Executive Licensing Panel - minutes

Centre 0291 (Fertility Unit Barking, Havering and Redbridge Hospitals Trust)

Interim Inspection Report

Tuesday, 7 May 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Dina Halai Dan Howard	Director of Strategy and Corporate Affairs Scientific Policy Manager Chief Information Officer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Jennifer Rogerson Amanda Evans	Licensing Manager Research Manager Research Manager

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:

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

1. Consideration of application

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

1.2. The panel noted that, since March 2016, the centre has operated as a satellite service to Guys Hospital ACU (centre 0102) as the primary centre providing all licensed activities including egg collection, embryo culture, storage and treatment services. This service is provided for NHS and self-funding patients wishing to undergo IVF treatment.

1.3. The panel noted that, in 2018, the centre reported 6 cycles of partner insemination with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

1.4. The panel noted that, in 2018, the centre did not report any multiple pregnancies.

1.5. The panel noted that the inspection took place on 12 March 2019.

1.6. The panel noted that at the time of inspection there was one 'other' area of non-compliance in relation to Zika and Ebola risks. Since the inspection, the Person Responsible (PR) has given a commitment to fully implement the recommendation made in the report.

1.7. The panel noted that one 'other' non-compliance was also identified regarding satellite services, but this would need addressing by the PR of the primary centre, so they can work with the satellite centre (0291) to implement the recommendation. Therefore, this non-compliance would not be for consideration by the panel, when making a decision regarding the continuation of the HFEA licence held by the satellite centre.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment (insemination using partner sperm) licence, particularly noting the positive feedback from patients.

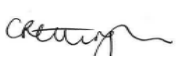
2. Decision

2.1. The panel was satisfied the centre was fit to have its treatment (insemination using partner sperm) licence continued.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

14 May 2019

Interim Licensing Report

Centre name: Fertility Unit Barking, Havering and Redbridge Hospitals Trust
Centre number: 0291
Date licence issued: 01 August 2017
Licence expiry date: 31 July 2021
Additional conditions applied to this licence: None
Date of inspection: 12 March 2019
Inspectors: Julie Katsaros and Karen Conyers
Date of Executive Licensing Panel: 07 May 2019

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 (SLCs).

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. The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

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 (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the positive feedback provided by patients.

The ELP is asked to note that this report makes recommendations for improvement in relation to one 'other' area of non-compliance or poor practice.

Since the inspection visit the PR has given a commitment to fully implement the following recommendation:

'Other' areas of practice that require improvement:

- The Person Responsible (PR) should ensure discussions and advice regarding patient travel history in relation to Zika and Ebola risks are clearly documented within the patient's notes.

Information about the centre

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

The centre provides partner intrauterine insemination (IUI) treatments only.

Since March 2016, the centre has operated as a satellite service to Guys Hospital ACU (HFEA licensed centre 0102) as the primary centre providing all licensed activities including egg collection, embryo culture, storage and treatment services. This service is provided for NHS and self-funding patients wishing to undergo IVF treatment.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are 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 2018, the centre reported six cycles of partner insemination with no pregnancies, which is in line with the national average.

Multiple births[2]

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

The single biggest risk of fertility treatment is a multiple pregnancy. The centre did not report any multiple pregnancies in 2018.

Witnessing

The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and to review witnessing in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The centre has a treatment only licence and therefore no gamete or embryos are stored at this centre.

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. Staffing levels were discussed with the PR and he explained that although there is a small number of staff, activity is managed around availability without compromising patient care.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: infection control and witnessing.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- patient support,
- information provision,
- consent,
- the use of CE marked medical devices and
- the use of the most recently issued HFEA consent form versions.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management
The centre does not keep, dispense or administer medicines therefore this area of practice is not applicable to this inspection.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Infection Control
It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials
It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: culture media, plasticware and consumables. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience
The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. No patients have provided feedback in the last 12 months. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

There were no patients available on the day of inspection to speak with the inspection team about their experiences.

