Executive Licensing Panel - minutes

Centre 0035 (Oxford Fertility)

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 Oxford Fertility has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including gamete and embryo storage, alongside embryo testing.

1.2. The panel noted that, in the 12 months to 30 April 2019, the centre had provided 1930 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the year ending 31 March 2019, show the centre's success rates are in line with the national averages, with the following exception:

- Clinical pregnancy rates following FET in patients aged less than 40 years are above average at a statistically significant level.

1.4. The panel noted that, in 2018, the centre reported 5 cycles of partner insemination, with one pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, for the period 1 April 2018 to 31 March 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is lower than the 10% multiple live birth rate target for this period.

1.6. The panel noted that an unannounced inspection took place on 26 June 2019.

1.7. The panel noted that at the time of inspection there were two major areas of non-compliance concerning storage consent and medicines management. There was also one 'other' area of non-compliance regarding the Quality Management System (QMS). Since the inspection, the Person Responsible (PR) has provided information to the centre's inspector, confirming that actions have been taken to implement these three recommendations made in the report.

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 progress made by the centre in meeting the HFEA multiple birth rate target and the positive comments made by patients in relation to their experience at the centre.

2. Decision

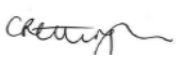
2.1. The panel noted that, in the 12 months to 28 May 2019, 133 patients had provided positive feedback on their experiences at the centre, through the 'Choose a Fertility' facility, available on on the HFEA website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.

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: Oxford Fertility
Centre number: 0035
Date licence issued: 01/10/2017
Licence expiry date: 30/09/2021
Additional conditions applied to this licence: None
Date of inspection: 26/06/2019
Inspectors: Andrew Leonard, Julie Katsaros, Victoria Brown (training)
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.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The 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 progress made by the centre in meeting the HFEA multiple birth rate target and the positive comments made by patients in relation to their experiences at the centre.

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

Major areas of non compliance:

- The PR should ensure that gametes and embryos are stored with effective consent to storage from the gamete providers.
- The PR should ensure the competence of all staff who are participating in licensed activity.

'Other' areas of practice that require improvement:

- The PR should ensure that audits are suitably robust and are documented effectively.

The PR has provided information to the centre's inspector confirming that actions have been taken to implement these three recommendations.

Information about the centre

Oxford Fertility has held a licence with the HFEA since 1992.

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

The centre provided 1930 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2019. In relation to activity levels this is a large centre.

The centre's licence was varied in July 2019, soon after the inspection, to change the Licence Holder but had not been previously varied since it was last renewed.

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 31 March 2019 show the centre's success rates in terms of clinical pregnancy rates, are in line with national averages with the following exception;

- clinical pregnancy rates following FET in patients aged less than 40 years are above average at a statistically significant level.

For the year 2018, the centre reported five cycles of partner insemination with one clinical pregnancy. Too few treatments have been performed by the centre to make an accurate comparison to national averages.

Multiple births[2]

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

HFEA held register data for the period 1 April 2018 – 31 March 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is significantly different (lower) than that required to meet 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: egg collection; embryo freezing; sperm preparation. All of the procedures observed were witnessed using an electronic witnessing system, with manual witnessing where appropriate, in accordance with HFEA requirements.

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[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%.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, 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 indicated that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are generally effective.

The centre did not however have written effective consent for the storage of cryopreserved embryos for one patient couple. The case was difficult and the patient couple were very distressed at the prospect of their embryos reaching the end of the statutory storage period and having to be allowed to perish, as the couple did not meet criteria for an extension of the statutory storage period. At the request of the couple, the PR has provided them with a month's further storage to come to terms with their loss, at the end of which the embryos will be allowed to perish. The inspection team were assured by centre staff that this situation is a very rare occurrence and also that the bring forward system is under review and contact times are to be longer before consent expiry than at present. While the inspection team sympathise and acknowledge the PR's humane approach to the gamete providers, they have to note that the one month extension of storage is unlawful and should not have been provided (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 and consent to storage of gametes and embryos.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements. This was because the inspection team noted that the reports

of audits of stored gametes and embryos and associated consents are not detailed enough regarding non conformances, corrective and preventative actions and their implementation. Some storage audit activities are also not documented within the audits. The various reports also are difficult to compile to provide an overarching summary of the compliance of the storage processes (recommendation 3).

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
- implications of treatment and consent
- storage consent
- surrogacy
- donor screening
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions

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 partially compliant with guidance. This was because the duty anaesthetist did not sign the controlled drugs (CD) register after supplying and administering CDs to two patients. He said that he would sign at the end of all procedures, as he did when working at the NHS hospital from which the centre sources anaesthetic services. He was advised that this was poor practice and that the CD register should be signed immediately drugs are supplied or administered. The anaesthetist thereafter failed to sign the CD register contemporaneously for drugs supplied and administered to the next patient. A witness signed all three entries appropriately. Similar failures to record on the anaesthetic chart the time of administration of controlled drugs, had been noted in the centre's audits and was being audited weekly to assess on-going compliance (recommendation 2).

