

# Minutes of the Extraordinary Authority meeting by teleconference on 21 April 2020

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## Details:

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Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence
Agenda item	2
Meeting date	30 April 2020
Author	Debbie Okutubo, Governance Manager

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## Output:

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For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes as a true record of the meeting
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High

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Annexes

## Minutes of the Extraordinary Authority meeting by teleconference on 21 April 2020

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Kate Brian	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Anne Lampe
Apologies	Richard Sydee	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Catherine Drennan	Dan Howard Paula Robinson Debbie Okutubo Jo Triggs

### Members

There were 12 members at the meeting – eight lay members and four professional members.

## 1. Welcome and apologies

- 1.1. The Chair welcomed everyone present to the second extraordinary Board meeting since the Government introduced its restrictions to reduce the spread of Covid-19.
- 1.2. The Chair commented that even though the focus of the meeting was to impart information, it was important to hear the views of members on the criteria to be used in deciding when to vary or lift General Direction 0014 (GD0014).
- 1.3. Authority members wanted to put on record their thanks to staff, clinics, patients, and stakeholders for the work and patience that was being shown at this difficult time.
- 1.4. To ensure that we continue to be a transparent public body, a short minute would be issued in draft shortly after each meeting.

## 2. Minutes of 18 March 2020 Authority meeting

- 2.1. Members agreed that the minutes of the meeting held on 18 March 2020 be signed by the Chair subject to minor typos to be corrected and a clarification relating to terms of office.

## 3. Update on impact of Covid-19

- 3.1. The Chief Executive introduced this item and gave an overview of the areas to be discussed.

Fertility sector

- 3.2.** The Director of Compliance and Information gave an update on the impact of Covid-19 on the fertility sector. Members were advised that all licensed centres had confirmed that they had ceased treatments on or by 15 April 2020.
- 3.3.** Centres due to be inspected by 31 August 2020 would have a deskbased analysis (DBA). With some exceptions, centres with a four- year licence with no concerns would have their licence extended by one year with no DBA required. No interim inspections would be conducted, and those that require a targeted/focussed inspection would be scheduled as soon as we are able to travel to inspections again. The remainder would have a DBA.
- 3.4.** Authority members were asked for their comments. Members agreed that the approach was appropriate and shared their experience and knowledge of clinics running with patient interaction via telephone or video conference.
- 3.5.** Members asked if clinics were aware that they would be having a DBA. The Director of Compliance and Information responded that the inspectors assigned to the clinic would have advised the relevant clinics of this.
- 3.6.** Members asked if any form of fertility treatment was still ongoing, and it was confirmed that the only service still being offered was fertility preservation for oncology patients.
- 3.7.** It was noted that patients had a wide range of concerns about the current situation, including those related to NHS funding, which the HFEA were pursuing to try and get some clarity for patients.

#### Patients and policy development

- 3.8.** The Director of Strategy and Corporate Affairs gave an update. It was noted that there had been a considerable number of enquiries from patients. There had also been a number of media enquiries.
- 3.9.** Members were also informed that there were ongoing discussions with the Department of Health and Social Care (DHSC) in relation to storage expiring while GD0014 was in place, and how this would be handled.
- 3.10.** Members noted the importance of keeping our communication with patients relevant and up to date.

#### The HFEA

- 3.11.** The Chief Executive gave an update on staff issues. It was noted that we have now been working remotely for the last five weeks and that staff sickness in the last five weeks had been relatively low.
- 3.12.** Regarding Covid-19 a small number had exhibited symptoms and a small number have needed to self-isolate or care for family. Staff members have been relatively well.
- 3.13.** We also have weekly all staff meetings and teams were meeting virtually with regular one to ones.
- 3.14.** A few members of staff had gone on secondments including working on the frontline.
- 3.15.** Regarding our finances, we have written to DHSC to highlight the impact that suspending treatment could have on HFEA income.
- 3.16.** It was noted that cash reserves will be sufficient to meet liabilities in the short term.

#### The office move

- 3.17.** Members were reminded that the office move was scheduled for later on this year, but it was now evident that there was a degree of slippage in fitting the new office out, which meant that the move date could change. Staff had been advised of this.

### PRISM

- 3.18.** The PRISM project was being run remotely and members were advised that latest developments were discussed on a monthly basis at the Audit and Governance Committee meeting (AGC).
- 3.19.** It was noted that one key milestone had slipped but the most difficult aspect of the remaining PRISM development work had been completed. It had taken longer than expected and our milestone for completing the major functionality had shifted from 23 April to 12 May.
- 3.20.** Overall, we were still on target to finish PRISM by late summer but the launch would need to be reviewed in light of the pandemic.
- 3.21.** It was noted that this would be considered further at the next AGC meeting.

### Open The Register (OTR) and Donor Conceived Register (DCR)

- 3.22.** The Chief Information Officer presented the report to the Authority. It was noted that the Opening the Register (OTR) and Donor Conceived Register (DCR) services had been reviewed in light of the impact of the Covid-19 pandemic.
- 3.23.** Members were advised that there was no access to clinic and other stored information to confirm the quality of OTR responses, and for this reason it was recommended that the OTR service be paused at the present time while we continue to deal with enquiries and counselling requests.
- 3.24.** Members were also informed that another consequence of the government restrictions during this Covid-19 pandemic was that DNA information could not be checked by the DCR service against other samples for matches to be made. It was therefore recommended that this service also be paused while we continue to deal with enquiries and counselling requests.
- 3.25.** Members agreed that this was a sensible way forward and noted that the full OTR and DCR services will restart once restrictions were lifted or relaxed, and the sector was sufficiently operational again.

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## 4. Resuming fertility treatments

- 4.1.** The Chief Executive presented this item to the Authority. He reminded members that General Direction 0014 (GD0014) came into force on 23 March 2020 and required all licensed centres to have in place a Covid-19 Treatment Strategy. He said that all centres had complied with GD0014.
- 4.2.** Continuing, the CE said that this was an extraordinary, temporary situation and that the aim was to ensure that as many patients as possible can resume treatment safely as soon as possible. To that end, the views of Authority members was being sought on the suggested criteria to be used in deciding when to vary or revoke GD0014.
- 4.3.** The CE proposed that any decision to vary or revoke GD0014 was best considered by reference to agreed criteria. The suggested criteria were:
- that government restrictions on social contact and travel are eased or lifted
  - that restarting fertility treatment would not have a negative impact on the NHS

- that there was no evidence that Covid-19 impacted on the health of pregnant women or their babies
  - that fertility clinics are able to provide a safe service.
- 4.4.** The CE noted that the measures and milestones against these criteria would be developed following the Authority decision.
- 4.5.** Members noted that the idea of agreeing criteria was a sensible first stage in establishing a clear exit strategy. Some commented on the progress that was being made in some European countries where the number of cases of Covid-19 was declining, for example in Denmark which had re-opened its IVF clinics alongside opening up other activities.
- 4.6.** Members also commented that some clinics were beginning to consider a range of practical measures to reconfigure services so that they can be delivered safely in future, such as:
- Having longer days to enable clinics and patients to maintain social distancing
  - Taking the temperature of patients when they attended the clinic
  - Ensuring that patients washed their hands.
- 4.7.** The impact of the pandemic on different categories of patients was considered. Members agreed that any prioritisation of patients when treatment resumed would be a matter for clinics and not the HFEA.
- 4.8.** Members considered the use of scarce personal protective equipment (PPE) for non-urgent treatment. This would inevitably require clinics to prioritise, balancing patient safety and fairness.
- 4.9.** It was noted that current Royal College of Obstetricians and Gynaecologists (RCOG) advice is that there was no conclusive evidence that Covid-19 increased risk to pregnancy. However, it was also noted that Covid-19 is a new illness and that much is not known and patient safety is paramount.
- 4.10.** It was agreed that the HFEA needed to communicate with clinics and patients throughout this period.
- 4.11.** Members agreed the broad framework presented and that further discussion with the professional bodies and clinics should take place.

### Decision

- 4.12.** A letter should be sent to all PRs summarising the criteria and next steps. Discussions with the British Fertility Society (BFS) and Association of Reproductive and Clinical Scientists (ARCS) and RCOG should continue.

