

# Authority extraordinary meeting – agenda

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**7 May 2020**

**Teleconference**

<b>Agenda item</b>	<b>Time</b>
1. Welcome, apologies and opening remarks	4.15pm
2. Minutes of 30 April 2020 extraordinary Authority meeting	4.30pm
3. Resuming fertility treatment: implementation	4.35pm
4. Close	5.10pm

# Minutes of the Extraordinary Authority meeting by teleconference on 30 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	7 May 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 of 30 April 2020 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 30 April 2020

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Anne Lampe	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian
Apologies	None	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Jo Triggs	Debbie Okutubo Rachel Cutting Catherine Drennan

### 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 extraordinary Authority meeting and noted that the focus of the meeting was to consider whether the conditions that led to the suspension of fertility services in relation to the Covid-19 pandemic had now sufficiently changed that it would be appropriate to revise the terms of the General Direction (GD) 0014.
- 1.2. The Chair advised everyone present that the meeting was being recorded and to ensure that we continued to be a transparent public body, a short minute would be issued in draft shortly after the meeting.

## 2. Minutes of the Meeting

- 2.1. Members agreed that the minutes of the meeting held on 21 April 2020 be signed by the Chair subject to the corrections submitted prior to the meeting.

## 3. Resuming fertility treatment

- 3.1. The Chief Executive (CE) introduced this item and gave an update on the relevant changes to the situation relating to the criteria agreed at the 21 April Extraordinary Authority meeting.
- 3.2. The CE advised that there was revised guidance from professional societies including the European Society of Human Reproduction and Embryology (ESHRE) and the American Society for Reproductive Medicine (ASRM) and that the British Fertility Society (BFS) and Association of Reproductive and Clinical Scientists (ARCS) were currently working on further guidance. In a statement on 27 April the Secretary of State for Health and Social Care, Matt Hancock MP, had advised that the government planned to restart non-Covid-19 services in the NHS in England, starting with the 'most urgent' such as cancer care and moving to others over time.

- 3.3.** It was noted that the NHS England Chief Executive had instructed the NHS on 29 April to prepare for the resumption of non-Covid-19 medical treatments.
- 3.4.** The CE commented that GD0014 in its present form needed to be reviewed in light of the revised guidance from the professional bodies and the move to reopen some NHS services. Also that Authority members should consider if circumstances had changed such as to warrant changes to GD0014.
- 3.5.** The criteria agreed by the Authority on 21 April 2020 to be considered were that:
- Government restrictions on social contact and travel are lifted
  - Restarting fertility treatment would not have a negative impact on the NHS
  - There was no evidence that Covid-19 impacted on the health of pregnant women and their babies
  - Fertility clinics are able to provide a safe service.
- 3.6.** The Chair welcomed comments from Authority members.
- 3.7.** It was noted that some clinics were ready to resume as soon as they could and some patients were also keen to get their fertility treatments going.
- 3.8.** Members commented that running a safe service remained a general obligation in providing health services and fertility clinics needed to provide a safe service both in private and NHS clinics. There was therefore a need for each clinic to consider local issues that may be relevant.
- 3.9.** There were further comments that staff safety and well-being needed to be taken into consideration.
- 3.10.** It was noted that we needed to be cautious as some staff were worried about how services would be delivered. Even though fertility treatment was not classed as urgent medical treatment, some patients were anxious about when they could restart their treatment.
- 3.11.** Another concern raised by members was the use of personal protective equipment (PPE) for fertility patients when staff on Covid-19 wards could not access it. It was noted that resources such as essential PPE should not be taken away from where it was needed to support the NHS efforts on Covid-19.
- 3.12.** There was a suggestion that communication to patients needed to explain what to expect and with clinics what was expected from them. Travelling to and from clinics could also be an issue for consideration.
- 3.13.** Members suggested that to ensure patients were making informed decisions and giving their consent from an informed perspective, clinics needed to be clear about both the known and unknown risks.
- 3.14.** There were further comments from members that the revised GD0014 requiring clinics to complete the HFEA Covid-19 treatment commencement self-assessment was a step in the right direction. Another re-assurance was that before a clinic could commence treatment it had to have received approval of its self-assessment from its HFEA inspector. Failure to do so could result in a regulatory sanction. Such an approval process was seen as an important safeguard.

## Implementation

- 3.15.** The Chair summarised the discussion and suggested that although there were a range of views members were largely in agreement with the direction of travel towards clinics being able to apply to restart treatment. It was also noted that within the next ten days non-urgent routine medical treatments in the NHS should plan to resume.
- 3.16.** There was a discussion about the proposed self-assessment mechanism. The Director of Compliance and Information suggested that it was more robust to require clinics to carry out their own self-assessments. Such an approach would ensure that the Person Responsible (PR) took full responsibility for the policies of their clinics. In this context it was noted that we were not proposing that clinics should be open or treatment should be offered by a certain date, but that clinics could apply to re-open when they felt they could offer treatment safely.
- 3.17.** In response to a question, the Director of Compliance and Information explained the process of clinics self-assessing to Members. It was noted that this was consistent with the existing inspection model where when inspectors attended clinics they looked through all relevant paperwork and stated whether it met the requirements in the audit checklist.
- 3.18.** It was noted that the current draft clinic self-assessment was based on ESHRE guidance and on the HFEA frequently asked questions (FAQs) and that Persons Responsible (PR) had a legal responsibility enshrined in the Act.
- 3.19.** Members advised should the revised GD0014 be issued the guidance needed to be sufficiently detailed to minimise the risk of clinics not complying. There was some discussion about the availability of different tests in the UK and in continental Europe, including how asymptomatic patients would be tested. It was noted that it was important that any specified tests should be readily available in the UK.
- 3.20.** During deliberations, it was confirmed that the BFS and ARCS had not released their revised guidance but had made available their draft position statements.
- 3.21.** Members wanted to know if BFS and ARCS guidance might lead to changes in our criteria and whether we needed to consider it prior to clinics opening.
- 3.22.** The CE responded that the position would become clearer over time and there would be a lead-in period before licensable treatment could take place. Should the Authority agree that treatment should resume then a formal letter would be written to PRs with the timescales.
- 3.23.** Members suggested that we should adopt the same time scale as the NHS as this would send a signal to clinics that we were reviewing GD0014. During discussion, it was agreed that a firm date was preferable as it would give clarity for clinics and patients. The week commencing 11 May 2020 was agreed as it would be in-line with the NHS timeline.

## Next steps

- 3.24.** The Director of Compliance and Information suggested that should the Authority agree, the self-assessment tool would be trialled with a few centres and we would ask them to ignore the testing element of that self-assessment as we were still expecting UK guidance from BFS.
- 3.25.** The outcomes of the trialling of the self-assessment, further information from BFS/ARCS and a revised GD0014 would be brought to the next Authority meeting.

**3.26.** In the meantime, the CE would issue a letter to PRs indicating what clinics could expect including reference to the self-assessment tool. The letter would also state that the revised GD0014 would be issued in the week commencing 11 May 2020 and that a number of activities were on-going to ensure that treatment could resume in a safe manner.

### Decision

**3.27.** Members stated that they were still cautious but they wanted as many patients as possible to resume fertility treatment in a safe environment and agreed that fertility treatment could in principle be resumed if clinics could demonstrate compliance with the Covid—19 self-assessment tool.

**3.28.** Members further agreed in principle the revised GD0014 and the approach to enforcement, but that treatment will only resume in each clinic when it had been approved safe to do so.

**3.29.** Members noted that some of the ESHRE guidance was not possible to apply to the UK as the UK Covid-19 testing regime was different from other parts of Europe.

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## 4. Any other business

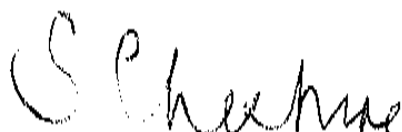
**4.1.** The Chair reminded Authority members that they would be contacted about the date of the next meeting.

