Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
15 April 2015

Minutes – item no. 2

Centre 0291 (Fertility Unit, Barking, Havering & Redbridge Hospitals Trust) – Interim Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Hannah Verdin Head of Regulatory Policy David Moysen Head of IT
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

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

The panel had before it:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 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 the 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 Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to Licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of Application

1. The panel noted that Fertility Unit, Barking, Havering and Redbridge Hospitals Trust has held a licence with the HFEA since 2007. The centre provides partner intrauterine insemination (IUI) only.

2. The panel noted that the centre's licence is due to expire on 31 July 2017.

3. The panel noted that the inspection took place on 10 February 2015.

4. The panel noted that in the 12 months to 31 December 2014, the centre provided 23 cycles of treatment. In relation to activity levels this is a small centre.

5. The panel noted that in 2014 the centre reported 23 cycles of partner insemination with 2 pregnancies. This equates to an 8% clinical pregnancy rate. The HFEA's analysis for 2014 has not yet been performed, therefore a comparison of the centre's results against the national average cannot be made, although it is expected that the analysis will show that the centre's results are in line with the national average.

6. The centre reported no multiple pregnancies in 2014.

7. The panel noted that at the time of the interim inspection on 10 February 2015 there were no areas of non-compliance identified.

8. The panel noted that the Inspectorate recommends that the licence is allowed to continue.

Decision

9. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment licence continued.

Signed: Date: 28 April 2015
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Fertility Unit Barking, Havering and Redbridge Hospitals Trust
Centre number: 0291
Date licence issued: 01/08/2014
Licence expiry date: 31/07/2017
Additional conditions applied to this licence: None
Date of inspection: 10/02/2015
Inspectors: Ms Janet Kirkland (Lead); Dr Andrew Leonard, Louise Winstone (observing)
Date of Executive Licensing Panel: 15 April 2015

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of a short notice interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence. The inspection team recommend the licence is allowed to continue.

A renewal inspection of the centre performed in January 2014 made recommendations to address 14 non-compliances. Due to the number of non-compliances the Executive Licensing Panel (ELP) on 24 April 2014 required that the centre be inspected within a year of the renewal of their licence. In consideration of the small number of treatments performed at the centre, a short notice focussed interim inspection of the centre was undertaken on 10 February 2015.

Prior to this inspection, the inspector for the centre liaised closely with the PR and was satisfied that the recommendations made in the renewal inspection report had been implemented. The focus of the inspection team at this inspection was to assess whether the corrective actions taken have been effective.

The inspection team found no non-compliances on this inspection. Evidence was seen that all recommendations made at the renewal inspection have been implemented. Audits of the effectiveness of the recommendations have been performed by the centre. The inspection team are satisfied with the progress made by the centre and that its systems should support compliant activity. For a small number of recommendations, the inspection team saw evidence that appropriate corrective actions have been implemented however the small number of cycles performed at the centre provides only a limited evidence base to support the effectiveness of the corrective actions. For this reason, the inspection team recommends that the PR continues to work closely with the centre's inspector and submits the results of audits when the number of patients treated is higher, such that the effectiveness of corrective actions can be determined with greater certainty.

The ELP is asked to note that the inspection team considered the centre to be fully compliant at the time of the inspection and therefore no recommendations were warranted.

Information about the centre

The Fertility Unit Barking, Havering and Redbridge Hospitals Trust is located in Queen's Hospital, Romford and has held a licence with the HFEA since 2007.

The centre provides partner intrauterine insemination (IUI) only.

The centre provided 23 cycles of treatment in the 12 months to 31/12/2014. In relation to activity levels this is a small centre.

Details of inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

In 2014 the centre reported 23 cycles of partner insemination with 2 pregnancies. This equates to an 8% clinical pregnancy rate. The HFEA's analysis for 2014 has not yet been performed therefore a comparison of the centre's results against the national average cannot be made although it is expected that the analysis will show that the centre's results are in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy. The centre reported no multiple pregnancies in 2014.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes and that identification errors do not occur. No procedures were taking place on the day of inspection and therefore witnessing in practice could not be observed. However, staff described the centre's manual witnessing procedure in detail and it was considered to be in accordance with HFEA requirements.

The inspection team was able to review six sets of patient notes and concluded that records of witnessing are accurately maintained.

Consent: Disclosure to researchers

Consent to disclosure to researchers is not relevant to centres which provide IUI treatment only. It was however noted at the previous inspection in 2014 that patients at the centre were providing consent to disclosure to researchers. Communications received at the HFEA after the renewal inspection in January 2014, as well as discussions with centre staff on inspection, provided assurance that this has been addressed and patients are no longer being asked to complete the consent to disclosure form.

Consent: To the storage of cryopreserved material

No gamete or embryo storage occurs at this centre therefore this theme was not relevant at this inspection.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

No procedures were carried out on the day of inspection and therefore the inspection team did not observe staffing from the perspective of an active clinic. However, a workforce review provided to the HFEA following the previous inspection, indicated a satisfactory level of staff for the activities performed at the centre and the PR confirmed that he is currently satisfied with the staff complement.

Patient experience

During the inspection there were no patients available to speak to the inspection team regarding their experiences at the centre. Twelve patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed with four of the individuals providing written feedback commenting that they have compliments about the care that they received and two had complaints.

Six of the feedback responses related to appointments being delayed or cancelled. This was brought to the attention of the centre team during the feedback session. The PR explained that the team are undertaking a review of the service and exploring different ways to improve the patient experience; the review will include consideration of this feedback. The centre's inspector asked to be informed of any changes made to the service.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team did not identify any non-compliance.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in January 2014, recommendations for improvement were made in relation to five major and nine 'other' areas of non-compliance.

The PR provided information and evidence after that inspection, that all the recommendations had been implemented apart from providing evidence of staff training in consent taking and incident reporting. At this inspection, the PR agreed to submit this evidence to the inspector prior to the date of the ELP and confirmed that he and the lead fertility nurse would be attending the seminar on consent at the forthcoming HFEA annual conference. The inspector received this documentation and is satisfied that it addresses the non-compliance regarding training documented in the previous report.

On-going monitoring of centre success rates

The HFEA risk tool is used to monitor the success rates of centres providing IVF and ICSI treatments. This IUI centre is not subject to on-going monitoring through the HFEA risk tool and has not therefore been issued with any performance alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The centre provided its annual IUI treatment return for 2014 within the required timescale.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

‘Critical’ area of non compliance

A ‘critical’ area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

‘Major’ area of non compliance

A ‘major’ area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

‘Other’ areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

Additional information from the Person Responsible
The PR informed the inspector by email and verbally that he is happy with the report.