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## 5. Strategy and business planning

- 5.1.** The Head of Planning and Governance presented to the Authority. It was proposed that we do not publish our originally intended business plan for 2020/21, but instead:
- Put in place an internal service delivery plan focused on managing the current situation from April to September 2020.
  - Establish a recovery plan for October 2020 to March 2021.
  - Delay the launch of our new strategy to October 2020, or later, and commence delivery in full from 1 April 2021, extending it by one year to 2024.

- 5.2. It was also noted that these were draft timescales and may be varied depending on the situation.
- 5.3. Members were advised that the Corporate Management Group (CMG) would be leading on this and that the recovery plan would focus on helping the sector to re-establish normal services to patients after the downtime.
- 5.4. Members approved the plan.
- 5.5. It was further stated that we would be seeking formal approval for these proposals with DHSC.
- 5.6. The business plan originally drafted for 2020/21 would largely become the business plan for 2021/22 and would be reviewed later on in the year so that necessary revisions could be made, reflecting the latest situation.

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## 6. Any other business

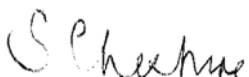
- 6.1. The Chair informed Members that the annual accountability meeting with DHSC would occur in the month of May and be done by letter and possibly video conferencing.
- 6.2. Members' terms of office were coming to an end over the coming months, but clarity from the DHSC on resolving this was anticipated shortly.
- 6.3. Authority members were currently going through their appraisals with the Chair.
- 6.4. The next extraordinary meeting of the Authority will be held on 7 May 2020.

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## 7. Chair's signature

I confirm this is a true and accurate record of the meeting.

### Signature



**Chair:** Sally Cheshire

**Date:** 30 April 2020

# Resuming fertility treatment: next steps

## Details about this paper

Area(s) of strategy this paper relates to:

Meeting:	Authority
Agenda item:	3
Meeting date:	30 April 2020 (Extraordinary meeting by teleconference)
Author:	Peter Thompson, Chief Executive
Annexes	Annex A – ESHRE revised guidance 23 April 2020 Annex B – ASRM revised guidance 24 April 2020 Annex C – revised GD0014 - draft

## Output from this paper

For information or decision?	For decision
Recommendation:	That the Authority consider whether circumstances have sufficiently changed to allow fertility services to resume and if so under what conditions (section 2); That should treatment resume, the Authority consider the terms of the draft revised General Direction 0014 (section 3).
Resource implications:	N/a
Implementation date:	Dependent on Authority decision
Communication(s):	Letter to all clinic PRs, with follow up to patients and public (section 5)
Organisational risk:	High

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## 1. Introduction

- 1.1.** When the Authority last met on 21 April 2020 it agreed the criteria which would guide any subsequent decision to vary or revoke General Direction 0014. Members also agreed that the primary aim should be to allow as many patients as possible to resume safe treatment as soon as possible. In addition, we want to see a safe and orderly restart of the sector.
- 1.2.** The progress of Covid-19 and the policy response is fast moving and over the past week two developments have occurred which suggest that now would be an appropriate time to review our position. Those developments are: revised guidance by the professional societies (ESHRE, 23 April – see Annex A, and ASRM, 24 April – see Annex B; and the establishment of a BFS/ARCS working group which is developing revised guidance which will issue shortly); and a statement on 27 April by the Secretary of State for Health and Social Care, that the Government planned to restart non-Covid-19 services in the NHS in England, starting with the ‘most urgent’ such as cancer and moving to others over time.
- 1.3.** This paper considers these developments in the light of criteria agreed on 21 April 2020 (section 2). If the Authority agree that circumstances have sufficiently changed to allow fertility services to resume, subject to certain conditions to ensure the safety of patients and clinic staff, the paper then sets out a mechanism to ensure that treatment can resume in an orderly and safe manner by means of a varied GD0014 (section 3). The implementation of any decision and its communication are briefly addressed in sections 4 and 5 respectively.
- 1.4.** Given that the Authority had a full discussion of the wider background and context only last week, the paper does not cover that same ground.

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## 2. Assessment

- 2.1.** This section provides a short assessment of the four criteria agreed on 21 April 2020 in the light of the developing position. It is suggested that any decision to allow treatment to resume, and under what conditions, is best made proportionately by considering the overall impact of all four criteria.

### 1 – that Government restrictions on social contact and travel are lifted

- The current restrictions on social distancing, travel etc are due to be reviewed on 7 May 2020. It might therefore be reasonable to conclude that any decision to restart fertility services should wait until then.
- However, the revised guidance from the professional societies (see criteria 4 below) set out ways in which services can be reconfigured to allow patients to be treated safely and clinic staff to work safely during the Covid-19 emergency. Given this revised guidance, it is an appropriate time to consider whether fertility services could restart when judged in the round, particularly given the developments in the NHS (see 2 below).
- ***Do the Authority agree?***

### 2 – that restarting fertility treatment would not have a negative impact on the NHS



- It is becoming increasingly clear that the picture across the UK varies greatly and that, thankfully, the NHS as a whole has not been overwhelmed. Indeed, NHS leaders are now worried that some people with serious non-Covid health issues are not being seen. The statement by the Secretary of State on 27 April is a recognition of that picture and signals a desire to restart non-Covid services in an orderly manner, beginning with the ‘most urgent’.
- Leaving aside debates about where fertility services sit in comparison to other ‘urgent’ services, there is a good case for allowing the resumption of IVF, provided that it can be done in a way which ensures steps are taken to mitigate complications where possible.
- We believe that circumstances have so changed that this criterion can be met.
- ***Do the Authority agree? If so, what conditions, if any, should be placed on treatment to mitigate any potential impact on the NHS?***

### **3 – that there was no evidence that Covid-19 impacted on the health of pregnant women or their babies**

- As the Authority noted last week, the position of the professional societies (e.g. the RCOG) is that there is no conclusive evidence to date that Covid-19 is a risk to pregnant women or their babies and therefore pregnancy should not be discouraged.
- ***Do the Authority agree that provided the potential risks are explained to any women undertaking fertility treatment, it would be reasonable to allow treatment to resume despite the continuing lack of evidence either way?***

### **4 – that fertility clinics are able to provide a safe service**

- Professional body guidance is developing in response to the Covid-19 pandemic. The revised guidance which issued late last week from ESHRE and the ASRM is evidence of that. The revised guidance from the BFS/ARCS is in production but the ‘milestones’ document should be published this week.
- Taken together, this revised guidance provides a detailed picture of how fertility services can be reconfigured safely within the context of the ongoing pandemic. In summary, the new guidance suggests that services should be adapted to minimise the risk of Covid-19 infection, including the strict triage of staff and patients, the use of PPE and adherence to Covid-19 specific standard operating protocols. It is also clear that activity levels and working patterns would need to change from the norm.
- Were a decision to be taken to resume services, in order to comply with current guidance on safe practice during the Covid-19 emergency, staff and patients would have to fully accept and adhere to the strict conditions and working practices imposed by the clinic. HFEA Inspectors would use an audit tool to determine implementation of safe working practices (see section 3).
- ***Do the Authority agree that this revised guidance provides a secure basis for the resumption of fertility services? If so, do you agree that it is primarily the responsibility of the PR to ensure that any clinic meets these requirements?***

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## **3. Revised General Direction 0014**

- ### **3.1.**
- The existing GD 0014 came into force on 23 March 2020. It is not time limited. It requires all licensed centres to have in place a Covid-19 Treatment Strategy. All centres are currently complying with this direction.

