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On Vigilance and Surveillance for
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Subject: measures to prevent the transmission of the novel Coronavirus (SARS-CoV-2) infection in Italy in the context of activities involving the collection and use of reproductive cells and MAR (medically assisted reproduction) treatments.

May 5th, 2020 update

Dearest colleagues,

given the rapid epidemiological evolution of the spread of SARS-CoV-2 in our country and the new Decree issued on April 26th, 2020 by the Prime Minister, which initiates the so-called "Phase two", the Italian National Transplant Center and the National MAR Registry updated the indications previously provided, in order to support the adoption of common guidelines with respect to resuming MAR treatments, which represents a delicate phase.

The following indications are to be considered as technical recommendations aimed at containing the spread of the virus in this phase of gradual resuming of MAR activities, which must provide for an organization of the work that privileges above all, the safeguarding of the health of the couples treated and of all staff members operating in MAR Centers.

These indications are in line with what is reported by the recent documents proposed by National and International Scientific Societies such as SIGO (Summary document of the Special Scientific Interest Group on sterility, on ART treatments and on the COVID-19 pandemic, https: // www. sigo.it), and ESHRE (Assisted reproduction and COVID-19. A statement from ESHRE for phase 2. ESHRE Guidance of recommencing ART treatments). Also, a recent ECDC document "Coronavirus disease 2019 (COVID-19) and supply of substances of human origin in the EU / EEA First update" (https://www.ecdc.europa.eu/en/publications-data/coronavirus-disease-2019-covid-19-and-supply-substances-human-origin) refers to the ESHRE documents regarding MAR. Please, refer to these and other Guidelines by Scientific Societies from the field, for the operational management of both clinical and laboratory activities.

Consistent with what is reported in the documents mentioned above, it is suggested that the procedures should gradually resume, including triage activities dedicated to both couples who need to start or complete a treatment, and to all staff working in MAR Centers. Triage activities will be aimed at the early identification of potentially dangerous situations, thus allowing to implement the appropriate containment actions of the infection where these are deemed necessary.

In order to safely resume the activities, the following elements must be taken into consideration: the updating of the operational procedures for contacting patients, the reorganization of reception areas and

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activities, the indications for the correct use of PPE, the utmost attention to the evaluation of the presence of possible pathologies that may worsen the course of SARS-CoV-2 infection and the evaluation of the opportunity or necessity of suspending the treatment, in case of confirmed or suspected infection of at least one of the components of the couple.

With regard to specific activities, it is recommended as follows:

- **Urgent treatments**

All the gametes' cryopreservation procedures aimed at preserving the fertility of cancer patients and of candidates for gonadotoxic therapies remain active, excluding only patients who present severe ongoing symptoms.

As far as the cryopreservation of gametes of positive COVID-19 subjects is concerned, if the collection cannot be postponed, it is suggested, as a precaution, the use of high security devices, or, if they are not available, the storage in a separate tank.

- **MAR treatments with or without the use of donated gametes**

To date, it is believed that the conditions exist for the resuming of temporarily suspended treatments and the start of new treatments, giving priority to those couples who need urgent treatment due to age or particular clinical conditions and to treatments suspended during the pandemic.

If the use of donated gametes becomes necessary, it is recommended to start the treatment of couples whose gametes had already been collected (through import or national donation) before the COVID-19 emergency outbreak and that are available at the center.

- **Gametes donation activities**

In case of donation of supernumerary gametes (the so-called egg or sperm-sharing), it would be appropriate to acquire, in addition to the usual anamnestic evaluation, the result of a swab for the search for SARS-CoV-2 infection at the time of collection/retrieval. In any case, the supernumerary gametes donated in this period should be cryopreserved and not used until definitive clinical laboratory confirmation of the negativity of the donor 14 days after collection/retrieval.

As far as non-shared donations are concerned, a detailed medical history of the donor must be drawn which, in addition to the usual assessments, carefully verifies the presence of symptoms for COVID-19. In case of full-blown symptoms or paucisymptomatic subjects the donation must be postponed until the donor has fully recovered. The same measures apply to subjects who have suffered from SARS-CoV-2 infection.

On all donors a nasopharyngeal swab within 72 hours prior to oocyte/semen collection must be performed. In case of a positive result, gametes cannot be used.

Gametes must remain in quarantine for at least 14 days after which the donor must be re-evaluated for confirmation of the absence of symptoms related to COVID-19 or for the execution of a new swab. If no signs of infection emerge, gametes can be used.

- **Import of donated gametes and embryos**

As far as the import of gametes from donations made to other countries is concerned, for donations performed after December 31st, 2019, MAR centers shall acquire an additional declaration from the sending foreign center certifying that the donors have been evaluated for the risk of infection with SARS-CoV-2 and

considered not at risk, also acquiring, for the agreeing centers, the protocol used for the evaluation of the donor for the risk of COVID-19.

These recommendations are subject to specific regional restrictions.

The regional MAR representatives are invited to promptly implement the foreseen actions, informing all the structures operating in their area of competence.

The indications outlined in this note may be updated in relation to the epidemiological evolution as well as the acquisition of further information about the pathogen in question.

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