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SARS-CoV-2 and Assisted Reproductive Technology Practice: An Asia Pacific Initiative on Reproduction (ASPIRE) Position Paper

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ABSTRACT

Background: Asia Pacific Initiative on Reproduction (ASPIRE) aims to improve knowledge and awareness of Assisted Reproductive Technology (ART) and infertility-related services, with the aim of improving the quality of patient care.

Methods: A survey was developed and responded by a group of 10 ASPIRE board members to gather in-depth information about current practices, recommendations, and perceptions about SARS-CoV-2 and ART. The collected data were summarized and individual responses pooled among questions requiring voting. The overall rates were computed by response category. The group discussed the summary evidence, until a consensus was reached concerning a series of recommendation on how to make decisions concerning ART service provision during the current (and any future) pandemic. A two-tier recommendation was developed based on agreement rate and implementation priority. Tier 1 comprises recommendations in which the rate of "absolutely agree" responses were ≥60%, whereas tier 2 refers to recommendations in which the rate of "absolutely agree" plus "agree" was >60%, but the rate of "absolutely agree" was ≤50%.

Results: The survey was responded by all participants between July 24 and July 30, 2020. Nine tier 1 and five tier 2 recommendations are provided concerning prevention, testing, personal protective equipment, informed consent, and quality management. The former indicates the situations in which most individuals should receive the intervention/procedure, whereas the latter relates to those that may be suitable for individual clinics and patients.

Conclusions: This document provides the ASPIRE viewpoint on better managing infertile patients seeking ART during the COVID-19 pandemic. This expert opinion guide aims to help both competent authorities and healthcare providers to deliver quality and safe ART.

***Keywords*:** SARS-CoV-2; COVID-19; Assisted Reproductive Technology; Intrauterine Insemination; Infertility; In Vitro Fertilization; Intracytoplasmic Sperm Injection; Guideline; Expert Opinion.

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INTRODUCTION

Severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) is a novel coronavirus and causative agent of COVID-19, a disease with potentially dangerous human health implications. Governments worldwide have announced different restrictive measures to contain the SARS-Cov-2, probably the most far-reaching restrictions on personal freedom in modern history. Because reproductive care is essential and there is a need to avoid a collapse in the healthcare system, reproductive medicine societies and regulatory authorities have issued guidance based on expert best judgment (American Society for Reproductive Medicine [ASRM], 2020; ASRM patient management; ESHRE guidance on recommencing ART treatments; European Association of Urology [EAU], 2020; European Society for Human Reproduction and Embryology [ESHRE], 2020; Society for Assisted Reproductive Technology [SART], 2020).

The Asia Pacific Initiative on Reproduction (ASPIRE) is a society of clinicians and scientists involved in providing Assisted Reproductive Technology (ART) treatments with its aim to improve the quality of patient care through outstanding infertility-related services. ASPIRE recognizes that every country in the Asia Pacific (APAC) is at different phase of the COVID-19 pandemic. The executive, therefore, collected information from its board members and key opinion leaders about their current ART practices, to develop specific recommendations that may be used as a general framework for the delivery of quality and safe ART services.

This position paper offers best practice statements based on their advice on the care of couples seeking ART during the current and perhaps in future pandemics of a similar nature. Specifically, we put into context the current situation of ART practices in APAC and clarify the need to prioritize patients for ART treatment. Furthermore, we also formulated recommendations on how to provide quality ART services in a safe environment. Lastly, an expert perspective on how ART centers "lockdown/slowdown" might affect infertility patients and the community is offered.

The pandemic facts in the Asia Pacific

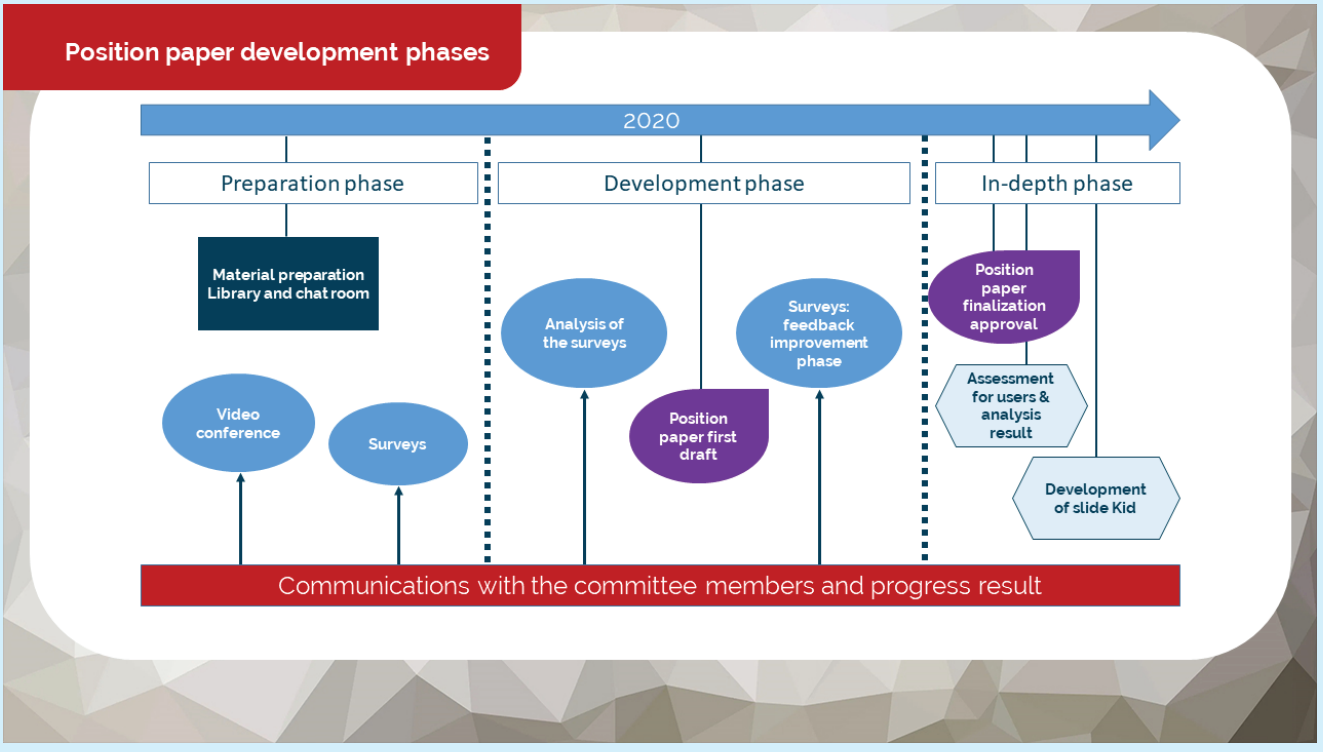
At the time of writing (September 1, 2020), more than 25 million infections by SARS-CoV-2 have been reported globally (www.worldometers.info/coronavirus). The APAC region has also been affected by the pandemic, with over 7 million cases reported to date. By far, India has been the most severely affected country, with cases exceeding 3 million, followed by Bangladesh, Pakistan, the Philippines, and Indonesia. The number of deaths remains between two and three per million population across the region, despite a wide variation among countries. In APAC, as in many other countries, SARS-Cov-2 has infected people at reproductive age. Although many individuals remain asymptomatic, Covid-19 has manifested particularly in those with pre-existing conditions, including cardiovascular disease, diabetes, chronic respiratory disease, hypertension, obesity, and cancer. However, it is not uncommon that infertility patients carry comorbidities, both males and females, thus making this population equally vulnerable.