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## 5. Chair's signature

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

Signature



Chair: Sally Cheshire

Date: 7 May 2020

# Resuming fertility treatment: implementation

## Details about this paper

Area(s) of strategy this paper relates to:	
Meeting:	Authority
Agenda item:	3
Meeting date:	07 May 2020 (Extraordinary meeting by teleconference)
Authors:	Peter Thompson, Chief Executive Rachel Cutting, Director Compliance and Information
Annexes	Annex A – letter to PRs 1 May 2020 (for information) Annex B – position statement from BFS/ARCS 1 May Annex C – revised guidance from BFS/ARCS 6 May Annex D – HFEA Covid-19 Treatment Commencement Strategy self-assessment tool (draft) Annex E – General Direction 0014 (version 2)

## Output from this paper

For information or decision?	For decision
Recommendation:	That the Authority notes the updates on guidance (section 3) and the self-assessment tool (section 4) and agrees that the revised General Direction 0014 should come into force on 11 May 2020 (section 5).
Resource implications:	N/a
Implementation date:	11 May 2020 - dependent on Authority decision
Communication(s):	See section 6
Organisational risk:	High

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## 1. Introduction

**1.1.** When the Authority last met at an extraordinary meeting on 30 April 2020 it agreed that:

- it was now possible to see a route to how fertility treatment could be offered safely, provided clinics were compliant with guidance from the UK and devolved governments, professional bodies and the HFEA.
- subject to the HFEA working with clinics, through an assessment process, on how a safe service could be delivered for patients and clinic staff, fertility clinics would be able to apply to reopen sometime in the week commencing 11 May 2020, once revised General Directions have been issued.
- the framework governing treatment during the ongoing Covid-19 pandemic would be set out in a revised General Direction 0014.

A letter issued to all PRs from the Chief Executive on 1 May 2020 (Annex A) setting out this decision and next steps.

**1.2.** This paper provides an overview of the application process to resume treatment (section 2); an update on current guidance (section 3); feedback on the self-assessment tool the HFEA have designed to assist clinics that wish to apply (section 4); agreement on a commencement date for the revised GD0014 (section 5); and communications (section 6).

**1.3.** The issues regarding the resumption of treatment have previously been considered in detail by the Authority and so are not covered again here.

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## 2. The process for allowing clinics to resume treatment

**2.1.** The Authority decided last week that the process for allowing a licensed centre to resume treatment should be set out in a revised GD0014. In outline the process would work like this:

- The centre decides that it wishes to reopen, taking into account local factors like staffing and equipment.
- The centre then develops a written Covid-19 Treatment Commencement Strategy, the requirements of which are defined in paragraph 6 (a) – (d) of GD0014.
- The centre then requests a copy of the HFEA Covid-19 Treatment Commencement self-assessment tool (see section 4 below).
- Having reviewed their Treatment Commencement Strategy against the self-assessment tool, the PR submits the completed self-assessment to their HFEA Inspector (GD0014 paragraph 7).
- The HFEA Inspector reviews the self-assessment tool within five working days of receipt.
- If approved, the centre can resume treatment.
- If not approved, the centre will need to address any shortcomings identified before resubmitting their revised self-assessment and seeking approval to resume treatment.
- Inspectors will ask for full copies of the Treatment Commencement Strategy or any other related documents if it is felt evidence is lacking in the submitted self-assessment tool.



- 2.2.** Any centre that resumes treatment services before they have received written approval from their inspector may be subject to regulatory sanction.
- 2.3.** The HFEA has previously decided that we would suspend onsite inspection visits until September 2020 because of the Covid-19 pandemic. This decision remains in place despite allowing centres to resume treatment. However, we have not suspended physical investigations of incidents and should a serious incident occur during this period we would investigate. Any on-site investigations will be undertaken in a way that minimises risk to patients, clinic staff and HFEA inspectors.

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### **3. Revised guidance**

- 3.1.** At its last extraordinary meeting on 30 April the Authority noted the revised guidance from ESHRE (23 April) and the ASRM (24 April) and that further revised guidance was also expected from the UK professional bodies, the BFS/ARCS. Since then, the BFS/ARCS have issued a 'position statement' (1 May, at Annex B) and revised guidance (6 May, at Annex C). The BFS/ARCS position statement noted that the criteria for assessing whether treatment could resume that the HFEA set on 21 April had, in the opinion of BFS/ARCS, largely been met. The revised guidance from BFS/ARCS is broadly similar to that produced by ESHRE, although there are some differences, for example around testing requirements and the requirement for a Code of Conduct.
- 3.2.** One element of that guidance that needs to be considered is the appropriate role of testing. When the Authority last met on 30 April, members noted the different testing regimes adopted by different countries and the necessity of ensuring that any requirements placed on UK licensed centres involved tests that could be reliably sourced in the UK. The revised BFS/ARCS guidance acknowledges that at the current time there is no widely available, reliable serological tests in the UK and reliance must be placed on symptomatic screening and antigen testing. It advises centres to follow local and national guidelines.
- 3.3.** It is likely that guidance on how to provide clinical services safely during the Covid-19 pandemic, whether from the UK or devolved governments or the professional bodies, will continue to evolve over the coming weeks and months. It therefore follows that centres will be required to keep their Treatment Commencement Strategies under regular review. We shall alert centres to relevant new guidance as it becomes available.

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### **4. HFEA Covid-19 Treatment Commencement self-assessment tool**

- 4.1.** The Authority agreed that a self-assessment tool was the most robust way of ensuring that centres developed appropriate policies and practices for ensuring that they offered safe services during the Covid-19 pandemic. This methodology is very much in line with our approach to inspections and monitoring compliance.
- 4.2.** The self-assessment tool has been organised into three broad headings (the current draft is at Annex D). The 47 questions reflect recommendations and guidance from ESHRE, BFS/ARCS, UK and devolved governments and highlight HFEA Licence Conditions and guidance which is particularly relevant during the COVID-19 emergency. The three headings are:
  - Risk assessment and review
  - Patient Information, consent and support

- Preparation to resume services
  - Staff and patient triage, screening and testing
  - Staffing
  - Operational aspects
  - Infection control practices
  - Clinical Treatment services

**4.3.** Since the last meeting (30 April) we have shared the draft self-assessment tool with 33 centres and at the time of writing had received feedback from 16 (48%). The centres are from both the NHS and the private sector and encompass a wide geographical spread. Feedback has been overwhelmingly positive. Centres have stated the document is comprehensive, thorough and provides a useful tool for centres to implement robust procedures to meet the requirements of the revised GD0014 (version 2) (at Annex E). It was felt appropriate to reference UK guidance for testing and PPE. Minor suggestions and comments have been incorporated in the current version.

**4.4.** The self-assessment tool refers to the 'current guidance'. As noted in section 3 above, over the coming weeks and months guidance may change and the HFEA expects any updated guidance to be reflected in centres' strategies. Inspectors will be in regular contact with PRs and if guidance changes we may ask to see evidence that this has been incorporated in each centre's Treatment Commencement Strategy.

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## 5. GD0014 commencement

**5.1** When the Authority last met it agreed that in principle centres could apply to reopen sometime in the week commencing 11 May. In view of the clarification on guidance (section 3) and the positive feedback on the self-assessment tool (section 4) we recommend that the revised GD0014 (version 2) should come into force on 11 May 2020 – **do you agree?**

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## 6. Communications

**5.2** Any decision will be communicated to PRs by means of a letter from the Chief Executive which will issue at 10.00am on Monday 11 May.

**5.3** We will also update information on our website and social media, particularly as centres reopen over time.

**6.1.** Any communications with patients will need to guard against over-optimism. The decision to vary GD0014 does not mean that the fertility sector is 'open'; rather it means that those centres that wish to reopen can apply for approval from the HFEA. We do not know how many centres will do so or when. Nor do we know how many patients centres will be able to treat, although numbers

will be lower than previous due to the demands of social distancing etc. If the centres that have expressed an interest in the self-assessment tool are any guide, then it is reasonable to assume that somewhere between one-third and one-half of all licensed centres are actively considering applying to reopen in some way over the next few weeks.



To all PRs

*By e-mail only*

1 May 2020

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10 Spring Gardens  
London  
SW1A 2BU

T 020 7291 8200  
F 020 7291 8201

Dear Colleague

### **Resuming fertility treatment: next steps**

I write further to my letters (sent by email) of 23 and 28 April 2020. This letter contains important information on next steps.

Late yesterday the Authority (our Board) held an extraordinary meeting to consider whether circumstances had sufficiently changed to allow licensed fertility treatment to resume. They reviewed the current position against the four criteria I set out in my letter to you of 23 April.

The Authority concluded that, assessed in the round, it was now possible to see a route to how treatment could be offered safely, provided clinics were compliant with guidance from the UK and devolved governments, professional bodies and the HFEA.

