Journal of Assisted Reproduction and Genetics (2020) 37:2669–2686
https://doi.org/10.1007/s10815-020-01958-5

COMMENTARY

COVID-19 risk assessment and safety management operational guidelines for IVF center reopening

Maria Graciela Alaluf[1] · Agustin Pasqualini[1] · Gabriel Fiszbajn[1] · Gustavo Botti[1] · Gustavo Estofan[1] · Claudio Ruhlmann[1] · Leticia Solari[1] · Claudio Bisioli[1] · Alicia Pene[1] · Constanza Branzini[1] · Andrea Quintero Retamar[1] · Valeria Checkherdemian[1] · Romina Pesce[1] · Idelma Serpa[1] · Fabian Lorenzo[1] · Conrado Avendaño[1] · Cristian Alvarez Sedo[1] · Stella Lancuba[1]

Received: 13 August 2020 / Accepted: 25 September 2020 / Published online: 7 October 2020

Abstract

Purpose To promote nationwide dissemination and implementation of COVID-19 Risk Assessment and Safety Management Operational Guidelines, drawn up by SAMeR Task Force in ART centers in Argentina. Our objective is to prevent and mitigate the transmission of SARS-CoV-2 at an institutional level, while reducing the risk of infection among both physicians and patients in the context of a critical scenario in the local and Latin American healthcare system.

Methods SAMeR Executive Committee set up a crisis committee which was made up of specialists in reproductive medicine, embryology, and healthcare management. A critical and updated review of the advances in science, documents, and recommendations released by other societies (ASRM, ESHRE, IFFS, Red LARA, societies of anesthesiologists, infectious diseases, and Occupational Safety and Health Administration—OSHA) was carried out. Likewise, there were joint meetings with the Ministry of Health of Argentina in order to draw up the guidelines. Simultaneously, ongoing medical training was carried out, thus providing added value to them, including two status surveys of the activities of the monovalent and polyvalent centers according to the country's epidemiological mapping. Four additional recommendations were made, and online training was given to healthcare workers. The aforementioned regulations were first analyzed by the healthcare providers and their practical suggestions were then added to the guidelines.

Results The one-off collaborative work and the actions coordinated with the National ART Program of the Ministry of Health of Argentina resulted in the development and implementation of the present COVID-19 Risk Assessment and Safety Management Operational Guidelines at a national level. SAMeR gave recommendations for the implementation of the Management Guidelines for the center reopening, providing new safety criteria against the threat of viral contagion. A new organizational culture was promoted through the awareness of all the healthcare workers and teaching responsibility. We continue working on the compliance with a new "Code of Conduct and Commitment in Healthcare" and with workplace safety measures. We helped with transforming the theoretical knowledge into practical measures for the healthcare workers in different services, with the aim to prevent, mitigate, and/or handle contingencies at the centers/services and gamete banks, in line with the actions agreed upon with the Ministry of Health.

Conclusions As an extraordinary and uncertain event, the SARS-CoV-2 pandemic helped consolidate a volunteer-based and collaborative panel of SAMeR experts who developed the COVID-19 Risk Assessment and Safety Management Operational Guidelines as a new and readily available tool for physicians, patients, and gamete banks care. Their implementation has provided specific guidelines to minimize risk for professionals in ART clinics, as well as guaranteeing patient safety.

This document will be constantly reviewed and updated, pursuant to the scientific evidence and epidemiological information available. Updated June 2020.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s10815-020-01958-5) contains supplementary material, which is available to authorized users.

✉ Maria Graciela Alaluf
dqc.gralaluf@yahoo.com.ar

[1] SAMeR (Argentine Society for Reproductive Medicine), Buenos Aires, Argentina

Keywords COVID-19 · IVF · Risk · Management · Guidelines · Safety

Conceptual framework

In the current context and as the COVID-19 pandemic starts to mitigate, the plan to resume the usual activities at the centers, within the health authority's regulations and the epidemiological surveillance, should follow the steps required for a safe practice and minimize the risks related to SARS-CoV-2-positive patients or staff during the treatment.

In order to carry out this task, safety, contingency criteria, and measures should be implemented in the clinical and laboratory activities regarding the new risks with the aim to guarantee best practices considering that:

1 The reopening of centers or services does not pose a risk of collapse of the healthcare system because the ART centers are mostly monovalent, with independent management of resources and supplies.
2 Today's evidence shows that the risk of complications is insignificant reduced, being in the case of intraperitoneal bleeding after puncture of 0.2%, in abscesses or infections of 0.04%, and in anesthetic problems (hypotension, pneumothorax, pulmonary edema, malignant hyperthermia) of 0.04% [1].

Establishing protocols to protect patients, physicians, laboratory staff, nurses, technicians, and administrative personnel, and communicating them, carrying out training and monitoring the strict compliance with those protocols will enable to perform the activities in a safe manner, thus minimizing risks, which is the main objective of the present document.

Whenever we talk about COVID-19 risk management, three types of risks that involve both patients and staff should be identified (Table 1).

The management of these new risks implies the need to redefine requirements to be applied to the daily practice using safety criteria and measures, and contingency plans.

The phase to restart activities refers to the gradual start of such activities in different stages to be fulfilled in general and specific processes and procedures, and the development of a risk map for the different operative areas.

Stages to restart activities and requirements to be met based on the risks

For the stage to restart activities, after being shut down during the lockdown, the ART centers should establish the general and specific requirements for each area and process based on the new risks, in order to allocate human resources, supplies, material, and equipment for every procedure carried out at the center.

This stage requires at least a 15-day work period before resuming the treatments. Below is a description of the basic points and action models arising from a thorough analysis of rules, protocols, guidelines, and recommendations from other countries which are in a de-escalation phase of the pandemic, using their experience and taking them into account for the protocols to be implemented at each center.

