaccines is already underway as a key strategy towards expediting the wide-scale availability of vaccines as soon as clinical trials demonstrate that they are both safe and efficacious.

6.0 Code of conduct for patient and staff

- Truthfully sharing of all information to the clinic when filling questionnaire for triage
- Complying with any requirements related to testing
- Restricting any movement to that which is absolutely essential
- Practise social distancing- by restricting social life and interactions beyond clinic in order to reduce risk of infection at work place
- Practising frequent hand hygiene
- Ensure wearing of appropriate masks
- Staff to read and abide by SOPs
• Complying with any quarantine requirements that may be required
• Self-shielding or maintaining self-imposed self-quarantine whenever possible
• Not creating, distributing, spreading and/or forwarding fake news or information relating to COVID-19 that could be detrimental to self, others
• All patients/partners/family to be patient and cooperate in triaging and following the local and national SOPs.
Appendix 1
ART Risk Assessment Triage Questionnaire

1. Have you been sick in the last two weeks?
2. Do you have fever (over 37.5°C)?
3. Do you have a sore throat?
4. Have you lost your sense of smell or taste?
5. Have you been in contact with somebody who has any of these symptoms?
6. Have you travelled to an area at high risk for COVID-19, nationally or internationally?
7. Do you work in a hospital/nursing home or healthcare facility?
8. Have you been in contact with somebody who has COVID-19?
9. Have you been diagnosed with COVID-19?
10. Do you reside in a containment zone/Hotspot area?
11. Do you live in a household with somebody who has been diagnosed with COVID-19 infection or has COVID-19 symptoms (fever, cough, loss of smell)?
12. If you have been COVID-19 positive and recovered, do you have certified medical evidence of clearance?
13. Do you have a severe medical condition like diabetes, respiratory disease, chronic kidney disease, etc.?
CONSENT FORM FOR ART PROCEDURES DURING THE COVID-19 PANDEMIC

COVID-19 is a rapidly evolving pandemic with limited information related to its effect on pregnant females and foetuses. Currently, there are no specific recommendations for pregnant women regarding the investigation and management of COVID-19.

I/we understand and agree to the following statements by signing below:

1. I/we have been fully informed that if myself or my partner are exposed or diagnosed with COVID-19, or have symptoms suggestive of COVID-19 infection (even in the absence of a positive COVID-19 test); my/our treatment cycle will be cancelled.

2. I/we have been informed that there is a risk of exposure of COVID-19 infection to myself or my partner while receiving ART treatment, by other patients or DOCTOR or ART clinic staff during the clinic visits.

3. I/we have been informed that, if there is a change in National or local regulations or guidelines as government directive to stop providing ART services or procedures, or Doctor/ART clinic is required to shut down; my/our treatment cycle may be cancelled.

4. I/we have been explained that, if the Doctor/ART clinic is not able to continue the treatment as a result lack of essential staff or supply shortages due to COVID-19 pandemic; my/our treatment cycle may be cancelled.

5. I/we have been informed about the potential risks of COVID-19 on pregnancy, if any, including birth defects, miscarriage, stillbirth, preterm birth or any other pregnancy complications.

6. I/we have been explained that we can opt to postpone the ART treatment in order to minimize the above-mentioned potential risks.

7. I/We understand that extra cost of the testing for COVID-19 will be borne by us.

8. I/we have been informed and agree to follow the ‘code of conduct’ for minimising the risk of Covid 19 infection.

9. I/we have been informed of the COVID-19 risk assessment triage questionnaire, what it is used for and that I/we have to answer it truthfully.
I/we completely understand that medical knowledge regarding COVID-19 infection and treatment is rapidly evolving and that additional unpredictable risks or considerations may come to light in due course of time which can affect my treatment course.

By my/our signatures, below I/We confirm that I/we have read the above, information on COVID-19, have had an opportunity to discuss this information and our treatment plan with the treating doctor, and agree to continue fertility treatment at this time.

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Source of photos

- Photo courtesy of Shutterstock
- Fortis Bloom IVF Centre, Gurgaon
- CORONA VIRUS, May 17, 2020, Forbes
Drafting Committee for formulating the “Guidelines for Recommencing ART Services during COVID-19 Pandemic”

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