The Authority decided that subject to the HFEA working with clinics, through an assessment process, on how a safe service can be delivered for patients and clinic staff, **fertility clinics will be able to apply to reopen sometime in the week commencing 11 May 2020** once revised General Directions have issued. We expect that subject to satisfactory approval from the HFEA, patient treatment could begin shortly after.

The Authority agreed that the framework governing treatment during the ongoing Covid-19 pandemic would be set out in a revised General Direction 0014, which will be issued that week commencing 11 May. Further details on this are set out below.

I know that Covid-19 has impacted on licensed centres in different ways and it is important to understand that the revised GD0014 is designed to accommodate the very different position that centres find themselves in. Crucially, the revised GD0014 will not require centres to resume treatment by a certain date. Rather, it will put the onus on centres to judge, taking into account local factors, whether they feel they can offer safe services, and for the HFEA to then assess the robustness of your plans. This 'bottom up' approach is consistent with the plans announced by the Chief Executive of NHS England on 29 April, when he asked local NHS Trusts to make a judgement about whether they have the capacity to offer at least some routine non-urgent elective care.

In order to help you prepare for the resumption of treatment this letter summarises the requirements that all licensed centres will have to follow. The revised GD0014 will require that *before* resuming licensed treatment a centre must develop a written Covid-19 Treatment Commencement Strategy. The Treatment Commencement Strategy must:

- record the measures that the centre will be taking to comply with current guidance on safe and effective treatment and the mitigating actions taken in relation to each risk;
- record the risk assessments undertaken by the centre to identify risks arising from the provision of treatment and the mitigating actions in relation to each risk;

- record the practical and logistical measures the centre will be taking to deliver treatment safely and in a manner that mitigates the risks arising from, or associated with, Covid-19 for both patients and staff;
- record all new or revised standard operating procedures or protocols which have been developed to enable treatment to resume safely whilst maintaining compliance with the Government's current requirements relating to freedom of movement and social distancing.

In drawing up a Treatment Commencement Strategy we will expect centres to refer to professional and UK and devolved governments guidance. As we are awaiting revised guidance from the BFS/ARCS the Authority agreed that any centre that wishes to consider their readiness to resume treatment in the short term should use the relevant sections of the guidance published by ESHRE on 23 April 2020 until UK guidance is available.

The revised GD0014 will require centres to complete the HFEA Covid-19 Treatment Commencement self-assessment before commencing treatment. This self-assessment tool is intended to assess whether centres' Treatment Commencement Strategies are robust and will measure compliance against current guidance. The self-assessment tool is in draft at the moment and we intend to trial it with a few centres over the next few days to test its effectiveness. The finalised tool will be available from your HFEA inspector once the revised GD0014 is issued.

The revised GD0014 will set an approval process as follows. The completed self-assessment must be provided to your inspector and centres may *not* commence treatment services until they have received the written approval of their inspector. Centres that resume treatment prior to receiving approval from their inspector may face regulatory action. We aim to complete our approval process within 5 working days of receiving the completed centre self-assessment.

I understand that some of you have been actively reviewing your services and are keen to reopen as soon as possible, while others have had staff redeployed and equipment sourced for other uses and are therefore unlikely to be able to reopen for some time. Whatever position you are in, I know that you will put the safety of your patients and your staff above all other considerations.

None of us know how long the Covid-19 pandemic will be with us, or whether there will be further waves over the coming months, but for the foreseeable future delivering fertility services safely will require different ways of working. Our revised GD0014 is designed to provide you with a framework for doing just that. Once issued, we will regularly review it to see whether it is continuing to achieve its aim of enabling as many patients as possible to have safe treatment through these difficult times.

Lastly, we will be undertaking communications activity aimed at patients and the wider public so that they are aware that fertility services will be able resume shortly.

If you have any questions or should you wish to participate in the trial of the self-assessment tool please contact: [Rachel.Cutting@hfea.gov.uk](mailto:Rachel.Cutting@hfea.gov.uk).

I hope this is helpful.

Yours,



Peter Thompson  
Chief Executive

## **British Fertility Society**

### **Position statement on the resumption of fertility treatment in the UK during COVID-19 pandemic**

May 1 2020

#### **Purpose:**

To propose the milestones that, if met, would support a decision to resume fertility clinic activities and treatments in the UK and to assess which of these can be considered to have been met.

Information gathering process:

A letter was sent to the memberships of the Association of Reproductive and Clinical Scientists (ARCS) and the British Fertility Society (BFS) on 9/4/20 to seek opinions and input into the milestones that must be passed to allow specific areas of our work to recommence. Alongside this, a review of the scientific evidence was undertaken, the evolving National COVID-19 guidance reviewed, and stakeholder and patient submissions were considered.

This document outlines the position of the ARCS and BFS Executive Committees regarding the milestones relevant to the resumption of treatment recently outlined by the Human Fertilisation and Embryology Authority (HFEA) and considers the feasibility and high-level requirements for routine fertility treatments to resume in the U.K. at this stage of the COVID-19 pandemic.

Detailed and best practice guidance for the resumption of treatment services will be addressed in a forthcoming publication by BFS/ARCS.

#### **Background:**

In a letter to clinics on 23/4/20 the HFEA outlined their criteria to vary or revoke General Direction 0014, they were:

1. That Government restrictions on social contact and travel are lifted or eased.
2. That restarting fertility treatment would not have a negative impact on the NHS.
3. That there was no evidence that Covid-19 impacted on the health of pregnant women or their babies.
4. That fertility clinics are able to provide a safe service.

These HFEA criteria reflect the original rationale for cessation of treatment services and represent a timely review given the changes in UK COVID-19 patterns and understanding over the period of the pandemic.

ARCS/BFS have considered the HFEA's published criteria and believe:

1. Restrictions on contact and travel: Once other comparable treatment services recommence and/or restrictions on social contact and travel are relaxed, infertility services should be reopened. Such a policy would be consistent with that already implemented by other European countries such

as Denmark and Spain. In addition, the NHS has now entered a second phase of work which includes the reintroduction of some urgent services in hospitals.

2. Impact on the NHS: Since the decision to cease fertility treatments was implemented, the NHS has, thankfully, maintained capacity to cope with the pandemic, and, whilst there are regional differences, much new capacity remains unused. The NHS has now entered a second phase, reintroducing a range of urgent services into hospitals and encouraging the use of primary and emergency care services.

An important consideration should be the avoidance of significant burden on the NHS through the management of complications of pregnancy and fertility treatment. Appropriate care in the use of ovarian stimulation protocols and surgical procedures can reduce these to a level which avoids a significant additional care burden. Any additional burden to the NHS represented by complications of early pregnancies arising from fertility treatment should be viewed in the context of the burden placed by all pregnancies. Fertility treatments account for fewer than 4% of pregnancies in the UK and no advice has been issued by the government to the general public not to conceive natural pregnancies.

The repurposing of fertility clinics, staff and equipment to support the NHS effort to care for coronavirus patients continues. Hence, a further milestone for reopening NHS and Private fertility clinics, should be the release of fertility clinic staff and facilities back from other use ensuring safe staffing levels. Whilst this milestone would not apply to those clinics that have not had their staff or facilities repurposed in this way, but may have furloughed staff, all centres need to ensure that they have sufficient staff available to safely manage the volume of work planned, and contingencies if staffing levels are compromised.

3. Pregnancy and babies: While data remain limited, there is growing evidence that the coronavirus has low impact on early pregnancy and perinatal risk. The RCOG, which is closely monitoring international evidence as it emerges, has now advised that pregnant women do not appear to be more likely to be seriously unwell than other healthy adults if they develop coronavirus. Moreover, they have stated that there is no evidence to suggest an increased risk of miscarriage, and that it is unlikely that if the mother contracts the virus that it would cause problems with the baby's development, stating that none have been observed thus far (RCOG, Coronavirus (COVID-19) infection and pregnancy – guidance for healthcare professionals: Version 8 – 17/3/20).

4. Fertility clinic safety of services: A key milestone for opening a clinic should be the availability of sufficient staff and equipment to operate a safe and effective service in a way that protects staff and patients from infection risk. An important part of this milestone is the provision of appropriate and sufficient PPE. It also requires caution and comprehensive risk assessment of all treatment services.