METHODS

Development group, online survey, and supporting resources

A group of 10 current or past executive ASPIRE board members developed this document, namely, Profs. Budi Wiweko (Indonesia), Ho Manh Tuong (Vietnam), Rong Li (China), Tin Chiu Li (Hong Kong), Chii-Ruey Tzeng (Taiwan), Gab Kovacs (Australia), Atsushi Tanaka (Japan), Jung Ryeol Lee (South Korea), Hrishikesh Pai (India), Haroon Latif Khan (Pakistan), from now on termed "Position Paper Development Group" (PPDG) in conjunction with Med.E.A. – Medical Education Academy. The latter is an independent global medical education provider dedicated to developing, implementing,

Fig. 1. Position paper journey.



and evaluating medical education programs worldwide, offering support to healthcare professionals in their continuing professional development. The Med.E.A. ART committee, namely Profs. C. Alviggi, P. Humaidan, R. Fischer, and S. Esteves offered technical support due to their previous experience developing similar position papers (Alviggi et al., 2020; Esteves et al., 2020). Prof. P.C. Wong, also a member of the Med.E.A. ART committee, provided technical support and served as a Med.E.A. APAC representative.

Figure 1 depicts the developmental phases. Briefly, Med.E.A committee developed a survey based on the publication of recent articles on SARS-CoV-2 and ART (Alviggi et al., 2020; Esteves et al., 2020). The survey gathered in-depth information from APAC executive members about their current practices and collected and classified their recommendations on how to make decisions concerning ART service provision during the current (and any future) pandemic.

The survey was developed in three parts, with a series of questions related to (i) Clinical practice, (ii) Recommendations, and (iii) Perceptions. Part A comprised of 27 questions related to demographic and current clinical practices during the SARS-Cov-2 pandemic. Part B included 29 voting questions concerning recommendations toward delivering safe and quality ART, whereas part C included six questions related to participants' perceptions of the SARS-CoV-2 pandemic on fertility (see Supplementary Material). The results of parts A and C were primarily used to put into context the current situation concerning ART practice in the APAC region, whereas those from part B were used to draft recommendations.

In part B, participants were asked to vote on several questions, as follows: (1) *Absolutely agree*, if they believe the statement is correct and most individuals in that situation should receive the intervention/procedure; (2) *Agree*, if they feel the statement is correct, but various choices might be suitable for individual clinics and patients, and that healthcare practitioners should reach a decision coherent with a patient-centered approach and local resources in a considered manner; (3) *Neutral*, when they do not support either side and prefer to abstain from making an opinion; (4) *Disagree,* when they oppose the statement and feel it should not be followed in most cases; and lastly (5) *Absolutely disagree*, when they consider the statement wrong, and, in any circumstances, it should not be followed.

Supporting online resources were made available to participants by Med.E.A., including a library and a chat room. The library was created and updated continuously based on a search for the evidence concerning SARS-Cov-2 and ART. The literature search was performed in PUBMED/MEDLINE from inception up to July 23, 2020.

At the project's onset, a video conference of all participants was held to provide detailed information about its general framework. The PPDG was asked to give feedback on the survey contents, and after approval, each member responded to all questions using an online platform. Responders were blind to other participants' responses.

Table 1. Clinical ART practices during the SARS-CoV-2 in APAC: summary of findings.

1. Only one country (Thailand) has a government decree issued to regulate ART practice during the pandemic, whereas Australia, India, Indonesia, and Thailand had recommendations issued by their national ART society.
2. Ninety percent of responders* feel there is a need to have recommendations to regulate ART practice during the SARS-Cov-2 pandemic.
3. Sixty percent responders rank ART services as high (40% responders) or intermediate (20% responders) priority. By contrast, IUI is ranked as low (50% responders) or intermediate (40% responders) priority by 90% of participants.
4. Sixty percent of responders' centers (6/10) never closed, whereas 3 out of 10 centers closed and reopened, and one center remained closed. In the absence of specific recommendations in most countries, this decision was overwhelmingly based on individual expert judgment.
5. The centers in operation are providing all types of ART-related and IUI services. Relevant services are also being provided by centers offering oocyte donation.
6. Most participant centers (60%) established criteria to prioritize patients for treatment during the pandemic. Besides cancer patients, advanced maternal age and poor ovarian reserve were the top priorities, followed by the POSEIDON criteria, history of implantation failure, and severe male factor infertility.
7. While patients' opinion influences the decision to provide services (50% responders), the recommendations by regulatory bodies (when existent) are also taken into account.
8. All but one participating center established a triage protocol to prevent contamination. In most cases (60% responders), a combination of T control, epidemiological questionnaire, and PCR testing is applied. Patients diagnosed with Covid-19 and those with symptoms or fever are generally excluded from treatment.
9. Once a patient is eligible for treatment, the epidemiological questionnaire is the most used checklist (60% responders) before ovarian stimulation, followed by PCR (40% responders).
10. Before OPU, PCR (or serology) has been used routinely by most (60%) responders. By contrast, testing is performed routinely by 40% of responders before ET. The availability of tests is mentioned as a critical issue by some responders.
11. Testing is routinely performed before sperm collection by 50% responders, but it is added in suspected cases based on the questionnaire's findings.
12. In case of positive testing or highly indicative symptoms, OPU is canceled by all responders.
13. In general (60% responders), patients are followed up with regard to Covid-19 after treatment.
14. Staff performing their duties is not tested routinely or periodically (70% responders).
15. In most cases (70% responders), there has been a reduction in IVF/ICSI cycles (vs. pre-pandemic period). This slowdown has been remarkable (≥50%) in countries like China (mainland), Thailand, Indonesia, India, Vietnam, and Pakistan. By contrast, the pandemic's impact was less pronounced in countries like Australia and China (Hong Kong). Apparently, there has been no detrimental effect on the number of IVF cycles in South Korea and Japan.
16. Overall, the reported percentage of infertility patients with either Covid-19 symptoms or diagnosis before treatment or OPU has been low (<10%). No cases of Covid-19 have been reported by the participants after OPU to date. The positivity rate among staff has been low (1%–2%), although staff has not been routinely tested in most cases.