- 3.2.** If the Authority is of the opinion that circumstances have changed sufficiently that treatment should be allowed to resume then one option would be to revoke GD0014. However, this would have the effect of simply returning licensed clinics to the same situation that existed prior to Covid-19. Given the current status of the pandemic and the need to ensure that the gains made so far from the lockdown in terms of reduced transmission rates and so on are not lost, that would not be a responsible response. Moreover, it may put the safety of individual patients and clinic staff at risk.
- 3.3.** It therefore follows that if fertility services are to resume then they should, for the time being at least, only do so within certain guidelines. No one knows how long Covid-19 will be with us, but for the time being at least, we should regard this as the 'new normal' and, as noted above, services will need to be reconfigured to ensure that they can be offered safely in these new circumstances. The HFEA has statutory powers to require clinics to record and report specified information and the failure to provide this information would allow us to move to enforcement sanctions. These powers are at the centre of the revised GD0014.
- 3.4.** To that end, we have revised GD0014 so that it requires clinics to have a Covid-19 Treatment Commencement Strategy (Treatment Commencement Strategy). This records the measures the clinic will be taking to comply with current professional body guidance on safe and effective treatment; records the risk assessments undertaken, the practical and logistical arrangements that will be put in place at the clinic and records all new or revised standard operating procedures or protocols.
- 3.5.** We have thought long and hard about the best means of ensuring that clinics put in place a robust Treatment Commencement Strategy. One option would be to require clinics to send their strategy to HFEA inspectors for approval. Although apparently attractive we consider this to be the least robust method and runs the risk of administrative backlogs should many clinics wish to restart at the same time. Inevitably there will be variation between clinics which would make the assessment of any clinic documents open to challenge and should there be issues later it would make regulatory action more difficult if the inspector had appeared to 'approve' a clinic policy. Moreover, this approach would also be inconsistent with how inspections are conducted; the inspection process utilises an audit approach with set questions to test the adequacy of a process, policy or activity.
- 3.6.** Instead, we recommend that any Treatment Commencement Strategy should be assessed by means of a detailed self-assessment which would be signed off by the PR as a true reflection of their ability to meet the requirements of the revised GD0014. The proposed HFEA Covid-19 Treatment Commencement self-assessment will test a clinic's Treatment Commencement Strategy by asking a series of detailed questions to confirm whether all recommendations within the professional guidance have been adopted. It will incorporate relevant aspects from the Code of Practice and Standard Licence Conditions, such as staffing levels and validation of equipment. This method will enable HFEA inspectors to undertake an in-depth assessment in a consistent manner and will drive compliance in clinics as it will provide a detailed framework to work to.
- 3.7.** The revised GD0014 therefore requires the clinic to complete the HFEA Covid-19 Treatment Commencement self-assessment. Before a clinic can commence treatment, it must have received approval of its self-assessment from its HFEA inspector. Any clinic that commences treatment

before having received this approval will be in breach of GD0014 and may face regulatory sanction.

- 3.8.** If approved, the revised GD0014 would apply to all licensed clinics, both private and NHS, across the UK. Crucially, it would not require clinics to resume treatment by a certain date. Rather, it puts the onus on the clinics themselves to judge, taking account of local factors relevant to their service provision, whether they have the resources to be able to offer a safe service. This way, those clinics that are able to reopen quickly can do so; those that need longer can take the extra time.
- 3.9.** That may mean that patients in some parts of the country are able to access services before others, but in a previous discussion the Authority concluded that it would not be fair to delay treatment to the speed of slowest. Anecdotal feedback suggests that private clinics have faced less disruption than most NHS clinics, so it is expected that as a whole the private sector will be able to reopen more quickly. It should, however, be noted that many private clinics treat NHS patients. ***Does the Authority agree with the revised GD0014 and the approach to enforcement?***

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## 4. Implementation

- 4.1.** Should the Authority decide to issue a revised GD0014 it will also need to consider if it should come into effect immediately or after a defined timescale. The HFEA CEO will notify the PRs of the revised GD and the requirements. The HFEA Covid-19 Treatment Commencement self-assessment would be sent to PRs to complete and return to their inspector. Satisfactory completion of the self-assessment would demonstrate the clinic's compliance with the main recommendations from professional guidance and demonstrate the robustness of the clinic's Covid-19 Treatment Commencement Strategy.

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## 5. Communications

- 5.1** Any decision will be communicated to PRs by means of a letter from the Chief Executive.
- 5.2** In view of the self-evident interest from patients we will use the key information from the Chief Executive's letter to update information on our website and social media. We will also publicise this information to key patient groups to ensure it is disseminated as widely as possible. We will consider any further engagement activities over the following days.

# ESHRE guidance on recommencing ART treatments



*Document prepared by the ESHRE COVID-19 Working Group*

*Published on the ESHRE website*

*Date of publication: 23/04/2020*

## **Principle (rationale)**

As the COVID-19 pandemic is stabilising, the return to normal daily life will also see the need to restart the provision of ART treatments. Infertility is a disease and once the risk of SARS-CoV-2/COVID-19 infection is decreasing, all ART treatments can be restarted for any clinical indication, in line with local regulations.

However, vigilance and measured steps must be taken for safe practice and to minimise the risks related to SARS-CoV-2/COVID-19-positive patients or staff during treatment.

## **Concept**

The working group identified six pillars of good medical practice proposed for the restart of activity in the ART clinic and laboratory.

1. Discussion, agreement and consent to the start of treatment
2. Staff and patient triage
3. Access to advice and treatment
4. Adaptation of ART services
5. Treatment cycle planning
6. Code of Conduct for staff and patients

ESHRE recommends that ART centres use this guidance having first followed the local and/or national legislation and local and/or national government advice related to COVID-19.

### **1. Discussion, agreement and consent to start treatment**

- a. High-risk patients (e.g. diabetes, hypertension, using immunosuppressant therapy, past transplant patients, lung, liver or renal disease) should not start ART treatment until it is deemed safe to do so by relevant healthcare professionals and/or local health authorities.
- b. All patients should be offered a choice to proceed with or postpone their ART treatment. In both cases patient preference should be clearly documented.
- c. Patients must be comprehensively informed, clearly understand the risks related to COVID-19 disease and acknowledge the increased risks in case of infection during pregnancy. Patients must also be informed on how to reduce the risk of infection in general.
- d. Patients must sign and adhere to the Code of Conduct.

## 2. Staff and patient triage and management

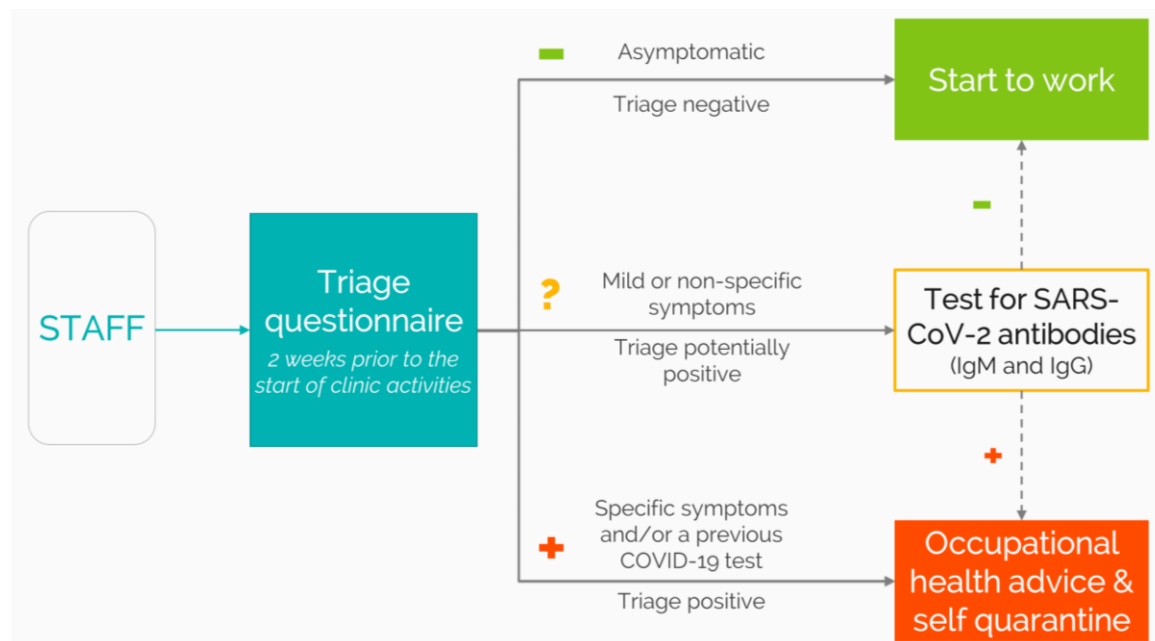
### Triage questionnaire

ESHRE provides an ART triage questionnaire which can be used/adapted for the triage of both staff and patients ([see Appendix 1](#)).

