Executive Licensing Panel - minutes

Centre 0339 (CREATE Fertility, London St Paul's)

Interim Inspection Report

Tuesday, 26 March 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Dan Howard Helen Crutcher	Director of Strategy and Corporate Affairs Chief Information Officer Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Joanne Anton Danielle Vincent Yvonne Akinmodun	Licensing Manager Policy Manager Communications Manager Head of Human Resources

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 CREATE Fertility, London St Paul's has held a treatment and storage licence with the HFEA since 2014. Its licence was varied in 2015 to include embryo testing. The centre provides a full range of fertility services and is part of a group that incorporates four other HFEA licensed centres (in Wimbledon, Birmingham, Manchester and Bristol).

1.2. The panel noted that, in the 12 months to 31 October 2018, the centre had provided 1333 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large centre.

1.3. The panel noted that, HFEA register data, for the year ending 30 July 2018, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages with exception of the following:

- The clinical pregnancy rate following FET cycles in patients aged both under 40 and aged 40 and over is below the national average at a statistically significant level.

1.4. The panel noted, however, that the centre's explanation of the apparent underperformance in success rates had been assessed by the HFEA and found that the centre does treat a high proportion of women aged over 42 and does perform a smaller number of stimulated cycles.

1.5. The panel noted that, in 2017, the centre reported fourteen cycles of partner insemination with two pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.6. The panel noted that HFEA register data, for the year ending 31 July 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance which is likely to be lower than the 10% multiple live birth rate target for this period.

1.7. The panel noted that the inspection took place on 22 November 2018.

1.8. The panel noted that at the time of inspection there were no recommendations for improvement

1.9. The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting the centre's very low multiple pregnancy rate.

2. Decision

2.1. The panel congratulated the centre on the level of compliance identified at the interim inspection.

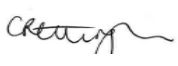
2.2. The panel particularly noted the low multiple pregnancy rate and the ongoing conversation regarding the analysis of the centre's success rates.

2.3. The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage 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

2 April 2019

Interim Licensing Report

Centre name: CREATE Fertility, London St Paul's
Centre number: 0339
Date licence issued: 23/07/2016
Licence expiry date: 22/07/2020
Additional conditions applied to this licence: None
Date of inspection: 22/11/2018
Inspectors: Sara Parlett and Janet Kirkland
Date of Executive Licensing Panel: 26 March 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 (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. 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

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the centre's very low multiple pregnancy rate.

The ELP is asked to note that this report makes no recommendations for improvement.

Information about the centre

CREATE Fertility, London St Paul's has held a treatment and storage licence with the HFEA since 2014. Its licence was varied in 2015 to include embryo testing.

The centre provides a full range of fertility services and provided 1333 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2018. In relation to activity levels this is a large centre.

The centre is part of a group that incorporates four other HFEA licensed centres (in Wimbledon, Birmingham, Manchester and Bristol).

A change of name from CREATE, St Paul's London to CREATE Fertility, London St Paul's was approved by the HFEA Licensing Officer in October 2017.

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 year ending July 2018 show the centre's success rates are in line with national averages with the following exceptions:

- The clinical pregnancy rate following FET cycles in patients aged both under 40 and aged 40 and over is below the national average at a statistically significant level.

However, this may not be an accurate reflection of the centre's success rates and this apparent underperformance may be due to the manner in which the HFEA presents data, which impacts on the centre due to the nature of the treatment it provides and its patient demographics. Refer to the 'on-going monitoring of centre success rates' section of this report for further detail.

In 2017 the centre reported 14 cycles of partner insemination with two pregnancies. This is in line with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 July 2018 shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be lower than the 10% multiple live birth rate target for this period.

[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 and embryo thaw. All of the procedures observed were witnessed using a manual 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, storage records and reports of audits of all stored gametes and embryos were reviewed. 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, storage, infection control, medicines management, consent to disclosure and legal parenthood.

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;

- implementation of new legal requirements on the importation and coding of gametes and embryos;
- action taken following a recent alert relating to mixed gas cylinders;
- HFEA Clinic Focus articles regarding: screening requirements.

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 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 a sample of reagents and plasticware 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 visit, no patients were available to speak to the inspection team.

The HFEA website has a facility on its 'Choose a Fertility Clinic' (CaFC) page enabling patients to provide feedback on their experience of their clinic. Only 17 patients have provided feedback about this clinic, giving an average 3.5 star rating.

For a large clinic, this may suggest that CaFC patient feedback may not be actively sought for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. However, from discussions with the PR on the day of inspection, this is not the case. Patients are encouraged to leave feedback on CaFC and

the PR is disappointed at the low response rate. The PR is actively considering innovative ways to promote the use of this facility; this will be followed up at the next inspection.

The website also gives the ability for patients to comment on the cost of treatment. Although the majority of patients confirmed that they had paid what they expected, four patients stated that 'it was way above the estimate'. This was discussed with centre staff in detail and the centre's approach to providing personalised costed treatment plans was reviewed. The inspection team considered the centre's presentation of costs was clear and transparent and compliant with Code of Practice guidance.

The centre's own most recent surveys of patient feedback of 89 patients in October 2018 was reviewed on inspection. Approximately 80% of patients stated they were likely or extremely likely to recommend the clinic to friends and family.

Patient feedback from CaFC and the centre's own survey included both positive and negative comments. However, no trends/themes were apparent in the negative feedback. Survey responses are reviewed and discussed regularly by centre staff and actions are taken to address any issues identified.

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;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

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 2016, recommendations for improvement were made in relation to one major and one 'other' area 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

In the last year, the centre has received five alerts related to frozen embryo transfer (FET) success rates.

The PR has responded to these alerts and a full analysis of success rates was provided to the HFEA in September 2018. In summary, the PR considers that two main factors are impacting on the centre's FET rates:

- **patient age:** the centre treats a higher proportion of women over 42 years old. When reviewing success rates in the 40-42 age range, success rates are within national averages.
- **natural cycles:** the centre performs more natural cycles (i.e. without ovarian stimulation) than other clinics and these patients are more likely to be poor prognosis patients.

Independent analysis of the centre's success rates compared to the sector was performed by the HFEA's intelligence team. This analysis agreed with the centre's explanations of the apparent underperformance in success rates. That is, the centre does treat a high proportion of women aged over 42 and does perform a smaller number of stimulated cycles (i.e. more natural cycles).

The inspection team is assured that poor prognosis patients are clearly informed of their lower chance of success and that the PR monitors success rates closely. The PR will continue to engage with the HFEA to assist in informing accurate interpretations of this centre's 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 clinic had technical issues earlier in 2018 with treatment data submission and there were a significant number of errors related to missing treatment and outcome forms. These issues have recently been resolved and therefore the centre is now 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 inspection in March 2016, 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 recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are 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 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	Inspection team's response to the PR's statement
None noted.			

‘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	Inspection team’s response to the PR’s statement
None noted.			

‘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	Inspection team’s response to the PR’s statement
None noted.			

Additional information from the Person Responsible
We are grateful to the inspection team for their time and guidance. Our team found the inspection to be a positive and constructive experience. We were able to interact openly to discuss positive changes to improve patient safety and experience. We are proud to deliver a safe, individualised and cost-effective treatment options to our patients. We continue to maintain lower multiple birth rates and complications in IVF. We have a caring and highly skilled team who are committed to delivering an excellent care in fertility treatments. As Person Responsible, I take this opportunity to thank our inspection team again.