Steps to be followed once the institution has agreed upon the general and specific information that will be provided to patients and staff:

The center should:

- Define in this stage the criteria for patient admission based on clinical risk for comorbidities or pre-existing medical conditions (e.g., diabetes, past transplant patients, or using immunosuppressant therapy). Such patients should not be admitted and be provided detailed and personalized information regarding the risks of the treatment in the current situation.
- Establish the general information on COVID-19 which will be on the bulletin board, leaflets, website, social media, etc., for instance, information on WHO guidelines on hand hygiene and the use of an alcohol-based hand gel, social distancing, the use of personal protection equipment ("PPE") whenever necessary, etc. [2].
- Develop specific information for patients regarding the rights to choose the treatment, to carry it out, or to

Table 1 Risk classification

Risk classification	Scope	Preventive actions
1. Stable risks	Healthcare workers	Require hospital biosafety measures
2. Pandemic risks	Whole population, including healthcare workers and patients	Require general preventive measures: social distancing, the use of face coverings, hand hygiene, and sanitizing surfaces
3. Risks associated with the own institutional processes of the specialty	Healthcare workers and patients	Preventive measures according to the risk map of the institutional processes of ART care

postpone it, and provide a detailed explanation of the current understanding of the potential effects of SARS-CoV-2 during the treatment, on gametes, embryos, during the pregnancy and on the newly born baby.
- Include this information in the specific Informed Consent to be signed by the patient together with the consent for the specific treatment to be carried out. In Argentina, we have a consent issued by the Ministry of Health which is drawn up together with SAMeR.
- Inform about the rules of conduct both patients and staff should comply with during the treatment. It is recommended to document the healthcare commitment by signing the "Code of Conduct", staff as well as patients

Code of conduct

- All staff members and patients will be instructed to avoid unnecessary exposure (both at work and in private).
- Staff will follow specific instructions for each service.
- Attendance at work will be tied to respecting the signed Code of Conduct.
- Activities that are not allowed will be clearly detailed.
- Compliance with a restricted social life and interactions.
- Patients and staff members should sign regularly that they are healthy and have respected the Code or inform the center's Human Resources officer of any infringements of the Code of Conduct previously signed.

A suggested model is given in Supplementary material 1; this should be an appendix to the Informed Consent of the patient's treatment, and which should be signed separately.

General requirements to access the gamete center/bank based on its structure for patients, staff of every area, and suppliers

Gamete centers or banks should draw up a map of the new risks based on their structure and the services they provide (diagnosis as well as care), either if it is a monovalent or polyvalent center. In the case of the latter, the access of patients and staff should guarantee a minimum contact with the rest of the institution.

In the case of monovalent centers, the exposure risks are low and can be controlled more easily.

Gamete banks which are part of a center should define the circuits of donors, whenever possible in independent facilities within the care structure or either alternating appointment booking, studies, and clinical-surgical procedures of donors [3].

If they are only gamete banks, they should define the risk map according to the other services provided of diagnosis or care. Based on the gamete center/bank size, the size of the waiting room, number of doctor offices, type of specialties, diagnostic tests, location of restricted areas, support areas, and single or multiple access should also be taken into account.

Once the risk map is defined, the protocols for the operating processes and access to the gamete center/bank are established by means of the TRIAGE performed to staff, patients, donors, suppliers, and others when entering the center.

Staff triage

When entering the center, all professional, technical, administrative, and support areas staff (permanent or outsourced) should fill in and sign a triage questionnaire regarding their health status and symptoms in general, their lifestyle and the people living in the same household and the information on the previous 14 days. This questionnaire is filed in the staff files. In addition, they should inform the Medical Board and the HR officer or the Area Head if they have any symptom related to COVID-19 and should fill in the triage questionnaire again, defined by the health authority and informed by the Occupational Risk Insurance Company [4] (Supplementary material 2).

Two or more of the following symptoms must be considered as a suspicious case: fever, cough, odynophagia, dyspnea, anosmia, ageusia, headache, and/or vomiting [5].

Based on staff triage results (Fig. 1):

- Triage negative and asymptomatic, they can start to work.
- Triage positive (two or more symptoms of suspicious case) and/or a previous positive COVID-19 test, they should go into self-quarantine and immediately contact the health authorities, pursuant to the current regulations.
- Once recovered after COVID-19 infection with a negative RT-PCR-test* (according to the current protocol) and with medical discharge, they can start work.

*(Quantitative Real-time Polymerase Chain Reaction)

Another measure is daily body temperature checks, preferably with a forehead infrared thermometer, before the staff goes into the locker room. The temperature should not exceed 99.5 °F. If the staff member's temperature is higher than this limit, they will be asked to remain in the isolation sector (preestablished at the center) for 10 min and later the temperature check will be repeated. If the deviation continues, they will be informed that they cannot go in and consult their healthcare provider. If they have any other symptom related to the current detection criteria of close contact or suspicious case, the corresponding protocol should be activated by contacting the health authority of reference (Occupational Risk Insurance Company, Private Health Insurance, etc.) [6].

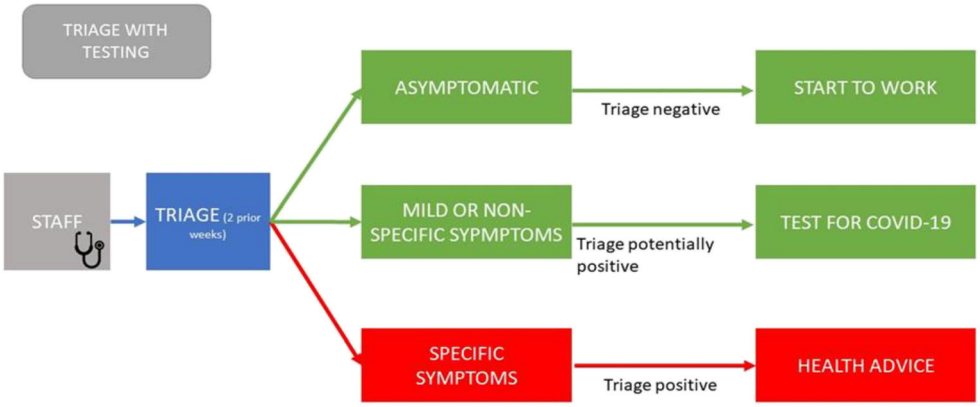

Fig. 1 Summary of staff triage. Adapted from ESHRE guidance on recommencing ART treatments [6]

All exclusive and non-exclusive staff of the center (e.g., anesthesiologists or technical professionals, surgical instrument assistants and/or maintenance staff) who are in charge of patient care or surgical tasks must comply with the code of conduct, triage, and, if required, do the COVID-19 RT-PCR test in order to access the surgical site.

Patient and donor triage

Important: As there is no massive testing, every patient or person entering the center should be considered as a suspected case of COVID-19 and, therefore, all additional safety measures should be taken for all staff (PPE/Biosafety, etc.).

Patients and donors fill in a similar questionnaire to the staff one, drawn up, and updated by the health authority (Supplementary material 2). Said questionnaire should be filled in by the patient/donor when booking the appointment, and then be sent by e-mail, and on the day of the appointment, it should be handed in signed when entering the center/bank. Reception staff will perform the triage questionnaire again and record it signed and dated as an affidavit. In the case of the beginning of a treatment, the patient's partner should fill in the same questionnaire. If a patient or donor is considered as a suspected case or a case of close contact with persons with COVID-19, this person should be isolated until the necessary measures for referring them to their health system can be taken. It is recommended to establish a room for that purpose, which must be isolated from the rest of the staff in the institution, and the staff in charge of the triage must be informed of this.