A number of professional societies and clinics have issued detailed guidance on how this can be achieved operationally (European Society of Human Reproduction and Embryology (ESHRE) 2020, American Society for Human Reproduction (ASRM) 2020 and ARCS/BFS guidance will follow soon. Clinics should be able to demonstrate the operational steps they have taken to implement suitable systems to address the risks associated with resumption of services. The highly regulated context in which UK HFEA licensed clinics operate will provide assurance to the public and policy makers that implementation of appropriate measures will be undertaken and seen to be so.

## **Conclusions**

On the 18/3/2020 ARCS/BFS published guidance recommending a cessation of elective fertility treatments in the U.K. This guidance was published against the backdrop of a growing and poorly understood pandemic and a well-founded fear that the health service could be overwhelmed with COVID-19 cases. Cases in the U.K. have now likely peaked and stabilised and it seems reasonable to suggest that, until a viable vaccine or treatment is available, a 'new normal' will prevail, with some activities being undertaken while social distancing and other mitigation strategies remain in place. With this being the case, as significant delays to treatment can be detrimental to patients with sub-fertility, BFS and ARCS consider that fertility treatment should be permitted at the same time as other serious non-emergency medical conditions. The two societies will provide guidance for reintroduction plans which should consider phasing, social distancing and prioritisation strategies.

In summary, the current view of the ARCS and BFS is that the key milestones against which the HFEA criteria are proposed to be measured have already been largely met or will be in the near future.

However, for clarity, ARCS and BFS have no regulatory authority over the sector and this document serves as a position statement. Any decision to allow fertility treatments to resume in the U.K. can only be taken by the HFEA through the revision or revocation of General Direction 0014 and it is incumbent upon the HFEA to determine the conditions under which any such revision would be made and monitored. When resumption of treatment services is permitted, BFS/ARCS would expect centres to give due consideration to their best practice guidelines which will be published soon.

**Dissemination:**

This document will be shared with HFEA, RCOG, available on ARCS and BFS Websites and to the public via social media feeds.

Posted in Covid 19 General Health



## **The Association of Reproductive and Clinical Scientists (ARCS) and British Fertility Society (BFS) U.K. best practice guidelines for reintroduction of routine fertility treatments during the COVID-19 pandemic.**

Prepared by the ARCS/BFS COVID working group\* on behalf of the Executive Committees of ARCS and the BFS.

Published on the ARCS and BFS websites

Date of publication: 6<sup>th</sup> May 2020

### **Introduction and background**

Arising in China in late 2019, the novel coronavirus (SARS-CoV-2) has swept the globe. Confirmed cases of COVID-19 have grown rapidly and, at the time of writing, exceed 3 million worldwide. The pandemic has resulted in unprecedented actions across health services worldwide and necessary responses are forcing economies into recession.

In March a letter from the Chief Executive and Chief Operating Officer of the NHS directed all NHS providers to, amongst other measures, prepare to '*postpone all non-urgent elective operations from 15th April at the latest, for a period of at least three months*'. On the 23<sup>rd</sup> of March 2020, the Prime Minister announced a 'lockdown' in order to limit the spread of the virus. This lockdown included strict social distancing rules and a moratorium on all but essential travel. Subsequently private hospitals cancelled all elective work and the NHS block booked their capacity for urgent NHS work.

Against this backdrop, ARCS and the BFS published initial guidance on the 16<sup>th</sup> March, which was updated and expanded on the 18<sup>th</sup> March. This guidance recommended that assisted conception centres cease all elective treatment activity as soon as possible to reduce the potential burden on the NHS from treatment complications, ensure social distancing, reduce risk of viral infection for patients and free up essential resources to aid in the fight against the pandemic. The BFS/ARCS guideline was followed on the 23<sup>rd</sup> March by the publication of General Direction 14 by the HFEA, which limited treatments to fertility preservation in patients who were, in the written opinion of a registered medical practitioner, likely to become prematurely infertile.

From the outset ARCS and the BFS have been acutely aware of the impact of the closure of the sector on patients, staff and the field of fertility treatment, and have supported the prospect of reopening services as soon as it is considered safe to do so, balancing risks and empowering our members to prepare and respond proportionately and professionally. On 1st May 2020, the BFS and ARCS published a position statement (1) detailing their view that the milestones necessary to allow treatment to resume in the U.K. had largely been met. On the same day the HFEA wrote to all licensed centres in the U.K. advising that,

from the 11th May 2020 they would be able to apply for treatment to restart, subject to their being able to demonstrate that steps necessary to protect staff and patients against infection had been put in place.

In order to provide clear guidance to centres as to what steps should be taken to provide this protection and how they should be implemented, the BFS and ARCS have produced this guideline document.

The BFS and ARCS recommend that this guideline should be used in conjunction with prevailing Government, health service and HFEA advice and regulations, to ensure safe and sustainable service delivery during the ongoing pandemic. The ARCS/BFS COVID working group have identified several areas where good clinical practice, based on five key principles, can help to minimise risk to patients and staff from the reintroduction of services.

## **1. Five Key Principles**

The following principles underpin the approach taken in developing this guidance:

- Resumption of fertility services must take place in a manner that minimises the chances of spread of COVID-19 infection to patients and fertility clinic staff.
- Centres should ensure a fair and transparent approach to any prioritisation policy.
- Resumption of treatment should not result in an undue burden on the NHS.
- Patients considering treatment should be fully informed about the effect of the ongoing pandemic on their treatment and give informed consent to having fertility treatment at this time.
- The fertility sector should adopt sustainable changes in working practices that help to build resilience against any future increases in the spread of COVID-19 in the community.

## **2. Ensuring patient safety**

### **a. Information and consent**

It should be recognised that patients are likely to be anxious about coronavirus infection and its potential effects on pregnancy. Patients should be made aware that the present experience is limited and does not indicate that the severity of infection is any worse in pregnancy. At this stage, there is no evidence of an increased risk of fetal anomalies or adverse pregnancy complications (RCOG) (2). Nonetheless, patients should be carefully counselled, taking into account their individual clinical situation and risk profile, and the likely persistence of the virus in the local community in the medium term. This counselling and the patient's decision whether or not to proceed with fertility treatment should be documented in the medical record.

### **b. Prioritisation and exclusions**

Patient prioritisation may form part of service resumption in the event that clinic resources do not allow all patients to be treated without delay. Fertility preservation for patients facing cancer chemotherapy or other treatment that is likely to affect their fertility should continue to be a priority. In addition, it is reasonable to prioritise patients in whom delay is most likely to significantly affect the outcome of treatment. Patients at special risk include those with a low ovarian reserve, advanced age and those facing extirpative pelvic surgery (for instance due to severe endometriosis or bilateral ovarian cysts). The above list is not exhaustive, and each clinic

should decide on which groups, if any, to prioritise based on the profile of its patient population and how it organises its care.

Particular caution should apply to patients with underlying medical problems whose co-morbidity places them at a higher risk of complications in the event of contracting coronavirus infection. This includes patients with obesity, hypertension, diabetes and those receiving immunosuppressive medication. It may be appropriate for such patients to delay conception until epidemiological evidence shows a sustained reduction in the community spread of the infection.

### c. **Triaging, screening and testing**

At the time of writing there are no widely available, reliable serological tests in the UK and reliance must be placed on symptomatic screening and antigen testing. It is likely that the coming weeks will see rapid progress in both the availability and efficacy of testing for coronavirus, and centres are advised to follow local and national guidelines and consider implementing a testing policy as soon as practicable.

- **Before starting treatment:** A screening questionnaire (see Appendix 1) and antigen test (if available) should be completed. Patients and donors with a diagnosis of COVID-19 infection should not start treatment until they have recovered and are not considered infectious. National guidelines should be followed in this regard. Centres should consider whether they advise patients and potential donors to self-isolate, if possible, from the start of ovarian stimulation treatment until egg collection.
- **During treatment:** A coronavirus screening questionnaire should be administered prior to every clinic visit. Patients and donors with a negative coronavirus antigen test at the start of treatment, and who remain negative on questionnaire screening throughout should be allowed to complete treatment. In centres that institute an antigen testing policy, consideration should be given to performing a further antigen test as close as reasonably possible to any surgical procedure depending upon local guidelines and availability of testing.
- **Action in the event of suspected COVID-19:** If a patient or donor develops symptoms suggestive of coronavirus or screens positive on the questionnaire during treatment, an antigen screen should be arranged and treatment should not proceed unless the patient screens negative as defined by national guidelines. In the event of a patient or donor presenting with suspected or confirmed Covid-19 after the ovulatory trigger, a multi-disciplinary individual risk assessment should take place to balance the risks of refraining from oocyte retrieval against those of proceeding. At present there is little data on the risks of minor surgical procedures in women with a diagnosis of Covid-19. Patients who become symptomatic after oocyte retrieval but prior to embryo transfer should be advised to freeze all their embryos for future use.

