Executive Licensing Panel - minutes

Centre 0359 (CREATE Fertility, Manchester)

Interim Inspection Report

Wednesday, 10 October 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Laura Riley Howard Ryan	Director of Strategy and Corporate Affairs Head of Regulatory Policy Report Developer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance 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:

- 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 CREATE Fertility, Manchester is located in Wilmslow and has held a licence with the HFEA since 13 June 2017. The centre provides a full range of fertility services.

1.2. The panel noted that, in the 12 months to 30 April 2018, the centre provided 77 cycles of treatment (excluding partner intrauterine insemination). In relation to activity level this is a small sized centre.

1.3. The panel noted that in 2017, the centre reported 6 cycles of partner insemination with no clinical pregnancies, which is likely to be in line with the national average.

1.4. The panel noted that, from February 2017 to January 2018, HFEA held register data showed that the centre's success rates for IVF and ICSI are in line with national averages.

1.5. The panel noted that, between February 2017 and January 2018, the centre had not provided any treatments that resulted in a multiple pregnancy.

1.6. The panel noted that the inspection took place on 19th June 2018.

1.7. The panel noted that at the time of the inspection, two 'other' areas of non-compliance were identified concerning the centre's website and the drug fridge. Since the inspection, the PR has complied with the recommendations made in the report. The panel acknowledged that the audit monitoring, regarding the temperature of the drug fridge, had been received and no issues were identified.

1.8. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence.

2. Decision

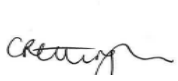
2.1. The panel congratulated the centre on its compliancy, noting the two 'other' non-compliances, identified at the inspection, had been fully addressed.

2.2. 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

17 October 2018

Interim Licensing Report

Centre name: CREATE Fertility, Manchester
Centre number: 0359
Date licence issued: 11/10/2017
Licence expiry date: 12/06/2019
Additional conditions applied to this licence: none
Date of inspection: 19/06/2018
Inspectors: Janet Kirkland, Lesley Brown, Julie Katsaros (observing)
Date of Executive Licensing Panel: 10 October 2018

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.

The ELP is asked to note that this report makes recommendations for improvement in relation to two 'other' areas of non compliance or poor practice.

Since the inspection visit the PR has complied with the following recommendations:

'Other' areas of non compliance:

- The PR should ensure that the source of the success rates displayed on the centre's website is clear;
- The PR should ensure that equipment is subject to appropriate monitoring and that staff are suitably trained and competent to interpret and act on any deviation from the normal.

Information about the centre

CREATE Fertility, Manchester is located in Wilmslow and has held a licence with the HFEA since 13 June 2017.

The centre provides a full range of fertility services.

The centre provided 77 treatment cycles (excluding partner intrauterine insemination) in the 12 months to 30 April 2018. 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]

For IVF and ICSI, HFEA held register data for the period February 2017 to January 2018 show the centre's success rates are in line with national averages.

For the year 2017 the centre reported six cycles of partner insemination with no clinical pregnancies. This is comparable to the national average.

Multiple births[2]

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

Between February 2017 – January 2018 the centre team have not provided any treatments which resulted in a multiple pregnancy.

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 with staff and reviewed the centre's own witnessing audit. 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. 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, the accuracy of storage logs and consent records were reviewed, the 'bring-forward' system was discussed with staff and storage records were audited. These

[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%.

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 clinical inspectors had the opportunity to see the procedure room and recovery area. It was noted that of four recovery bays, two could not be seen clearly from the nursing station. The inspection team was concerned about occasions when only one nurse was in the recovery area following a procedure as she would be unable to see all of the patients from the station. This may compromise the care of patients. This was discussed with one of the nursing team who explained that each patient is monitored by them until fully recovered in the bay opposite the nursing station prior to another patient being accepted in to the recovery area.

The PR directed that further nursing activity enquiries should be directed to the Clinical Director or Nurse Manager. As neither were present on the day of the inspection the lead inspector subsequently spoke with the lead nurse to clarify matters related to medicines management and the centre's processes for ensuring effective consent to legal parenthood is in place when relevant (see below).

Whilst the staffing levels appeared suitable for the activities being carried out on the day of the inspection, the inspection team were initially concerned whether the centre had enough staff on duty when procedures were being performed. This was discussed with the PR who assured the inspection team that the centre had sufficient staff to ensure the safety of both patients and staff. Following the inspection, he provided a comprehensive written account of actions put in place to ensure the safety of staff and patients. He described a standard policy of operating with a 'one in and one out' strategy for egg collections, so usually only one patient is recovering at a particular point in time, and careful scheduling of egg collections to minimise overlap between patients.

He also described a system whereby Create clinics can avail themselves of staff cover from other Create centres (elsewhere in the country) when necessary.

The inspection team acknowledge that on the day of inspection the centre was 'quiet' with minimal activity, and therefore the number on staff of duty was commensurate with the level of activity.

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 centre has held a licence for less than two years and has therefore not yet audited all activities that would normally be reviewed at this inspection. However, the effectiveness of the centre's QMS was assessed by reviewing the reports of the following available audits: consent to treatment, legal parenthood, and witnessing.

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
- HFEA Clinic Focus articles regarding: screening requirements, equipment failures

The centre has processes in place for implementing learning and generally implements guidance issued by the HFEA, however the inspectors noted a non-compliance when reviewing the centre's website. The website displays success rates over a two to three year period however the centre has only been providing treatments for twelve months. The PR explained that as the centre did not yet have enough data to publish its own results and the data on the website was for the Create centre in St Paul's. It was not clear to the inspection team at the time of reviewing the website that the success rates displayed were for the Create centre in St Pauls, rather than for Create Fertility, Manchester.
(see recommendation 1).