Upon admission to start the stimulation, if available, patient testing can be carried out (RT-PCR or IgG test for antibodies). RT-PCR testing is recommended for donors at the beginning of the stimulation phase.

In the event the test was not available or it was not performed for any reason, a specific consent should be signed stating the reason why the test was not performed, and agreement between the patient/donor and the professional and the center/gamete bank to carry on with the treatment.

Only patients with negative triage will go into oocyte retrieval. However, donors under treatment who go into oocyte retrieval should have RT-PCR-negative testing 1 to 5 days before.

If the triage result gives data of a possible infection, the patient is referred for medical advice to their health system because they must have regular SARS-CoV-2 RT-PCR and/or IgM/IgG tests, or any equivalent tests. The professional in charge of patient referral can consider carrying out additional tests to the contacts based on the national recommendations and/or test availability.

All patients with a previously confirmed COVID-19 infection must have the medical discharge (with a negative RT-PCR test result) and a medical authorization before analyzing the possibility to start their treatment. If COVID-19 patients have been on ventilators, they must also provide information on testing and a medical specialist report of their discharge.

Based on patient/donor triage results, they can (Fig. 2):

a. be admitted directly:

- Both patients are triaged as low risk (negative clinical history, lifestyle compatible with low/minimal risk of contact with potentially infected persons).
- Both patients are asymptomatic.
- The donor is considered low risk based on the results of the previous specific questionnaire of socio-environmental aspects (Supplementary material 3).

b. have additional testing:

- If any of both partners and the donor has any non-specific symptoms before starting ovarian stimulation.
- Patients who have recovered from a previous COVID-19 infection and have the medical discharge and authorization to start the treatment with a negative RT-PCR prior to starting treatment.

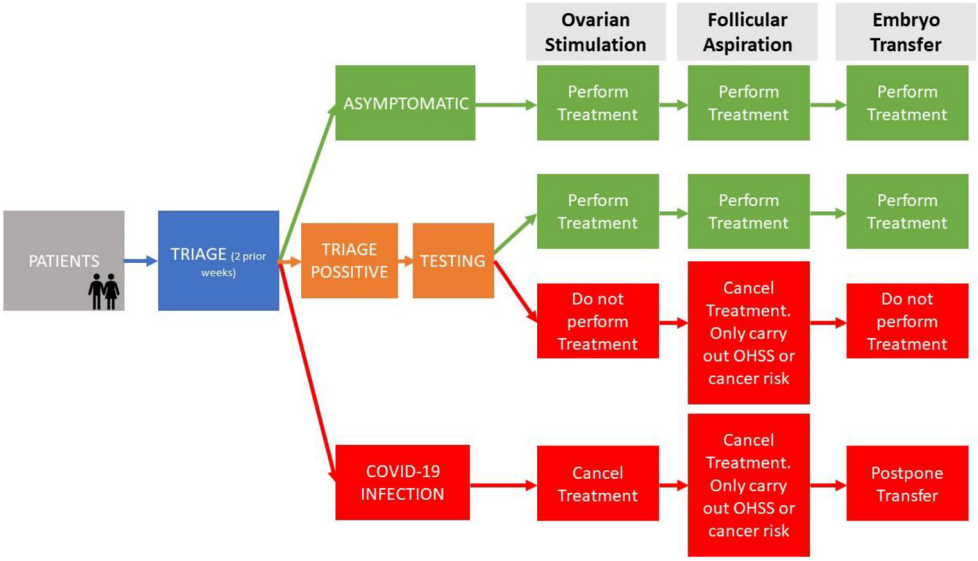

Fig. 2 Summary of patient triage. Adapted from ESHRE guidance on recommencing ART treatments [7]

Repeat the triage at the beginning of ovarian stimulation:

- If negative, continue the treatment.
- If symptoms persist,

- Perform SARS-CoV-2 IgM/IgG and RT-PCR testing to decide:

  If IgM/IgG negative and RT-PCR negative, continue the treatment.
  If IgM/IgG o RT-PCR positive, postpone the treatment and refer for further testing.

Patients with non-specific symptoms arising during ovarian stimulation:

- Perform SARS-CoV-2 IgM/IgG and RT-PCR testing:

  If IgM/IgG negative and RT-PCR negative, continue the treatment.
  If IgM/IgG o RT- PCR positive, postpone the treatment and refer for further testing.

c. not be admitted:

- If patients and/or their partners or donors are symptomatic or COVID-19 positive, postpone the treatment and refer for further testing and follow-up until the patient has been cleared by an infectologist specialist.

In every case, when selecting and admitting patients/donors, the provider must consider the local viral transmission.

Systematic testing is suggested in donors given their socio economic background, residing in areas of high transmission risk. On the other hand, testing could also avoid potential legal conflicts (Supplementary material 3).

If the patient/donor symptoms appear on the eve of the oocyte retrieval, there are three available courses of action: (1) Repeat RT-PCR test if possible; (2) After a thorough assessment of risks and benefits, carry out the procedure and quarantine eggs so as to avoid incursion into potential sanitary hazard exposure; (3) Suspend the procedure.

Interpreting COVID-19 test results

RT-PCR	IgM	IgG	Diagnosis
–	–	–	Negative
+	–	–	Initial stages of infection
+	+	–	Early stage of infection
+	+	+	Active stage of infection
+	–	+	Advanced stage of infection
–	+	–	Early stage—false-negative RT-PCR?
–	+	+	Disease in progression
–	–	+	Resolution stage of infection

Adapting general protocols on biosafety and flow of circulation of the gamete center/bank based on risks

The adaptation of the gamete center/bank to the new risk should include:

– Staff training on COVID-19 regulations.

– Changes to the operating processes and work shifts due to COVID-19.
– Contingency plans to ensure the continuity of ART treatments.

Staff training

All staff must be properly trained on the new work methodology which should include:

- Training on COVID-19-specific risks and biosafety practices.
- Document and keep records of staff training.
- Train all staff so that they can recognize COVID-19 symptoms.
- Train all staff on the correct use of PPE in every area or task, and how to safely put it on and remove it [8].
- It is important that all staff comply with the strict safety and hygiene measures both in the workplace and at home. This commitment is documented by signing the Code of Conduct.

Hand washing

When carrying out the different essential activities of the center and/or maintenance tasks, staff of all areas must wash their hands regularly with water and liquid soap and/or use alcohol-based hand gel, especially during the different procedures or support tasks.