### Procedure for staff

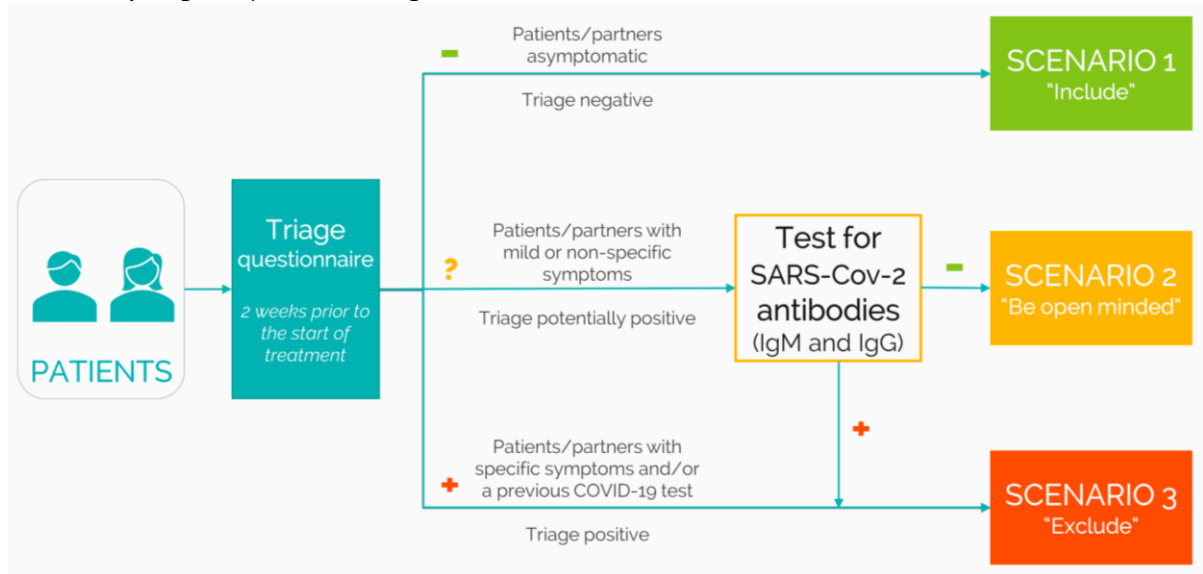
- Triage information regarding health status, symptoms and lifestyle of the clinic team members and of individual(s) living in the same household should start at least two weeks before the beginning of clinical activities at the centre.
- Staff, suspected of infection after triage, should undergo regular SARS-CoV-2 IgM/IgG testing or equivalent tests. Additional and/or more frequent testing can be considered in line with national recommendations and/or availability of tests.
- All staff members who test positive, either for SARS-CoV-2 IgM or IgG, irrespective of symptoms, should receive occupational health advice and go into self quarantine
- Staff who are symptomatic should be referred for medical advice and testing and should not re-attend work until the infection is cleared and documented by negative RT-PCR test or equivalent.
- Contact tracing and testing should be routine if a staff member is diagnosed with COVID-19 infection.
- Depending on the size of the unit, staff should be subdivided in “mini-teams” with minimum interactions among them. Teams should work according to a rotating schedule, similar to the one adopted for weekend work.

Summary Figure staff triage





Summary Figure patient triage



### 3. Access to advice and treatment

Patient education on COVID-19 risk and prevention is an essential step prior to acceptance for treatment. Patient education should include:

- Tutorials on the use of personal protective equipment (PPE), if required.
- Advice on continuation of social distancing and avoidance of unnecessary human physical contact.
- Information about symptoms of SARS-CoV-2/COVID-19 infection or exposure occurrence
- Agreement that treatment can be discontinued if the patient encounters a high-risk situation

### 4. Adaptation of ART services

The treatment of each patient should be completely re-thought and individualised.

In order to reduce unnecessary visits and staff-patient contact, telemedicine should be used for all treatment steps that do not require the physical presence of patients at the centre.

Guidance on adaptation of services in the centre is summarised below:

#### Sanitation

- Routine sanitation of all areas should be performed according to local protocols.
- Specific COVID-19 sanitation procedures should be implemented in case of COVID-19 positive patients or staff members.

#### Staff and centre adaptation

Adaptation should include:

- COVID-19-specific training
- COVID-19-specific standard operating procedures
- Adjusted work shifts



- Emergency agreements between ART centres to guarantee continuity of treatment provision.

### Access procedures

- Limitation of the number of persons simultaneously present in the centre
- Provision of protective screens for administrative staff
- Provision of personal protective equipment and sanitation devices for patients and staff
- Restriction of access for partners and accompanying persons
- Redesign of waiting rooms and working spaces to guarantee appropriate distancing
- Management of appointments according to specific timetables, also for scans and blood tests
- Subdivision of staff into mini-teams to reduce unnecessary exposure of patients and staff members
- Follow-up of patients three weeks after oocyte retrieval and/or embryo transfer, in order to identify potential COVID-19 positive patients and implement necessary measures (i.e. contact tracing and sanitation)

## 5. Treatment cycle

### Ovarian stimulation monitoring

During this phase the following specific precautions should be taken:

- Minimal exposure for both staff and patients.
- Isolation of staff showing symptoms of infection
- Use of personal protective equipment (PPE) by staff
- Minimal number of visits and optimised number of blood tests
- Vaginal probe and tissue hygiene
- Re-triage and action depending on pre-triage results or new non-specific symptoms.

### Oocyte retrieval

In addition to general precautions and based on triage results, the following recommendations are made:

- |                     |   |
|---------------------|---|
| <b>Scenario I</b>   | Follow standard procedures unless changes occur between ovulation trigger and oocyte retrieval  |
| <b>Scenario II</b>  | If positive re-triage, consider SARS-CoV-2 IgM/IgG and/or RT-PCR testing for COVID-19. Based on the result, decide whether to continue the treatment or to postpone it. |
| <b>Scenario III</b> | If the patient tests positive for SARS-CoV-2/COVID-19, before ovulation trigger or embryo thawing, postpone treatment, refer and isolate.                               |
- Exceptions could be made for patients at high risk of OHSS. In this case, oocyte retrieval could be performed and unit sanitation should follow



according to specific COVID-19 sanitation procedures put in place by national or local competent authorities.

- If a potentially SARS-CoV-2/COVID-19 positive patient must continue treatment (i.e. oncology patient or high risk of OHSS), the following measures should be adopted to reduce risks of transmission to staff members, as follows:
  - FFP2/3 masks according to clinical duty requirements
  - Gowning
  - Disinfection of operating theatre, transfer room and IVF laboratory after the procedure
- The procedure should be cancelled for newly diagnosed COVID-19 positive patients.

### Laboratory

- a. Routine good laboratory practice should be followed and laboratory staff should wear masks and gloves.
- b. Staff should be organised in mini-teams.
- c. Extra care should be taken to reduce exposure to native follicular fluid and sperm by dilution and safe disposal of fluids in individual closed containers, as quickly as possible.
- d. Published guidelines and good laboratory practice principles should be followed at all times ([www.eshre.eu/guidelines](http://www.eshre.eu/guidelines)).
- e. Should a patient become suspect or positive for COVID-19 during embryo culture, a freeze-all policy should be adopted.

