Licence Committee - minutes

Centre 0094 (Barts Health Centre for Reproductive Medicine Executive Update – Incident Report

Thursday, 10 January 2019

Church House, Dean's Yard, Westminster, London SW1P 3NZ

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore	
Members of the Executive	Dee Knoyle Sandrine Oakes (Observer) Nicola Lawrence (Observer) Sara Parlett (Observer)	Committee Secretary HFEA Inspector (induction) HFEA Inspector (induction) HFEA Inspector
Legal Adviser	Dawn Brathwaite	Mills & Reeve LLP
Specialist Adviser		
Observers		

Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

Papers enclosed:

- Executive Update
- Barts Health NHS Trust Serious Investigation Report (SUI)
- Licence Committee Minutes - 6 September 2018 - Renewal

Papers submitted to the Licence Committee on 6 September 2018

- Renewal Inspection Report
- HFEA Incident Investigation Report
- Centre's Incident Investigation Report
- Renewal Application Form
- Previous licensing minutes to the last licence renewal
    - Variation - premises - 10 May 2018
    - Variation - Licence Holder - 29 March 2017
    - Interim inspection report - 19 October 2016
    - Variation - Licence Holder - 7 August 2015
    - Variation - centre name - 25 July 2014
    - Whistleblower report - 10 July 2014
    - Renewal inspection report - 10 July 2014

1. Background

1.1. Barts Health Centre for Reproductive Medicine, centre 0094 has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The Licence Committee considered the centre's renewal inspection report alongside a Grade A incident report at its meeting on 6 September 2018.

Licence Committee Meeting held on 6 September 2018

Licence Renewal

1.3. The Licence Committee considered issuing a three-year licence, rather than the usual four, due to the number and seriousness of the non-compliances identified. After careful consideration, and having noted that the major areas of non-compliance had been addressed and accountability and engagement shown by Barts Health NHS Trust, the committee agreed to endorse the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions. However, the committee also agreed that a targeted inspection to follow up the implementation of the recommendations made in the renewal inspection report should be completed within one year of the new licence coming into effect.

Grade A Incident

1.4. The centre had a Grade A incident in 2018. An incorrect gas cylinder was connected to the incubator, attached as the back-up cylinder and became active on 27 July 2018. Centre staff noticed that embryos for eleven patients showed poor development, equivalent to a day behind the expected period. Some embryos were also showing signs of degeneration.

1.5. The centre investigated the issue and found that an incorrect gas cylinder was connected to the culture incubators. Instead of pre-mixed 5% oxygen/ 6% CO2/ N2 the cylinder contained pre-mixed 9% helium in air. The helium cylinder had been delivered to the department in error. The centre does not use helium.

1.6. All eleven patients affected were informed and their embryo transfers cancelled. The centre allowed the embryos in culture to perish due to concerns over the effect of helium gas on the viability of the embryos and risk to the unborn child. The committee was satisfied that patients were appropriately informed and corrective action had been taken.

1.7. The committee agreed that the centre's response to the Grade A incident was exemplary. The committee noted that the Executive endorsed the centre's action plan as thorough and robust, identifying the root causes and opportunities available to ensure that an incident of this nature does not recur. The committee also noted that the Executive planned to submit a copy of Barts Health NHS Trust Serious Untoward Incident (SUI) report to the Licence Committee once it was signed off by the Trust. This report has now been submitted for consideration by the committee.

2. Consideration of application

2.1. The committee deliberated on the content of Barts Health NHS Trust Serious Untoward Incident (SUI) report.

2.2. The committee discussed the severity of the incident and impact on the patients affected, with sympathy.

3. Decision

3.1. The committee noted the content of Barts Health NHS Trust Serious Untoward Incident (SUI) report.

3.2. The committee was reassured by the centre's response and actions, identifying the root causes, in order to avoid such an incident happening again.

4. Chair's Signature

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

Signature

Name

Kate Brian

Date

5 February 2019

Executive Summary to Licence Committee 10 January 2019

Centre number	0094
Centre name	Barts Heath Centre for Reproductive Medicine
Person Responsible	Bonnie Collins

Update to Licence Committee re Serious Untoward Incident Investigation report **– for information only**.

Background

1. In June 2018 the centre reported the following via our incident reporting system: embryos for eleven patients showed poor development, equivalent to a day behind the expected period. Some embryos were also showing signs of degeneration.

2. The centre investigated the issue and found that the incorrect gas cylinder was connected to the culture incubators. Instead of pre-mixed 5% oxygen/ 6% CO2/ N2 the cylinder contained pre-mixed 9% helium in air. The helium cylinder had been delivered to the department in error. The centre does not use helium.

3. All eleven patients were informed, and their embryo transfers were cancelled. The centre allowed the embryos in culture to perish due to concerns over the effect of helium gas on the viability of the embryos and the risk to the unborn child.

4. The committee noted the findings of both the centre's and the HFEA's investigations into the incident and in particular, the fact that the Executive acknowledged the positive and proactive way the incident had been handled by the Trust. The Trust had put patients and their needs at the centre of its actions. All the patients affected by the incident had started or were about to start a complementary cycle of treatment.

5. The committee noted the Executive endorsed the centre's action plan as thorough and robust, identifying the root causes and opportunities available to ensure that an incident of this nature does not recur. The committee also noted that the Executive would share a copy of the Trust's Serious Untoward Incident (SUI) report with the committee at a future meeting once this had been signed off by the Trust.

6. The Trust has completed and signed off their SUI report. This is now provided to the Licence Committee, for their information only.

7. The Executive can also confirm that an Alert was issued to the sector about the safe distribution and receipt of special mixed gas cylinders. Actions taken in response to this Alert are followed up during routine centre inspections.

Paula Nolan
Clinical Governance Lead