Executive Licensing Panel - minutes

Centre 0096 (Sunderland Fertility Centre) Interim Inspection Report

Friday, 15 January 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) David Moysen Hannah Verdin	Director of Strategy & Corporate Affairs Head of IT Head of Regulatory Policy
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers	Anjeli Kara	Regulatory Policy Manager

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 Sunderland Fertility Centre, centre 0096, has held a licence with the HFEA since 1992. The centre provides basic fertility services and sperm storage facilities. The centre holds a treatment (insemination using partner/donor sperm) and storage licence, although it does not provide insemination treatment using donor sperm.

1.2. The panel noted that the centre's licence is due to expire on 31 May 2018.

1.3. The panel noted that the inspection took place on 17 November 2015.

1.4. The panel noted that in 2014 the centre reported 83 cycles of partner insemination with seven pregnancies. This represented a clinical pregnancy rate of 8%. This was in line with the national average. In relation to activity levels this is a small centre.

1.5. The panel noted that at the time of the interim inspection on 17 November 2015, three other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has started to address the non-compliances and has committed to fully implementing the outstanding recommendations.

1.6. The panel noted that the inspectorate recommends the continuation of the centre's treatment (insemination using partner/donor sperm) and storage licence.

2. Decision

2.1. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment (insemination using partner/donor sperm) and storage licence continued.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Juliet Tizzard

Date

25 January 2016

Interim Licensing Report

Centre name: Sunderland Fertility Centre
Centre number: 0096
Date licence issued: 1 June 2014
Licence expiry date: 31 May 2018
Additional conditions applied to this licence: None
Date of inspection: 17 November 2015
Inspectors: Lesley Brown (Lead), Grace Lyndon, Andrew Leonard
Date of Executive Licensing Panel: 15 January 2016

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

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

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 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

The inspection team recommends the continuation of the centre's licence.

The ELP is asked to note that at the time of the inspection, there were recommendations made in relation to three 'other' areas of practice that required improvement.

The PR has implemented the following recommendation;

- The PR should take action to comply with best practice guidance concerning documenting the identity of the person interpreting ultrasound imaging.

The PR has given a commitment to fully implement the following recommendations:

- The PR should review the performance of the quality management system to ensure learning and continual improvement.
- The PR should develop quality indicators relevant to sperm storage.

Information about the centre

The Sunderland Fertility Centre has held a licence with the HFEA since 1992. The centre provides basic fertility services and long term sperm storage facilities. The centre does not provide insemination treatment using donor sperm but holds a 'treatment (insemination using partner / donor sperm) and storage' licence. This is because this licence type is the most suitable for the centre's range of activities.

The centre provided 83 cycles of partner intrauterine insemination in 2014. 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

In 2014 the centre reported 83 cycles of partner insemination with seven pregnancies. This represents a clinical pregnancy rate of 8%, which is in line with the national average.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes and that identification errors do not occur. The following activities were observed in the course of the inspection: the identification of the sperm provider prior to procurement; the receipt of sperm in the laboratory; sperm preparation; and the identification of the patient and gametes prior to insemination. All of the procedures observed were witnessed in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

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

On inspection, storage audits and storage records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicated that the centre's processes for storing sperm in line with the consent of the sperm 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: 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 prescribed 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 and consent to storage.

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 centre's audits of: patient information; witnessing; the IUI checklist; consent; storage; consumables; and traceability
- the use of CE marked medical devices
- HFEA Clinic Focus articles regarding: screening requirements and standards for reporting and interpreting ultrasound imaging

The centre is broadly effective in implementing learning from guidance from the HFEA. A review of the radiological scanning sheet found that there are no identifiers describing the individual who interprets ultrasound imaging investigations. The centre has therefore not complied with best practice guidance issued in May 2015 (recommendation 1). Discussions with centre staff revealed staff meetings, where learning from Clinic Focus and other sources can be shared and appropriate actions considered, have not taken place for some time, nor has the QMS undergone formal, at least annual, review for the past two years (recommendation 2).

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.

The centre does not keep medicines as part of its licensed activities therefore this area of practice is not applicable to 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'.

In the course of the inspection the centre's own audit of the CE mark status of medical devices was reviewed. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, we spoke to two patients about their experiences at the centre. 21 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with twelve of the individuals providing written feedback, the majority giving compliments about the care received.

On the basis of this feedback and observations made in the course of the inspection, it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients 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 and discussions during the visit to the centre, indicate that the centre is non-compliant with the following HFEA requirements:

- The centre has not developed quality indicators relevant to sperm storage (recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013, recommendations for improvement were made in relation to four '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 2013 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.

The clinic is compliant with requirements to submit information to the HFEA

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 carried out.

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 area of non compliance requires immediate action to be taken by the Person Responsible.

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.

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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. The individual who interprets ultrasound imaging investigations is not identified in the patient records. The centre has therefore not complied with best practice guidance issued in Clinic Focus in May 2015 (SLC T2).	The PR should take action to comply with best practice guidance concerning the documenting of the identity of the person interpreting ultrasound imaging. The PR should advise the HFEA of the actions taken by 17 February 2016.	The scan form has been modified to include a space to identify the individual performing/interpreting the findings. The new form is now in use from 01/12/2015	The Executive acknowledges the PR’s response and assurance that the non compliance has been fully addressed. No further action required.
2. The ability of the QMS to support learning and continual improvement is open to question (SLC T32, Interpretation of mandatory requirements 23A) because: • as discussed in (1), Guidance in relation to scanning practices had not been acted on; • staff meetings, where learning can be shared and appropriate actions	The PR should take immediate action to review the performance of the QMS to ensure learning and continual improvement. As part of this review the PR should consider whether there are barriers to the implementation of learning from guidance provided by the HFEA and/or other sources.	Multi-disciplinary meetings have now been scheduled on a bi-monthly basis from January 2016.	The Executive acknowledges the PR’s response and his commitment to fully implementing the recommendation. Further action required.

considered, have not taken place for some time; and • the QMS has not undergone formal, at least annual, review for more than two years.	The PR should provide feedback on this review to the centre's inspector, and should implement any corrective actions found to be necessary, by 17 February 2016.	Formal review of the QMS will take part in Janusy/February 2016	
3. The centre has not established quality indicators for sperm storage (SLC T35). Although a non compliance of this type would ordinarily be categorised as 'major' in line with the compliance assessment framework, in this instance it has been downgraded as an 'other' to reflect the infrequency of the need for this service and therefore the low risk.	The PR should ensure the establishment of quality indicators and objectives for sperm storage procedures. Documentation demonstrating the establishment of the quality indicators and objectives should be provided to the HFEA by 17 February 2016.	Discussions with the Senior BMS are ongoing to establish the quality indicators and objectives for the sperm storage procedures.	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. Further action required.

Additional information from the Person Responsible