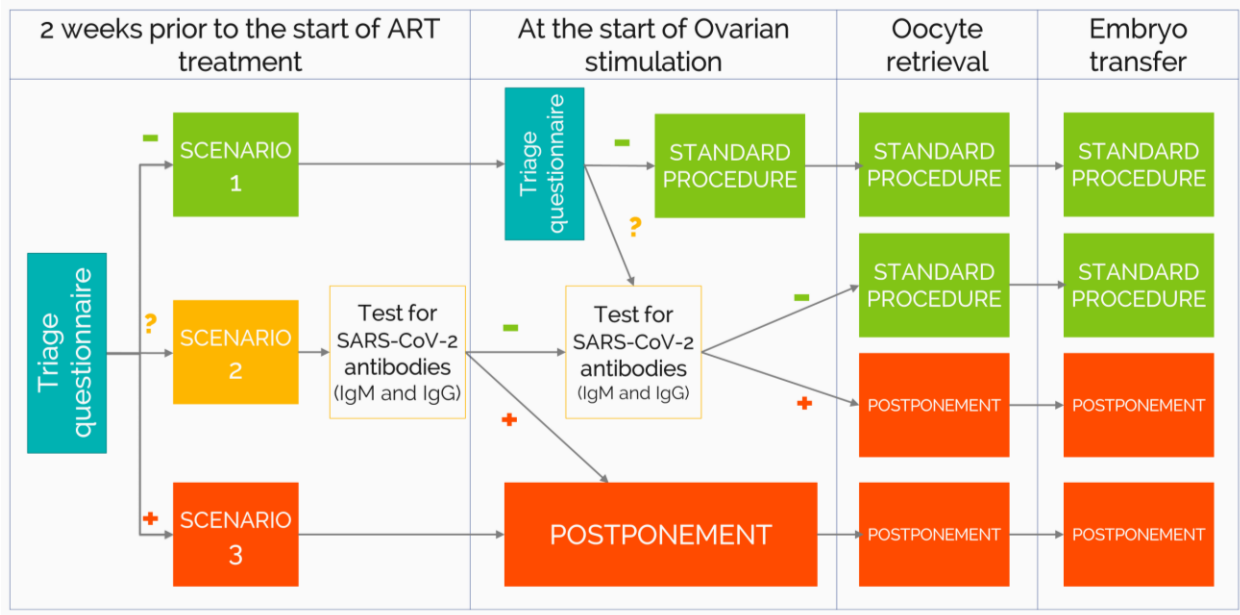
### Embryo transfer

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

### Cryopreservation

- a. High security straws and/or vapour phase storage tanks should be used for cryopreservation of samples from COVID-19 positive patients.

Summary Figure treatment cycle



## 6. Code of Conduct for staff and patients

All staff members and patients will be instructed to avoid unnecessary exposure (both at work and in private).

- Each service will prepare compulsory instructions for staff
- Attendance at work will be tied to respecting the signed Code of Conduct
- Activities that are not allowed will be clearly detailed ("Expose yourself less" principle)
- Restricted social life and interactions
- Patients should sign regularly that they are well and have respected the Code.
- Staff members should sign regularly that they are well and have respected the Code or inform the centre's Person Responsible of any infringements of the Code of Conduct previously signed.

## Appendix 1 - ART Triage Questionnaire

1. Have you been sick in the last two weeks?
2. Do you have fever (over 37,5°C)?
3. Are you coughing at present?
4. Do you have a sore throat?
5. Have you lost your sense of smell or taste?
6. Have you been in contact with somebody who has any of these symptoms?
7. Have you travelled to an area at high risk for COVID-19, nationally or internationally?
8. Do you work in a hospital/nursing home or healthcare facility?
9. Have you been in contact with somebody who has COVID-19?
10. Have you been you diagnosed with COVID-19?
11. Do you live in a household with somebody who has been diagnosed with COVID-19 infection or has COVID-19 symptoms (fever, cough, loss of smell)?
12. If you have been COVID-19 positive and recovered, do you have certified medical evidence of clearance ?
13. Do you have a severe medical condition like diabetes, respiratory disease, chronic kidney disease, etc.? *(this question can be skipped when using the ART triage questionnaire for staff)*

## Disclaimer

*This guidance represents the views of ESHRE, which were achieved after careful consideration of the scientific evidence available at the time of preparation. In the absence of scientific evidence on certain aspects, a consensus between the relevant ESHRE stakeholders has been obtained.*

*ESHRE makes no warranty, express or implied, regarding the guidance and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. ESHRE shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein. While ESHRE makes every effort to compile accurate information and to keep it up-to-date, it cannot, however, guarantee the correctness, completeness, and accuracy of the guidance in every respect.*

*The advice expressed herein is not binding on professionals working in the field of human reproduction and embryology. Hence, this advice will never lead to the liability of ESHRE in case a professional is willing to implement it. Notwithstanding the foregoing, ESHRE will not be liable for indirect damages or consequential damage.*



AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM)  
PATIENT MANAGEMENT AND CLINICAL RECOMMENDATIONS  
DURING THE CORONAVIRUS (COVID-19) PANDEMIC

***Update #3 (April 24, 2020 through May 11, 2020)***

Infertility is a serious disease that requires treatment in a timely manner. With the passage of time, an increasing number of patients whose care has been delayed are now in a situation that has become more urgent. Since the publication of Update No. 2 of the "American Society for Reproductive Medicine (ASRM) Patient Management and Clinical Recommendations During the Coronavirus (COVID-19) Pandemic" on April 13, 2020, the ASRM Coronavirus/COVID-19 Task Force ("the Task Force") has observed that:

- There have been 2.7 million confirmed cases worldwide so far, with more than 880,000 confirmed cases and more than 50,000 deaths in the U.S. alone.
- It has now become more apparent that there are regional differences in both case numbers and timing of the apex of disease incidence.
- While no community is unaffected, measures taken in many states and cities across the U.S. are leading to a decrease in the number of new cases per day. In some localities, we are seeing evidence of a "flattened" transmission curve. The predicted peak demands on the resources of local healthcare systems have been reached in some communities, while in others demand is rapidly increasing toward their apex.
- While not lessening concerns for the severity of the disease, these developments across the U.S. cautiously suggest that most patients falling ill with COVID-19 will be able to access the care that they need in the context of a healthcare system that is not overburdened.
- Over time, both the modes of disease transmission and the impact of mitigation strategies have become better understood. Effective strategies include the use of non-medical grade face masks in public, physical distancing, frequent handwashing, contact tracing, and the rapid response to testing and isolation in individuals who have been exposed to COVID-19 or who are under investigation for infection.
- Living and operating in a society where COVID-19 exists is becoming a reality for many. Data suggest that COVID-19 will remain a factor to be managed in our lives and practices for a prolonged period of time. The ultimate response to this pandemic may rely on the development of a vaccine that prevents COVID-19, or of effective treatments, or both. Until then, detailed contact tracing and ready access to SARS-CoV-2 testing will remain key components of an effective public health response. Such data will continue to guide quarantine and isolation procedures, and community mitigation strategies, at the local level.

The Task Force<sup>1</sup> reaffirms that fertility care is an essential health service. Nonetheless, the Task Force recognizes the need to minimize the spread of COVID-19 and preserve critically needed local healthcare resources to address the pandemic, while simultaneously acknowledging the essential timeliness and importance of access to fertility treatment.

In the early stages of the U.S. COVID-19 pandemic, the Task Force recommended implementing a moratorium on non-urgent care until the conditions on the ground, the ability of healthcare systems to deal with disease surge, and the transmission rates could be better defined and managed. As the pandemic has progressed in the U.S., the Task Force observes that there are clear regional differences in cases and healthcare system capacity, that some localities have reached their apparent apex of transmission, and that the disease will be with us for some time. Consequently, this update to the Task Force recommendations identifies the elements required or recommended to allow for a carefully considered and gradual resumption of patient care.

In considering when and how to provide reproductive care, the risk of viral transmission to patients, physicians, and staff, and the utilization of critically needed healthcare resources must be weighed against the time sensitive nature of infertility. This calculation includes understanding the worsening prognosis of treatments with the passage of time, and the threat of decreased access to care that occurs with further delays.

The Task Force notes that while the *approaches* to responsibly resuming care of patients do not vary across communities, the *resources and expertise* required to execute them may. This update also provides suggestions for general resources that practices may wish to utilize or reference. Practices with the necessary internal expertise and resources may choose to develop their own tools and resources to meet the needs outlined.