**d. Reducing face-to-face interactions**

Centres should consider ways in which the frequency and duration of visits required to undergo fertility treatment may be reduced without compromising safety and quality. Telephone and video consultations should replace face-to-face interactions in most situations, depending on the patient profile and the expectations from the consultation. Patients with a learning disability or complex needs may not be suitable for treatment without a face-to-face consultation. Centres should ensure that any software used meets the requirements of data protection. Clinicians may require training in the performance of 'virtual' consultations, including the need for confidentiality, accurate patient identification and provision of sufficient time for patients to assimilate information and ask questions. Recording of consultations should only be allowed with consent from both sides. Consent for fertility treatment may be taken remotely, provided the clinician is satisfied that the patient thoroughly understands the implications of consenting. Software packages exist to aid this process.

Centres that provide group patient information sessions should explore the use of videos and podcasts that can be accessed from home, avoiding the need for patients to congregate in large numbers.

Online counselling options should be available to patients.

Centres should aim to reduce the number of visits required for monitoring ovarian stimulation, particularly in women with a normal ovarian reserve.

Centres should minimise the number of accompanying persons. Virtual consultations, including those where an interpreter is needed, offer a way of managing care safely without the need for multiple attendees in person.

**e. Minimising clinical risk**

Clinical protocols to minimise the risk of OHSS are a well-established part of modern reproductive medicine practice, based on the value of a GnRH-Antagonist protocol and GnRH-agonist trigger in appropriate cases. Centres should bear in mind the value of these and of careful ovarian stimulation to minimise the risk of hospital admission for patients and to reduce the burden on the NHS. Operative and infective complications following oocyte retrieval are rare, and preventative measures such as prophylactic antibiotics should be considered to reduce risk where appropriate. The use of empirical immunosuppressive treatments should be avoided.

**f. Minimising risk in the laboratory**

Evidence to date suggests that the respiratory virus responsible for COVID 19 is not present in follicular fluid or seminal plasma, nor associated with gametes or embryos. Standard infection control procedures and good laboratory practice are, therefore, considered appropriate in the IVF laboratory during this time. This includes standard IVF laboratory PPE and the use of biological safety cabinets. When working with follicular aspirates or semen, which may contain blood, class 2 workstations offer the most protection for the operator. Safety glasses may be used with class 1 workstations, for additional protection, but the risk of possible impairment on microscopy

should be considered. Laboratory staff should aim to minimise handling and sharing of pipette handles/teats, pens and keyboards etc. and clean down equipment, such as microscope controls and eyepieces between operators.

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

**g. Patient Personal Protective Equipment (PPE)**

Centres should consider asking all visitors to the centre to use a face covering, and masks may be provided for those who need them. Provision must be made for safe disposal of PPE used by visitors.

### **3. Practical preparation for service resumption**

**a. Clinic Layout**

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

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

- Patient reception
- Patient waiting areas
- Consultation and counselling rooms
- Clinical rooms used for ultrasonography or phlebotomy
- Procedure rooms for oocyte recover or embryo transfer
- Laboratories
- Administration offices
- Communal staff areas (e.g. dining room, staff room)

The following measures, relating to clinic layout, should be considered:

- Physical barriers between staff and patients, and/or appropriate PPE for the activity being undertaken
- Spacing of furniture to ensure physical distancing is maintained between persons not from the same household (e.g. waiting area chairs, workstations in administrative offices)
- Signage and information clearly describing the requirements in place

## b. Physical distancing

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

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

- Patient arrival and checking in process at the clinic
- Patient consultation
- Patient consent taking
- Phlebotomy
- Ultrasonography
- Counselling
- Semen production
- Oocyte or Surgical sperm recovery
- Embryo transfer
- Staff meetings
- Confidentiality
- Witnessing
- Staff work discussions
- Staff breaks
- Use of corridors, communal areas, lifts and stairways

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

- Reconfiguration of areas of the clinic (see section above)
- Implementation of restrictions to the use of communal (social) areas, such as the staff room
- Staff working from home should be encouraged where possible
- Production and delivery of semen samples from home, following guidelines to avoid compromising the sample
- Implementation of virtual meetings wherever possible, minimising face to face appointments. (e.g. consultation, injection teaching and counselling)
- The use of electronic platforms for consent-taking, where available
- Use of approved electronic communications and messaging systems wherever possible
- Implementation of restrictions on partners and companions for appointments, where possible and appropriate
- Limiting staff and patient numbers permitted in each clinic area

## c. PPE

Public Health England (PHE) has produced a comprehensive set of documents regarding the prevention and control of COVID-19. <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe>

The guidance is designed for UK use of PPE in relation to COVID-19. These are applicable to all health care settings and are updated as necessary.

Centres should refer at all times to this PPE guidance. Other local guidelines may apply for NHS centres but are likely to broadly conform with those from PHE.

Whilst ensuring appropriate PPE use, centres should work to conserve stocks and inappropriate overuse should be avoided as PPE remains a national resource issue.

Practice and procedures in the sector should be covered either under outpatient or secondary care guidance or in guidance on the safe handling of materials in a laboratory setting as detailed in the documents referenced below, however these should not be taken in isolation without reference to the more detailed PHE guidance to ensure the correct measures are being used:

Table 1

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/879107/T1\\_poster\\_Recommended\\_PPE\\_for\\_healthcare\\_workers\\_by\\_secondary\\_care\\_clinical\\_context.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879107/T1_poster_Recommended_PPE_for_healthcare_workers_by_secondary_care_clinical_context.pdf)

Table 2

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/878750/T2\\_poster\\_Recommended\\_PPE\\_for\\_primary\\_outpatient\\_community\\_and\\_social\\_care\\_by\\_setting.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878750/T2_poster_Recommended_PPE_for_primary_outpatient_community_and_social_care_by_setting.pdf)

<https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens>

Centres should ensure that they review published national guidelines regularly for updates to ensure that they continue to comply.

Centres should include a description of their zones of work and acknowledgement of the PPE needs in their strategy document. In addition, it is recommended that centres maintain a record confirming that all relevant members of staff have undergone training in the proper donning and doffing of PPE.

**Appendix 2** provides a summary of recommendations applicable to the fertility setting. It should be seen as a guide only and not without reference to national guidance which may change over time.

#### **d. Equipment**

Centres should ensure that equipment is fit for purpose and has been maintained appropriately during any period of close down. Maintenance and servicing schedules should have been maintained except where allowed through HFEA guidance (3).

All equipment should be validated for use. Up-to-date validation documentation should be maintained.

Where possible centres should consider using equipment that may allow for greater physical distancing, automation or facilitate a more flexible workflow within the department (e.g. use of time lapse devices, computer assisted semen analysis (CASA) and electronic witnessing systems in the laboratory).

Staff should minimise sharing of any equipment where possible and equipment should be cleaned between operators (e.g. microscope eyepieces or keyboards).

#### e. Consumables

Centres should work to ensure that the supply chain for all consumables is intact. This should include, where necessary, contacting suppliers to ensure availability.

Contingency plans must be in place, for each critical consumable, should supply chain fail. Particular attention should be given to the supply of laboratory media, which may have short shelf life, embryo safe cleaning products, fertility drugs, liquid nitrogen and gas cylinders containing carbon dioxide, nitrogen, and oxygen. Some products may be in particularly high demand as much of the world reinitiates fertility treatments at a similar time and following a likely reduction in manufacturing. Stockpiling is not advised.

## 4. Operational preparation for service resumption

### a. Scheduling of appointments and procedures

In order to minimise the footfall through centres and facilitate physical distancing it is important to keep visits and the time spent in the clinic to a minimum. It is recognised that this will reduce work capacity in many centres and some measures may include an element of compromise. Risk assessment should be undertaken where necessary.

