Executive Licensing Panel Minutes

Centre 0359 (CREATE Fertility, Manchester)

Interim Inspection Report

Date:	23 February 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Helen Crutcher Joanne Anton	Director of Finance and Resources Risk and Business Planning Manager Head of Policy
Executive:	Bernice Ash	Secretary
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 CREATE Fertility, Manchester has held a licence with the HFEA since 2017 and provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos and embryo testing.

1.2. The panel noted that the centre is part of a group that incorporates four other HFEA licensed centres (in St Paul's London (0339), Wimbledon London (0299), Birmingham (0348) and Bristol (0368)).

1.3. The panel noted that the centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

1.4. The panel noted that, in the 12 months to 31 December 2020, the centre had provided 580 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre.

1.5. The panel noted that, HFEA register data, for the year ending September 2020, show the centre's success rates, for IVF and ICS1, are in line with the national average.

1.6. The panel noted that, in 2019, the centre reported 6 cycles of partner insemination, with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

1.7. The panel noted that, HFEA register data, for the year ending September 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 1%. This represents performance that is significantly less than the 10% multiple live birth rate target for this period.

1.8. The panel noted that, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), combined with an on-site visit on 9 December 2020, was conducted for this inspection.

1.9. The panel noted that, at the time of the inspection, there were no areas of non-compliance.

1.10. The panel noted the centre is well led and provides a good level of patient support.

1.11. The panel noted that the inspection team recommends the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting their very low multiple pregnancy rate.

2. Decision

2.1. The panel congratulated the centre on having no areas of non-compliance and its very low multiple pregnancy rate, but noted there are some continuing data submission issues regarding late 'intention to treat' and treatment forms. The Person Responsible (PR) is aware of this problem and has provided a commitment to ensure these are submitted in a timely manner; this will be followed up by the centre's inspector.

2.2. The panel noted that, in the last 12 months, only eight patients had provided feedback on their experience of the centre, through the 'Choose a Fertility Clinic' facility available on the HFEA website; the panel suggested that the centre should actively encourage patients to use this mechanism to provide feedback.

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

3. Chairs signature

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

Signature

Richard Sydee

Name

Date

26 February 2021

Interim Licensing Report

Centre name: CREATE Fertility, Manchester
Centre number: 0359
Date licence issued: 13 June 2019
Licence expiry date: 12 June 2023
Additional conditions applied to this licence: None
Date of inspection: 9 December 2020
Inspectors: Sara Parlett, Grace Lyndon and Paula Nolan
Date of Executive Licensing Panel: 26 January 2021

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.

The inspection was conducted via a Desk Based Assessment using a Risk Based Approach (DBA/RBA) combined with an on-site visit.

Summary for the Executive Licensing Panel

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

The centre is well led and provides a good level of patient support.

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

Information about the centre

CREATE Fertility, Manchester has held a licence with the HFEA since 2017 and provides a full range of fertility services.

The centre provided 580 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2020. In relation to activity levels this is a small centre.

The centre is part of a group that incorporates four other HFEA licensed centres (in St Paul's London (0339), Wimbledon London (0299), Birmingham (0348) and Bristol (0368)).

Other licensed activities at the centre include the storage of gametes and embryos and embryo testing.

The centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

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 September 2020 show the centre's success rates are in line with national averages.

For the year 2019 the centre reported six cycles of partner insemination with no pregnancies. This 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 September 2020 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 1%. This represents performance that is significantly less than the 10% multiple live birth rate target for this period.

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 activity was observed in the course of the inspection: sperm preparation. A desk based review of the centre's own audit of witnessing practice was also performed. These activities indicated that witnessing procedures are compliant with HFEA requirements.

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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%.

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.

During the inspection process, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed. The 'bring-forward' system was discussed with staff and storage records were reviewed. 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: medicines management; infection control; legal parenthood; witnessing; 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:

- Treatment data verification.
- Preparation for EU transition.
- New storage regulations.
- Reopening of the clinic during the Covid-19 pandemic.

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 process, 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 process, 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 centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback
The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only eight patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up

at the next inspection. The PR requested the HFEA posters which inform patients about this facility; the link to download this has been sent to him.

The website also gives the ability for patients to comment on the cost of treatment. All patients confirmed that they had paid what they expected to.

The centre's own most recent patient survey responses were also reviewed. Feedback is collected on a monthly basis and was positive. 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;
- 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 2019, recommendations for improvement were made in relation two 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last inspection 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.

There are currently some data submission issues at this clinic, with a number of missing or late 'intention to treat' and treatment forms. The PR is aware and has committed to

ensuring these forms are submitted. A recommendation is not considered necessary at this stage, but progress with submission will be followed up by the centre's inspector.

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.

At the last inspection in 2019, 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. Four 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.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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	Executive review
None noted.			

‘Major’ areas 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	Executive review
None noted.			

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas 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 noted.			

Additional information from the Person Responsible
The PR and staff of CREATE are grateful to the inspection team for their time, support and understanding during the inspection process during these difficult times. We are committed to delivering the most cost effective and safe care to our patients. CREATE Fertility takes pride in reducing complications, preventing OHSS, providing less invasive and successful treatment options for women and couples.