Executive Licensing Panel - minutes

Centre 0322 (Brighton Fertility Associates)

Interim Inspection Report

Tuesday, 12 November 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Niamh Marren Danielle Vincent	Director of Finance and Resources Regulatory Policy Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing 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 Brighton Fertility Associates has held a licence with the HFEA since 2012. The centre's licence was varied from a 'storage only' to a 'treatment (insemination using partner/donor sperm) and storage' licence in March 2014. The centre provides basic fertility services and the storage of gametes including donor sperm.

1.2. The panel noted that, in the 12 months to 31 July 2019 the centre had provided 41 cycles of donor insemination treatment. In relation to activity levels this is a small sized centre.

1.3. The panel noted that, HFEA register data, between 1 August 2018 to 31July 2019, show the centre's success rates, in terms of clinical pregnancy, are in line with the national averages.

1.4. The panel noted that, in 2018, the centre reported nine cycles of partner insemination, with two pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, for the year 2018, one of the two clinical pregnancies following partner insemination treatment was a multiple pregnancy. The Person Responsible (PR) has provided assurance that she continuously monitors the multiple pregnancy rate.

1.6. The panel noted that the inspection took place on 21 August 2019.

1.7. The panel noted that, at the time of inspection, there were no areas of practice that required improvement.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment (insemination using partner/donor sperm) and storage licence.

2. Decision

2.1. The panel congratulated the centre on the good inspection, particularly noting that no areas of non-compliance were identified.

2.2. The panel was satisfied 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

Richard Sydee

Date

18 November 2019

Interim licensing report

Centre name: Brighton Fertility Associates
Centre number: 0322
Date licence issued: 20 February 2018
Licence expiry date: 19 February 2022
Date of inspection: 21 August 2019
Inspectors: Louise Winstone, Sandrine Oakes and Victoria Brown (observer)
Date of Executive Licensing Panel: 12 November 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.

The ELP is asked to note that at the time of the inspection there were no areas of practice that required improvement.

Information about the centre

Brighton Fertility Associates has held a licence with the HFEA since 2012. The centre's licence was varied from a 'Storage only' to a 'Treatment (insemination using partner/donor sperm) and storage' licence in March 2014. The centre provides basic fertility services and the storage of gametes including donor sperm.

The centre provided 41 cycles of donor insemination treatment in the 12 months to 31 July 2019. 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]

HFEA held register data for the year 1 August 2018 to 31 July 2019 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

In 2018, the centre reported nine cycles of partner insemination with two pregnancies. This represents a clinical pregnancy which is in line with the national average.

Multiple births[2]

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

For the year 2018, one of the two clinical pregnancies following partner insemination treatment was a multiple pregnancy. The PR provided assurance that she continuously monitors the multiple pregnancy rate.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos 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 procedures 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 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.

This centre only stores gametes and it is important that it has measures in place to ensure that gametes are stored in accordance with the consent of the gamete provider.

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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 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%.

On inspection, reports of audits of all stored gametes and of the accuracy of storage logs 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 in line with the consent of the gamete provider 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 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; legal parenthood; witnessing and consent to storage.

The centre's procedures for auditing and acting on the findings of audits are compliant with HFEA 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
- counselling
- extension of storage consent
- screening
- the use of the Single European Code
- the use of CE marked medical devices
- the centre's audit of legal parenthood

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. This centre does not store or administer medicines therefore requirements related to their use were not relevant at 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 all 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

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their centre. Only four patients have provided feedback in the last 12 months, giving an average 4.5 stars rating to the centre on the HFEA website. This is a small centre however for the system to work well, it's important that every patient knows about the rating system. The inspection team discussed this with the PR. She felt the clinic was actively seeking feedback from patients and donors and was promoting the HFEA website. The PR is asked to consider ways to promote the use of this facility and this will be followed up at the next inspection.

The centre's own most recent patient survey responses (January to August 2019) were reviewed. Only one donor had completed the survey during this time period and the response was positive. The low level of response to the patient survey was discussed at length with the PR during the inspection. The PR advised that all patients and donors are given a questionnaire following their attendance at the centre and are provided with a self-addressed envelope to enable an easy return of their completed questionnaires. The centre still, however, struggle to receive responses back. The PR is urged to consider alternative ways to collect feedback.

No patients or donors were available to speak to inspectors during this visit.

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.

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 major and two 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in August 2017 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.

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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the renewal inspection in 2017, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of a recent legal parenthood consenting audit. Six sets of records where treatment with donor sperm had recently been provided were audited by the inspection team. The inspection team noted that in three of the records audited the couples were married or in a civil partnership and they had completed WP ('Your consent to your

partner being the legal parent') and PP ('Your consent to being the legal parent') forms. However, these forms are intended for patients who are not married or in a civil partnership. When couples are married or in a civil partnership the partner is automatically the legal parent of the child or children born following the treatment. This was discussed with the PR and she has been asked to review the practice of completing consent to legal parenthood forms for couples including those who are married or in a civil partnership. This will be reviewed at the next inspection.

Annex 1

Areas of practice that require the attention of the Person Responsible

This 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 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.

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
None identified.			

‘Other’ areas of practice that requires improvement

‘Other’ 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
None identified.			

Additional information from the Person Responsible
After the helpful discussion with the inspectors we will review what consents we do with our married DI couples, as we have always completed WP and PP forms for all clients. Although this is entirely appropriate for unmarried couples to be clear on legal parenthood issues it was "over the top"and unnecessary for married clients. As there is not an appropriate DI consent form it was useful to discuss legal parenthood using this form, including withdrawal of consent. However, after review we can incorporate this by including this part of informed discussion in another area of a BFA consent. The staff have worked hard to provide a personalised and caring supportive environment for our patients, so I am very glad this interim report reflects their continued hard work and attention to detail. I am extremely proud of my team.