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.

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 the following medical devices was reviewed in the course of the inspection: media, vitrification kits, consumables and plastic ware. We found the centre to be compliant with HFEA requirements in using only CE marked medical devices.

Patient experience

There were no patients available on the day of the inspection to speak with the inspection team about their experiences. One patient provided feedback directly to the HFEA in the time since the last inspection. The nurse interviewed on inspection described a process whereby patients can complete a feedback form which can then be posted in a box at the reception.

The centre’s audit of patient feedback dated April 2018 was provided to the lead inspector after the inspection. The audit included a review of 40 feedback forms received over a twelve-month period. Feedback was predominantly positive including references to ‘excellent care’ and ‘positive experiences’. There was some negative feedback regarding telephone contact with the clinic and lack of clarity regarding the cost of treatment. The audit report included actions that the centre had taken to address these concerns.

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.

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 its self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is partially compliant with HFEA requirements because, in addition to the non compliance documented elsewhere in the report, the inspection team observed the following:

The drug fridge in the centre is monitored daily. Three digital readings displayed on the fridge are recorded. Whilst a member of the centre team could describe the process for documenting the readings they did not have an understanding of what the readings actually meant. At the time of the inspection there was also a red light illuminated on the fridge and the inspection team were informed that it was always illuminated but the staff member did not know why. This was brought to the attention of the PR who contacted the fridge manufacturer to confirm what the readings on the fridge indicated.

The inspection team therefore considered that the drug fridge was not being monitored appropriately as staff interviewed on the day of the inspection were not aware of the meaning and therefore possible impact of the temperatures they were recording and the significance of the illuminated red light (see recommendation 2).

Following discussion of our findings, the PR suspended the use of the fridge and its contents until such times as he was assured that the integrity of its contents had not been compromised by the monitoring issues. The PR contacted the supplier of the fridge and concluded that as the fridge is only one year old, has passed servicing at the correct interval, and that the minimum temperature data provided supporting information, that there had been no risk of any compromise to patient care from the usage of the fridge.

The PR has also taken immediate action to ensure that staff are suitably trained in the effective monitoring of the temperature of the fridge.

Compliance with recommendations made at the time of the last inspection

Following the initial inspection in June 2017 recommendations for improvement were made in relation to two major and two 'other' area(s) 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 initial inspection in 2017 the centre has not received any alerts related to treatment outcomes.

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 on time and to expected standards of quality.

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.

The centre commenced activities in June 2016 and was therefore not in operation in February 2014 when the HFEA asked all centers to audit their practices in this area.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed four sets of records where treatment with donor sperm had recently been

provided in circumstances where consent to legal parenthood was required; relevant consent was seen to be present in each patient record.

The lead inspector also had a telephone interview with the lead nurse to discuss the process of ensuring that patients are fully informed regarding consent to legal parenthood and that effective consent is in place. The lead nurse informed the inspector that there are several checks in place during a patient's treatment cycle to ensure that consents have been completed appropriately and that the process of obtaining consent is audited biannually. Centre staff also reported that the centre's normal practice was to offer counselling to all patients receiving donor gametes and to document this offer of counselling in the patient records. The inspection team therefore considers the process used to obtain consent to legal parenthood to be 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.

‘Other’ 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
1. The Centre’s website displays success rates over a two to three year period however the centre has only been providing treatments for twelve months. The PR	The PR should ensure that the the source of the success rates displayed on the centre’s website is clear.	We welcome working with the HFEA in a collaborative manner to improve the information available to patients. The success rates on our dedicated Manchester clinic page indicated the source of data, and the HFEA	The inspector acknowledges the PR’s response. It was useful to discuss this concern with the centre and to work together to ensure that information available to

explained that as the centre did not yet have enough data to publish its own results the data on the website was for the Create centre in St Paul's. It was not clear to the inspection team at the time of reviewing the website prior to the inspection that the success rates displayed were for the Create centre in St Pauls. HFEA Code of Practice, guidance note 4.12.	The PR to inform the centre's inspector of the actions taken to comply with this recommendation when responding to the inspection report.	accepted that it was an acceptable practice to utilise these success rates. As our organisation operates multiple clinics, success rates from other areas of the website would benefit from further clarification. After receiving feedback from the HFEA, we adjusted the presentation accordingly. We would like to thank the HFEA for their advice and we are grateful for their helpful input.	patients is both accurate and clear.
2. The drug fridge was not being monitored appropriately as staff interviewed on the day of the inspection were not aware of the meaning, and therefore possible impact, of the temperatures they were recording and the significance of an illuminated red light.	The PR took action following the inspection to assure himself of the integrity of the contents of the fridge. The PR also took immediate action to ensure that staff are suitably trained in the effective monitoring of the temperature of the fridge.	I agree with the inspectors comments, assurance was provided in the timescale requested. The fridge has since been linked to the laboratory 'Britannia' alarm and monitoring system. Thus is continuously monitored and staff will be alerted should the temperature deviate from the required range.	The inspector acknowledges the PR's response. Audit to be received by 19 September 2018.

SLC T24, T25, T15.	The PR has stated that he will audit the monitoring of the fridge. The centre's inspector to be provided with a summary of the audit after a period of three months. By 19 September 2018.	An audit will be sent to the inspector in the time frame requested.	

Additional information from the Person Responsible