- **Number of visits:** centres should advise that only individuals required for each appointment should attend (this may include those accompanying disabled patients or interpreters when needed). As much activity as possible should be undertaken by phone or video call. Centres must ensure that appropriate confidentiality and clinical record keeping is maintained at all times.

Consideration may include condensing visits into a single pathway e.g. scan and blood tests can be undertaken without a return to the waiting area and “drop-in” visits discouraged. Treatment protocols should be reviewed to minimise the number of clinic visits required for monitoring and treatment. Persons accompanying patients home after procedures such as oocyte retrieval should remain outside the clinic.

- **Duration of visits:** centres should aim to encourage patients to attend at their given appointment time and should aim to avoid them from being kept waiting. Consideration to the length of appointments to allow for unexpected delays should be given, ensuring they are well spaced and also the addition of a buffer to allow catch-up if needed. Protocols should be reviewed to reduce the length of time spent in the department by individuals e.g. drop off appointments for semen analysis.



## **b. Working patterns**

Working patterns within centres may need to change to accommodate social distancing measures to ensure safety for staff and patients. Staff returning to centres will need to adopt a flexible approach to working. Managers need to find a balance between allowing flexibility and facilitating collaboration for all staff. This may involve risk assessments of the clinic and departments to demonstrate alternative ways of working. This may involve:

- splitting the workforce into teams to work across a longer period of the day and to ensure that staff numbers are restricted in the clinic.
- to work shifts and avoid crossover of staff for long periods of time
- to work virtually where possible to avoid patients coming into the clinic.
- to work from home where possible and to avoid staff numbers in highly populated areas such as administration offices

## **c. Staff responsibilities**

Fertility clinic staff have been identified as key workers and with that has come some social privilege but also a responsibility to the wider community to ensure that they comply with national lockdown guidance at home and whilst travelling to and from work. They must ensure proper reporting of symptoms and contacts as well as submitting to testing as appropriate, to reduce the risk of bringing COVID-19 into the healthcare setting.

Physical distancing within work spaces is equally important where possible to reduce the risk of spread of infection within staff groups as workload increases.

## **d. Maintaining safe working practices**

- Maintain working from home where feasible and effective and when appropriate confidentiality measures can be maintained
- Bring back homeworkers only as needed
- Consider implementing shifts working with two teams (or more if appropriate) and condensed working hours providing a shorter working day with fewer breaks to incorporate fewer in the department for longer with longer down time
- Review clinic zones in conjunction with work scheduling to avoid staff moving between zones more than necessary
- Consider scheduled breaks in the working day and where those may be taken in order to reduce rest area overcrowding
- Consider staff protection (see above) when close working is unavoidable e.g. some laboratory spaces/practices

## **e. Training**

Many centres are involved in training whether through formal training programmes or local skills training and CPD. COVID-19 work patterns should not be a barrier to continuing to support training in all areas of practice. Consideration to work patterns must include the potential for inclusion of relevant trainees. Physical distancing rules apply and measures put in place to reduce risk where that

is not feasible. Since changes in practice are likely to exist for some time this is an important training period for both new and existing practitioners and indeed, they may bring useful ideas and insights from experience elsewhere.

#### **f. Reciprocal agreements**

Contingencies should be in place to allow for unexpected staff reduction and centres should investigate the feasibility of sharing staff across facilities. This may occur within groups, within or across NHS Trusts or for stand-alone centres by arrangement with their neighbours. It is recommended that the breadth and scope of reciprocal arrangements between centres should be reviewed, to incorporate staffing, consumable provision and general support, where applicable and where possible.

Whilst it is generally considered that the peak of the COVID-19 pandemic has passed in the UK, a caveat to increasing public freedoms is the risk of a “second wave” of infection. Since the incidence of asymptomatic infection and population immunity can only be estimated, the severity of a second wave and the effect on workplaces where staff have previously been relatively protected should be considered. In a staged resumption of treatments, centres need to take into account the potential for a number of staff being sick or isolating at any one time. The workforce may also be depleted by members of staff who remain shielding currently. The volume and complexity of work undertaken should be matched by an appropriate number of staff with the appropriate skill mix.

#### **g. SOP & policy updates**

In March, Persons Responsible were required to confirm that they had a COVID 19 strategy in place and that this was formally documented. Centres’ strategy documents should now be revised, or new versions created to encompass the points indicated within this guidance, and in order to fulfil the requirements of the HFEA, as specified within the self-assessment questionnaire, demonstrating how treatment can be offered safely.

Centres should develop COVID-19 specific documentation to reflect changes in their practice. It should not be necessary to rewrite the full complement of centres’ SOPs. This should include the relevant risk assessments undertaken.

Many lessons will have been learnt during the COVID-19 pandemic and centres may well need, for the foreseeable future or wish permanently to change working practices and SOPs may be updated as per the centre’s document control policy in a stage-wise fashion.

BFS and ARCS would be very pleased to hear from centres who wish to share new best practice developed from this time of change.

## **5. Information, conduct consent and support**

### **a. Patient information**

Centres are responsible for ensuring patients are given timely information before considering treatment. Patient information must set patient expectations regarding the adaptations within the

centre and in treatment pathways and procedures, and include risks of attending the clinic and proceeding with treatment, during the COVID-19 pandemic.

While data remains limited, there is growing evidence that the coronavirus has low impact on early pregnancy and perinatal risk. The RCOG, which is closely monitoring international evidence as it emerges, has now advised that pregnant women do not appear to be more likely to be seriously unwell than other healthy adults if they develop coronavirus. Moreover, they have stated that there is no evidence to suggest an increased risk of miscarriage, and that it is unlikely that if the mother contracts the virus that it would cause problems with the baby's development, stating that none have been observed thus far (RCOG, Coronavirus (COVID-19) infection and pregnancy – guidance for healthcare professionals: Version 8 – 17/3/20).

Centres should ensure patients have access to information regarding the following:

- Signposting to current Government guidance relating to minimising spread of infection
- The symptoms of Covid-19 and what to do if concerned
- Clinic policy on screening and testing for Covid-19
- The safety measures within the clinic (e.g. physical distancing, using PPE as described and washing and sanitation of hands)
- The triage process in place at the clinic
- Any clinic policy on prioritisation of patients and rationale for this
- Clinic policy regarding attendance of partners or companions for the different types of appointments
- Clinic policy in the event of suspected or confirmed infection, according to stage of treatment.
- The availability of online resources to minimise clinic visits (e.g. on line consent completion, virtual appointments, patient information, counselling etc.)

#### **b. Staff information**

Centres should ensure staff are given timely information before resumption of treatment services. Staff information must set expectations regarding the adaptations within the clinic and in treatment pathways and procedures, and include risks of attending the clinic and treating patients, during the COVID-19 pandemic.

#### **c. Staff conduct**

Staff have a responsibility to try to minimise the spread of COVID-19 and to follow Government guidance as well as specific safety measures introduced in centres relating to their conduct and interactions with others.

Staff should maintain up to date knowledge of, and adhere to, Government guidelines and clinic policies established to stop the spread of COVID-19.

#### **d. Patient and staff support**

- **Patients**

Patient support during the pandemic is critical. Staff should be aware that there may be heightened anxiety around COVID-19. Centres should ensure appropriate self-help and counselling provision in order to cater for this and the potential anxieties created by both the delays already experienced and by undergoing treatment during the pandemic.

Centres should signpost to and assist patient support groups where they exist. These groups should be encouraged to meet through social media and video conferencing.

- **Staff**

The period of time which centres were closed and staff were not participating in their usual daily practice will vary according to setting. Many staff will have been away from the workplace for a period of furlough or redeployment and, depending on their role, the duration away and their level of experience and confidence, may require some reorientation, refresher training, competency assessment and support. This should be judged on a case by case basis.

Prior to their involvement in treatment services, staff are expected to ensure that they are competent and confident enough to be able to operate a safe and effective service. Staff should be encouraged to request support from clinic leaders for themselves or colleagues as required to achieve this.

Staff support policies and procedures should be in place to ensure that:

- The mental well-being of staff is considered and reviewed as necessary
- Staff support and counselling systems are in place should they be needed
- Staff continue to be engaged and encouraged to provide feedback on progress and potential improvements to treatments during the COVID-19 pandemic
- Peer support is available as needed
- Staff safety in the workplace is paramount and centres should ensure that risk assessments are in place where appropriate to minimise the risk of infection.