Hands should be washed following WHO guidelines. The duration recommended for hand washing before entering restricted areas is from 40 to 60 s. Use alcohol-based hand gel after hand washing.

Equipment for hand hygiene should be available in every circulation, administrative, and support area, and such equipment should be maintained, providing liquid soap and disposable towels and/or alcohol-based hand gel.

Hands should always be washed:

– Before entering.
– Between every patient contact.
– After removing gloves or any PPE.
– After blowing your nose, coughing, or sneezing.
– After going to the toilet.
– Before eating or drinking.

General and specific cleaning of every area of the center

The center should adapt the daily cleaning, in accordance with the hospital hygiene, to the number of staff present in the different operative areas, should increase its frequency in general circulation or open areas, restrooms, and make additional hygiene of door handles in the different working areas.

For cleaning, products authorized for hospital use, based on neutral detergent, sodium hypochlorite, 70% ethanol solutions, low concentration quaternary ammonium, or hydrogen peroxide, will be used in the procedures in place authorized for the specialty (Table 2).

Whenever a surface is dirty, it should be cleaned with detergent or water and soap before disinfection. Avoid products with volatile compounds [9]. These viruses become inactive after 5 min of being in contact with disinfectants of everyday use.

Cleaning by area

Detailed information is described in Table 3.

Waste management

There is limited evidence available regarding the natural history of COVID-19, source(s), transmission mechanisms, dissemination capacity, and virus persistence in the environment and fomites.

There is no evidence to date of the risk of infection from waste due to the new coronavirus. However, as observed in other respiratory viruses, waste is deemed as a potential risk of infection for any person in contact with it.

Waste does not require special treatment. Due to SARS-CoV-2 and/or the fact that it is an ART Center, the relevant current regulations of municipal, provincial, and national agencies should be complied with [10].

Cleaning staff, with the appropriate PPE, are responsible for sealing, picking up, and taking any waste to the temporary storage room of the institution after each shift.

Circulation, clothing, and use of personal protection equipment

There should be a schedule with the protocol for the access to the gamete center/bank or service and for the circulation of staff in the different administrative and professional areas (internal and external), and of the support staff (cleaning and security), as well as for patient circulation. The schedule should be adapted to the general movement and building structure to restrict the simultaneous circulation of staff while performing different tasks.

Cleaning, security, and technical staff should enter the center before the rest of the staff performing the reception and admission of patients for consultation, procedures in critical areas and diagnostic areas (ultrasound and blood tests).

In bigger centers, staff can be subdivided into smaller work teams to keep social distancing and interactions among them to the minimum. The same can apply to the rest of the staff and

Table 2 Disinfection methods

Disinfection	Preparation	Use	Recommendations
Sodium hypochlorite	-0.1% (1000 ppm) aqueous solution -Daily preparation	-Final disinfection of surfaces -It must not be directly sprayed onto surfaces to prevent the aerosolization of the virus	-When cleaning blood spills or fluids, a 0.5% (5000 ppm) concentration is recommended. -Never mix chloride solutions with detergent
Ethyl alcohol 70%	-Commercially prepared -7 parts of 96% ethyl alcohol and 3 parts of distilled water every 48 h (alcohol evaporates)	-It is used on smaller surfaces, e.g., thermometers, keyboards, door handles -Disinfection of supplies or materials operative surfaces or equipment	-It should not be used in embryology labs
Quaternary ammonium compounds of fourth generation or potassium peroxymonosulfate or stabilized hydrogen peroxide	-Follow manufacturer's instructions for appropriate dilution	-They are used for one-step cleaning and disinfection -Preferably used in restricted operative areas	

patients so that you can guarantee the availability of staff in the event of a COVID-19 contingency.

All staff should have a negative triage test, wash their hands, or use alcohol-based hand gel and wear face masks and shoe cover for entering. Instead of shoe cover, a shoe soles disinfecting floor mat can be placed at the building entrance. In the open areas of reception and security, protective plastic or glass screens, and floor markings to identify 1.5-m distance can be placed, as well as between workstations. Staff cannot use institutional uniforms, clothing used in restricted areas, or healthcare footwear outside the institution.

Security staff should keep a record of staff, patients, and others who access the institution daily in the event of a contingency.

Clothing and footwear used during traveling in public transportation should be changed when entering the house and be washed separately from the clothes of the family.

Clothing of critical areas should be sent to healthcare laundry services and later sterilized. If possible, disposable protective clothing should be always used. In Table 4 is described the Summary of circulation and clothing by operative circuit.

Circulation and access of suppliers or external supplies

Suppliers of documentation, supplies, and materials can only access the security area. No suppliers are allowed to access with the exception of the maintenance service authorized or medical gas suppliers who should wear face coverings and disposable protective clothing and shoe cover.

Maintenance staff should take all supplies or material received to the warehouse/storage room or should be picked up by the area staff. The external surface of cold chain drugs and reactive drugs should be disinfected and the area staff receiving such drugs should be informed of the required maintenance conditions.

Personal protection equipment

The type of PPE used will vary according to the level of protection required. All staff should use the PPE that provides them with the highest safety level, without obstructing their ability to maneuver in order to maximize their technical skills and abilities during procedures without risking their environment to get infected [11, 12].

The procedure for putting on and removing the PPE should be adapted to the specific needs and availability of each workplace and each procedure to be performed [8]. Following the Occupational Safety and Health Act of 1970 standards (www.osha.gov), procedures of the specialty are rated as low exposure risk.

Table 5 describes the potential risks and care according to the procedures and/or activities of care for staff as well as patients [13].

Risk assessment and management in patient care

Appointment booking

Remote consultation is preferred to face-to-face consultation, provided it is feasible and the reason allows it. Appointments should be booked allowing enough time between patients and for cleaning. The days and times of medical consultations should be scheduled in such a way as to have a limited number of patients in the waiting room.