*N = 10 responders; OPU: oocyte pick-up.

Evidence summary and formulation of recommendations

The data were collected and summarized by Med.E.A technical committee. Summary tables of findings were prepared and shared with PPDG for analysis and comments. The results were made available to participants without identifying individual responders. Individual responses were pooled among questions requiring voting, and the overall rates were computed by response category. The PPDG discussed the summary evidence, and all comments were processed by the technical committee, either by adapting the content or by replying to the participant, or both.

RESULTS

All survey questions were responded to by all participants ($n = 10$). The survey was carried out between July 24 and July 30, 2020.

Part A: Clinical ART practices in APAC during SARS-Cov-2 pandemic

Table 1 summarizes the key findings related to current clinical practices. In general, there were considerable heterogeneity in ART practices during the SARS-Cov-2 pandemic. The reason may be related to the paucity of government decrees to regulate ART practice, although national ART societies of Australia, India, Indonesia, and Thailand have issued recommendations. In most cases, the decision to offer ART services to the community has been based on individual expert judgment. Notably, some participants' centers never closed, whereas others closed for several weeks and reopened recently. All types of ART-related services including IUI were being offered, although participants rank these services differently; IVF and ICSI were considered of either high or intermediate priority, whereas IUI was given a low priority.

Most fertility clinics have established criteria to prioritize patients for treatment. Besides cancer patients, advanced maternal age and poor ovarian reserve were the top priorities, followed by the POSEIDON criteria (Poseidon Group et al., 2016), history of implantation failure, and severe male factor infertility. Notably, patients' opinion has had a marked influence on the decision to provide services, although the recommendations issued by regulatory bodies (when existent) have also been considered.

Regarding triage and testing, participants' fertility centers established a triage protocol to prevent contamination; however, practices vary considerably. Temperature control, epidemiological questionnaire, and RT-PCR testing, or a combination of these, have been applied. There is a consensus that patients diagnosed with Covid-19 and those with symptoms or fever should be excluded from treatment.

Once a patient is eligible for treatment, the epidemiological questionnaire has been the most used checklist before ovarian stimulation, followed by PCR. RT-PCR (or serology) done before oocyte pick-up (OPU) has been used routinely by most participants. By contrast, testing has not been consistently performed before semen collection and embryo transfer. In any case, there is a consensus that in the face of a positive PCR result or highly indicative symptoms, OPU should be canceled.

Patients are followed up with regard to Covid-19 after treatment. Overall, the reported percentage of infertility patients with either Covid-19 symptoms or diagnosis before treatment or OPU has been low (<10%), but the real figures are difficult to estimate due to inconsistent testing. Unlike patients, staff performing their duties were not tested periodically. The test availability and accuracy are frequently mentioned as limiting factors to the widespread testing implementation.

Part B: Recommendations

A consensus was reached within the group after the first round of voting and discussion. Since the rates varied across individual questions, a two-tier recommendation was developed. Tier 1 comprises recommendations in which the rate of "absolutely agree" responses was ≥60% (Table 2), whereas tier 2 refers to recommendations in which the rate of "absolutely agree" plus "agree" was >60%, but the rate of "absolutely agree" was ≤50% (Table 3).

Based on the survey results, recommendations were also formulated concerning prevention (Table 4), personal protective equipment (PPE) (Table 5), informed consent (Table 6), and quality management system (QMS) (Table 7). Lastly, a template was developed to help clinics to organize according to the proposed recommendations (Annex).

Part C: Perceptions

The overall perception has been that the number of ART cycles dropped significantly (by approximately 50%) compared to the pre-pandemic period. This slowdown is remarkable (≥50% reduction)

Table 2. Tier 1 recommendations (most individuals should receive the intervention/procedure).

1.	Before any treatment initiation, active SARS-CoV-2 infections and suspected cases* should be excluded.
2.	Tele-health and phone counseling should be encouraged.
3.	In the case of face-to-face visits, time slots for patients should be adequate to avoid crowded waiting rooms and waiting rooms should be adapted to social distancing (1.5–2 m distance between chairs).
4.	Adherence to regulatory recommendations regarding infection prevention should be of utmost importance for patients and health practitioners (see Tables 4 and 5).
5.	Special attention has to be given to air quality control, including the use of air filtration and air pressurization, particularly in surgical and laboratory areas.
6.	Good standard laboratory practices should be strictly applied when handling gametes and embryos within the embryology and andrology labs.
7.	A thorough discussion between patients and healthcare providers should occur for responsible shared decisions (e.g., impact of age, type of infertility, risk/benefits; see Table 6).
8.	A dedicated informed consent, detailing the risks of attending the facility during the SARS-CoV-2 pandemic should be created (see Table 6 for critical items to be included).
9.	Advanced planning should guide the restart of ART services, considering a risk management analysis (see Table 7 and Annex for suggested QMS plan).

*Direct contact with anyone proved or suspect of COVID-19, symptoms as dry cough, fatigue, chest pain, diarrhea, skin eruptions, headache, and other possibly associated with Coronavirus fever.

Table 3. Tier 2 recommendations (may be suitable for individual clinics and patients, but healthcare practitioners should reach a decision coherent with a patient-centered approach and local resources in a considered manner).

1. Face-to-face visits should be limited.
2. ART treatments should be carried out, as much as possible, in free-standing medical facilities. Patient-friendly protocols (e.g., GnRH antagonist; self-injections) should be considered as the preferred choice.
3. Only samples (oocyte/sperm/embryo) from patients with negative results or who have acquired herd immunity should be cryopreserved*.
4. Psychological support should be offered to those patients in need.
5. Financial aid might be offered to those patients in need (might be particularly relevant to patients under economic pressure due to the pandemic).

*If in any case specimens' freezing of diagnosed SARS-CoV-2 patients is carried out, specimens should be frozen in closed systems (e.g., oocytes, embryos) or using high security straws (e.g. sperm).

Table 4. Prevention recommendations.

Physical distancing measures for staff and patients.	Highly recommended
Patients should use PPE at all times when attending the facility.	Highly recommended
Healthcare providers should use PPE during service delivery.	Mandatory
PPE for healthcare providers should include both N95 mask (or similar) and face shield.	Highly recommended
Staggering appointments to limit patients in the waiting area together.	Recommended
Training staff (receptionists, nurses, technicians, doctors) on PPE needs and usage.	Highly recommended
Companions not allowed into clinics.	Recommended
Do not show up for a scheduled appointment if having any symptoms.	Highly recommended
Strictly follow appointment time.	Recommended
Staff should be divided into two working shifts avoiding contact.	Recommended
Only essential staff should stay in the operating theater/laboratory.	Suggested

PPE: personal protective equipment.

