Executive Licensing Panel Minutes

Centre 0358 (CARE Fertility Birmingham)

Interim Inspection Report

Date:	9 February 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Laura Riley Anna Coundley	Director of Strategy and Corporate Affairs Head of Regulatory Policy Policy Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Nora Cooke-O'Dowd	Licensing Manager Head of Intelligence

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 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 June 2017. The centre is part of the CARE Fertility group and provides a full range of fertility services, including embryo testing.

1.2. The panel noted that, in the 12 months to 30 September 2020, the centre had provided 505 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom has impacted on treatment numbers.

1.3. The panel noted that, HFEA register data, for the year ending 30 June 2020, show the centre's success rates are in line with the national averages, with the following exception;

- the clinical pregnancy rate following IVF in patients aged less than 38 years (involving fresh embryos created from patient's eggs) is above average at a statistically significant level.

1.4. The panel noted that, in 2019, the centre reported 12 cycles of partner insemination, with two pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, between 1 July 2019 and 30 June 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. This represents performance that is not likely to be significantly different from the 10% multiple live birth rate target for this period.

1.6. The panel noted that, due to the Covid-19 pandemic, a desk a Desk Based Assessment and Risk Based Approach (DBA/RBA), combined with a short notice on-site inspection, was conducted on 17 November 2020.

1.7. The panel noted that, at the time of the inspection, there was one 'other' area of non-compliance regarding the centre's electronic bring-forward system for stored eggs. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendation made in the report.

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

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

2. Decision

2.1. The panel noted that the centre's clinical pregnancy rate, following IVF in patients age less than 38 years (involving fresh embryos created from patient eggs) is above average at a statistically significant level.

2.2. The panel noted that the centre's most recent patient survey had only achieved an average response rate of 28%; 99% of respondents provided positive post consultation feedback and 98% of respondents stated they would recommend CARE. The centre should encourage more patients to complete the survey.

2.3. The panel noted that, in the last 12 months, only three 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 actively encourages patients to use this mechanism to provide feedback.

2.4. 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

Clare Ettinghausen

Name

Date

15 February 2021

Interim Licensing Report

Centre name: CARE Fertility Birmingham
Centre number: 0358
Date licence issued: 27 June 2019
Licence expiry date: 26 June 2023
Additional conditions applied to this licence: None
Date of inspection: 17 November 2020
Inspectors: Lesley Brown (lead), Polly Todd
Date of Executive Licensing Panel: 9 February 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.

This 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

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note that the clinic's clinical pregnancy rate following IVF in patients aged less than 38 years (involving fresh embryos created from patient's eggs) is above average at a statistically significant level.

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

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

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendation:

'Other' areas of practice that require improvement:

- The PR should risk assess the current limitations of the centre's electronic bring forward system for stored eggs.

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 June 2017. It is part of the CARE Fertility group.

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

The centre provided 505 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2020. In relation to activity levels this is a medium centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

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]

HFEA held register data for the year ending 30 June 2020 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exception:

- the clinical pregnancy rate following IVF in patients aged less than 38 years (involving fresh embryos created from patient's eggs) is above average at a statistically significant level.

For the year 2019 the centre reported 12 cycles of partner insemination with 2 clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

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

Between 1 July 2019 and 30 June 2020, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. 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. The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and had performed a desk based review of the centre's own audit of witnessing

[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%.

practice. 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.

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 broadly effective, with one exception. During a review of the centre's bring forward system for stored gametes and embryos it was noted that the full functionality of the electronic system used to manage stored eggs was not yet operational and as a result it was not possible to identify what, if any actions, are needed within a specific date range. The inspection team noted that all eggs currently in storage at the centre have effective consent to storage until 2027, therefore this issue does not pose an immediate risk that samples are in storage beyond their consented storage period. However, the inspection team was concerned that staff at the centre had not realised this weakness in the system and that it could also potentially affect frozen eggs with a shorter period of consent to storage received from other centres. See recommendation 1.

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; patient consent audit; traceability. The annual CARE group quality management review presentation was also provided and reviewed.

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:

- leadership
- patient support
- information provision
- implications of treatment and consent
- counselling
- extension of storage consent
- consent
- surrogacy
- screening
- egg sharing
- ovarian hyperstimulation syndrome reporting
- data protection and confidentiality
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- data submission to the HFEA
- 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
- HFEA Clinic Focus articles regarding release of PREP test

The centre has been effective in ensuring compliance with guidance issued by the HFEA:

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Prescription of intralipid 'off label'

Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This

guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

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, including measures taken in response to the coronavirus pandemic, 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 assessed by a desk based review of an audit of CE marking provided by the PR. We found the centre to be 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 three patients have provided feedback in the last 12 months, giving an average 3.5 star rating to the clinic. For the

system to work well, it's important that every patient knows about the rating system. The PR provided evidence to show that the HFEA feedback facility is promoted via patient information leaflets.

The centre's own most recent patient survey responses were therefore reviewed. The centre achieved an average response rate of 28%. Feedback showed that 99% of respondents provided positive post consultation feedback and 98% of respondents provided feedback saying they would recommend CARE. The ten most common negative responses were also analysed as part of their own patient feedback review.

No patients were available to speak to inspectors during this visit.

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 to one critical and three 'other' areas 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 last renewal inspection in January 2019 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.

Information regarding the clinic's compliance with requirements to submit information to the HFEA was not available for this report.

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 was established after 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

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.			

‘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.			

‘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
1. The centre’s electronic bring-forward system, for stored eggs, is not currently functioning as intended. This may put the centre at risk of storing material beyond the consented or statutory storage period. SLC T2, COP GN 17.22 This non compliance has been graded an ‘other’ as the inspection team noted that all eggs currently in storage at the centre have effective consent to storage until 2027, therefore this issue does not pose an immediate risk that samples	The PR should risk assess the current limitations of the centre’s electronic bring forward system for stored eggs. The findings of the risk assessment, along with any identified actions should be submitted to the centre’s inspector by 17 February 2021. The Licence Holder should consider if this finding is relevant to other CARE centres within the group.	We have carried out a risk assessment and submitted this to the inspector. The actions identified are a weekly manual check of the oocyte store, as well as adding a check for consent expiry to any oocytes imported into storage until such time as the electronic system can be updated to ensure automation of this check, The risk of the team being unaware of any oocyte samples approaching expiry is considered to be very low due to the relatively few patients with stored oocytes and the infrequency of transfer in of oocytes.	The executive acknowledges the PR’s response and confirms receipt of the completed risk assessment. The PR has confirmed that the limitations of the centre’s electronic bring forward system has been risk assessed, with manual risk control measures introduced. No further actions required.

are in storage beyond their consented storage period.		This non compliance has been disseminated to the CARE PRs group and the LH for consideration in other CARE centres.	

Additional information from the Person Responsible
We found the inspection process during COVID lockdown to be a very efficient way of carrying out inspections. Contact on the day was minimised and all parties were able to be well prepared.