

Executive Licensing Panel - minutes

Centre 0322 (Brighton Fertility Associates) – Interim Inspection Report

Friday, 30 October 2015

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) Hannah Verdin David Moysen	Director of Strategy & Corporate Affairs Head of Regulatory Policy Head of IT
Members of the Executive	Dee Knoyle	Secretary
External adviser	None	
Observers	None	

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 Brighton Fertility Associates, centre 0322, has held a licence with the HFEA since October 2013 and provides treatment (insemination using partner/donor sperm) and storage.
- 1.2. The panel noted that the centre's licence is due to expire on 19 February 2018.
- 1.3. The panel noted that the inspection took place on 8 September 2015.
- 1.4. The panel noted that in the 12 months to 31 July 2015, the centre provided 17 cycles of donor insemination treatment. In relation to activity levels this is a small centre.
- 1.5. The panel noted that between June 2014 and May 2015 the centre reported three cycles of treatment with one pregnancy.
- 1.6. The panel noted that the centre has not reported any multiple pregnancies for the period between June 2014 and May 2015.
- 1.7. The panel noted that at the time of the interim inspection on 8 September 2015, no areas of non-compliance were identified.
- 1.8. The panel noted that the inspectorate recommends the continuation of the centre's treatment (insemination using partner/donor sperm) and storage licence.

2. Decision

- 2.1. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment (insemination using partner/donor sperm) 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

10 November 2015

Interim Licensing Report



Centre name: Brighton Fertility Associates
Centre number: 0322
Date licence issued: 20/02/2014
Licence expiry date: 19/02/2018
Additional conditions applied to this licence: None
Date of inspection: 08/09/2015
Inspectors: Shanaz Pasha (Lead), Andrew Leonard
Date of Executive Licensing Panel: 30/10/2015

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 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 Executive Licensing Panel is asked to note that there are no recommendations for improvement.

Information about the centre

Brighton Fertility Associates is located in Brighton and has held a licence with the HFEA since October 2013.

The centre provides treatment (insemination using partner/donor sperm) and storage.

The centre provided 17 cycles of donor insemination treatment in the 12 months to 31/07/2015. In relation to activity levels this is a very 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 outcomes¹

Between June 2014 and May 2015, the centre reported three cycles of donor insemination treatment in patients under 35 years of age with one pregnancy. This rate is consistent with the national average pregnancy rate.

Multiple births²

The centre has not reported any multiple pregnancies for the period between June 2014 and May 2015.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes and that identification errors do not occur. The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with the PR and review the documentation of witnessing in patient records and the centre's last audit of witnessing practice. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes is an important service offered by fertility clinics. It enables patients to preserve their fertility prior to undergoing other medical treatment. It is important that the centre has measures in place to ensure that gametes are stored in accordance with the consent of the gamete providers.

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

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%.

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 of the centre.

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 staffs are following prescribed 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: legal parenthood, witnessing and consent to storage.

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 use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- the HFEA reports of adverse incidents from 2010-2012 and 2013.
- HFEA Clinic Focus articles regarding: screening requirements, equipment failures

This evaluation indicated that the centre has been effective in ensuring compliance with guidance issued by the HFEA.

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.

Medicines are not stored in this centre.

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 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 reviewed in the course of the inspection: We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Five patients have however provided feedback directly to the HFEA in the time since the last inspection. This feedback was positive, with three of the individuals providing written feedback giving compliments about 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:

- 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;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

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.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013, one recommendation for improvement was made in relation to one major area of non compliance.

The PR subsequently provided information and evidence that the recommendation was fully implemented within the required timescale.

On-going monitoring of centre success rates

Since the renewal inspection in October 2013 the centre has not received any performance related risk tool 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. This information is held in the HFEA Register.

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

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order 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. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe.

On inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and no anomalies were identified.

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 identified			



'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 identified			



'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
None identified.			

Additional information from the Person Responsible

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