The centre's audit of patient feedback, dated January 2019, was provided to the lead inspector after the inspection. The audit included a review of 25 feedback forms received over a twelve-month period. Feedback was positive and patients complimented the care received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;

- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

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

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is fully compliant with HFEA requirements with the following exception:

- The PR assured the inspection team that travel history discussions are being held with patients undertaking treatment cycles in relation to Zika and Ebola risks. However, the outcome of the discussions or the advice given is not documented in the patient's records (see recommendation 1).

During the renewal inspection in 2017, the PR was advised to liaise with the primary centre's PR (0102) to ensure that a formal audit be completed by the primary centre within the required timeframes. The primary centre has failed to audit the satellite services at centre 0291. Such services are undertaken under the authority of a primary centre's licence and the primary centre is responsible for non-compliances in the satellite service. The primary centre's inspector has been informed of this non-compliance and will contact the PR of the primary centre to discuss what actions he needs to take to ensure compliance. (See Annex 1 section - Non-compliance in the transport/satellite activities at the base of this report)

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to one 'other' area of non-compliance. The PR subsequently provided information and evidence that the recommendation was fully implemented within the required timescales.

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 centre is not subject to ongoing 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 2018 within the required timescale.

Legal parenthood

The centre does not provide treatment with donor gametes, therefore requirements related to legal parenthood consent were not relevant at this inspection.

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 made.

Critical areas 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 non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
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 who may be 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;
- which can comprise 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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
none			

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non-compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
1. The PR assured the inspection team that travel history discussions are held with patients undertaking treatment cycles in relation to Zika and Ebola risks. However, the outcome of the discussions and any advice given is not documented in the patient’s records. SLC T46d.	The PR should ensure discussions and advice regarding patient travel history in relation to Zika and Ebola risks are clearly documented within the patient’s notes. Confirmation of this should be provided when responding to the report. Three months after the implementation of the new process, the centre should audit to ensure the process has embedded effectively by carrying out an audit. A summary of this audit should be sent to the centre’s inspector by 12 June 2019.	Having spoken to our consultants, I have been assured that they discuss the travel hisotry of the patients at the time of the initial consultation. As none of the patients had been to Zika or and Ebola infested areas, they had not recorded the information. I have aksed them to start recording the out-come of their discussions withteh patients on travel history and to document the response. As required, I will audit to ensure that the proces has embedded effectively and send the summary of the audit to my	The Executive acknowledges the PR’s response and commitment to implementing this recommendation. No further action required other than submission of an audit summary by 12 June 2019.

		centre's inspector by 12th of June 2019.	

Non-compliance in the transport/satellite activities

This area of practice related to the centre's satellite services requires improvement. Such services are undertaken under the authority of a primary centre's licence and the primary centre is responsible for non-compliances in the satellite service. The non-compliance and recommendations will therefore be notified to the PR of the primary centre, so he can work with the PR of the satellite centre to implement the recommendations. This non-compliance will not be considered by the licensing committee when making a decision regarding the continuation of the HFEA licence held by the satellite centre.

Area of practice and reference	Action required and timescale for action	PR's Response	Executive Review
Satellite services A. The PR at centre 0291 was not aware whether the primary centre had audited the centre's satellite activity provided to centre 0102. This was noted at the time of the renewal inspection when the inspection team advised the PR to liaise with the primary centre's PR to ensure that a formal audit be completed by the primary centre within the required timeframes. SLC T32 and SLC T36.	The PR should ensure that the auditing of the satellite activities is carried out by the primary centres, and that those audits assess all relevant activities. The PR should work with the PR of the primary centre to ensure that this audit is conducted. Confirmation that an audit of satellite activity has been completed is expected by 12 June 2019.	After exchanging number of emails, I have now finally received an email from the Qaulity Control Manger, [redacted], that an audit of all the relevant activities will be made available for me to forward to my centre's inspector. My centrre's inspector has been kept in the loop of all the emails exchanged and is aware of this reassurance.	The Executive acknowledges the PR's response and efforts to address this matter. No further action required other than confirmation to the centre's inspector that an audit of satellite activity has been completed by 12 June 2019.

Additional information from the Person Responsible