

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

Details:

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
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Output:

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

Annexes

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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. Some members emphasised that the safety of staff would be crucial.
- 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 ensuring suitable practices within 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 to ensure that suitable practices are used and all licence conditions complied with as 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 sounded a note of caution, if BFS and ARCS guidance might lead to changes in our criteria and asked whether we needed to consider this 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.

4. Any other business

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

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