## WHEN TO RESUME CARE

- National, regional, state, and municipal regulations produced by authoritative health organizations and agencies dictate what is and is not permitted within their jurisdiction based on their analysis of disease transmission and hospital capacity data.
- However, individual programs, physicians, and other healthcare providers need to be flexible and fully prepared to recognize and address the status of their local coronavirus transmission rate, medical conditions, and the impact that resuming operations would have on their community's risk and resources, even when clinical activities are permitted by law.

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<sup>1</sup> This guidance document was developed under the direction of the Coronavirus/COVID-19 Task Force of the American Society for Reproductive Medicine. These recommendations are being provided as a service to its members, other practicing clinicians, and to the patients they care for, during the coronavirus pandemic. While this document reflects the views of members of the Task Force, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Clinicians should always use their best clinical judgment in determining a course of action and be guided by the needs of the individual patient, available resources, and institutional or clinical practice limitations. The Executive Committee of the American Society for Reproductive Medicine has approved this guidance document.

The ASRM Coronavirus/COVID-19 Task Force members for this update included Ricardo Azziz MD, MPH, MBA, Natan Bar-Chama, MD, Marcelle Cedars, MD, Christos Coutifaris, MD, PhD, Mark Cozzi, MBA, Jodie Dionne-Odom, MD, Kevin Doody MD, Eve Feinberg MD, Elizabeth Hern MBA, Jennifer Kawwass MD, Sigal Klipstein MD, Paul Lin MD, Anne Malave, PhD, Alan Penzias, MD, Samantha Pfeifer, MD, Catherine Racowsky, PhD, Laura Riley, MD, Enrique Schisterman, PhD, James Segars, MD, Peter Schlegel, MD, Hugh Taylor, MD, and Shane Zozula, BS, in consultation with other experts, including Peter Klatsky, Lora Shahine, and Richard Scott.

- Before reproductive care practices can safely resume, several milestones should be considered, including a sustained reduction in cases in their area ([e.g. for at least 14 days](#)) and the ability of their local hospitals to safely treat all patients without resorting to crisis standards of care.
- Ultimately, as we consider offering services to our patients, local conditions and government regulations should ultimately guide what an individual practice, and physicians and other healthcare providers involved in reproductive care can and should offer their patients.
- Prior to resuming, practices must ensure that they are adequately prepared to provide patient care in a manner that limits risk to patients, staff, and physicians and other healthcare providers. This includes substantial self-education and staying up to date, as new information emerges, on the risk of disease transmission by symptomatic and asymptomatic individuals. Additionally, practices must ensure that they are prepared to perform a *formal risk assessment* of practice activities and the physical plant by the practice leadership team using publicly available resources or with the assistance of experts. Practices should create or adapt existing written risk mitigation policies and procedures that include having an adequate supply of necessary resources and training for all staff.
- Formal risk assessment includes identifying and categorizing the predictable risks associated with each procedure the clinic plans to offer (see section on Risk Assessment below).
- Consequently:
  - When:
    - education and staff training are achieved and certified,
    - a documented risk mitigation strategy is in place for the operation of the clinic as a whole, and
    - a documented risk mitigation plan is in place for each procedure.
  - Then:
    - the clinic may select the tests and or treatments to resume,
    - consider reinitiating a limited number of services when initially resuming care,
    - begin at a pace that allows new policies and procedures to be operationally observed to ensure that they are working as designed, and
    - monitor, reassess and modify clinic operations as community conditions change, knowledge of the disease increases, and additional resources to mitigate, test for, and combat the disease become available.

## PREPARING TO RESUME CARE: RISK ASSESSMENT

Practices should perform a ***formal documented risk assessment*** to determine what activities, if any, are feasible at this time, accounting for local prevalence and trends, availability of Personal Protective Equipment (PPE) for all patients, staff, and physicians and other healthcare providers, and availability and type of selective testing, facility physical plant factors, and staff training (**Table 1**). It should be recognized that this will require an iterative cycle of surveillance and ongoing risk assessment. In simple terms, [the elements of a COVID-19 Formal Risk Assessment](#) could include:

- An assessment of who might be harmed and how.
- An evaluation of actions that are currently being taken to control the risks.
- A plan for further actions required to control the risks.
- A determination of who should carry out these actions.
- A timeline for the implementation of these actions.

The U.S. Occupational Safety and Health Administration (OSHA) and the CDC, among others, provide more detailed risk assessments (**Table 1**).

Considerations **FOR** offering evaluation and/or treatment:

- Delaying treatment may have permanent negative consequences to:
  - Treatment outcome
  - Mental health (e.g. patient's clinical depression, severe anxiety)
  - Access to care (e.g. loss of employment, loss of health insurance, and harm to practices leading to fewer services being available in a community)
- The ability to mitigate risk to patients and staff with carefully considered policies and procedures.

Considerations **AGAINST** offering evaluation and/or treatment:

- To avoid complications arising from assisted reproduction treatment (ART) and/or pregnancy (e.g. ovarian hyperstimulation syndrome, ectopic pregnancy, spontaneous abortion) that may further burden local healthcare facilities at a time when significant resources are required for the care of critically ill COVID-19 patients.
- The potential risk of exposure and transmission to patients, physicians and other healthcare providers and staff.
- A requirement for local reallocation of healthcare resources (e.g. PPE, nursing and anesthesia staff, ventilators, and testing).
- When delaying treatment will not significantly impact treatment outcome and time is required for cases of COVID-19 to decrease within a given community prior to initiating infertility care.

Practices and providers should familiarize themselves and their staff with resources produced by authoritative health organizations and agencies and with local or institutional guidance and regulations. It is important to check these resources regularly and frequently for updates and revisions on the full spectrum of topics necessary to care for patients in the era of COVID-19. Examples of such sources are listed in **Tables 1 and 2**.

## **PREPARING TO RESUME CARE: RISK MITIGATION**

### **POLICIES AND PROCEDURES**

#### **A) Healthcare Staff**

- Each practice should have written policies and procedures specific to the COVID-19 pandemic, including written documentation of risk mitigation procedures that must be acknowledged in writing and followed by every member of the staff, including physicians and other healthcare providers. OSHA and CDC recommendations are cited in resources listed in **Table 1**.
- Each practice should consider having policies and procedures to protect staff who are at [higher risk for severe COVID-19 illness](#) or live with a person who is at higher risk.
- Sick call policies should be in place for healthcare workers with symptoms or positive testing. Alternative and back-up scheduling may be useful to plan for potential staff absences due to COVID19.
- Authoritative health organizations and agencies have published procedures to [return to the workplace after known or suspected infection](#). Providers should consider incorporating recommendations from these authoritative bodies in their own policies and procedures.
- Programs that are within larger institutions should follow and be in compliance with their institution's policies and procedures.

#### **B) Patient Care**

- Each practice should consider creating and providing [educational materials](#) for their patients [regarding COVID-19 risk mitigation](#) strategies as they apply to patient care (**Table 1**).



- It is important to provide information to patients regarding the potential risks of pursuing care during the COVID-19 pandemic. Elements may include:
  - o Unknown impact of pregnancy on susceptibility to or severity of COVID-19.
  - o Unknown impact of COVID-19 on pregnancy including maternal and fetal risks. Some warnings should be given related to general risk of febrile illness and experience with other viral infections.
  - o Disclosure regarding limited access to or unknowns regarding COVID-19 testing.
  - o Potential for treatment cancellation due to exposure, infection, unavailability of PPE, or changes in regulations. Statement of treatment cancellation should include some mention of financial consequences of cancellation.
  - o Risk of exposure at clinic during treatment.
  - o Option to postpone treatment.
  - o Opportunity to have questions answered.
- Physicians are advised to document COVID-19 patient counseling and assent in the medical record.
- It is important to recognize that patients may interpret a physician's willingness to treat as an indication that their risk is minimal, and this may well not be the case. The issue of risk/benefit should be highlighted as a starting point for all patients treated in this environment.
- Anyone, patients or staff, who are considered to be infectious should not enter the clinic until they meet criteria for [ending isolation](#) after known or suspected infection.

