

Minutes of Authority extraordinary meeting 7 May 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	01 June 2020
Author	Debbie Okutubo, Governance Manager

Output:

For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes of the extraordinary Authority meeting held on 7 May 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

Minutes of the extraordinary Authority meeting on 7 May 2020 held via teleconference

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 Rachel Cutting	Catherine Drennan Joanne Triggs Paula Robinson Debbie Okutubo
---------------------	---	--

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 the application process for licensed centres to resume treatment and to agree a commencement date from which centres could apply to the HFEA under a revised General Direction 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 minute would be issued in draft shortly after the meeting.

2. Minutes of the extraordinary meeting on 30 April 2020

- 2.1. Members agreed that the minutes of the meeting held on 30 April 2020 be signed by the Chair subject to the corrections submitted prior to the meeting.

3. Resuming fertility treatment: implementation

- 3.1. The Chair gave a brief introduction and commented that the proposal for decision was that from 11 May clinics could apply to re-open by providing specified information to their inspector and receiving approval from the inspector to restart treatment. Professional bodies had produced updated guidance and a number of clinics had trialled the self-assessment questionnaire and given useful feedback.
- 3.2. Following the Chair's introduction, the Chief Executive (CE) was invited to outline further details.

- 3.3.** It was noted that the British Fertility Society (BFS) and the Association of Reproductive and Clinical Scientists (ARCS) had released their position statement and we had updated the information to be requested from clinics drawing on that guidance.
- 3.4.** Members were invited to comment. It was noted that the UK strategy remained to only test symptomatic people for Covid-19 and this was a position that was not likely to change. It was suggested that this could cause anxiety as some patients and/or staff who had the virus but remained asymptomatic could still spread the virus.
- 3.5.** Officers responded that individual centres were likely to take different approaches to testing but we could not go against the UK-wide testing strategy. BFS guidance clearly states “if available”.
- 3.6.** Officers further commented that the issues raised were valid but that licensed centres would ultimately decide if they wanted to re-open based on local factors. It would then be up to the HFEA to decide whether centres had evidenced that they met the requirements laid out in the self-assessment tool.
- 3.7.** The Director of Compliance and Information addressed the meeting and stated that the draft self-assessment tool had been sent to 33 licensed centres and 20 had responded with a good mix of respondents.
- 3.8.** In response to a question it was noted that patient safety and staff wellbeing were addressed in the questionnaire.
- 3.9.** The Director of Compliance and Information outlined the proposed application and assessment process. It was for licensed centres to indicate to their inspector that they wished to re-open. Inspectors would then send the person responsible (PR) the self-assessment questionnaire, which sets out the essential requirements that centres need to follow in their treatment commencement strategy. Once the licensed centres responded, the inspectorate would aim for a turnaround period of five days for assessing each response. If approved the centre could then resume treatment.
- 3.10.** If not approved the centre would need to address all areas of concern and re-submit a revised self-assessment for approval.
- 3.11.** Officers clarified that it was a self-assessment tool per clinic and per PR rather than for one per group of clinics.
- 3.12.** Members wanted to know what would be done about ongoing monitoring of compliance with the treatment commencement strategy. Officers responded that centres would be expected to keep up to date with updated guidance and inspectors would be in touch and carry out a desk-based assessment should the need arise. Monitoring of treatment numbers and incidents would continue.
- 3.13.** In response to a question, it was noted that physical inspections had been halted until the end of August 2020 and the situation would need to be reviewed after that, depending on the wider approach to the pandemic across the UK.
- 3.14.** Members requested feedback on progress on how centres were managing at the next meeting.
- 3.15.** There was a concern raised that clinic staff who were shielding or living with vulnerable people would be required to go into their clinics. Officers commented that staff concerns were part of the self-assessment questionnaire and inspectors could ask additional questions on how staff were being kept safe.

