Executive Licensing Panel - minutes

Centre 0358 (CARE Birmingham)

Interim Inspection Report

Friday, 6 July 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Dan Howard Howard Ryan	Director of Strategy and Corporate Affairs Chief Information Officer Data Analyst
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Richard Chamberlain	Senior Governance Manager Temporary Committee Clerk (Induction)

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 CARE Fertility Birmingham is a private centre, located in Edgbaston, Birmingham and has held a treatment (including embryo testing) and storage licence with HFEA since 27 June 2017. The centre provides a full range of fertility services.

1.2. The panel noted that, between 27 June 2017 and 30 April 2018, it provided 191 cycles of treatment (excluding partner intrauterine insemination). In relation to activity, this is a small sized centre.

1.3. The panel noted that, between 27 June 2017 and 30 April 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 19%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.4. The panel noted, regarding pregnancy outcomes, HFEA held register data, for the period 27 June 2017 to 31 January 2018, shows that the centre's success rates for IVF and ICSI, HFEA, are in line with national averages.

1.5. The panel noted that, in 2017, the centre reported 2 cycles of partner insemination with 1 pregnancy.

1.6. The panel noted that the inspection took place on 16 May 2018.

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

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

2. Decision

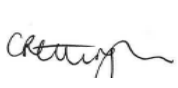
2.1. The panel congratulated the centre on having no areas of non-compliance.

2.2. The panel was satisfied that 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 July 2018

Interim Licensing Report

Centre name: **CARE Fertility, Birmingham**
Centre number: **0358**
Date licence issued: **27 June 2017**
Licence expiry date: **26 June 2019**
Additional conditions applied to this licence: **None**
Date of inspection: **16 May 2018**
Inspectors: **Lesley Brown (Lead), Polly Todd.**
Date of Executive Licensing Panel: **6 July 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 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 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 Executive Licensing Panel is asked to note that there are no areas of practice that require improvement.

Information about the centre

CARE Fertility Birmingham is a private centre, located in Edgbaston, Birmingham and has held a Treatment (including embryo testing) and Storage licence with HFEA since 27 June 2017.

The centre provides a full range of fertility services including embryo testing.

The centre provided 191 cycles of treatment (excluding partner intrauterine insemination) between 27 June 2017 and 30 April 2018. In relation to activity levels this is a small centre.

The licence was varied in February 2018, to reflect a change of Person Responsible.

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 27 June 2017 to 31 January 2018 show the centre's success rates are in line with national averages:

In 2017, the centre reported 2 cycles of partner insemination with 1 pregnancy.

Multiple births[2]

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

Between 27 June 2017 and 30 April 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 19%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. Preparation for embryo transfer was observed in the course of this inspection. The observed procedure was witnessed using an electronic witnessing system, along with manual witnessing steps, in accordance with HFEA requirements. The centre's own witnessing audit was also reviewed. 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

[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, a review of the centre's records of consent to storage of gametes and embryos showed that all gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period. 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: 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 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
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding: Finding out if an EU clinic is licensed, knowledge of new legal requirements on the importation and coding of gametes and embryos and awareness of consultation on HFEA Code of Practice update.

The centre has been effective in ensuring compliance with guidance issued by the HFEA. The centre was also able to demonstrate learning from the findings of inspections of other centres within the CARE Fertility Ltd group.

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. It was noted the carry-over of drugs was not witnessed in a number of cases, however this had been identified and recorded on the centre's own audit, and appropriate action taken. It was also noted that the proprietary name of Alfentanil was not recorded at the top of the page in the controlled drugs register, corrective action was taken immediately. Due to the immediate corrective actions the centre was assessed as being 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 the following medical devices was reviewed in the course of the inspection: media, media supplements, flush solution, vitrification kits, sperm prep kits, culture dishes, tubes, sperm pots and pipettes used to handle gametes and embryos. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

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 feedback, collected during April 2018 was reviewed. Thirty patients provided feedback following consultation, with a further 19 patients providing feedback following treatment, rating the centre as excellent and would recommend the service to others.

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.

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 initial inspection in 2017, a recommendation for improvement was made in relation to one major area of non compliance.

The PR subsequently provided information and evidence that the recommendation was fully implemented prior to the report being considered by ELP.

On-going monitoring of centre success rates

Since the centre was initially licensed in June 2017, the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

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 09 May 2018.The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

To provide assurance of the 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.

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			

‘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			

‘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			

Additional information from the Person Responsible