When booking an appointment, patients should be informed of the triage performed before entering and of every institutional rule: hand washing, the compulsory use of face covering, the use of shoe cover, the

Table 3 Description of cleaning tasks by area

Area/s	Frequency	Products	Method	Additional recommendations
-Administrative areas -Reception area -Waiting room	-Daily at the start and finish of the working day -Clean at every shift change	-Disinfection solutions–sodium hypochlorite -70% ethyl alcohol	-Ventilate rooms -Clean floors, doors, and equipment -During the working day, clean desk objects, computers, and phones	-Increase frequency for surfaces in contact with patients -Remove any decorations, vases, or reading material from the waiting room -Information available only on visual media or a TV screen
-Elevators	-Daily -Depending on the use, increase frequency	-Disinfection solutions -70% ethyl alcohol	-Clean the interior and floor, door, and control panel (contact)	
-Restrooms -Physician's offices	-Daily -Depending on the use, increase frequency	-Disinfection solutions–sodium hypochlorite	-Clean floors, doors, toilets, and urinals	
-Offices for care and diagnosis	-Daily at the start and finish of the working day -Clean between every patient contact	-Disinfection solutions -70% ethyl alcohol	-Ventilate daily and/or between every patient contact -Clean floors and furniture -Clean objects on desks, phones, and external surface of equipment	-Change or remove the disposable stretcher cover -Clean and disinfect the surfaces which have been in contact with patients
-Warehouses -Maintenance of external areas	-Daily in external areas -Other areas depending on the use or regular cleaning	-Disinfection solutions -70% ethyl alcohol	-Clean floors -Clean facilities and/or workbenches -Clean work equipment and desk objects	-If external service, medical gas suppliers and/or N2 tank filling suppliers enter, the area or sector used should be cleaned again, like any element they have been in contact with
-Cleaning of restricted areas*	-Daily at the start and finish of the working day -Between procedures -Intensive cleaning according to schedule or COVID-19 contingency	-Standard disinfection solutions -70% ethyl alcohol	-Clean floors, walls, and equipment of surgical and lab areas in accordance with the protocol -Supplies and materials should be disinfected before entering -Anesthesiologists will be responsible for cleaning their equipment in accordance with their protocol	-Reinforce the cleaning of areas of access and internal circulation of patients and professionals -Reinforce the cleaning of locker rooms at shift change

*Operating and recovery rooms, laboratory, cryopreservation, and areas of internal circulation and support (locker rooms, sterilization room, etc.)

Table 4 Summary of circulation and clothing by operative circuit

Staff	Clothing	Clothing for external use	Clothing for internal use	Circulation and task areas	Additional recommendations
-Administrative -Reception -Security	General	-When entering, spray it with 70% alcohol -Store it in a locker or disposable bag until leaving	-Institutional uniform -Footwear for internal use or shoe cover -PPE	-Open -Remain at workstation in reception during shift -Refreshments and lunch in turns	-Uniforms are stored separately -Only circulate to another area as an exception
-Professionals -Physician's offices -Diagnostic areas (ultrasound)	General	-When entering, spray it with 70% alcohol -Store it in a locker or disposable bag until leaving	-Gowns for internal use -Healthcare footwear or shoe cover -PPE	-Open -Remain in doctor office or diagnostic area during shift -Only circulate to related areas	-Gowns are stored separately
-Lab technician/-embryologists	General	-When entering, spray it with 70% alcohol -Store it in a locker or disposable bag until leaving	-Gowns for internal use -Healthcare footwear or shoe cover -PPE	-Open -Remain in extraction booth during shift -Minimum circulation to related areas	- Gowns are stored separately -Disinfect surfaces in contact with patients
Cleaning/janitor	General	-When entering, spray it with 70% alcohol -Store it in a locker or disposable bag until leaving	-Gowns for internal use -Safety footwear -PPE	-Open -Circulate in open areas according to cleaning schedule and protocols	-Gowns are stored separately -Change clothes if tasks are performed in restricted areas
-Professionals of restricted areas*	Exclusive for restricted areas	-When entering, spray it with 70% alcohol -Store it in a locker or disposable bag until leaving	-Gowns for internal use -Healthcare footwear -PPE	-Restricted -Access restricted area through the dressing room -Minimum circulation in the area and do not leave the area during shift	-As long as the pandemic lasts, professionals should be clean-shaven -Do not enter or leave each sector of the area -The access of non-authorized staff, except cleaning staff, is forbidden

*Include physicians, anesthesiologists, embryologists, lab technicians, and surgical instrument assistants

Table 5 Adapted from (ASRM) to the current regulations of the health authority and scientific societies (Argentine Society for Intensive Care/Argentine Association of Nurses in Infection Control)

Risk assessment and care in procedures and activities of care

Procedure/activity	Potential risk	Type of face mask	Other PPE	PPE for patient
Access to the center	Droplets	Surgical	Gloves	Face covering
Patient admission	Droplets	Surgical	-	Face covering
Vital signs	Droplets	Surgical	Gloves	Face covering
Medical consultation	Droplets	Surgical	-	Face covering
Blood collection	Droplets, splashes, needles	Surgical	Gloves, face mask	Face covering
Transvaginal ultrasound	Droplets	Surgical	Gloves, face mask	Face covering
Hysterosalpingography	Droplets, splashes	Surgical	Gloves, face mask	Face covering
Endometrial biopsy	Droplets, splashes	Surgical	Gloves, face mask	Face covering
Sample management (blood, sperm, follicular fluid)	Splashes	Surgical	Gloves, face mask	N/A
Lab procedures (ICSI, biopsy, sperm analysis preparation, etc.)	Droplets, splashes	Surgical	Gloves, (face mask in the case of sperm)	N/A
Intrauterine insemination	Droplets	Surgical	Gloves	Face covering
Embryo transfer	Droplets	Surgical	Gloves, face mask	Face covering
Access to the operating room	Droplets	Surgical	Gloves	Face covering
Intravenous therapy	Droplets, splashes, needles	Surgical	Gloves, face mask	Face covering
Airway management	Droplets, aerosolization	N95 or similar	Gloves, face mask	N/A
Oocyte retrieval	Droplets, splashes, needles	Surgical	Gloves, face mask	N/A
Outpatient hysteroscopy	Droplets, splashes	Surgical	Gloves, face mask	N/A
Operating room hysteroscopy	Droplets, splashes	Surgical	Gloves, face mask, gown	N/A
Recovery area	Droplets, splashes	Surgical	Gloves, face mask	Face covering
Cleaning	Droplets	Surgical	Gloves, face mask or goggles, gown	N/A

restrictions of circulation and of touching surfaces during the consultation in the center.

Patients/donors should be informed to observe the consultation times and attend without an accompanying person unless they require so. Answer any questions from patients/donors using the information available so that consultations are as brief as possible (Supplementary materials 3 and 4).

Patient/donor access and admission for consultation or studies

Every center will define the first contact point with patients/donors when entering according to the building structure. Patients will be allowed in only if they comply with all the requirements established. If patients/donors have to sign any document or receive any documentation to access critical areas or deliver samples, or as a requirement of the healthcare provider, a pen to be used only by them should be used and later disinfected using disposable gloves. The documents received by the staff should be placed in plastic folder leafs sheets, taken to the corresponding area, and filed.

When receiving a sperm sample, lab staff will be informed for its reception. The patient should place the sample in a container which will be disinfected after use. If the patient must enter to get the sample, the usual steps of patient access and circuit are followed according to the location of the sperm collection room.

