Executive Licensing Panel - minutes

Centre 0348 (CREATE Fertility Birmingham) Interim Inspection Report

Friday, 30 June 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Anna Coundley Anna Quinn	Director of Strategy & Corporate Affairs Information Access and Policy Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

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:

- 8th 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 CREATE Fertility Birmingham is based in Solihull. The centre has held a treatment and storage licence with the HFEA since 29 April 2016 and provides a full range of fertility services.

1.2. The panel noted that the inspection took place on 4 April 2017.

1.3. The panel noted that in the 12 months to 28 February 2017, the centre provided 105 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.4. The panel noted that HFEA register held data, for the period December 2015 to November 2016, showed that the centre's success rates for IVF and ICSI, are in line with national averages.

1.5. The panel noted that between December 2015 and November 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.6. The panel noted that at the time of the inspection, one 'other' area of non-compliance was identified concerning success rates displayed on the centre's website. Since the inspection, the PR has confirmed that this issue has been rectified.

1.7. The panel noted that the inspectorate recommends the continuation of the centre's Treatment and Storage licence.

2. Decision

2.1. The panel was satisfied that the centre was fit to have its Treatment and Storage licence continued.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

11 July 2017

Interim Licensing Report

Centre name: CREATE Fertility Birmingham
Centre number: 0348
Date licence issued: 29 April 2016
Licence expiry date: 28 April 2018
Additional conditions applied to this licence: None
Date of inspection: 04 April 2017
Inspectors: Janet Kirkland Machattie (lead), Douglas Gray (Scientific inspector)
Date of Executive Licensing Panel: 30 June 2017

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. New centres however generally receive a licence to operate for two years and are therefore subject to an interim inspection after a period of approximately twelve months following the granting of the licence and commencement of activities. 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 centre's licence became active on 29 April 2016. This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. For 2015-2017 the focus of an interim inspection is:

- **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

The inspection team recommends the continuation of the centre's licence.

The ELP is asked to note that a recommendation has been made to address one 'other' area of practice that requires improvement:

'Other' area of practice that requires improvement:

- the PR should ensure that the success rates displayed on the centre's website are specific to treatments provided at the centre alone.

Since the inspection the PR has confirmed that he has complied with this recommendation.

Information about the centre

CREATE Fertility Birmingham is located in Solihull and has held a licence with the HFEA since 29 April 2016.

The centre provides a full range of fertility services. The PR intends to apply for a variation of the centre's licence to add embryo testing to the licensed activities performed at the centre.

The centre provided 105 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. 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 important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period December 2015 to November 2016 show the centre's success rates are in line with national averages.

In 2016 the centre reported three cycles of partner insemination with no pregnancies, which is likely to be in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between December 2015 and November 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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[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%.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The scientific inspector was not able to observe any laboratory activities during the inspection however he discussed the centre's witnessing process with the PR and reviewed the documentation of witnessing in patient records. These activities indicate that witnessing procedures at the centre are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection the records of stored gametes and embryos were reviewed and the 'bring-forward' system was discussed with the PR. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out.

Quality Management System (QMS)

It is important that centres audit all 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.

Centres are required to audit their activities at least every two years. The centre has held a licence for less than two years and has therefore not yet audited all activities that would normally be reviewed during an interim inspection. However, the effectiveness of the centre's QMS was assessed by reviewing the reports of the following available audits: consent to treatment, consent to disclosure, welfare of the child and provision of information.

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:

- the centre's audits of consent to treatment, consent to disclosure, provision of information and welfare of the child;
- the use of CE marked medical devices;
- the content of the centre's website;
- HFEA Clinic Focus articles.

The centre has processes in place for implementing learning and generally implements guidance issued by the HFEA, albeit a recommendation has been made elsewhere in this report regarding the content of the centre's website (see recommendation 1).

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

The clinic's processes for medicines management and the safe storage, disposal and administration of medicines are compliant with guidance.

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 are 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.

Infection control practices at the centre are 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 medical devices was discussed during the course of the inspection. The centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

There were no patients available on the day of the inspection to speak with the inspection team about their experiences and the HFEA has not received any patient feedback since the licence was granted in 2016. The lead nurse however described a process to the inspection team whereby feedback is actively sought by giving each patient a satisfaction questionnaire to complete. The responses are reviewed by the centre team and any issues identified would be discussed and acted on accordingly.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional.

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, identified one 'other' non-compliance.

- The centre's website displays success rates over a four year period. This was discussed with the PR as the centre has only been providing treatments for twelve months. The PR explained that the results displayed reflected the results for treatments provided across the CREATE group of fertility centres. The inspectors considered that this may be misleading to patients who would want to know their chances of success at CREATE Fertility Birmingham (recommendation 1).

Compliance with recommendations made at the time of the last inspection

Following the initial licence inspection in 2016, recommendations for improvement were made in relation to one major and two 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

The centre has not received any performance related risk tool alerts to date.

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. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

The centre commenced activities in April 2016 and was therefore not in operation in February 2014 when the HFEA asked all centers to audit their practices in this area.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed three sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required; relevant consent was seen to be present in each patient record. The PR also assured the inspection team that the center's normal practice was to offer counselling to all patients receiving donor gametes and to document this offer of counselling in the patient records. The inspection team therefore considers the process used to obtain consent to legal parenthood to be compliant with HFEA requirements.

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 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 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 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.

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 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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. The success rates displayed on the centre’s website were derived from data not specific to the centre, and are thus potentially misinforming patients. CoP Guidance 4.5.	The PR should review the centre’s website to ensure that patients are able to clearly differentiate success rates from treatments provided at the centre alone. This recommendation should	Thank you for alerting me to this. The website has had a statement added to clarify that the success rates are from our London clinics. We will publish Birmingham's results when we have sufficient numbers to be meaningful.	No further action is required.

	be implemented by 4 July 2017 and the centre's inspector informed of the changes made.		

Additional information from the Person Responsible
The PR and staff of Create Fertility Birmingham are grateful to the inspection team for their time and thorough inspection. We always appreciate the guidance from the inspection team and the HFEA in general for their support. We are committed to delivering the most cost-effective and the best care to our patients. Create Fertility takes pride in reducing complications, preventing OHSS and providing less invasive and successful treatment options to women and couples .