## PHYSICAL DISTANCING, SANITIZING SURFACES, AND FREQUENT HANDWASHING

Studies of the COVID-19 show different durations of viral activity on a variety of materials under laboratory conditions. How this translates into actual infectious risk in the real world is unknown. Practices should:

- Screen patients and every member of the staff daily, including physicians and other healthcare providers, who enter the facility. This may include such elements as [questioning](#) regarding possible risk of exposure and/or the presence of signs and symptoms of COVID-19, and checking body temperature, before the individual enters the facility.
- Maintain physical distancing between individuals as [recommended by the US CDC](#).
- Develop a face mask policy for patients and staff. [CDC recommends wearing a face mask](#) when in public spaces as a protective measure against asymptomatic viral transmission.
- Establish a frequency protocol and specific procedure for [cleaning/decontaminating all surfaces](#) touched by patients and staff during the ordinary course of operations.
- Consider posting public notices or signs for patients and staff, regarding avoiding touching one's face, mouth and eyes.
- Require [frequent hand washing](#) with soap and water for 20 seconds (or cleansing with a sanitizing gel) as a critical component of COVID-19 risk mitigation.

## TESTING AND DOCUMENTING IMMUNITY

The landscape for testing for the novel coronavirus causing COVID-19 (i.e. SARS-CoV-2) for presence of the virus (e.g. by PCR) is evolving rapidly. Broad use of testing will allow for the early identification of infected individuals and is an important tool for minimizing viral transmission to patients and staff. For example, testing is currently recommended for all patients undergoing scheduled surgery who have the potential for intubation. However, as rapid testing is not yet widely available, the role of testing all patients and staff for viral presence in the provision of other forms of reproductive care is currently undefined. Nevertheless, as testing becomes more reliable and accessible, providers should develop and incorporate a testing strategy for patients and staff. Continuing consultation with [authoritative sources, including the U.S. FDA](#), is strongly suggested. We also note that:

- The interpretation of SARS-CoV-2 tests is not straightforward. Up-to-date information on [diagnostic testing is maintained and available on the FDA website](#).

- The sale of fraudulent COVID-19 test products is real and remains a threat to the public health. Practices can help mitigate this issue by [reporting suspected fraud to the FDA](#).

Physicians and other healthcare providers should be aware of the limitations of serological tests to detect antibodies to SARS-CoV-2. The [FDA warns against the use serological \(antibody\) tests](#) as the sole basis to diagnose COVID-19, recommending that they be used primarily to provide information regarding whether a person may have been exposed.

If testing is not readily available or routinely used, practices should implement evidence-based infection prevention techniques including access control, workflow and distancing processes, and distribution of PPE appropriate for the clinical tasks to the clinical team, to create a safe environment in which fertility care can occur.

## USING STANDARD OR UNIVERSAL VS. ENHANCED OR EXPANDED PRECAUTIONS IN REPRODUCTIVE MEDICINE

[Universal or Standard precautions](#) is an approach to the prevention of transmission of blood and human body fluid-borne pathogens. During the COVID-19 pandemic, Enhanced or Expanded precautions ([transmission-based precautions](#)) are recommended to provide additional protection to interrupt transmission by aerosolization or droplets, or contact with contaminated surfaces. Reproductive medicine practices typically offer both diagnostic and therapeutic procedures, each of which is associated with varying levels of invasiveness and disease transmission risk (see **Table 3**). Practices should evaluate the risks associated with each activity and procedure and determine whether their facility has the appropriate PPE, staffing level and staff training to safely proceed.

## AVAILABILITY OF PPE AND OTHER RESOURCES

The demands of the COVID-19 pandemic on local healthcare systems vary in timing and magnitude by locality. [As the transmission and disease rate peaks in a locality and the local incidence begins to decline](#), the strain on the healthcare system will ease, and PPE and other necessary resources will become more readily available.

Staff must be trained in the proper use of PPE, including proper donning and removing techniques. Providers should post reminder [“how to” signs](#) in areas where staff don and remove PPE.

- Providers must maintain sufficient PPE, potentially [utilizing CDC recommended methods for preserving PPE](#), and other necessary supplies to ensure the safety of patients and staff.
- The type of PPE necessary for specific activities within the clinic setting will vary (**Table 3**).
- Providers must maintain adequate minimal staffing levels to meet the scope of services they offer.

Patients should wear cloth or surgical grade masks [at all times when in the clinic](#), except when under anesthesia.

## PRACTICE PATTERN CONSIDERATIONS

Altering practice patterns can help reduce disease transmission risk by minimizing the number of in-person interactions. Some approaches to do this may include:

- Having some staff members work remotely from home full or part-time where feasible.
- Continuing to use telehealth to the greatest extent possible to minimize number of patients in the office at one time.
- Minimizing the number of in-cycle monitoring visits to the fewest necessary, as determined by medical feasibility.
- Counseling and consenting patients electronically.

- Spreading out necessary appointments to limit the number of patients in the office at one time.

## RESUMING CARE

With appropriate risk assessment, risk mitigation, consideration of resource availability, and thorough counseling, it is possible to resume providing reproductive services in an environment where COVID-19 exists. Newly established protocols, procedures, and systems to provide care in this environment should be monitored to ensure that they are functioning as intended as services resume and volume increases. Attention should be given to controlling the number of in-vitro fertilization (IVF) cycles to ensure that the capacity of the IVF laboratory is not exceeded.

It may not be possible to offer all patients access to care immediately upon resumption. The final decision on how to prioritize patient care is best handled at the local level, in consultation with patients, as physicians and other reproductive healthcare providers carefully assess local and regional conditions. Some considerations could include:

- The impact of delay on patient prognosis due to medical factors, such as age, ovarian reserve or endometriosis.
- The number of patient visits required (e.g. treatments that are associated with the fewest visits may be prioritized first).
- The impact of treatment delay on the mental and emotional well-being of patients.
- The impact of delay on patient ability to pursue or access treatment due to insurance coverage or employment status.

As practices begin to resume services, they should consider adapting or adopting strategies that can be found on the [SART.org website: COVID-19 resources for professionals and providers](#).

Due to the impact of treatment delay, as well as the risks associated with reproduction during the COVID-19 pandemic, practices are advised to ensure that every patient is provided with a list of resources for support and counseling, including but not limited to, a referral [list of mental health professionals](#), who specialize in fertility/infertility counseling in reproductive medicine.

As conditions remain fluid, practices should strive to monitor, reassess and modify clinic operations as community conditions change, knowledge of the disease increases, and additional resources to mitigate, test for, and combat the disease become available.

We hope that the threat from the virus continues to fade and that all our patients will be able to receive the treatments they need without delay. However, it should be noted that progress in disease mitigation and containment with an eye toward effective medical treatment and vaccine prevention is by no means guaranteed. As such, conditions must be monitored closely as changes to implementation and expectations may be required.

**Table 1. Risk assessment and mitigation, practice consideration, and professional training & education resources**

What	Link
Risk Assessment	<p><a href="#">CDC Guidance for Healthcare Personnel with potential exposure to patients with COVID-19</a></p> <p><a href="#">Managing risks and risk assessment at work (includes downloadable Risk Assessment Template)</a></p> <p><a href="#">People at Higher Risk of Severe Illness</a></p> <p><a href="#">OSHA Hazard Recognition</a></p> <p><a href="#">OSHA Guidance on Preparing Workplaces for COVID-19</a></p> <p><a href="#">College of Reproductive Biology (CRB) guidance</a></p>
Risk Mitigation	<p><a href="#">Strategies to Mitigate Healthcare Personnel Staffing Shortages</a></p> <p><a href="#">Social Distancing, Quarantine and Isolation</a></p> <p><a href="#">Hand Washing</a></p> <p><a href="#">Use of Face Masks</a></p> <p><a href="#">How to protect yourself and others (Poster)</a></p> <p><a href="#">Putting on and Removing PPE (Poster)</a></p> <p><a href="#">How our facility is keeping patients safe from COVID-19 (CDC poster referencing outpatient dialysis but applicable content)</a></p> <p><a href="#">Cleaning and Disinfecting Your Facility</a></p> <p><a href="#">Evaluating and Testing Persons for COVID-19</a></p> <p><a href="#">Strategies to Optimize the Supply of PPE and Equipment</a></p> <p><a href="#">Guide to Infection Prevention for Outpatient settings: Minimum expectation for safe care</a></p> <p><a href="#">Universal and Transmission Based (enhanced or expanded) precautions</a></p> <p><a href="#">FAQs on Diagnostic Testing for SARS-CoV-2</a></p> <p><a href="#">Report Suspected Fraudulent COVID-19 products</a></p> <p><a href="#">The Use of Personal Protective Equipment by Anesthesia Professionals during the COVID-19 Pandemic</a></p>