To transport cryopreserved material (gametes/embryos) between centers and gamete banks, the corresponding protocols will be followed together with biosafety measures for material class B if the patients have no onset of symptoms 14 days before the procedure took place [14].

Circuit for medical consultations and diagnostic or follow-up studies

Redesign the waiting room to ensure patients/donors can maintain the distance one another and establish the maximum room capacity.

If the access to doctor offices is through a small elevator, only one person will be allowed at a time.

During the consultation or study, distancing and biosafety measures should be taken.

Criteria for patient/donor selection for treatment

In every case, before starting their treatment, medical advice will be provided, evaluating the scientific evidence on SARS-CoV-2 infection available at the moment of the treatment.

During consultation, patients will be informed of the importance to notify the medical team of any change in the couple's health condition during the treatment, and patients must sign the COVID-19 informed consent. The complete information must be recorded in the clinical history.

Every case should be analyzed by assessing medical parameters such as age, ovarian reserve, associated pathology, and any comorbidities and inform the patient of such risk. The aim of such classification is to perform treatments gradually at the center and, therefore, be able to control the number of patients coming for treatment.

The patient/donor selected should have the triage test at least 15 days before starting the treatment. The patient's partner should make all the diagnostic studies in accordance with the protocol for andrological evaluation to determine the quality of the sample to be used. He should also comply with all the requirements for the COVID-19 prevention protocols established by the center during the whole treatment, including the collection of sperm samples and its delivery.

As there is evidence of the presence of SARS-CoV-2 in some sperm samples of symptomatic patients or donors [15], available literature does not endorse systematic RT-PCR testing in men undergoing IVF treatment. Triage is recommended, proceeding with semen collection if negative. If triage is positive, semen collection is suspended.

In semen donors, there are two courses of action:

1. Triage, if negative: sperm cryopreservation and quarantine. Repeat triage after 21 days.
2. Eventual RT-PCR.

Circuit for patients/egg donors for accessing treatment in surgical site

After admission, all the documentation attached to the clinical history and any records corresponding to additional requirements for COVID-19 infection prevention are verified.

Patients/donors go to the locker room for patient access in the restricted area when they will be welcomed by the nursing staff who will inform the patient of the protocol for access. Patients/donors will change their clothes in the patient's locker room and go to the recovery area through the dressing room.

Nursing staff will prepare the recovery area in accordance with the PPE requirements for nurses as well as for patients.

Procedures in surgical area

Follicular aspiration

The patient that goes to the operating room must always wear a face mask. The follicular aspiration procedure is usually

Table 6 Planning post-treatment monitoring of patients/donors

Procedure	1st monitoring	2nd monitoring	Observations
Follicular aspiration	Within 24 h via telephone or other means of communication	7 to 14 days after procedure Face-to-face consultation	Monitor COVID-19 infection up to 21 days after procedure
Embryo transfer	Within 24 h via telephone or other means of communication	It coincides with hCG control and (+ or −) results Face-to-face consultation If positive, pregnancy and/or live birth monitoring should be carried out	Monitor COVID-19 infection up to 21 days after procedure

carried out under anesthesia. In this case, the general recommendations regarding airway management of current protocols must be followed using the corresponding PPE. Although the transmission rates are unknown, there is strong evidence of transmission to healthcare workers, especially anesthesiologists, who are in contact with saliva and respiratory secretions [16].

Any direct upper airway instrumentation generating respiratory droplets and/or spray, which are the main vehicle for virus transmission, is considered aerosol-generating procedures (AGPs) [17]. Sedation with spontaneous breathing, rapid induction or sedative agents, or moderate sedation should be used to avoid cough reflex. Another alternative is the use of paracervical block using the transvaginal technique associated with intravenous conscious sedation.

Upon the induction of anesthesia, only the anesthesiologist and assistant should be present in the operating room minimizing the risk of exposure to the aerosols generated by the rest of the team. In the case of follicular aspiration, the use of a closed system is recommended.

A protocol should be in place for patient and procedure programming to be able to apply the corresponding biosafety measures.

A minimum number of persons should participate in the procedure, thus not allowing the circulation of any other person once the surgery has started.

All the equipment or material in contact with the patient secretions should be carefully manipulated, washed, and disinfected in accordance with current standards.

The operating room environmental conditions should be maintained (air filtration and air-conditioning). However, if the center is inside a polyvalent institution, based on the type of facilities, it should be evaluated whether it is necessary to turn off the system during follicular aspiration.

Embryo transfer

Frozen or fresh embryo transfers might be deferred or not according to each clinical case, associated risks, and the agreement with the patient to postpone treatment, which is recorded in the informed consent. This procedure is carried out without anesthesia.

Post-treatment management and monitoring of patients/donors

Monitoring after procedure should be planned together with the patient/donor/recipient to minimize face-to-face contact.

When leaving the center, patients/donors will receive instructions for monitoring and how to get in contact if they have any query or emergency at home. As patients will be alone during the procedure, the relative or accompanying person must check in at the reception and security area to receive the authorization for the patient to leave the center (Table 6).

Records management and data protection of clinical history

Every action carried out in patient/donor/recipient care, any measure taken to prevent or mitigate risks of infection, and any deviations or contingencies should be recorded in the clinical history, whose legal requirements and data are protected by current regulations or the one corresponding to the applicable country.

Clinical histories can be either in paper records or digital format. If in digital format, all the system must be protected with information security and data protection measures.

COVID-19 risk management in labs

In a COVID-19 pandemic scenario, work teams of ART labs face an extraordinary challenge. The specific work in labs includes protocols for handling samples of patients with infectious diseases.

There is no evidence to date of any COVID-19 infection in any ART lab, neither in handling gametes or embryos, where the relevant measures established by the different societies and scientific associations of Clinical Embryologists are used to control risks [18].

Lab risk assessment

Every laboratory should make a risk assessment according to the type of institution it belongs to:

- Laboratories in *polyvalent institutions*: Lab staff should minimize the contact with the staff and patients of the rest of the institution.
- Laboratories in *monovalent centers*: Lab staff has little direct contact with patients; therefore, there is low exposure risk.

Resuming activities

Most laboratories have been partially or totally inactive during the current lockdown. Therefore, it is necessary to organize, at least 15 days in advance, how to resume the following activities:

- Carry out staff triage and document its results before starting to work.
- Perform the new operative training and the training on the new protocols and biosafety measures.
- Clean and disinfect facilities and equipment.
- Start up the equipment.
- Analyze lab size to calculate the number of staff that can work simultaneously.