Table 5. Personal protective equipment requirements.

	Patient	Receptionist	Doctor[1]	Doctor[2]	Nurse	Lab personnel
Ordinary mask	+	NA	NA	NA	NA	NA
Surgical mask	++	++	++	++	++	++
N95 mask*	NR	Optional	Optional	Optional	Optional	Optional
Gloves	Optional	Optional	+	++	++	++
Googles	Optional	Optional	Optional	Optional	Optional	Optional
Face shield	NR	++	+	+	++	Optional
Gown/coverall	NR	NR	Optional	+	Optional	Optional

[1]When seeing patients (consultations/ultrasound/physical exam); [2]During procedures (oocyte/sperm retrieval, embryo transfer).
*or equivalent; NR: not required; NA: not applicable.
+: recommended; ++: highly recommended.

in countries like China (mainland), Thailand, Indonesia, India, Vietnam, and Pakistan, and less pronounced in Australia, South Korea, and Japan.

There is a consensus view that ART Clinic lockdown/slowdown will be detrimental for society. Overwhelmingly, respondents feel that patients have been reluctant to undergo ART treatment due to fear of being infected or for economic reasons. The PPDG also believes IVF clinics must find ways of protection from potential liability issues.

Most respondents believe serology testing may help identify presumably staff and patients who have serological immunity. However, there is uncertainty with respect to testing accuracy and post-infection immunity. There is also a general perception that pregnancy may act as a co-morbidity in Covid-19 infection and that the virus may be present in biological fluids and specimens of infected patients (e.g., asymptomatic patients). The key findings are summarized in Table 8.

Table 6. Items to be included in the dedicated informed consent form.

1. Risk of contracting the disease in the workplace, in transit, social life, and in the clinic.
2. Limitations of current diagnostic/screening testing.
3. Little-known impact on gametes, embryos, pregnancy, and fetus.
4. Risk of treatment suspension and financial loss (e.g., due to infection, legislation, limitation of mobility, lockdown).

Table 7. Items to be considered in the quality management system plan.

1. Patient prioritization for treatment.
2. How working lists should be filled.
3. Staff scheduling.
4. Inventory (minimum materials/reagents quantity and emergency plan).
5. Disinfection protocols.
6. PPE needs and training.
7. Treatment workflows (including the interval between procedures).

Table 8. Key Findings on the perceptions related to the impact of the SARS-CoV-2 pandemic on fertility.

1. Overall (60%), participants feel ART Clinic lockdown/slowdown will be detrimental for society.
2. Overwhelmingly (90%), participants feel patients are reluctant to undergo ART treatment during the pandemic due to fear of being infected or for economic reasons. They also believe IVF clinics must find ways of protection from potential liability issues.
3. Most participants (80%) believe serology testing may help identify staff and patients who are presumably immune.
4. There is a general perception that pregnancy may act as a co-morbidity in Covid-19 infection and that the virus may be present in biological fluids and specimens of infected patients (e.g., asymptomatic patients) undergoing treatment.

DISCUSSION

This ASPIRE guideline aims to supply healthcare providers with expert judgment for ART services during the SARS-CoV-2 pandemic. With a solid consensus, the key recommendations were formulated considering an assessment of current ART practice across APAC, considering the balance of benefit versus harm, patient preferences, clinicians' expertise, and resource use. The guideline includes 14 best practice recommendations and a series of supporting documents to help implementation.

The "time" variable is crucial in specific subgroups of infertile patients, affecting both women and men. Besides reproductive-age oncological patients, loss of time is particularly consequential among patients with advanced maternal age, poor ovarian reserve, and low prognosis for reproductive success (American College of Obstetricians and Gynecologists Committee on Gynecologic Practice and Practice Committee [ACOG], 2014; Adamson et al., 2018; CDC, 2020; Esteves et al., 2019; Human Fertilisation & Embryology Authority [HFEA], 2017). Severe male factor infertility patients may also have a limited time window to achieve biological parenthood (Esteves et al., 2020). These patient categories can be considered the most vulnerable and, therefore, should be prioritized for treatment. However, patient and healthcare provider autonomy have to be respected. Expert judgment and shared informed decision, considering patient preferences, remain critical to allow infertile patients to find the best possible way to secure parenthood.

Safety in ART is also paramount (ASRM, 2016; ESHRE, 2015; European Directorate for the Quality of Medicines [EDQM], 2019). This critical aspect involves discussing the ovarian stimulation protocols that could optimize outcomes while avoiding complications such as OHSS (Alviggi et al., 2020). Patients whose ovarian reserve is still fair could be counseled to undergo ovarian stimulation and IVF for oocyte freezing or embryo freezing, as appropriate. In patients of advanced age and low ovarian reserve, multiple ovarian stimulations (e.g., consecutive stimulation or DuoStim) and fresh or frozen embryo transfer — with or without preimplantation genetic testing (PGT-A) — should be considered. Moreover, personalized gonadotropin dose for ovarian stimulation, use of a GnRH antagonist protocol, and GnRH agonist triggering may be considered as the preferred regimen.

Besides clinical considerations, ART services provision should only be undertaken with appropriate medical infrastructure support. We reiterate the above guidance issued by health regulatory authorities, that is, care should be offered if social distancing can be maintained, areas regularly disinfected, and screening for signs and symptoms of the infection undertaken before allowing patients into the facility. The use of self-injection gonadotropins (e.g., pen devices) in combination with tele-consultation may be considered to avoid multiple clinic visits.

Our recommendations are unlikely to burden further the medical infrastructure currently used for treating Covid-19 patients, but patients might be reluctant to use services based on fear of being infected or because of economic reasons. The existing data indicate that a subject can be infectious 3–5 days before the onset of actual symptoms of the viral infection, and the risk of such cases spreading the infection has not been rigorously researched (Yuen et al., 2020). While testing patients and staff is recommended, clinics may lack prompt access to these tests. Moreover, some countries face a shortage of test kits, which have only been made available for symptomatic patients and frontline health providers. Besides, these tests' accuracy has been questioned, with some reports suggesting that some of the SARS-CoV-2 kits in the market have a false negative rate of 30%–40% (Colin et al., 2020; West et al., 2020). Thus, it remains to be determined how clinics can best screen patients and healthcare providers optimally.

Likewise, it remains to be decided who – patients or clinics – will bear the testing-related costs, PPE, and reduced patient volume due to extra measures instituted to avoid infections. Along these lines, clinics and hospitals providing ART services may need to determine ways of protecting themselves from potential liability issues. Although the overall mortality rate among men at reproductive age remains low, it should be considered that contamination of patients and staff could occur with SARS-CoV-2 in the context of asymptomatic shedding (van Doremalen et al., 2020).

