HFEA Licence Committee Meeting

19 September 2013

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

Minutes – Item 9

Centre 0070 (The Bridge Fertility Centre) – Grade A Incident

Members of the Committee: Sally Cheshire (lay) Chair Gemma Hobcraft (lay) Bishop Lee Rayfield (lay) (video) Debbie Barber (professional) Andy Greenfield (professional) Committee Secretary: Lauren Crawford	Legal Adviser: Graham Miles, Morgan Cole Observing: Sam Hartley, Head of Governance and Licensing, HFEA Juliet Tizzard, Interim Director of Strategy, 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:

- The MHRA report on the equipment
- Further information about the number of patients affected and which treatments have been affected
- Previous Committee Papers:
    - HFEA's root cause analysis
    - Centre's final incident inspection report
    - Centre's interim incident reports (1 – 7, including service report for autodialler and most current donor sperm replacement update)
    - Templates of letters sent to patients
    - Initial information from the MHRA (provided by the PR)
    - Previous Executive Licensing Panel minutes for last 3 years:

    a) 17 December 2010 – variation of licence (change of Person Responsible)
    b) 27 June 2012 – licence renewal report
    c) 28 November 2012 – variation of licence (change of Licence Holder)
    d) 15 March 2013 – variation of licence (change of Person Responsible)

    - Tabled papers: photos from Statebourne Cryogenics to accompany January 2013 report (described out at page 50 onwards).

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)
- 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 this Grade A incident has previously been considered and adjourned at the Committee's last meeting (19 September).

2. The Committee had then decided to adjourn the item for receipt of further information. This information should include:
    a. The MHRA report on the equipment
    b. Further information about the number of patients affected and which treatments have been affected to update the summary as at 7 June 2013.

3. The Committee noted this is an incident reporting donor semen samples thawed for treatment in mid-January 2013 that appeared to have a significantly lower post thaw recovery than expected.

4. The Committee noted that the MHRA report has now been received. The MHRA does not undertake site visits or carry out incident inspections. The MHRA's response was limited to requesting that a service engineer from the company that supplied the equipment carry out an equipment review and then that the MHRA be provided with a copy of the report.

5. The Committee noted that, in a covering e-mail sent to the Executive attaching the documents, the MHRA Senior Medical Device Specialist advises that the overall conclusion appears to be that there was an inappropriate 'set up' of the devices and inadequate maintenance leading to a failure of the devices to fill properly. There was no evidence that there were any device-

specific malfunctions. Furthermore, the setting up of multiple Biosystem tanks to a single supply vessel was not specifically excluded in the 'information for use' and the MHRA has recommended to the manufacturer that this requirement is included in equipment updates, with a view to the prevention of similar issues occurring in future. In any event, it is the MHRA's understanding (further to correspondence from the manufacturer) that other users have a single Biosystem connected to a supply vessel.

6. The Committee noted the response from the PR regarding the affected patients and the status of each case. Further they noted the PR has also informed the Executive that, as regards patients who have not responded to letters, the centre is further attempting to make contact by telephone calls, secure email checks and then finally an 'Equifax' search to try and locate them.

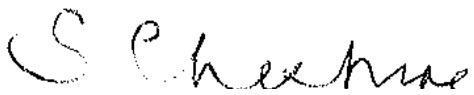
Decision

7. The Committee were satisfied that the Inspectorate and the centre had done all that they could in this matter.

8. The Committee was satisfied that the affected patients have been contacted.

9. The Committee agreed that this incident can be closed off, with no further updates required.

Signed: Date: 21/11/2013



Sally Cheshire (Chair)