Access, circulation, and daily tasks

Staff should comply with COVID-19 infection prevention requirements of the center set forth in the protocols of access, circulation, clothing, and cleaning in restricted areas.

While performing daily tasks:

- The access to the lab of unauthorized staff or cleaning staff outside their working hours is forbidden.
- Among the PPE, a disposable long-sleeved double gown or repellent-fabric overall should be used.
- In laboratories increase routine cleaning of surfaces which are frequently touched during procedures. Smooth surfaces are significant passive vectors in virus and bacteria transmission [19].
- Avoid entering any documentation to laboratories, and if required, it should be put in plastic folder leafs sheets.
- The supply of materials required for procedures should take place before starting to avoid opening doors, staff entering, and leaving and any air turbulences.
- Work with positive pressure on to protect gametes and embryos [20].

Laminar flow: biological safety cabinet class II with vertical airflow is recommended. If horizontal airflow is used, use eye protection [21].

The use of UV-C light at 254 nm for 20 min in biological safety cabinets eliminates germs, such as coronavirus, from work surfaces ([1]).

Manipulation of follicular fluid, sperm, gametes, and embryos

Containers with sperm samples should have double wrapping. Before entering the lab, the double wrapping should be removed, and the exterior of the container disinfected.

The risk of having any viral particles in the sperm or testicle is low [22]. Nevertheless, an extra washing should be added to the protocol for sample processing before using them for IVF or ICSI. However, this is not required for cryopreservation where the whole sample is used.

In the case of oocyte and embryo manipulation, another step of washing (dilution) should be added in every manipulation stage:

- Extra washing capsule after oocyte retrieval
- Extra washing in cumulus denudation
- Extra washing during embryo tray changes

Embryo transfers

To limit the team members in the transfer room, the embryologist should:

- Verify the patient identity through the intercom system.
- Deliver the catheter loaded with embryos without entering the transfer room.

Deferred transfer: It is recommended to implement a freeze-all policy for all patients and/or partners, especially when they have become symptomatic after oocyte retrieval as an alternative to avoid risk of COVID-19 disease. However, the lack of strong evidence this recommendation should be taken with caution [23].

Cryopreservation

There is no evidence to date for viral transmission in liquid nitrogen in other infectious diseases transmitted in frozen gametes and embryos of infected patients. The only available evidence is experimental. However, based on the limited information available to date, reproductive material of patients infected with COVID-19 should not be stored [24].

However, if reproductive material of patients infected with SARC-CoV-2 must be stored, provided there is no further

[1] Gamete and embryo manipulation require special consideration as both UV light and alcohol are harmful elements for the normal embryonic development.

information, the protocol used for the cryopreservation of reproductive material of seropositive patients with infectious transmissible diseases like HIV must be used [25].

If patients become symptomatic or test positive for COVID-19 after oocyte retrieval, the embryos obtained are frozen using high security embryo straw and/or liquid nitrogen.

Fertility and oncofertility preservation

If patients, for different social or medical reasons, need to perform a treatment, a gamete, or tissue cryopreservation procedure, the criteria for clinical selection and COVID-19 risk used for donors can be applied. If indicated by a physician, additional measures required by the patient's clinical condition will be taken.

COVID-19 risk management for gamete donors

In gamete, egg, and sperm banks, any risks related to donors' socio-environmental and economic profile are significant. Therefore, some preventive or mitigation measures of operating risks with donors in our country or in Latin America are different from the measures taken in countries where the population has a different degree of economic development and social well-being.

There is evidence to date that in places with a larger concentration of the population transmission is higher, the R0 (the basic reproduction number, which estimates the speed at which a disease is capable of spreading in a population) increases, the inoculum of viral particles is higher, and the "social, preventive, and mandatory isolation" is not implemented in the same way in places with limited health resources as in a residential neighborhood of big urban areas [26].

On the other hand, the pandemic has had an impact on work activities (many of them informal labor) and this can determine donors' answers during the selection, motivated by the need for economic compensation.

To sum up, the current knowledge on specific risks in gamete donation programs is mainly about the risks of the agents involved in these procedures: recipients and professionals, mostly during the period of studies for selecting donors and, in the case of egg donors, due to the potential complications in the procedures. Therefore, it is essential to take all the necessary measures to prevent any infection.

Recruiting donors

If the laboratory or bank has a stock of vitrified oocytes or frozen sperm samples before the pandemic started, these should be used in the treatments as the first option. Consequently, the circulation of patients and/or healthcare workers would be reduced; therefore, new donors will not be evaluated so the time and risks posed by new treatments will decrease.

Oocyte retrieval from fresh cycles with/without synchronization with recipient's cycle

In the case of new egg donors, the requirements for COVID-19 infection prevention should be added to the protocol for clinical assessment and genetic and infectious disease testing at gamete centers and banks. Among these requirements, it is of significant importance to analyze the donor's current socio-environmental situation before the appointment, as there might be some answers that cannot always be validated to make the overall analysis of donors (Supplementary material 3).

Donor admission to the program

Once the donor is admitted to the donation program, COVID-19 specific diagnostic testing and screening should be carried out based on the epidemiological risk.

With reference to donor testing, currently there is no specific algorithm to perform the different diagnostic testing. It must be considered that a negative result in viral detection does not ensure that a patient is virus free; in addition, the duration of the immunity is still unknown. The viral RNA detection by RT-PCR is the technique with the highest sensitivity, with a 64% detection rate in nasopharyngeal swabs. Most false negatives can result from a sampling error, transport delays, or a too early sample regarding the disease evolution. The specificity is almost 100% but there can be false negatives due to cross-contamination [27].

Ovarian stimulation and follicular aspiration

In case ovarian stimulation and follicular aspiration are planned, the following points should be considered:

- Record in the clinical history the risk advisory provided in each consultation, the presence or lack of respiratory symptoms of potential COVID-19 and make a risk-benefit assessment whether to continue or not with ovarian stimulation. The start of the stimulation can be altered based on epidemiological map of the state, region, or province.
- Donors under treatment who will go into the operating room (follicular aspiration) must have the RT-PCR nasal test done, 1 or 5 days prior to follicular aspiration.

