HFEA Licence Committee Meeting

13 March 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 7

Centre 0196 (Jessop Fertility) - Grade A Incident Report IN03437

Members of the Committee: Andy Greenfield (lay) (Chair) Bishop Lee Rayfield (lay) Debbie Barber (professional) Jane Diblin (lay) Committee Secretary: Lauren Crawford	Legal Adviser: Rosalind Foster, Browne Jacobson Observing: Sam Hartley, Head of Governance and Licensing, HFEA

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- HFEA incident investigation report
- Incident report submitted by the PR
- Licensing history
    - 2012 Renewal of licence and change of centre name
    - 2010 interim inspection
    - 2010 variation of licence to change the Person Responsible

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012

- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that Jessop Fertility (previous known as The Centre for Reproductive Medicine and Fertility) has been licensed since 2001 and provides a wide range of assisted conception licensed treatments to National Health Service (NHS) and self-funding patients. The centre carries out approximately 800 cycles of licensed treatment a year.

2. The Committee noted that the previous renewal inspection took place on 1 & 2 May 2012. At the time of inspection no critical non-compliances, no major non-compliances and 2 other non-compliances were noted. The Executive Licensing Panel (ELP) granted the centre a four year licence with no additional conditions.

3. The Committee noted that the Person Responsible (PR) is also the Principal Embryologist for the centre and has held the post of PR since November 2010. This is the first time an incident of this nature has been reported by the centre.

Discussion

4. The Committee noted that on the 16 July 2013 the centre first noticed that the oocytes of two patients had failed to fertilise whilst using a particular incubator (incubator 1). The issue was investigated and reported to be an isolated failed fertilisation and suspected infection in the culture dish.

5. The Committee noted that on the 17 July there was another incident with the incubator where fertilised embryos failed to cleave. The centre took immediate action and changed all oocyte culture dishes and opened new bottles of media.

6. The Committee noted further that this centre later found that the eggs (mixed with sperm) of two patients, which had been cultured in incubator 1 had all failed to fertilise, and that the embryos of two patients, whose embryos had been normal on 17 July had all arrested at the 2 cell stage of development. These embryos were also being kept in incubator 1.

7. The Committee noted that centre carried out a full investigation. The problem appeared to be isolated to incubator 1. The incubators are constantly monitored for temperature and CO2 on the centre's monitoring system. No differences or fluctuations were observed. Oxygen is not continually monitored as it was decided that if a nitrogen cylinder ran out it was not critical as embryos can be cultured in atmospheric oxygen levels. The incubator oxygen levels are constantly elevated during the day when the doors are opened and closed anyway.

8. The Committee noted that all conditions were the same with regard to consumables and media and therefore the only variable was the oxygen concentration within the incubator. The oxygen level within the incubator should have been 5% but was found to be 3% when the level was checked with an oxygen monitor. The centre concluded that due to the sensor failing then it was likely that the mix of gas was incorrect and too much nitrogen entered the incubator causing a too low an oxygen concentration. Although there is little scientific literature on the effects of low level oxygen on human embryos development, there is one study which showed that rat oocytes failed to develop if cultured in anaerobic conditions.

9. The Committee noted that the centre carried out further investigations and confirmed that the failure of gametes and embryos, cultured in incubator 1, to fertilise or to develop was due to a faulty oxygen sensor.

10. The Committee noted that there were seven patients affected by this incident who did not have embryo transferred. All of these patients were informed and have been offered a further cycle.

11. The Committee noted that all corrective measures needed have been taken. The Centre has fitted independent oxygen probes on all incubators.

12. The Committee noted that there are no further corrective actions to be taken in regards to this incident and that the Executive has no recommendations. The Executive will ask the PR to write a brief article on this incident which will be shared via HFEA Clinic Focus.

Decision

13. The Committee was satisfied that the necessary corrective actions have been taken by both the centre and the Executive in this case, and closed this incident.

14. The Committee noted the lessons learned by both the centre and the Executive and urged the centre to complete the arrangements for sharing and learning by drafting an article for Clinic Focus.

Signed: Date: 27/03/2014

Andy Greenfield (Chair)

Incident Investigation Report

Centre no 0196 – incident number IN03437

Since October 2009 the HFEA has published A grade incident reports and the associated Licence Committee minutes on our website.