We also realize that much is unknown about SARS-CoV-2 and its implication on female and male reproductive health. At present, limited data exist about potential routes of SARS-CoV-2 infection in reproductive systems (Hallak et al., 2020; Segars et al., 2020). There is a little data on virus load in follicular fluid, semen, or testicular/ovarian tissue biopsies of SARS-CoV-2-infected patients (Pan et al.,

2020; Song et al., 2020). Nevertheless, angiotensin-converting enzyme 2 (ACE2) receptors are used by the virus to enter host cells, exist in the ovary and testis (Li et al., 2020; Pan et al., 2013; Wang and Xu, 2020; Xu et al., 2006).

As far as pregnancy is concerned, it has been suggested that pregnant women might be at a higher risk of developing complications, including miscarriage, preeclampsia, and preterm birth (Chen et al., 2020; Dong et al., 2020; Liu et al., 2020; Rasmussen et al., 2020; Schwartz, 2020; Schwartz and Graham, 2020; Yu et al., 2020; Zeng et al., 2020a, 2020b). However, the evidence is still limited; we should, therefore, continue to look critically and objectively at the SARS-CoV-2 evidence. Serology testing could help identify immune patients for treatment who may pose lower risk of either pregnancy complications or propagating the disease when attending fertility clinics (Petherick, 2020), but this deserves further investigation.

CONCLUSIONS

This document provides the ASPIRE viewpoint on better managing infertile patients seeking ART during the COVID-19 pandemic. This expert opinion guide aims to help both competent authorities and healthcare providers to deliver quality and safe ART.

DECLARATION OF INTERESTS

The authors declare that Med.E.A. were sponsored by Merck, but the position paper was developed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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AUTHORS' CONTRIBUTIONS

All authors, listed as "Position Paper Development Group Members" contributed equally to the manuscript, by voting, analyzing the survey results, discussing the draft recommendations, until consensus within the group was reached.

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SUPPLEMENTARY MATERIAL

SURVEY

It will take approximately 30 minutes to complete this survey.

SECTION A. Demographics and Clinical Practice (27 questions)

A1. Which is your country?

_____

A2. Does your government issue a decree to regulate ART (IUI/IVF/ICSI) practice during the pandemic? Check one.
☐ Yes
☐ No

A3. Did your national human reproduction society issue recommendations to regulate ART (IUI/IVF/ICSI) practice during the pandemic? Check one.
☐ Yes
☐ No

A4. Do you feel that recommendations/decrees to regulate ART (IUI/IVF/ICSI) practice are needed? Check one.
☐ Yes
☐ No

A5. How do you rank IVF/ICSI services during the pandemic? Check one option.
☐ Low priority (clinical harm very unlikely if postponed 6 months or longer)
☐ Intermediate priority (clinical harm possible if postponed 6 months or longer but unlikely)
☐ High priority (clinical harm very likely if postponed

A6. How do you rank IUI services during the pandemic? Check one option.
☐ Low priority (clinical harm very unlikely if postponed 6 months or longer)
☐ Intermediate priority (clinical harm possible if postponed 6 months or longer but unlikely)
☐ High priority (clinical harm very likely if postponed

A7. Based on the day you received this questionnaire, did your center reinitiate activities and since when? Check one option.
☐ Never closed
☐ Not reopened
☐ <15 days
☐ 16–30 days
☐ 31–45 days
☐ >45 days

A8. How is the decision primarily taken to close or reinitiate activities, or never close, in your center? Check one option.
☐ Independent decision by each professional
☐ A decision taken by the majority of professionals in the center
☐ Follow societies guidelines, like ESHRE, ASRM
☐ Governmental decrees

Respond Q9–26 only if your center currently provides services or plans to do so in the very near future.

A9. If your center is providing services now what procedures are you doing? Check all your options.
☐ Ovarian stimulation
☐ Follicular aspiration
☐ IVF/ICSI
☐ Embryo biopsy
☐ Embryo cryopreservation
☐ Embryo transfer, fresh or frozen
☐ Oocyte cryopreservation
☐ Sperm cryopreservation
☐ Surgical sperm retrieval (PESA, TESA, MESA, TESE)
☐ Semen analysis
☐ Intrauterine insemination

A10. If you have an oocyte donation program, which procedures do you perform? Check all your options.
☐ No oocyte donation program
☐ Donor ovarian stimulation
☐ Follicular aspiration
☐ Cryopreservation of oocytes/embryos
☐ Embryo transfer to receptors

A11. Did your center establish any criteria to select patients who might undergo treatment during the pandemic? Check one.
☐ Yes
☐ No

A12. If your answer is YES, which criteria are used to prioritize patients for treatment? Check all your options.
☐ Cancer patients (fertility preservation)
☐ Bologna criteria
☐ Poseidon criteria
☐ Advanced maternal age
☐ Poor ovarian reserve
☐ History of poor ovarian response in previous cycles
☐ History of implantation failure or miscarriage
☐ Severe male factor infertility
☐ Advanced paternal age
☐ Other:_____(Please explain)

A13. How do patients' opinion affect your decision to deliver services during the pandemic? Check one option.
☐ Extremely/highly (my decision to deliver services is patient-driven)
☐ Moderately (in same cases I will deliver services event if the rules in place say otherwise)
☐ Minimal/None (follow rules established)

A14. Has your center established any triage before a cycle is initiated in order to prevent contamination with Covid-19? Check one.
☐ Yes
☐ No

A15. If YES, what kind? Check all your options.
☐ Epidemiological questionnaire
☐ Temperature control
☐ PCR-RT
☐ Serological testing

A16. Which would you consider to be exclusion criteria if positive during the last 14 days? Check all your options.
☐ Diagnosed with COVID-19 (PCR-RT positive and/or IgM positive)
☐ Having traveled by plane in the last 14 days
☐ Direct contact with anyone proved or suspect of COVID-19
☐ Symptoms as dry cough, fatigue, chest pain, diarrhea, skin eruptions, headache, and other possibly associated with Coronavirus
☐ Fever
☐ Other: _____

A17. Once a patient is selected for treatment during the pandemic, please describe the procedures used in your center prior to ovarian stimulation. Check all your options.
☐ No specific procedure performed
☐ Check on clinical symptoms
☐ PCR nasopharynx swab
☐ Antibodies tests (IgG /IgM)
☐ PCR nasopharynx swab + antibodies test (IgG)

A18. Do you request PCR nasopharynx swab and/or antibodies (IgG and IgM) before follicular aspiration? Check one.
☐ Yes
☐ No

A19. Do you request PCR nasopharynx swab and/or antibodies (IgG and IgM) before embryo transfer? Check one.
☐ Yes
☐ No