Table 7 Plans for contingency management

Risk detection area	Description of contingency	Actions to minimize risks
Reception	Detection of close contact or suspected case [6] upon customer admission (triage, questionnaire, temperature check)	-Interrupt patient admission and refer to the corresponding healthcare service to continue with care until COVID-19 is confirmed or not. -Record the contingency -Ventilate the area, perform additional cleaning and disinfection of everything that has been in contact with the patient
Doctor or diagnostic office	A patient under care in the center has symptoms or a positive COVID-19 test result during the diagnostic stage	-Activate the protocol to isolate every contact the patient had in the center for over 15 min in the last 72 h and the health authority should perform the monitoring until medical discharge
Physician's office	A patient has symptoms or a positive COVID-19 test result during ovarian stimulation	-Cancel the cycle -Isolate any healthcare worker or staff who has been in close contact with the patient in the last 14 days to continue with their care in accordance with the protocol for suspected case
Laboratory	Symptomatic or COVID-19-positive patients upon reception of biological material in the lab, which cannot be cancelled due to medical criteria	-Process sample with protocol for high-risk sample management, as in the case of HIV -Activate protocol for contingency cleaning
Patient care	The couple present symptoms or a positive COVID-19 test result during patient ovarian stimulation	-Cancel sperm sample reception at the lab and keep oocytes frozen
Patient care/-laboratory	Symptomatic or COVID-19-positive patients detected after embryo transfer	-Activate protocol for cleaning* if the detection took place within 12 to 24 h of transfer -Evaluate with physicians any close contact and what to do if there are any extra frozen embryos -Provide patients with any information available for advice
Patient care/-laboratory	Asymptomatic patient or during the window period after treatment	-Inform the lab for material handling -Isolate and test all staff who have been in close contact -Activate protocol for contingency cleaning
Medical director/HR	A staff member has symptoms or positive COVID-19 test result	-Evaluate the close contacts with the rest of the staff and patients in the last 72 h for isolation -If the center has an alternative team to carry out the services, after cleaning and disinfection of all facilities, can continue with medical attention*
Medical director	A staff member has symptoms or positive COVID-19 test result, and for some reason all staff must be totally isolated	-Establish a referral agreement with another center for patients under treatment which could not be postponed nor cancelled until reopening -Reopen when the quarantine time of contacts is over, and the staff test results are negative (at least 14 days) -Clean and disinfect all facilities -Activate the protocols for maintenance of equipment with biological material to ensure its preservation under controlled conditions for storage

*Protocol for contingency cleaning:

- Close all areas used by the infected person.
- Wait 24 h before cleaning and disinfecting. If you cannot wait 24 h, wait as much as possible.
- Clean and disinfect all areas used by the infected person.
- If 7 days have gone by since the infection was informed, it is not necessary to perform additional cleaning or disinfection.

During the pandemic, aspirated and frozen samples of donors should be identified.

Monitoring, preventing complications, and controlling donors after follicular aspiration

It is necessary and essential to keep a proactive and direct communication with the oocyte donor after follicular aspiration due to the risks that may arise after the procedure. Donors should be called 24 and 48 h after the procedure to monitor symptoms such as abdominal pain or fever to prevent complications and hospitalization.

Monitor donors for 14 and/or 21 days after follicular aspiration to determine the appearance of any symptoms related to COVID-19. The monitoring should be recorded in the clinical history. Maintain the traceability of donor/recipient data.

Sperm samples from new donors

Sperm donor applicants should call reception for an appointment and comply with all protocols for COVID-19 infection prevention. To book an appointment, the previous questionnaires included in donor selection should be filled in. The questionnaire results will decide whether donor can attend or not.

The day the sample is taken, donors should respect the circuit of access to the patient's room and sample delivery.

Admission to the sperm donation program

Once the sperm donor is admitted to the program, COVID-19 specific diagnostic testing and surveys are done.

Like in egg donation, there is no specific algorithm to perform the different diagnostic testing. The viral RNA detection by RT-PCR in oropharyngeal swab is recommended during donor screening.

Donation scheduling

Once the donor is admitted according to the andrology lab tests, the appointments for donations are booked and the RT-PCR test is done 1 or 5 days before the first donation.

There should be a protocol including donor monitoring (telephone triage and symptoms) for 21 after each donation. If any symptoms appear, perform serologic tests for COVID-19 diagnosis. If they give a positive result, identify the frozen samples, and do not use them until there is scientific evidence proving they can be used.

Lab tests, sample storage, and distribution

Patient samples are processed in andrology labs and stored in accordance with the protocols in place. Samples taken during the pandemic should be stored, if possible, in a separate tank, which should be labelled "COVID-19," preferably using high security straws.

If it is not possible to have an additional flask, the location of the frozen samples in the lockdown flask must be recorded during this period to be able to trace them until their final destination.

The use of the sample will depend on the result of donor monitoring and any lab tests done.

The traceability of data of donor samples, as well as of the corresponding recipient, the center where the sample was delivered, and the type of procedure for which it was used, should be kept. If low complexity procedures are used, the recipient and result should be recorded.

Preventive actions for preventing specific contingencies in gamete banks

Gamete banks should have protocols of proceedings to temporarily exclude gamete donors with SARS-CoV-2 infection.

A protocol including donor monitoring (telephone triage) for 21 days after donation should be established.

It is important to remind everyone of the importance of the triage and donor monitoring during the entire program, and of not using samples of COVID-19-infected donors.

COVID-19 risk management

As SARS-CoV-2 infection complies with the WHO definition where "a risk factor refers to any attribute, characteristic, or exposure of an individual, which increases the likelihood of developing a noncommunicable disease," contingency plans and the criteria for a subsequent risk assessment should be established according to the potential damage.

Classification of risks and assessment criteria

Risks are classified in serious, moderate, or low according to the impact and detection point in the risk map, considering the severity of the damage to the health and the probability of occurrence.

The analysis of results will allow to determine in the future whether the preventive measures taken in the procedures were enough to prevent or mitigate risks, as well as any safety standards. The sources of information used to draw up the operating protocols were based on new knowledge of the mechanisms of virus infection or transmission in the specialty, as today there are no comparative studies available with validated results of preventive protocols implemented by ART centers in other countries or geographic regions.

Plans for contingency management

Information is depicted in Table 7.

Definition of close contact: Close contact in the community [6]:

- Healthcare worker or any individual providing care to a suspected or confirmed case while they had symptoms and that they did not use the appropriate personal protective equipment.
- Any individual who was within 6 ft (e.g., partners, visits) of a suspected or confirmed case for at least 15 min while the case had symptoms.
- Any individual who had close contact with a confirmed COVID-19 case at work.
- Any individual who shared the same room with a confirmed case (no specific exposure time has been defined yet).

Authors' contributions All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by all the authors. The first draft of the manuscript was written by M.G. A, A. P, G. F, G. B, G. E, C. R, L. S, A. P, C. B, A. QR, V. Ch, R. P, I. S, F. L, C. A, C.A.S, and S. L and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Data availability The present manuscript was based on the scientific evidence and epidemiological information available up to June 2020.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Consent to participate Not applicable

Consent for publication Not applicable

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