#### **\*The ARCS/BFS COVID working group:**

Jane Stewart & Jason Kasraie (co-chairs), Gwenda Burns, Alison Campbell, Debbie Evans, Nicholas Macklon, Raj Mathur.

#### **Disclaimer**

This guidance represents the views of ARCS/BFS, which were reached 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 members of the COVID-19 working group and the Executive teams has been obtained.

ARCS/BFS are not liable for damages related to the use of the information contained herein. We cannot guarantee correctness, completeness or 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, however it represents best practice in the view of the BFS and ARCS.

## References:

1)<https://www.britishfertilitysociety.org.uk/2020/05/01/position-statement-on-the-resumption-of-fertility-treatment-in-the-uk-during-covid-19-pandemic/>

2)<https://www.rcog.org.uk/globalassets/documents/guidelines/2020-04-17-coronavirus-covid-19-infection-in-pregnancy.pdf>

3)<https://www.hfea.gov.uk/treatments/covid-19-and-fertility-treatment/coronavirus-covid-19-guidance-for-patients/frequently-asked-questions-for-patients-on-coronavirus-covid-19/>

## Appendix 1:

### Triaging Questionnaire for Covid-19

Have YOU or YOUR PARTNER or ANY MEMBER OF YOUR HOUSEHOLD been diagnosed with Covid-19?

Have YOU or YOUR PARTNER or ANY MEMBER OF YOUR HOUSEHOLD had any of the following symptoms in the last 2 weeks

1. Fever (feeling hot or a temperature above 37.5 degrees Celsius)
2. Persistent cough
3. Loss of the sense of smell
4. Loss of the sense of taste
5. Sore throat

Have YOU been in contact with anyone in the last 2 weeks who has any of these symptoms or has been diagnosed with Covid-19?

**Appendix 2. PPE – recommended for COVID-19 protection.**

This Table is adapted from [www.gov.uk](http://www.gov.uk): *Table 1. Recommended PPE for healthcare workers by secondary care clinical context* and *Table 2. Recommended PPE for primary outpatient community and social care by setting* for the fertility sector. It should be used as a preliminary guide only and with reference back to Public Health England publication COVID-19: infection prevention and control guidance available at <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control>

Reference to the website will provide the most up to date guidance which may change as the pandemic changes. Local guidance may also apply.

**PPE in the setting of a fertility clinic**

Setting	Context – as described <a href="http://www.gov.uk">www.gov.uk</a> <sup>1</sup>	Areas in the fertility clinic workplace	Gloves - disposable	Plastic apron - disposable	Fluid-resistant coverall or gown - disposable	Fluid resistant surgical mask	FFP respirator	Eye/face protection	
<b>Fertility Centres – see guidance on triage. This should minimise the chance of “confirmed or possible cases” entering the Centre therefore reducing risk.</b>	Social distancing – where 2m distance possible	Waiting areas Clinical consultation				YES Sessional use <sup>2</sup>			
	Working in reception/communal area and unable to maintain 2 metres social distance	Reception/admin staff check in etc Consultation				YES Sessional use <sup>2</sup>			OR ensure appropriate physical screen protection <sup>3</sup>
	Working in an inpatient area with possible or confirmed case(s) (not within 2 metres)	Day case theatre Other clinical zone – not direct patient care: Clinic support Chaperone Showing men to semen production room Assisting direct patient care procedures				YES Sessional use			

	Direct patient care – possible or confirmed case(s) (within 2 metres)	Undertaking clinical examination, venepuncture, ultrasound scanning, IUI, embryo transfer etc.	YES – single use <sup>4</sup>	YES – single use		YES – sessional use		YES – sessional use	
	Operating theatre with possible or confirmed case(s) – no aerosol generating procedures <sup>5</sup>	Undertaking procedures in conscious sedation/local anaesthetic theatre area	YES – single use	YES – single use	Consider – depending on procedure and setting and normal protocol	YES – single or sessional use		YES – sessional use	
		Associated staff – runner etc	YES – single use	YES – single use		YES – sessional use		YES – sessional use	
	Performing a single aerosol generating procedure on a possible or confirmed case in any setting outside a higher risk acute care area <sup>6</sup>	GA or heavy sedation procedures where AGP a risk	YES – single use		YES – single use		YES	YES – single use/ reuse with cleaning	
		Working in diagnostic Andrology laboratory <sup>7</sup>	YES Sessional use			YES Sessional use		YES – sessional use	
		Working in Clinical Embryology laboratory <sup>7</sup>	YES – single use			YES – sessional use		YES – sessional use	

- 1 <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control>
- 2&4 see descriptors in website above
- 3 e.g. Perspex screen
- 5 conscious sedation, low flow oxygen supplementation and use of Entonox are not considered aerosol generating processes. Follicular fluid aspiration is not an aerosol generating process.
- 6 Procedures including AGPs should only be performed where strictly necessary and should be avoided where there is a risk of COVID-19. Consideration to alternatives (local or regional anaesthesia, conscious sedation, deferment) should be made and if alternatives are not available consideration given to screening patients beforehand. It is not expected that this will form a routine part of most fertility centres work and therefore the complex risk assessments and measures in relation to AGPs are not discussed as they are beyond the scope of this guidance.
- 7 <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens> - handling bodily fluids to be performed within in a microbiological safety cabinet only. Eye protection to minimise risk of infection from microscope eyepieces used by colleagues.





Human  
Fertilisation &  
Embryology  
Authority

# Covid-19 self assessment

**For the commencement  
of treatment services**

The HFEA issued revised GD0014 (version 2) on \*\*\* which requires clinics to have a Covid-19 Treatment Commencement Strategy. The Strategy 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 (SOPs) or protocols.

The revised GD0014 also requires the clinic to complete the HFEA Covid-19 Treatment Commencement Self-assessment which has been developed to measure the robustness of the clinic's Treatment Commencement Strategy and assess the clinic's compliance with guidance from the UK and devolved governments, professional bodies such as BFS/ARCS, ESHRE, as well as Standard Licence Conditions and guidance in the HFEA Code of Practice. 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.

#### How to complete this questionnaire:

- Please answer **all** 47 questions.
- In the 'evidence reference' column, please provide either the title of the document/record or its unique identifying reference. Please supply the last date of review
- **Only** provide a comment if you have answered 'no' to a question. There is an additional comments section at the end of this tool if you need to expand on any comments.
- There is a further comment box at the end of the questionnaire if you need to expand further on any of your 'no' answers.
- Please sign at the end and return the completed form to your inspector.

**Your inspector will review your responses and will be in contact with you within five working days with a view to your proposal to commence treatment services.**

**If you answer 'no' to any of the questions, the executive will determine the further steps that you need to take before activity can commence.**

**We reserve the right to request centres to provide any or all of the evidence referenced in support of compliance and for that evidence to be provided in a timely manner.**

Question	Yes/No	Evidence reference	Comment
<b>Risk assessment and review</b>			
1			
	Have you recorded the risk assessments undertaken to identify risks arising from the provision of treatment service during the emergency situation resulting from the Covid-19 pandemic and the mitigating actions taken in relation to each risk?		

2	Does this risk assessment also apply equally to your satellite and transport partners? [if no satellite/transport partners, please leave this row blank].			
3	Do you have a process in place for an immediate review of your Treatment Commencement Strategy, policies and procedures in response to any changes or updates in guidance from the UK and devolved governments, professional bodies and HFEA?			
<b>Patient information, consent and support</b>				
4	Before considering treatment, will patients be fully informed of the risks related to Covid-19 – including increased risk when attending clinic (eg due to travel on public transport) and the RCOG guidance on risks in pregnancy?			
5	Following the provision of this information, will all patients be offered a choice of whether to proceed with or postpone their treatment, with this decision being clearly documented in the patient notes?			
6	Will patients be provided with information regarding plans for patient prioritisation during the Covid-19 emergency?			
7	If PPE is to be worn by patients in the centre are the patients provided with effective training in how to put on and take off the PPE, without exposing themselves to risks of Covid-19 infection? [If not applicable because PPE will not be expected to be worn by patients, leave this blank].			
8	Will patients, before a treatment cycle commences, consent to the possibility of the treatment cycle being terminated if they encounter a situation which places them at high risk of Covid-19 infection?			
9	Will patients be provided with information regarding the financial implications of treatment cycle cancellations due to Covid-19 emergencies?			

