Executive Licensing Panel - minutes

Centre 0365 (IVF London)

Interim Inspection Report

Tuesday, 3 September 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Laura Riley Yvonne Akinmodun	Director of Strategy and Corporate Affairs Head of Regulatory Policy Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Jeffrey Bowe Dee Knoyle	Licensing Manager Senior Auditor, Government Internal Audit Agency Committee Officer

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 IVF London is located in Elstree and has held a licence with the HFEA since 2018. The centre provides a full range of fertility services including embryo testing. Other licensed activities at the centre include storage of gametes and embryos.

1.2. The panel noted that, in the period between 1 October 2018 to 31 May 2019, the centre had provided 36 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a very small sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the period 1 October 2019 to 31 May 2019, show the centre's success rates are in line with the national averages.

1.4. The panel noted that, in 2018, the centre did not report any partner insemination treatments.

1.5. The panel noted that, between 1 October 2018 and 31 May 2019, the centre did not report any multiple pregnancies for all IVF, ICSI and FET cycles.

1.6. The panel noted that an unannounced inspection took place on 2 July 2019.

1.7. The panel noted that at the time of inspection there was one major area of non-compliance concerning medicines management. Since the inspection, the Person Responsible (PR) has confirmed that the recommendation made in the report has been implemented.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting the positive comments made by patients who provided feedback to the HFEA.

2. Decision

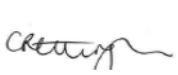
2.1. The panel particularly noted the positive patient feedback, provided through the 'Choose a Fertility Clinic' facility, available on the HFEA's website.

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

10 September 2019

Interim Licensing Report

Centre name: IVF London
Centre number: 0365
Date licence issued: 17 September 2018
Licence expiry date: 16 September 2020
Additional conditions applied to this licence: None
Date of inspection: 2 July 2019
Inspectors: Nicola Lawrence and Karen Conyers
Date of Executive Licensing Panel: 3 September 2019

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.

Newly licensed centres usually receive a licence to operate for two years and are subjected to an unannounced interim inspection after one year, to assess whether they are operating in a compliant manner. If the licence is renewed, it can be awarded 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 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 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.

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 positive comments made by patients who provided feedback to the HFEA.

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

Since the inspection the Person Responsible (PR) has confirmed that the following recommendation has been implemented:

Major area of non compliance:

- The PR should ensure the safe custody of the keys to cabinets where controlled drugs are stored at all times.

Information about the centre

IVF London is located in Elstree and has held a licence with the HFEA since 2018.

The centre provides a full range of fertility services including embryo testing. Other licensed activities of the centre include storage of gametes and embryos.

The centre provided 36 cycles of treatment (excluding partner intrauterine insemination) in the period 1 October 2018 to 31 May 2019. In relation to activity levels this is a very 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 1 October 2018 to 31 May 2019 show the centre's success rates are in line with national averages.

For the year 2018 the centre did not provide any partner insemination treatments.

Multiple births[2]

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

Between 1 October 2018 and 31 May 2019, the centre did not report any multiple pregnancies for all IVF, ICSI and FET cycles. This represents performance that is likely to be lower than 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 to review witnessing in patient records. These discussions 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, the centre's 'bring-forward' system and storage logs were 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.

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.

As the centre only opened in October 2018, it was not required that audits of all critical activity should have been undertaken by the time of the inspection. Such audits should however be performed by the time of the renewal inspection in 2020. The inspection team was however able to assess the effectiveness of the centre's QMS by reviewing the reports of the following audits: medicines management and infection control.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements. However, it was noted that the centre's audit of medicines management did not include a check of the custody of the key to the cabinet where controlled drugs are stored (see section 'Medicines management' below).

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 clinic staff 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
- ovarian hyperstimulation syndrome reporting
- data protection and confidentiality
- the use of CE marked medical devices
- HFEA Clinic Focus articles regarding screening requirements.

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 to 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 partially compliant with guidance because: the key to the cabinet where controlled drugs are kept is routinely kept in the same larger outer cupboard which houses this cabinet. Therefore, all staff accessing the outer cupboard can also access the cabinet where controlled drugs are kept. Furthermore, on the day of inspection, the outer cupboard was not locked, therefore controlled drugs were accessible to all members of staff. It was noted that the centre's audit of medicines management did not include any check of the custody of the key to the cabinet where controlled drugs are kept.

See recommendation 1.

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.

Although the centre offers intralipid therapy to patients, they have not administered intralipid therapy to any patients to date.

Written information to be 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 and found them to be compliant with guidance. However, it was noted that used linen was stored in a cloth bag on the floor of the store room adjacent to theatre. The PR provided evidence that a new linen skip had been ordered, therefore no further recommendation is considered necessary at this time.

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: culture media and plasticware used to culture and manipulate gametes and embryos. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Nine patients have provided feedback in the eight months to 4 June 2019, giving an average five star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff at the clinic.

The centre's own patient survey was reviewed on inspection and also demonstrates a theme of positive feedback.

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;
- 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 initial licence inspection in 2018, no recommendations for improvement were made.

On-going monitoring of centre success rates

Since the initial licence inspection in August 2018 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.

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.

While the focus on legal parenthood consenting has been in place since February 2014, this centre only opened in 2018. The centre's proposed legal parenthood consenting practices were considered compliant at the time of licensing in 2018.

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. 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.

The inspection team noted that the centre does not routinely ask for or check for evidence of marital status for couples having treatment with donor sperm or embryos created with donor sperm and this was discussed with the PR during the inspection. The PR assured the inspection team that he will ensure that the centre's processes for checking marital status will be made more robust, therefore no further recommendation is considered necessary at this time.

Annex 1

Areas of practice that require the attention of the Person Responsible

This 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’ 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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
1. **Medicines Management** The key to the cabinet where controlled drugs are stored is routinely kept in the larger outer cupboard which houses this cabinet. Therefore, all staff with access to the outer cupboard also have access to the cabinet where controlled drugs are kept. Furthermore, on the day of inspection, the outer cupboard was not locked, therefore controlled drugs were accessible to all members of staff. SLC T2.	The PR should ensure the safe custody of the keys to the controlled drugs cabinet at all times. Keys to cabinets where controlled drugs are stored should not be accessible to unauthorised personnel. The PR should review medicines management practices and investigate why this non-compliance occurred, including any staff training requirements. The PR should also review the centre’s audit of medicines management to	The PR will ensure the safe custody of the keys to the cabinets where controlled drugs are stored at all times. Key to cabinets where controlled drugs are stored are not accessible by unauthorised personnel. The audit tool and previous audits record the check of custody of the key to the cabinet where controlled drugs are kept.	The Executive acknowledges the PR’s response and implementation of this recommendation. The PR has provided evidence that a new key safe has been installed and has given a commitment to audit the effectiveness of this action within the required timescales. No further action is required.

NICE Guideline [NG46] April 2016 ‘Controlled drugs: safe use and management’; The Misuse of Drugs (Safe Custody) Regulations 1973.	ensure that it is robust and assesses relevant regulatory requirements. A summary report of this review should be provided to the centre’s inspector when responding to this report.	Immedialtely following this inspection, the PR reviewed the clinic's medicines management practices and investigated why this non-compliance occurred and has reviewed staff training requirements. The PR has also reviewed the centre's audit of medicines management to ensure that it is robust and assesses relevant regulatory requirements. A summary report of this review has been provided separately to the centre's inspector with this response.	

‘Other’ areas of practice that requires improvement

‘Other’ 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	Executive review
None			

Additional information from the Person Responsible