

Executive Licensing Panel - minutes

Centre 0327 (Boston Place) Interim Inspection Report

Friday, 13 January 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Howard Ryan Trisram Dawahoo	Director of Strategy & Corporate Affairs Report Developer Digital Communications 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 Boston Place is located in London. The centre has held a licence with the HFEA since May 2013 and provides treatment to self-funded patients and is part of the Fertility Partnership group of fertility centres. The centre provides a full range of fertility services.
- 1.2. The panel noted that the inspection took place on 15 November 2016.
- 1.3. The panel noted that in the 12 months to 31 October 2016, the centre provided 695 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium centre.
- 1.4. The panel noted that the centre has no areas of non-compliance.
- 1.5. The panel noted that the inspectorate recommends the continuation of the centre's licence.

2. Decision

- 2.1. The panel congratulated the centre on having no areas of non-compliance and was satisfied that the centre was fit to have its 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

24 January 2017

Interim Licensing Report



Centre name: Boston Place
Centre number: 0327
Date licence issued: 24 May 2015
Licence expiry date: 23 May 2019
Additional conditions applied to this licence: None
Date of inspection: 15 November 2016
Inspectors: Gill Walsh and Louise Winstone. Anita Bharucha – Observer
Date of Executive Licensing Panel: 13 January 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. 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 an unannounced 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. In particular, we note that there were no areas of non-compliance or poor practice identified at this inspection. The centre is to be commended for their work in achieving compliance since the last inspection.

Information about the centre

Boston Place is located in central London and has held a licence with the HFEA since May 2013. The centre provides treatment to self-funded patients and is part of the Fertility Partnership group of fertility centres.

The centre provides a full range of fertility services including embryo testing.

The centre provided 695 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2016. In relation to activity levels this is a medium sized 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

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

In 2015, the centre reported 33 cycles of partner insemination with 2 pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births²

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

Between August 2015 and July 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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 following laboratory activities were observed in the course of the inspection: egg collection; thawing of gametes and sperm preparation. All of the procedures observed were witnessed using an electronic witnessing system in accordance 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, reports of audits of all stored gametes and embryos and consent records were reviewed and the 'bring-forward' system was discussed with staff. 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: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

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: witnessing, consent to storage, egg donor screening, controlled drugs and infection prevention and control.

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 as described above;
- 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 HFEA Alert regarding storage expiry dates CE(16) 02;
- the centre's audit of legal parenthood;
- the HFEA reports of adverse incidents from 2010-2012 and 2013;
- HFEA Clinic Focus articles regarding:
 - new CoP guidance on PGS/PGD
 - Zika virus
 - equipment failures

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.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Prescription of intralipid 'off label'

Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

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: all media including that used for flush, fertilisation and vitrification and all plastic-ware including pipettes, dishes and sperm pots. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, we spoke to two patients about their experiences at the centre. Four patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive with one of the individuals providing written feedback giving compliments about the care received. The centre's own mechanism for receiving patient feedback and responding to it was also discussed.

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 compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in November 2014, which was the first inspection since the centre was licensed, recommendations for improvement were made in relation to seven major and four 'other' areas of non-compliance.

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

In responding to the report immediately after the inspection, the PR did not provide commitment to implement one recommendation relating to the timing of screening for egg donors. There was at that time some debate as to what constituted 'at the time of donation'. This recommendation was subsequently implemented and a review of egg donor records at this inspection confirmed this.

On-going monitoring of centre success rates

Since the last renewal inspection in November 2014 the centre has not received any HFEA risk tool alerts relating to success rates.

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 HFEA register team has confirmed that there are currently no significant data submission issues and that the centre 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.

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 submitted the report of the audit to the HFEA within the required timeframe. The audit showed that there were no couples affected by legal parenthood consent anomalies.

At the centre's licence renewal inspection in November 2014, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent

taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

To provide further 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. Effective consent to legal parenthood and the offer of counselling was seen to be in place prior to consent and treatment in all cases.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

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 at this inspection			



'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 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 at this inspection			



‘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 at this inspection			

Additional information from the Person Responsible

Many thanks for this. I have no comments to add to the report I'm delighted to say!