A20. Do you request PCR nasopharynx swab and/or antibodies (IgG and IgM) before sperm collection? Check one.
☐ Yes
☐ No

A21. Is PCR nasopharynx swab and/or antibodies (IgG and IgM) performed routinely and periodically in the staff of the unit? Check one.
☐ Yes
☐ No

A22. If a patient and/or her couple has symptoms or positive testing during stimulation, would you proceed to follicular aspiration? Check one.
☐ Yes
☐ No

A23. Do you follow up your patients as regards Covid-19, 14 days after follicular aspiration or embryo transfer? Check one.
☐ Yes
☐ No

A24. What is the percentage (%) of ART cycles currently per month, compared to months before the pandemic? Check one.
☐ 0–20
☐ 21–40
☐ 41–60
☐ 61–80
☐ 81–100
☐ >100

A25. So far, what percentage of patients have you had with either positive symptoms or positive RT-PCR (or IgM) during ovarian stimulation? Check one.
☐ No cases
☐ 1%–2%
☐ 3%–5%
☐ 6%–10%
☐ >11%

A26. So far, what percentage of *patients* have you had with either positive symptoms or positive testing 14 days after aspiration? Check one.
☐ No cases
☐ 1%–2%
☐ 3%–5%
☐ 6%–10%
☐ >11%

A27. So far, what percentage of cases have you had with either positive symptoms or positive testing in your *staff*? Check one
☐ No cases
☐ 1%–2%
☐ 3%–5%
☐ 6%–10%
☐ >11%

SECTION B. Recommendations (29 questions)

Note: Please respond *absolutely agree* if you believe the statement is correct and most individuals in that situation should receive the intervention/procedure. By contrast, respond *agree* if you feel the statement is correct, but various choices might be suitable for individual clinics and patients, and that healthcare practitioners should reach a decision coherent with a patient-centered approach and local resources in a considered manner. Along these lines, *neutral* means you do not support either side and prefer to abstain from making an opinion. Responding *disagree* implies that you oppose to the statement and feel it should not be followed in most cases, whereas *absolutely disagree* means that you consider the statement wrong and, in any circumstances, it should be followed.

B1. Before any treatment initiation, active SARS-CoV-2 infections and suspected cases should be excluded. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B2. Testing patients and staff using molecular or serological testing should be: (Check one)
☐ Weighed on an individual basis, considering availability, accuracy, and costs
☐ Mandatory
☐ Not required

B3. Only samples (oocyte/sperm//embryo) from patients with negative results or who have acquired herd immunity should be cryopreserved. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B4. Tele-health and phone counselling should be encouraged. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B5. Face-to-face visits should be limited for patients who demand treatment. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B6. In case of face-to-face visits, time slots for patients should be adequate to avoid crowded waiting rooms and waiting rooms should be adapted to 1.5–2 m distance between chairs.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B7. Adherence to regulatory infection prevention recommendations should be of utmost importance for patients and health practitioners. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B8. Prevention recommendation should include: (Check all your options)
☐ Physical distancing measures for staff and patients
☐ Hand hygiene
☐ Proper personal protective equipment (PPE) should be used by patients during service delivery
☐ Proper PPE should be used by healthcare providers during service delivery
☐ Staggering appointments so that no patients are in waiting area together
☐ Training staff (receptionists, nurses, technicians, doctors) on PPE needs and usage
☐ Do not bring companions
☐ Do not show up for a scheduled appointment if having any symptoms
☐ Strictly follow appointment time

B9. Which PPE should *patients* use when attending the clinic? Check all your options.
☐ None
☐ Ordinary mask
☐ Surgical mask
☐ Gloves
☐ Googles

B10. Which PPE should *doctors* use when seeing patients (consultations/ultrasound/physical exam)? Check all your options.
☐ None
☐ Ordinary mask
☐ Surgical mask
☐ N95 (or equivalent) mask
☐ Gloves
☐ Googles
☐ Face shield
☐ Gown/coverall

B11. Which PPE should *doctors* use during procedures (oocyte/sperm retrieval, embryo transfer)? Check all your options.
☐ None
☐ Ordinary mask
☐ Surgical mask
☐ N95 (or equivalent) mask
☐ Gloves
☐ Googles
☐ Face shield
☐ Gown/coverall

B12. Which PPE should *receptionists* use when providing services? Check all your options.
☐ None
☐ Ordinary mask
☐ Surgical mask
☐ N95 (or equivalent) mask
☐ Gloves
☐ Googles
☐ Face shield
☐ Gown/coverall

B13. Which PPE should *nurses* use when providing services? Check all your options.
☐ None
☐ Ordinary mask
☐ Surgical mask
☐ N95 (or equivalent) mask
☐ Gloves
☐ Googles
☐ Face shield
☐ Gown/coverall

B14. Which PPE should *lab personnel* use when handling gametes and embryos? Check all your options.
☐ None
☐ Ordinary mask
☐ Surgical mask
☐ N95 (or equivalent) mask
☐ Gloves
☐ Googles
☐ Face shield
☐ Gown/coverall

B15. ART treatments should be carried out, as much as possible, in free-standing medical facilities. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B16. Medical staff should be divided in two working shifts avoiding contact. Check one.
☐ Only doctors
☐ Only embryologists
☐ Only nurses
☐ All the staff

B17. During *oocyte retrieval*: (Check all your options)
☐ Procedures should be performed on an outpatient basis under local anesthesia.
☐ Procedures should be performed on an outpatient basis under the anesthesia SOP used before the pandemic
☐ Only essential staff should stay in the operating theatre.
☐ PPE measures should be strictly followed.
☐ Other: _____

B18. During *sperm retrieval*: (Check all your options)
☐ Procedures should be performed on an outpatient basis under local anesthesia.
☐ Procedures should be performed on an outpatient basis under the anesthesia SOP used before the pandemic.
☐ Only essential staff should stay in the operating theatre.
☐ Use of electrocautery should be avoided (surgical smoke might carry the virus if a patient is infected but asymptomatic.
☐ PPE measures should be strictly followed.
☐ Other: _____

B19. During *embryo transfer*: (Check all your options)
☐ Procedures should be performed on an outpatient basis under local anesthesia.
☐ Procedures should be performed on an outpatient basis under the anesthesia SOP used before the pandemic
☐ Only essential staff should stay in the operating theatre.
☐ PPE measures should be strictly followed.
☐ Husband or any accompanying person not allowed.
☐ Other: _____