10	Have you further developed your patient support policy to outline how you will ensure patients can receive appropriate support during this time?			
11	<p>Is there a 'code of conduct' for staff and patients which sets out their responsibilities and requires them to follow all of the following points:</p> <ul style="list-style-type: none"> <li>• avoid unnecessary exposure to risks of Covid-19 infection at work and in private?</li> <li>• restrict interactions in line with government guidelines on social distancing and remaining at home, where appropriate?</li> <li>• sign to agree to abide by the code of conduct?</li> <li>• review (and document) thereafter to confirm they are well and have adhered to the code of conduct, or to provide the PR with updates regarding their health and wellbeing and whether they have infringed the code of conduct and been potentially exposed to Covid-19?</li> </ul>			
<b>Preparation to resume services</b>				
<b>Staff and patient triage, screening and testing</b>				
12	Will you use a screening/ triage questionnaire for both patients and staff (eg risk assessing health status and risk factors such as associated symptoms for patients/staff and any household members)?			
13	Will the staff triage information include retrospective collection from the previous two weeks, before the recommencing of clinical activities at the centre?			
14	Will staff that are suspected of infection be referred for testing and not work until the symptoms have cleared (or, if no symptoms, where triaging indicates risk)?			
15	Will testing and quarantine be in accordance with best practice guidance issued from Public Health England/ Department of Health and Social Care?			

16	Will staff that test positive for Covid-19 receive occupational health advice and remain in self quarantine until advised it is safe to return to work?			
17	As contact tracing technology becomes available, will you encourage its use if a staff member/patient is diagnosed with Covid-19? In the absence of an automated system, will you ensure that contact tracing is performed to the best of your ability?			
18	Will a patient/partner triage questionnaire be completed (remotely) two weeks before attending the clinic in preparation for treatment and at each visit?			
19	Will the triaging of patients include consideration of risks of treatment and the need to reduce further impact on NHS resources (eg. OHSS, multiple pregnancy risks)?			
<b>Staffing</b>				
20	Do you have enough staff for the anticipated volume of patients to be treated?			
21	Will working patterns be reviewed to consider <ul style="list-style-type: none"> <li>• Splitting the work force into mini teams</li> <li>• Longer working hours covered by shift patterns</li> <li>• Careful scheduling of breaks</li> <li>• Working from home or virtually wherever possible</li> </ul>			
22	Do you have contingency plans for staff who may have to self isolate due to exposure to Covid-19?			
23	Do you have staff support policies in place?			
24	Do you have plans to undertake reorientation/competency assessment of staff who have been away from the work place for a period of time?			
<b>Operational aspects</b>				
25	Have you considered how you will adapt your			

	service to reduce visits to the clinic?			
<b>26</b>	Have you developed guidance to reduce the risk of infection for both patients and staff including applying social and physical distancing?			
<b>27</b>	<p>Have you made arrangements to restrict access to the clinic? If yes, does this include all of the following points:</p> <ul style="list-style-type: none"> <li>• controlled entry to the clinic?</li> <li>• use of communal areas such as lifts / corridors?</li> <li>• patient arrival and check in process at the clinic?</li> <li>• management of appointments to avoid unnecessary social contact (including bloods/scans/procedures)?</li> <li>• re-configuring of waiting rooms and clinical/laboratory areas?</li> <li>• limits on the number of staff and patients in each area?</li> <li>• allowances for social distancing?</li> <li>• alternative consultation arrangements (eg video call/telephone etc.)?</li> <li>• restricted access for partners/accompanying persons?</li> </ul>			
<b>28</b>	<p>Do you have SOPs/risk assessments in place that include consideration of all of the following points:</p> <ul style="list-style-type: none"> <li>• processes in the event of a patient or staff member testing positive for the virus?</li> <li>• staff training on all new policies and protocols with the re-starting of treatment?</li> <li>• staff training in the use of PPE?</li> <li>• work rotas to minimise the number of staff coming into contact with patients (and vice versa)?</li> <li>• laundering of uniforms and PPE?</li> <li>• arrangements for patient PPE if indicated?</li> <li>• revising cleaning contracts/provision?</li> </ul>			
<b>29</b>	<p>Will PPE for staff and patients be used in accordance with Public Health England guidance:</p> <p><a href="https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control?">https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control?</a></p>			

<b>30</b>	Do you have business continuity plans in the event that the centre is unable to carry out licensed treatments? Has this been reviewed to ensure it is valid and workable in the current climate?			
<b>31</b>	Have you ensured third party laboratory services, for all necessary diagnostic tests, will be provided in an appropriate timeframe for treatment service delivery?			
<b>32</b>	Before commencing treatment services, has a full stock take of all consumables, media, reagents and medications been completed?			
<b>33</b>	Have critical suppliers been contacted to ensure the chain of supply is intact?			
<b>34</b>	Have appropriate checks been performed to ensure all critical equipment is in full working order and within specified service intervals? Have formal re-validation documents been prepared, where required?			
<b>35</b>	If equipment is not within specified service intervals, has the equipment been taken out of use or is it being used in line with the guidelines issues by the HFEA in 'Frequently asked questions' re. the Covid-19 pandemic, on 22 April 2020?			
<b>36</b>	Has critical parameter monitoring data for equipment (where collected) been reviewed to determine whether performance problems arose during the lock down period which need to be investigated?			
<b>Infection control practices</b>				
<b>37</b>	Where licensed premises have been used for non-IVF related activities during the lock-down period, have you assessed whether a deep clean is required, followed by a review of air quality (where relevant)? [if n/a, please leave this row blank].			
<b>38</b>	Do you have revised practices and policies for decontamination of all areas, according to level of risk? Does this take into account the			

	enhanced use of PPE and safe storage/disposal of clinical waste?			
<b>39</b>	If a patient is suspected or tests positive after egg collection, do you have procedures in place to ensure a freeze all is done? [for centres that do not freeze gametes/embryos, please leave this row blank]			
<b>40</b>	Have you risk assessed the number of people present for all procedures to keep these to a safe minimum?			
<b>41</b>	Have you taken precautions in the laboratory to reduce exposure to the virus? Including <ul style="list-style-type: none"> <li>• The type of workstations used and required PPE</li> <li>• Minimising handling and sharing of equipment</li> <li>• Reviewing witnessing procedures to allow safe distances of staff while maintaining robust witnessing procedures</li> </ul>			
<b>42</b>	Following professional body guidance, have you assessed, and revised where appropriate, your processes to ensure safe cryopreservation of Covid-19 patients' gametes/embryos to mitigate the risk of transmission of the virus?			
<b>43</b>	Do you have contingency plans in place in the event of PPE shortages?			
<b>Clinical treatment services</b>				
<b>44</b>	Have you reviewed your SOPs for minimising OHSS and other complications to ensure potential hospital admissions are minimised?			
<b>45</b>	Do you have a policy to set out acceptance and prioritisation of patients for treatment services specific for the pandemic? This should be based on a patient's characteristics and risk profile?			
<b>46</b>	Will you consider delaying starting treatment for high risk patients (ie those with medical risk, eg diabetes, hypertension)?			
<b>47</b>	If a patient had Covid-19 which required respiratory support, will you require evidence of a favourable assessment from a relevant			



	clinician prior to starting licensed activity?			
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**For continuation of comments [please include a reference to the relevant question number]**

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Please complete the section below and sign where indicated:

The PR is reminded of their statutory duties under Section 17 (b), (c), (d) and (e) of the HF&E Act 1990 (as amended).

Making false claims or misleading statements in this self assessment may call into question your suitability to hold a licence and may result in a referral to your professional body or regulator.

**I (insert PR name) confirm that the information provided on this self assessment is true and accurate.**

**I confirm that all licensed activities will be undertaken in a manner compliant with all conditions on my centre's licence.**

**I confirm that the answers given apply equally to satellite and transport partners (where applicable).**

Signature of PR: .....

Date: .....

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

**Covid-19 Treatment Commencement Strategy**

**Ref: 0014  
Version:2**

<b>These Directions are:</b>	General Directions made by the Authority in accordance with paragraph 5.1.1 (p) of Standing Orders of 31 January 2019
<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**

**Version control**

Name of Directions: Covid-19 Treatment Strategy

Reference number: 0014 (version 2)

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

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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, 6 and 7 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 specified guidance on safe and effective treatment during the Covid-19 emergency;
  - (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 (available from the centre's inspector) 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.