Background of the licence and the licencing history

Jessop Fertility (previous known as The Centre for Reproductive Medicine and Fertility) has been licensed since 2001 and provides a wide range of assisted conception licensed treatments to National Health Service (NHS) and self-funding patients. The centre carries out approximately 800 cycles of licensed treatment a year.

The previous renewal inspection took place on 1 & 2 May 2012. At the time of inspection no critical non-compliances, no major non-compliances and 2 “other” non-compliances were noted. The Executive Licencing Panel (ELP) granted the centre a four year licence with no additional conditions.

The Person Responsible (PR) is also the Principal Embryologist for the centre and has held the post of PR since November 2010.

This is the first time an incident of this nature has been reported by the centre.

Summary Incident Description & Consequences

On 16 July 2013 the gametes and embryos of 5 patients were being cultured and stored in 2 incubators. It was noted that the all oocytes of two patients, being cultured and kept in in incubator 1, had failed to fertilise. The centre carried out a preliminary investigation in that they checked all media and consumable used and noted that, apart from the oil all had been used in other cases. There was also o reported problems on facility monitoring system (CO_2 and temperature to incubator). Therefore, the centre concluded that this was an isolated failed fertilisation and suspected infection in culture dish.

On 17 July the fertilised embryos of a third patient, which had been moved from incubator 2 into incubator 1 had all failed to cleave. The centre took immediate action and changed all the oocyte culture dishes and opened new bottles of media.

Five egg collections were carried on the 17 July.

On the 18 July the centre found that the eggs (mixed with sperm) of two patients, which had been cultured in incubator 1 had all failed to fertilise and the embryos of two patients, whose embryos had been normal on 17 July had all arrested at the 2 cell stage of development. These embryos were also being kept in incubator 1. All embryo development in incubator 2 was normal and as expected with regard to blastocyst development.

The centre carried out a full investigation.

The problem appeared to be isolated to incubator 1. The incubators are constantly monitored for temperature and CO_2 on the centre's monitoring system. No differences or fluctuations were observed. Oxygen is not continually monitored as it was decided that if a nitrogen cylinder ran out it was not critical as embryos can be cultured in atmospheric oxygen levels. The incubator oxygen levels are constantly elevated during the day when the doors are opened and closed anyway.

All conditions were the same with regard to consumables and media and therefore the only variable was the oxygen concentration within the incubator. The oxygen level within the incubator should have been 5% but was found to be 3% when the level was checked with an oxygen monitor. The centre concluded that due to the sensor failing then it was likely that the mix of gas was incorrect and too much nitrogen entered the incubator causing a too low an oxygen concentration. Although there is little scientific literature on the effects of low level oxygen on human embryos development, there is one study which should that rat oocytes failed to develop if cultured in anaerobic conditions.

The centre carried out further investigations and confirmed that the failure of gametes and embryos, cultured in incubator 1, to fertilise or to develop was due to a faulty oxygen sensor.

Incident type:	Equipment failure
Specialty:	Gamete and embryo culture
Effect on patient:	Seven patients were unable to have embryos transferred
Severity level:	Grade A

Scope and Level of Investigation
HFEA Root Cause Analysis
Discussions with senior staff
Centre no 0196 investigation report

Involvement and support of Patient and Relatives
All patients were fully informed and offered another cycle of treatment free of charge.

Chronology of events - See table overleaf

Notable Practice
As soon as the PR was made aware of the situation she immediately informed the executive.

Care and Service Delivery Problems (Themed and prioritised)
Seven patients did not have embryo transfer as either their eggs failed to fertilise or their embryos failed to develop beyond the 2 cell stage of development.

Contributory Factors
Due to a faulty oxygen sensor in incubator one eggs and embryos were being cultured in sub-optimal conditions

Root Causes
A faulty oxygen sensor was in use in one of the incubators used to contain patients' gametes and embryos.

Lessons Learned
All corrective measures have been taken. The centre has fitted independent oxygen probes on all incubators.

Recommendations There are no further recommendations relating to this adverse event.			
Action Plan - All corrective actions have been taken.			
Implementation, monitoring and evaluation arrangements All actions have been implemented.			
Arrangements for sharing and learning The executive will ask the PR to write an article to be published in clinic focus.			
Author	Chris O'Toole	**Date**	13 February 2014

Chronology of events	
Date & Time	**Event**
18 July 2013	Centre report incident to the HFEA
12 December 2013	Confirmation of the root cause of incident and confirmation corrective actions had been tasken