	<p><a href="#">Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission</a></p> <p><a href="#">How to protect yourself and others (CDC patient education)</a></p> <p><a href="#">ASRM COVID-19 Resources for Patients</a></p>
Practice Consideration	<p><a href="#">SART.org COVID-19 Resources for Professionals and Providers</a></p> <p><a href="#">Online Patient Screening Questionnaire (developed by Apple and the CDC)</a></p> <p><a href="#">The Human Diagnosis Project COVID-19 self-assessment tool</a></p> <p><a href="#">Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings</a></p> <p><a href="#">Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19</a></p> <p><a href="#">Surgical Mask and Gown Conservation Strategies</a></p> <p><a href="#">Embryology Laboratory Suggestions for COVID-19</a></p> <p><a href="#">Transmission based precautions</a></p> <p><a href="#">Ambulatory Care Clinical Tool Kit</a></p>
Healthcare Professional Training & Education	<p><a href="#">CDC Healthcare Professional Training Site</a></p> <p><a href="#">Managing Stress and Anxiety</a></p> <p><a href="#">Guidance for the Selection and Use of PPE in the Healthcare Setting</a></p>

<b>Table 2. Links to authoritative health organizations and agencies regarding COVID-19</b>		
<b>Organization</b>	<b>Website</b>	<b>Content</b>
World Health Organization	<a href="http://www.who.int">www.who.int</a>	Advice for the public Advice for health workers Country and Technical Guidance Situation updates Research and development
US Centers for Disease Control and Prevention	<a href="http://www.cdc.gov">www.cdc.gov</a>	Advice for the public Advice for health workers Situation updates Research and development
US State and Territory Health Departments	<a href="http://www.cdc.gov/publichealthgateway/healthdirectories/healthdepartments.html">www.cdc.gov/publichealthgateway/healthdirectories/healthdepartments.html</a>	Link to health departments in all 50 states, 8 US territories and freely associated states, and the District of Columbia.
Massachusetts Medical Society	<a href="http://www.massmed.org/About/State-Medical-Societies-in-the-US-/#.XpyuIS3MxBw">http://www.massmed.org/About/State-Medical-Societies-in-the-US-/#.XpyuIS3MxBw</a>	Links to the 50 State Medical Societies in the US
Johns Hopkins University & Medicine	<a href="https://coronavirus.jhu.edu/map.html">https://coronavirus.jhu.edu/map.html</a>	COVID-19 Dashboard
Institute for Health Metrics and Evaluation	<a href="http://www.healthdata.org">http://www.healthdata.org</a>	COVID-19 Projections

<b>Table 3. Risk assessment and mitigation for reproductive care procedures and activities</b>				
<b>Procedure/Activity</b>	<b>Potential Risk</b>	<b>Mask Type Required for Staff</b>	<b>Other PPE Required for Staff</b>	<b>PPE Required for Patients</b>
Clinic Entry Screening	Droplet	Medical Grade	Gloves	Cloth Mask
Patient Registration	Droplet	Cloth Mask	---	Cloth Mask
Vital Sign Measurement	Droplet	Medical Grade	Gloves	Cloth Mask
In Office Consultation	Droplet	Cloth Mask	---	Cloth Mask
Phlebotomy	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves	Cloth Mask
Ultrasound	Droplet	Medical Grade	Gloves	Cloth Mask
Saline Infusion Sonogram	Droplet, Splash	Medical Grade	Face Shield, Gloves	Cloth Mask
Hysterosalpingogram	Droplet, Splash	Medical Grade	Face Shield, Gloves	Cloth Mask
Office Hysteroscopy	Droplet, Splash	Medical Grade	Face Shield, Gloves	Cloth Mask
Endometrial Biopsy	Droplet, Splash	Medical Grade	Face Shield, Gloves	Cloth Mask
Specimen Handling (Blood, Semen, Follicular Fluid)	Splash	Medical Grade	Face Shield, Gloves	N/A
Lab Procedures (ICSI, biopsy, specimen prep, etc.)	Droplet, Splash	Medical Grade	Gloves	N/A
Intrauterine Insemination	Droplet	Medical Grade	Gloves	Cloth Mask
Embryo Transfer	Droplet	Medical Grade	Gloves	Cloth Mask
Pre-Op Holding Area	Droplet	Medical Grade	Gloves	Cloth Mask
IV Line Insertion	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves	Cloth Mask
Airway Management	Droplet, Aerosolization	N95 or Equivalent	Face Shield, Gloves	N/A
Oocyte Retrieval	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves	N/A
Operative Hysteroscopy	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves, Gown	N/A
Operative Laparoscopy	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves, Gown	N/A
Open Reproductive Surgery	Droplet, Splash, Needle Stick	Medical Grade	Face Shield, Gloves, Gown	N/A
Post Anesthesia Care Unit	Droplet, Splash	Medical Grade	Face Shield, Gloves	Cloth Face Mask when able

Based on CDC guidance for the selection and use of PPE in Healthcare Settings (<https://www.cdc.gov/hai/pdfs/ppe/ppeslides6-29-04.pdf>)



# Directions given under the Human Fertilisation and Embryology Act 1990 (as amended)

**Covid-19 Treatment Strategy**

**Ref: 0014  
Version:2**

<b>These Directions are:</b>	General Directions
<b>Sections of the Act providing for these Directions:</b>	Sections 12(1)(g), 13(2)(b) and 13(2)(f) and 23 of the Human Fertilisation and Embryology Act 1990 (as amended)
<b>These Directions come into force on:</b>	XX May 2020
<b>These Directions remain in force:</b>	Until revoked
<b>This version was issued on:</b>	XX May 2020

**INSERT SIGNATURE**

**Sally Cheshire CBE XX May 2020**

In accordance with emergency powers set out in paragraph 5.2.1 of the Authority's Standing Orders of 31 January 2019.



**Version control**

Name of Directions: Covid-19 Treatment Strategy

Reference number: 0014

Date version 1 issued: 23 March 2020

Chair's Letter reference: N/A

Date version 2 issued: XX May 2020

Chair's Letter reference: N/A

DRAFT

1. This General Direction revokes General Direction 0014 (version 1) published by the Authority on 23 March 2020.
2. For the purposes of this General Direction, treatment services refers to those treatment services which, by GD0014 (version 1), centres were required to suspend by 15 April 2020.
3. Licenced centres may resume treatment services provided the requirements set out at paragraphs 4, 5 and 6 below have been satisfied.
4. Subject to paragraph 2, when centres choose to resume treatment is a decision for each PR taking account of local factors relevant to that centre's service provision.
5. Licensed centres must develop a written Covid-19 Treatment Commencement Strategy ('Treatment Commencement Strategy')
6. The centre's Treatment Commencement Strategy must:
  - (a) Record the measures the centre will be taking to comply with current guidance on safe and effective treatment during the Covid-19 emergency published by specified national and international professional bodies;
  - (b) record the risk assessments undertaken by the centre to identify risks arising from the provision of treatment service during the emergency situation resulting from the COVID-19 pandemic ("the Covid-19 emergency") and the mitigating actions taken in relation to each risk;
  - (c) record the practical and logistical measures the centre will be taking to deliver treatment safely during the Covid-19 emergency, and in a manner that mitigates the risks arising from, or associated with Covid-19 for both patients and staff;
  - (d) record all new or revised standard operating procedures or protocols which have been developed to enable treatment to resume safely during the Covid-19 emergency whilst maintaining compliance with the Government's current requirements relating to freedom of movement and social distancing.
7. The PR must complete the HFEA Covid-19 Treatment Commencement self-assessment and ensure that a copy of the completed assessment is provided to the centre's inspector.
8. Centres may not commence treatment services until they have received written approval from their inspector.