Licence Committee - minutes

Centre 0075 (London Women's Clinic, Darlington) Renewal Licence

Thursday, 11 January 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Lee Rayfield (Chair) Ruth Wilde Kate Brian Anita Bharucha	
Members of the Executive	Dee Knoyle Bernice Ash Nana Gyamfi	Committee Secretary Committee Secretary (Observing) Licensing Information Officer (Observing)
Legal Adviser	Jane Williams	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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Renewal inspection report
- Renewal application.
- Licensing minutes from the last three years:
  - 25 August 2017: Licence variation, Change of PR
  - 13 July 2017: Interim inspection report and media allegations report
  - 4 May 2017: Interim inspection report
  - 9 March 2017: Executive update
  - 14 July 2016: Unannounced inspection report
  - 21 March 2016: Interim inspection report
  - 12 March 2015: Renewal inspection report

1. Background

1.1. The committee noted that London Women's Clinic, Darlington has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The committee noted that the current licence was granted on 1 April 2015 for a three-year period and has been varied to reflect an additional condition placed on the licence in July 2017 and a change of Person Responsible (PR) in September 2017.

1.3. The committee also noted that the centre has been the subject of significant regulatory scrutiny since the renewal inspection in 2014 as a result of regulatory concerns, whistle blowers' concerns and media allegations.

1.4. The report of the targeted interim inspection on 5 and 6 December 2016 and the findings of the investigation of the media allegations in May 2017 raised further concerns about the centre's ability to achieve and maintain regulatory compliance. Despite being given several opportunities and support to achieve compliance, the Executive could not be assured of the PR's ability to discharge her duty under Section 17 of the HF&E Act 1990 (as amended).

1.5. Therefore, when the interim inspection and media allegation investigation reports were submitted for the consideration of the Licence Committee in July 2017, a recommendation was made to seek a voluntary undertaking from the Licence Holder (LH) and Person Responsible (PR) to identify a suitable alternative PR. If the LH and PR were unable to provide such an undertaking, the Licence Committee was invited to consider suspending the clinic's licence with immediate effect, under section 19C of the HF&E Act 1990 (as amended). A further recommendation was made that an additional condition be placed on the centre's licence, preventing the centre from undertaking treatment services where a patient donates her eggs to receive 'benefits in kind', until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements.

1.6. The LH and PR agreed to take the recommended action and an application for a variation of the licence, changing the PR, was approved by the Executive Licensing Panel on 5 September 2017.

2. Consideration of application

Application

2.1. The committee noted that an application for the renewal of the treatment and storage licence was submitted by the centre. The committee also noted that since this application was submitted for consideration by the Licence Committee, the application to vary the centre's existing licence to reflect a change of PR had been approved by the HFEA Executive Licensing Panel. The name on the renewal licence application form is therefore that of the former PR and not the current PR named in the renewal inspection report.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The committee noted that in the 12 months to 31 August 2017, the centre provided 356 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

2.4. The committee noted that for IVF and ICSI, HFEA-held register data for the period July 2016 to June 2017 showed the centre's success rates were in line with national averages with the following exception:

- success rates following IVF involving fresh embryos in women under 38 years old were lower than average at a statistically significant level.

2.5. The committee noted that in 2017, the centre did not undertake any cycles of partner insemination.

2.6. The committee noted that between July 2016 and June 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryos transfer) cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.7. The committee noted that the renewal inspection took place on 17 and 18 October 2017 and the report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre. The committee noted that at the time of the renewal inspection one 'critical', one 'major' and two 'other' areas of non-compliance were identified.

2.8. The committee noted the level of engagement the Executive had with the centre and that several management reviews had taken place: Whilst it was considered that there was no immediate risk to patients, gametes and embryos or staff, the information received indicated that not only had there been a breach of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, but that the centre had completed the new consent to extend storage incorrectly, by miscalculating the storage expiry date and by completing a medical practitioner statement after the consent period had expired. Considering this information, it was agreed that the non-compliance relating to the storage of gametes, originally graded as an 'other' area of non-compliance, be escalated to 'critical' and that a further management review meeting be held to reconsider the recommendation relating to the granting or period of the centre's licence, in line with the HFEA 'Compliance and enforcement policy' and 'Guidance on licensing'. This meeting was held on 8 December 2017. Following the review of information, there were a number of areas of practice that require improvement, including two 'critical', one 'major' and one 'other' areas of non-compliance which resulted in the following recommendations:

Critical areas of non-compliance:

- The PR must take immediate action to stop the use of embryos for validation of equipment.
- The PR should ensure that all gametes or embryos are being stored in accordance with the relevant statutory storage regulations.

Major areas of non-compliance:

- The PR should ensure that, where audits show that quality indicators/objectives are not met, appropriate corrective actions are taken and are documented.

Other areas that requires improvement:

- The PR should ensure that a suitably trained and competent controlled drug accountable officer (CDAO) is appointed.