B20. Special attention has to be given to air quality control, including use of air filtration and air pressurization, particularly in surgical and laboratory areas (in closed-controlled air systems, the airflow might produce an increase in the viral spread from potential asymptomatic patients). Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B21. Good standard laboratory practices should be strictly applied when handling gametes and embryos within the embryology and andrology labs. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B22. Measures to avoid cross-contamination (e.g., protect specimens and laboratory staff — who might be asymptomatic for COVID-19–, and vice-versa) should include: (Check all your options)
☐ Use of PPE (e.g., googles/face shield, N95 mask, gown/coverall, and gloves)
☐ Class II safety cabinets should be used (protection to specimen handled as well as the operator performing the work)
☐ Use of high-security straws for sperm cryopreservation
☐ Use of closed system for embryo/oocyte cryopreservation
☐ Adequate interval between procedures to allow disinfection
☐ Avoid mouth pipetting
☐ Time-lapse incubators preferred
☐ One patient per incubator's chamber preferred
☐ Other: _____

B23. A thorough discussion between patients and healthcare providers should be made for responsible shared decisions. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B24. A dedicated informed consent detailing the risks of attending the facility during the SARS-CoV-2 pandemic should be created. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B25. The informed consent should include, as minimum requirement, information about: (Check all your options)
☐ Risk of contracting the disease, in the workplace, in transit, in social life, and in the clinic
☐ Risk of treatment suspension risk and financial loss (e.g., due to infection, legislation, limitation of mobility, lockdown)
☐ Little-known impact on gametes, embryos, pregnancy, and fetus
☐ Limitations of current diagnostic/screening testing
☐ Other: _____

B26. Psychological support should be offered to those patients in need. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B27. Financial aid might be offered to those patients in need (might be particularly relevant to patients under economic pressure due to the pandemic). Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B28. Advanced planning should guide the restart of ART services taking into consideration a risk management analysis. Check one.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

B29. Quality management planning should include: (Check all that apply)
☐ Which patients to prioritize
☐ How working lists should be filled,
☐ Staff scheduling
☐ Inventory (availability of materials/reagents)
☐ Disinfection protocols
☐ PPE availability and training
☐ Treatment workflows (including interval between procedures)
☐ Other: _____

SECTION C. Perceptions (6 questions)

C1. ART Clinic lockdown/slowdown might be detrimental for the society as a whole? (decrease in the number of infants expected to be born – but who will not be born due to ART lockdown/slowdown – will likely have an economic impact of workforce decline in future)
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

C2. Patients are reluctant to undergo ART treatment during the pandemic due to fear of being infected or for economic reasons.
☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

C3. Serology testing is helpful in the identification of presumably immune staff and patients (less risk of either pregnancy complications or propagating infection when attending fertility clinics)

☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

C4. IVF clinics must find ways of protection from potential liability issues (Although overall mortality rate is low among individuals at reproductive age, infection of patients and staff could occur in the context of asymptomatic transmission)

☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

C5. Pregnancy may act as a co-morbidity in Covid-19 infection.

☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

C6. Presence of virus in biological fluids and specimens of infected patients (e.g., asymptomatic patients) undergoing treatment is a real concern.

☐ Absolutely agree
☐ Agree
☐ Neutral
☐ Disagree
☐ Absolutely disagree

THANK YOU.

Name of IVF Center

COVID 19 – PLAN FOR SERVICE PROVISION

Version of dd/mm/yyyy

Table of contents

PATIENTS TO BE TREATED AND SERVICES TO BE PROVIDED WITH PRIORITY

By taking into account the health constraints in force, elements provided by our institution, our resources, and recommendations of our scientific societies or by our entities, we have planned to treat our patients and deliver our services with priority as follows:

Typology (classification) of patients and techniques favorable for resumption	**ART (IUI[1], IVF/ICSI[2], TEC[3])** • • **Andrological services** • • **Preservation of fertility** • **Donation** •
Projects/Clinical research *To be re-scheduled by order of priority and of feasibility*	•
Human and technical resources mobilized during the pandemic	•

[1]IU: Intra-uterine insemination; [2]IVF/ICSI: In-vitro fertilization/Intra-cytoplasmic sperm injection; [3]TEC: Transfer of frozen embryos.

RE-ORGANIZATION/ADJUSTMENT OF ACTIVITIES

Subject	Impacts		Adjustments, change to activities, impact on work load*
	Y	N	
Scheduling of cycles			
Processes of management – ART			
Conduct of additional management			
Process of management – Preservation of fertility			
Process of management – Donation			
Delivery			
Availability of products			
Workflow			
Circulation of healthcare professionals			
Circulation of couples			
Flow of materials/products			
Conditions for reception of healthcare professionals			
Conditions for reception of couples			
Arrangement of workstations			
Bio-decontamination			
Activities of service providers on-site			

*See Annexes of tier 1 and tier 2 ASPIRE recommendations.

PREPARATION OF FACILITIES PRIOR TO RESUMPTION

Type of facility	Actions taken*

*The associated actions are detailed in the annexes (prevention recommendations and PPE requirements).

ORGANIZATION OF RESUMPTION OF TEAMS

Salaried workers available For a minimum duration of one month		**Salaried workers to protect**	
Adequacy of competence compared to planned activities			
Availability of teams and methods of protection			
Adaptation of working hours for staff +/– rotation of teams			
Modalities for intervention of outside service providers			

Report actions in the plan of action and plan in it the update of your single document.

SCHEDULE OF RESUMPTION

For this chapter you can complete a free text area at your convenience or complete the following proposed table.

Period (dates)	Planned activities (types and volume)

MODALITIES FOR INFORMATION OF TEAMS AND SERVICE PROVIDERS

Subjects	When	Method**

*See Annexes: i. Items to be included in the dedicated informed consent form as per ASPIRE recommendations; ii. PPE requirements; iii. Recommendations.

**Formal confirmation, authorisation, email, signs, etc.

MODALITIES FOR INFORMATION OF COUPLES*

Subjects	When	Method**

*See Annexes: i. Items to be included in the dedicated informed consent form as per ASPIRE recommendations; ii. PPE requirements; iii. Recommendations.

**Formal confirmation, authorization, email, signs, etc.

MODALITIES FOR COORDINATION WITH OTHER UNITS IN THE INSTITUTION AND/OR THE NETWORK OF CORRESPONDENTS

Subjects	When	Method

*See annex. Quality Management System Plan.

MODALITIES FOR MONITORING OF RESUMPTION*

For this chapter, you can complete a free text area at your convenience by specifying how you plan to monitor the proper conduct of your activity and if necessary, to readjust modalities of operation in case of identification of new risks or of new elements enabling to widen the scope of activity.

*See annex. Quality Management System Plan.

ANNEX – KEY FACTORS WHICH CAN HAVE AN INFLUENCE ON SERVICE PROVISION

(behavior of clients, regulatory and health-related constraints, availability of resources, behavior of suppliers, etc.)

