Executive Licensing Panel - minutes

Centre 0299 (CREATE Fertility, London Wimbledon)

Interim Inspection Report

Wednesday, 25 April 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Caylin Joski-Jethi Erin Barton	Director of Strategy and Corporate Affairs Head of Intelligence Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Laura Riley Lisa Whiting	Senior Governance Manager Head of Regulatory Policy Data and Insights Analyst

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, London Wimbledon has held a treatment (including embryo testing) and storage licence with the HFEA since 2008 and provides a full range of fertility services.

1.2. The panel noted that, in the 12 months to 30 November 2017, the centre provided 564 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels, this is a medium sized centre.

1.3. The panel noted that for IVF and ICSI, HFEA held register data, for the period ending 31 August 2017, shows the centre's success rates are in line with the national average.

1.4. The panel noted that, in 2016, the centre reported 12 cycles of partner insemination with one pregnancy. This is in line with the national average.

1.5. The panel noted that the inspection took place on 6 February 2018.

1.6. The panel noted that at the time of the inspection, one major area of non-compliance or poor practice was identified concerning equipment and materials, alongside two 'other' areas regarding medicines management and premises and facilities. The panel noted that since the inspection, the Person Responsible (PR) has provided evidence that actions had been taken to implement the recommendations relating to equipment and materials and medicines management, and has committed, where required, to audit the effectiveness of these actions within the prescribed timescales. The Executive and the PR will liaise to ensure the recommendations concerning premises and facilities are appropriately implemented.

1.7. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting the progress made by the centre in meeting the HFEA multiple birth rate targets and the positive comments made by patients in relation to their experiences.

2. Decision

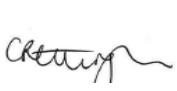
2.1. The panel was pleased to see that the centre had actively sought patient feedback and had used comments received to help improve the services provided.

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

1 May 2018

Interim Licensing Report

Centre name: CREATE Fertility, London Wimbledon
Centre number: 0299
Date licence issued: 1 August 2016
Licence expiry date: 31 July 2020
Additional conditions applied to this licence: None
Date of inspection: 6 February 2018
Inspectors: Mhairi West (lead), Sara Parlett, Grace Lyndon
Date of Executive Licensing Panel: 25 April 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. For 2015-2018 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 progress made by the centre in meeting the HFEA multiple birth rate targets and the positive comments made by patients in relation to their experiences.

The ELP is asked to note that this report makes recommendations for improvement in relation to one major and two 'other' areas of non compliance or poor practice as follows:

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that reagents and consumables in use at the centre are CE marked to the appropriate standard (where possible).

'Other' areas of non compliance:

- The PR should ensure that alterations made within the controlled drugs register are in line with regulations.

The executive and PR will continue to liaise to ensure that the following recommendation is appropriately implemented:

'Other' areas of non compliance:

- The PR should ensure that all medical gases are stored according to medical gas safe storage regulations.

The executive is confident that this can be resolved satisfactorily and does not consider that the on-going discussion of this one 'other' non compliance affects the recommendation for the continuation of the centre's licence.

Information about the centre

CREATE Fertility, London Wimbledon has held a treatment and storage licence with the HFEA since 2008.

The centre provides a full range of fertility services and provided 564 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2017. In relation to activity levels this is a medium size centre.

The centre's licence was varied in September 2017 to add embryo testing, and in October 2017 to reflect a change of name from CREATE Centre for Reproduction and Advanced Technology to CREATE Fertility, London Wimbledon.

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 ending 31 August 2017 show the centre's success rates are in line with national averages.

In 2016, the centre reported 12 cycles of partner insemination with one pregnancy. 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 August 2017 shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not likely to be significantly different to 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 activities were observed in the course of the inspection: sperm preparation and preparation for embryo transfer. 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

[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%.

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 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 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: it was a busy clinic day and there were sufficient staff to see all patients; 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, legal parenthood, medicines management and patient feedback.

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 centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding screening requirements related to Ebola and Zika

The centre is broadly effective in implementing learning from guidance from the HFEA as they have not ensured compliance with guidance related to CE marked medical devices (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 broadly compliant with good practice guidance. The way in which corrections are made to the controlled drugs book is not in line with regulatory requirements in this area (see recommendation 2).

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 media and plastic ware was reviewed in the course of the inspection. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible as 60mm dishes and 15ml conical tubes were not CE marked to the appropriate level (see recommendation 1).

Patient experience
During the inspection, no patients were available to speak with the inspectors about their experiences at the centre.

The centre's most recent patient survey responses were also reviewed. Feedback was generally positive with most individuals providing written feedback giving compliments about the care received.

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.

A small number of negative trends were noted (for example appointment waiting time delays) and corrective action to address these has been implemented by centre staff. This demonstrates that the clinic uses feedback to improve its services. The inspection team encourages the centre to continue to monitor patient feedback to ensure the actions taken are effective.

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, the inspection team identified the following areas requiring improvement:

- In the outdoor gas cylinder store, four large, eight medium and one small cylinder were not chained to prevent them falling over, and the store did not have signage to indicate the contents (see recommendation 3).

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 two major and three 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in February 2016 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. There are currently no significant data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 17 January 2018.