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 at the renewal inspection at the centre in April 2017, and was considered suitable. Written information provided to patients offered intralipid therapy was also considered compliant with guidance.

Processes and information related to intralipid therapy were not reviewed 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: culture media, vitrification media and plasticware used in the processing of 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. 133 patients have provided feedback in the 12 months to 28 May 2019, giving an average 4.5 star rating to the clinic. The numbers of patients feeding back to the HFEA is significant however the centre has provided approximately 1900 treatment cycles over the feedback collection period. Ideally the number of patients feeding back to the HFEA about the centre's activities would be higher. The PR is asked to consider ways to promote the use of this facility.

The website also gives the ability for patients to comment on the cost of treatment. Most patients (82%) confirmed that they had paid what they expected to or less. A good

proportion of the 133 patients who provided feedback, also provided individual comments to the HFEA complimenting staff and the support received at the clinic.

The centre's own most recent patient survey responses were reviewed. Feedback was comparable to that provided to the HFEA.

During the inspection the inspectors spoke to two patients who also provided positive feedback on their experiences.

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 except where noted previously in this report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in April 2017, recommendations for improvement were made in relation to three major and six 'other' areas of non compliance or poor practice.

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

On-going monitoring of centre success rates

Since the last renewal inspection in April 2017, the centre has received no performance related risk tool alerts which raise concerns regarding the centre's performance.

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 and it is generally compliant with HFEA data submission requirements. There have been a number of risk tool

alerts related to the reporting of data to the HFEA about donor treatment: the PR is reminded to submit such data in a timely manner. The inspection team make no further recommendation on this matter at this time.

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 April 2017, 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. 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.

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
1. Storage consent The centre did not have written effective consent for the storage of cryopreserved embryos for one patient couple (HF&E Act 1990 (as amended), Schedule 3, 8(1)).	The PR should ensure that gametes and embryos are only stored when effective consent is in place to do so. The PR should provide the HFEA with an update on the case which led to this non compliance with the response to this report.	The couple have now allowed their embryos to be used for training and they are no longer in storage as per the agreed terms of the extension. We accept that this extension should not have been provided as the couple did not meet the criteria to extend storage and appreciate the inspection teams response to this unusual situation.	The inspection team notes the PR’s response and that actions have been taken to address this non compliance. No further actions are required
2. Medicines management The duty anaesthetist did not sign the CD register after	The PR should ensure the competence of all staff who are participating in licensed activity	The individual incident and this report have been discussed with the lead	The inspection team notes the PR’s response, the actions taken and the plans for weekly

supplying and administering CDs to two patients. Even though advised that he should do, he failed to sign the CD register contemporaneously for the next patient's CD supply and administration. A witness signed all three entries appropriately. SLC T2; DH: Controlled Drugs (Supervision of management and use) Regulation 2013; http://www.legislation.gov.uk/uksi/2001/3998/regulation/19/made	and that they adhere to the centre's established protocols and procedures. If a staff member is unable to work according to the centre's established protocols and procedures, necessary training should be provided. If no improvement is seen, the PR should consider whether continued employment of such staff members is compatible with the centre's compliant operation. The centre's inspector should be advised of the actions taken to implement this recommendation in the response to this report.	anaesthetist who agreed that the practice on the day was not appropriate and has raised this with all anaesthetists within her team so that the clinic expectations for compliance to protocol are clear. This practice will be monitored by the clinic going forward through observation within the weekly CD audit to provide assurance of best practice. Any further non-compliance will not be acceptable.	audit to assess whether the actions taken have been successful. The centre's inspector would like the PR to send to the inspector by 15 October 2019, a summary of the findings of the weekly audits between 1 July and 30 September 2019, including non conformances and planned actions to address them. No further actions are required besides the submission of the audit summary to the centre's inspector.

‘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
3. QMS The reports of audits of stored gametes and embryos and associated consents are not detailed enough regarding non conformances, corrective and preventative actions and their implementation. Some storage audit activities are also not documented within the audits. The various reports also do not provide an overarching summary of the compliance of the storage processes. SLC T36.	The PR should ensure that audits are suitably robust and are documented effectively The PR should ensure that audits of stored material and storage consents are documented in appropriate detail. The centre's inspector should be informed by 26 September 2019 of the actions taken to implement this recommendation.	We accept the comments by the inspection team regarding the storage audits presented and will ensure going forward that the audit reports are consolidated to provide a comprehensive summary demonstrating the level of compliance; the areas of activity and provide relevant detail in respect of any non-conformance. Detail of corrective actions are now recorded and tracked within QPulse through to completion. The lab staff will work with the QM to ensure the storage audit is conducted and documented effectively as per the audit requirements.	The inspection team notes the PR’s response, that corrective and preventative actions are now logged on the QPulse system and that the QM will work to ensure that the storage audit activities are consolidated. No further actions are required.

Additional information from the Person Responsible