2.9. The committee noted that the PR was encouraged to ensure that the Quality Management System is used to best effect to monitor and improve success rates to improve the quality of the service offered to patients.

2.10. In light of the findings of the management review meeting, it was considered appropriate to return the report to the PR and invite further comment. The PR responded within the given timeframes.

2.11. The committee noted that since the inspection and second review of this report, the PR has fully implemented the recommendations to address the critical area of non-compliance relating to the use of embryos for validation of equipment and the major area of non-compliance relating to quality indicators/objectives.

2.12. The committee also noted that, where required and by the dates specified, the PR will provide an update summary of audits conducted to ensure corrective actions taken are effective. The PR has given a commitment to fully implement the recommendations to address the critical area of non-compliance relating to storage and the other area of non-compliance to ensure that a suitably trained and competent controlled drug accountable officer (CDAO) is appointed.

Recommendations

2.13. The Executive was initially minded to propose the renewal of the centre's treatment and storage licence for a period of three years, rather than the usual four, with the existing licence condition remaining on the licence. The Executive was also minded to recommend an interim inspection take place within one year of the licence coming into force.

2.14. However, further supporting documentation submitted by the PR raised concern about the centre's 'bring forward' system and a serious failing relating to the storage of gametes. The Executive was not assured that the centre understands how to calculate storage consent periods and so cannot be assured that there will not be problems with other consents. It was agreed that the non-compliance relating to the storage of gametes, originally graded as an 'other', be escalated to 'critical'.

2.15. The Executive therefore reconsidered its recommendation relating to the granting or period of the centre's licence, in line with the HFEA 'Compliance and Enforcement Policy' and 'Guidance on licensing'.

2.16. The Executive acknowledged that the current PR, in the short period of being in post, has demonstrated a willingness to make changes and improvements, engaged with the inspection process and provided information when requested. The failures in compliance identified in the renewal inspection report may have arisen prior to the current PR's appointment. However, two critical areas of non-compliance of a serious nature were identified and in light of 'serious wide-ranging concerns and either a poor history of compliance or insufficient information to assure a committee that required improvements will be made', the Executive recommended the following:

Licence

- The renewal of the centre's treatment and storage licence for one-year (rather than the usual four) to afford the new PR an opportunity to demonstrate that she can embed changes, sustain improvements and act upon the recommendations set out in this report.

Licence Condition

- The current condition on the licence that 'the centre must not provide treatment services where a patient donates her eggs to receive "benefits in kind" until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements' remains in place.

  At the time of the renewal inspection, the additional licence condition was discussed with the new PR. The PR wanted to establish the processes and procedures implemented to date and ensure they are embedded, before making an application to have the condition removed. As such, the centre's egg sharing practices and procedures, which are currently suspended, were not reviewed at the inspection. The PR will provide the necessary information and documents required by the Executive when she feels it appropriate to apply to have the licence condition removed.

3. Decision

3.1. The committee had regard to its decision tree, the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, the HFEA Compliance and Enforcement Policy and HFEA Guidance on licensing.

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Mrs Jacqueline Biro

3.3. The committee noted that the proposed PR, Mrs Jacqueline Biro is willing to assume the responsibility of the role of PR.

3.4. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge their duties under section 17 of the HFE Act 1990 (as amended). The committee noted that the inspectorate was satisfied that the proposed PR had satisfactorily completed the PR entry programme. The committee agreed to the appointment of the proposed PR.

Activities

3.5. The committee was satisfied with the suitability of the activities applied for.

Premises – Woodlands Hospital, Morton Park, Darlington, Durham, DL1 4PL

3.6. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.7. The committee was satisfied that the third party premises are also suitable.

Licence

3.8. The committee noted the level of engagement and progress made by the new PR but, mindful of the serious concerns raised at inspection, considered carefully the duration of the licence it should grant in light of the 'Guidance on licensing'. Weighing all factors in the balance, the committee ultimately decided that a one-year licence was proportionate in light of the history of poor compliance and low success rates following IVF involving fresh embryos in women under 38 years old. The committee agreed that this would provide the PR with an appropriate timeframe within which to demonstrate that she can embed changes, sustain improvements and act upon the recommendations set out in the report. The committee felt that the decision to grant a one-year licence supported the centre in its desire to remediate whilst safeguarding the interests and expectations of patients.

3.9. The committee agreed in summary:

- To renew the centre's treatment and storage licence for a period of 1 year
- The existing licence condition that 'the centre must not provide treatment services where a patient donates her eggs to receive "benefits in kind" until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements', remains in place.

3.10. The committee noted that the Executive will continue to monitor the centre's success rates and follow up at the next inspection scheduled in 2018. The PR is expected to embed changes, sustain improvements and act upon the recommendations set out in this report.

3.11. The committee requested that the centre's future renewal inspection report is submitted to the Licence Committee for consideration.

4. Chair's signature

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

Signature

Name

Lee Rayfield

Date

8 February 2018