Factors identified

No.	Factor	Level of impact (Nil, Low, Strong/ Very strong)	Level of uncertainty (Nil, Low, Strong/ Very strong)
1	Conditions of deconfinement defined by the national and local authorities, the regulatory authorities, and scientific societies		
2	Requests from couples		
3	Availability of laboratory technical equipment (requisition medical biology activity?)		
4	Availability of facilities in the center (apart from the Covid area)		
5	Availabilities of treatments: stimulation, reagents, anesthetic medicinal products and consumables (patient, laboratory, OR (operating room))		
6	Availability of the OR/SSPI[1] and of healthcare professionals involved in management in ambulatory practice and in the OR		
7	Availability of the ART team upstream of resumption (requisition for other activities?)		
8	Availability of correspondents and of the network (monitoring of stimulation)		
9	Availability of PPE[2] (masks, gloves, water-alcohol solution)		
10	Obligation to comply with social distancing		
11	Modalities for travel: transport, lodging, etc.		
12	Availability of technical solutions for tele-consultation		
13	Pre-existence of authorization of viral activity		

[1]SSPI: Recovery room; [2]PPE: Personal protective equipment.

Key factors retained

Factor with the highest (+) impact	
Factor with the highest uncertainty	

ANNEX. ASPIRE RECOMMENDATIONS

(most individuals should receive the intervention/procedure)

1. Before any treatment initiation, active SARS-CoV-2 infections and suspected cases* should be excluded.
2. Tele-health and phone counseling should be encouraged.
3. In the case of face-to-face visits, time slots for patients should be adequate to avoid crowded waiting rooms and waiting rooms should be adapted to social distancing (1.5–2 m distance between chairs).
4. Adherence to regulatory recommendations regarding infection prevention should be of utmost importance for patients and health practitioners (see Tables 4 and 5).
5. Special attention has to be given to air quality control, including the use of air filtration and air pressurization, particularly in surgical and laboratory areas.
6. Good standard laboratory practices should be strictly applied when handling gametes and embryos within the embryology and andrology labs.
7. A thorough discussion between patients and healthcare providers should occur for responsible shared decisions (e.g., impact of age, type of infertility, risk/benefits; see Table 6).
8. A dedicated informed consent, detailing the risks of attending the facility during the SARS-CoV-2 pandemic should be created (see Table 6 for critical items to be included).
9. Advanced planning should guide the restart of ART services, considering a risk management analysis (see Table 7 and Appendix for suggested QMS plan).

*Direct contact with anyone proved or suspect of COVID-19, symptoms as dry cough, fatigue, chest pain, diarrhea, skin eruptions, headache, and other possibly associated with Coronavirus fever.

ANNEX. ASPIRE RECOMMENDATIONS

(may be suitable for individual clinics and patients, but healthcare practitioners should reach a decision coherent with a patient-centered approach and local resources in a considered manner)

1. Face-to-face visits should be limited.
2. ART treatments should be carried out, as much as possible, in free-standing medical facilities. Patient-friendly protocols (e.g., GnRH antagonist; self-injections) should be considered as the preferred choice.
3. Only samples (oocyte/sperm/embryo) from patients with negative results or who have acquired herd immunity should be cryopreserved*.
4. Psychological support should be offered to those patients in need.
5. Financial aid might be offered to those patients in need (might be particularly relevant to patients under economic pressure due to the pandemic).

*If in any case specimens' freezing of diagnosed SARS-CoV-2 patients is carried, out, specimens should be frozen in closed systems (e.g., oocytes, embryos) or using high security straws (e.g., sperm).

ANNEX. PREVENTION RECOMMENDATIONS

Physical distancing measures for staff and patients.	Highly recommended
Patients should use PPE at all times when attending the facility.	Highly recommended
Healthcare providers should use PPE during service delivery.	Mandatory
PPE for healthcare providers should include both N95 mask (or similar) and face shield.	Highly recommended
Staggering appointments to limit patients in the waiting area together.	Recommended
Training staff (receptionists, nurses, technicians, doctors) on PPE needs and usage.	Highly recommended
Companions not allowed into clinics.	Recommended
Do not show up for a scheduled appointment if having any symptoms.	Highly recommended
Strictly follow appointment time.	Recommended
Staff should be divided into two working shifts avoiding contact.	Recommended
Only essential staff should stay in the operating theater/laboratory.	Suggested

ANNEX. PPE REQUIREMENTS

	Patient	Receptionist	Doctor[1]	Doctor[2]	Nurse	Lab personnel
Ordinary mask	+	NA	NA	NA	NA	NA
Surgical mask	++	++	++	++	++	++
N95 mask[3]	NR	optional	optional	optional	optional	optional
Gloves	optional	optional	+	++	++	++
Googles	optional	optional	optional	optional	optional	optional
Face shield	NR	++	+	+	++	optional
Gown/coverall	NR	NR	optional	+	optional	optional

*According to ASPIRE Position Statements; PPE: personal protective equipment.
[1]When seeing patients (consultations/ultrasound/physical exam); [2]During procedures (oocyte/sperm retrieval, embryo transfer); [3]or equivalent; NR: not required; NA: not applicable.
+: recommended; ++: highly recommended.

ANNEX. ITEMS TO BE INCLUDED IN THE DEDICATED INFORMED CONSENT FORM

(the table below can be modified as needed)

1. Risk of contracting the disease in the workplace, in transit, social life, and in the clinic.
2. Limitations of current diagnostic/screening testing.
3. Little-known impact on gametes, embryos, pregnancy, and fetus.
4. Risk of treatment suspension and financial loss (e.g., due to infection, legislation, limitation of mobility, lockdown).

ANNEX. ITEMS TO BE INCLUDED IN THE QUALITY MANAGEMENT SYSTEM PLAN

(the table below can be modified as needed)

1. Patient prioritization for treatment.
2. How working lists should be filled.
3. Staff scheduling.
4. Inventory (minimum materials/reagents quantity and emergency plan).
5. Disinfection protocols.
6. PPE needs and training.

ANNEX – TESTING AND TRIAGE

Description of plausible triage scheme for access to treatment (can be adapted)

First triage	3–5 days before the initiation of COS or endometrial preparation for ET • Questionnaire • PCR-RT + Serology testing (IgM + IgG)
Continuous monitoring	During COS or endometrial preparation for ET • Questionnaire + Temperature checking
Subsequent triage	Approximately 3 days before ovulation triggering or embryo thawing (FET cycles) • Questionnaire • PCR-RT

Description of plausible scenarios (can be adapted)

Scenario 1	Patient and/or partner with negative questionnaire, negative IgG/IgM or positive IgG/negative IgM, and negative RT-PCR.
Scenario 2	Patient and/or partner with positive questionnaire or mild symptoms, and negative serology and RT-PCR.
Scenario 3	Patient and/or partner with Covid-19 symptoms and/or positive SARS-COV-2 test (RT-PCR or IgM)