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 that inspection in February 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. No recent treatments had been provided in circumstances where consent to legal parenthood using the HFEA WP/PP forms was required. However, three sets of records where treatment with donor sperm had recently been provided, in circumstances where posthumous consent to legal parenthood using the HFEA PBR form, 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 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 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. Equipment & materials The following medical devices used by the centre are not CE marked: 60mm dish, 15ml conical tube. SLC T30.	The PR should ensure that reagents and consumables in use at the centre are CE marked to the appropriate standard (where possible). We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this, the PR should provide a list of all medical devices currently in use in the clinic, when responding to this report. The list should document the CE mark status of each device and where devices are not	The Licence Condition T30 requires that "where possible" only CE marked medical devices must be used. It is not an absolute requirement. We have carried out risk aseesments and validation of the products to ensure that the products are safe. Furthermore, your report relates to only two items and the two items mentioned in your report were in fact CE marked (IVD). We are therefore not clear why this is categorised as a "major non-compliance". We would like to request that you to reconsider whether it	The executive acknowledges the PR’s response and confirms the receipt of a list of medical devices and their CE status demonstrating that all materials in use are now CE marked at the appropriate level. The PR is reminded that it is a requirement to use CE marked medical devices, where they are available. Furthermore, these must be CE marked at the appropriate level. IVD CE marked devices are not intended to be used for the processing of gametes or embryos that will be used in

	appropriately CE marked, the list should document either the anticipated time by which the appropriate CE mark is expected to be obtained or the action that will be taken to ensure compliance within the next 12 months.	should to be classified as a "major non-compliance". This appears to be disproportionate . However, in response to your report, we have now substituted these two items with products with appropriate CE mark status. I have attached a full list of all medical devices currently used and their CE mark status as requested.	fertility treatment, as directed by IVD Medical Devices Directive 98/79/EC. The categorisation as a major non compliance is in line with the compliance team's assessment framework which is used to ensure consistency of grading of non compliances across inspections. No further action required.

‘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
2. Medicines management Alterations made within the controlled drugs book were not compliant with regulations. SLC T2. The Misuse of Drugs Regulations 2001 20(c).	The PR should ensure that alterations made within the controlled drugs register are in line with regulations. No cancellation, obliteration or alteration of any such entry shall be made, and a correction of such an entry shall be made only by way of marginal note or footnote which shall specify the date on which the correction is made; The PR should ensure that all appropriate staff are trained in this element within their medicines management training. A summary of the actions taken should be provided when responding to this report. An audit should be performed to ensure that the corrective	Our Head of Nursing has undertaken further nurse training with all the relevant nursing staff in reponse to your report to ensure that no cancellation, obliteration or alteration of an entry is made and any correction of the drug entry is made only by the way of a marginal note or footnote which specifies the date on which the correction is made. I am satisfied with this. We will send you an updated SOP and an audit as requested before the 6th of May.	The executive acknowledges the PRs response and implementation of further training to respond to this recommendation. Further action is required.

	actions are effective and a summary of the audit should be provided to the centre's inspector by 6 May 2018.		
3. Premises and Facilities In the outdoor cylinder store there was no signage to show the contents of gas cylinders and relevant warnings, and there were no measures to prevent the cylinders toppling over. SLC T17. British Compressed Gases Association (BCGA) 2016 Code of Practice 44, The Storage of gas cylinders 6 (6.2). DH (2006) Medical gases Health Technical Memorandum 02-01: Medical Gas Pipeline Systems, Part B	The PR should ensure that all medical gases are stored according to medical gas safe storage regulations. The PR should confirm to the centre's inspector that this has been completed by 6 May 2018.	These cylinders have been inspected on numerous occasions by the HFEA during the last 10 years and also on numerous occasions by the CQC when we were registered with the CQC by different inspectors and regulators, and this is the first time that any criticism has ever been made of our gas storage.It is suggested that our storage is in breach of BCGA Code of Practice 44, paragraph 6.2 on the storage of gas cylinders - because our cylinders are not chained. It is not a requirement of the Code of Practice that cylinders are chained; rather, the Code states that cylinders should be stored upright and measures are taken to prevent them from falling over. Chaining is given an example of such a measure. Our cylinders are stored in a secure cage which is small enough to prevent the cylinders falling over, though we note the recommendation	The executive acknowledges the PR's response to this non compliance. However the executive can only comment on what was observed on the day of the inspection. The executive has given the PR the current standards and the reasons for our concern during the inspection, which the PR then took on board. The guidance given is current best practice for all establishments that store cylinders and should be adhered to for the health and safety of patients, staff and the public. The PR's attention is drawn to the BCGA Code of Practice, where it states that measures should be taken to prevent cylinders from falling over. The size of the store does not prevent this. It is the view of the executive that there was not sufficient

		that they be chained or strapped in the Code. It is also suggested that our storage is in breach of the Department of Health's Technical Memorandum on 'Medical gas pipeline systems' . This document is intended for use in NHS Trusts and other NHS organisations; it does not apply to private clinics. In any event, the document does not make it a requirement that cylinders are chained as the Report suggests. The Memorandum does attach significance to the security of strored cylinders, and we are happy to confirm that the cage in which the cylinders are stored is robust and secure. We will ensure that the requested signage is displayed as requested by the deadline.	space for manoeuvring through for the changing of the large cylinders at the far end of the store. In addition, there was not adequate means of securing large heavy cylinders to prevent falling. The PR should carry out a robust and comprehensive risk assessment of the cylinder store against the BCGA 2016 and the DH Medical Gases Health Technical Memorandum 02-01: regulations in their entirety. The PR should forward a copy of the risk assessment to the centres inspector by 6 June 2018.

Additional information from the Person Responsible
On behalf of all staff at Create, Wimbledon, I am grateful to the inspection team for their time and advice during the inspection. I am pleased that we have caring and skilled staff and our patient satisfaction is good. We provide cost-effective services with good success rates and low complication rates. Our multiple birth rate is low and we will continue with our efforts to provide the best care for our patients. Thank you all.