- 3.16.** A member noted that their experience was that staff who were shielding or needed to self-isolate were staying at home and given administrative duties where appropriate.
- 3.17.** The Chair commented that there were mixed reactions from clinics, with clinics responding differently but that all clinics would have to be transparent about their practices.
- 3.18.** A member commented that some patients who were keen to resume treatment had now started thinking of the practicalities involved in attending appointments as well as their personal safety.
- 3.19.** The CE commented that should any centre staff feel that they were being asked to do something which they felt uneasy about they could contact the HFEA in a whistle blowing capacity and other channels for feedback would also be made available.
- 3.20.** The Chair commented that HFEA should look into having a dedicated email address for centre staff and patients for feedback. Also, the frequently asked questions (FAQs) section on the website should be updated for patients with further questions on testing, personal protective equipment (PPE) and risk.
- 3.21.** The Chair also suggested that if members had further comments on the self-assessment tool then they should be sent to the Director of Compliance and Information.
- 3.22.** Members were assured that the HFEA could take regulatory action against non-compliance. Incidents and near misses were also captured by us. Also clinics had to notify us if staff or patients tested Covid-19 positive.
- 3.23.** It was noted that in cases where centres do not adhere to guidance the responsibility was that of the PR. It was therefore suggested that the guidance needed to make it clear where liability lay. We also needed to be realistic about the risks we would allow clinics to take which should all be addressed in the letter to the PRs.
- 3.24.** The Head of Legal responded to a question that in terms of litigation it was unlikely that we would face any legal challenge as a regulator for enabling clinics to commence treatment if patients felt it was still unsafe, but it could not be ruled out. She further commented that the self-assessment tool was developed based on UK and international guidance available on safety and good practice and this is what we would rely on if challenged, to support the decision to allow clinics to commence treatment.
- 3.25.** Members commented that centres might want to adapt a policy of having patients read and sign a consent form that stated that relevant risks had been explained to them.
- 3.26.** Some members commented that many centres have been reviewing their protocols and were probably already compliant with the new HFEA guidance. There were further comments that centres were running a business so they would not knowingly open themselves up to litigation. Some clinics were still offering storage facilities and therefore patient safety remained paramount.
- 3.27.** In response to a question, staff suggested that although it was down to individual clinics to decide how best to treat individual patients, it might not be wise for patients with comorbidities to access treatment at present. Similarly, high risk patients and/or extremely vulnerable patients should be cautious about coming forward for treatment during the Covid-19 pandemic. However, where they do, it would be for clinics to decide whether treatment could safely go ahead. Staff also commented that centres need to follow the guidance on the use of treatment add-ons.

- 3.28.** Summing up after asking each individual Authority member for their views, the Chair noted that members approved the issuing of the revised GD0014 to come into force on the 11 May 2020 subject to any issues raised.
- 3.29.** The CE remarked that the covering letter to PRs would state that it was a live situation and as the situation developed so would the guidance.
- 3.30.** The website would be kept updated and patients advised to keep in touch with their centres.
- 3.31.** Lastly, a second open letter to patients would be published by the Chair summarising the outcome of the meeting and that the priority remained the safety of patients and clinic staff.
-

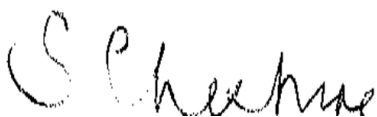
4. Any other business

- 4.1.** The Chair reminded Authority members that they would be contacted about the date of the next Authority meeting which will be around the first week in June, but that the 13 May meeting was cancelled.
- 4.2.** The 2 July Authority meeting will go ahead as scheduled but, similar to this one, future meetings will be shorter and be a virtual meeting covering a mix of business as usual and Covid-19 updates.
- 4.3.** There was also the likelihood of an Authority meeting in August.
- 4.4.** Members were informed that the Government had proposed that the 10-year storage period for gametes and embryos should be extended by two years as a result of the Covid-19 pandemic. Guidance and a new consent form would be issued when the regulations come into force. Members were asked to delegate approval of a revised General Direction 0007 (which lists HFEA consent forms) to the Chair. Members agreed with this delegation.
- 4.5.** It was agreed that an appreciation letter will be sent to all HFEA staff from the Chair on behalf of the Authority members for their hard work to date.
-

Chair's signature

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

Signature



Chair: Sally Cheshire

Date: 01 June 2020