Executive Licensing Panel - minutes

Centre 0096 (Sunderland Fertility Centre)

Interim Inspection Report

Tuesday, 28 January 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dina Halai Laura Riley	Director of Strategy and Corporate Affairs Scientific Policy Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Bernadette O'Leary	Licensing Manager Clinical Inspector (Induction)

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

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

1.2. The panel noted that, in 2018, the centre reported 26 cycles of partner insemination, with four pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.3. The panel noted that, in 2018, the centre reported no multiple births.

1.4. The panel noted that a short notice inspection took place on 26 November 2019.

1.5. The panel noted that at the time of inspection there was one major area of non-compliance concerning premises. There was also one 'other' non-compliance regarding infection control. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement both recommendations made in the report, and has committed, where required, to audit the effectiveness of those actions within the required timescales.

1.6. The panel noted that the inspectorate recommended the continuation of the treatment (insemination using partner/donor sperm) and storage licence, particularly identifying the centre is well led and provides a good level of patient support.

2. Decision

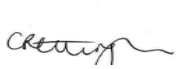
2.1. The panel noted that no patients had provided feedback on their experience of the centre, in the last 12 months, through the 'Choose a Fertility Clinic' facility available on the HFEA website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.

2.2. The panel was satisfied 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

Clare Ettinghausen

Date

4 February 2020

Interim Licensing Report

Centre name: Sunderland Fertility Centre
Centre number: 0096
Date licence issued: 31 May 2018
Licence expiry date: 30 May 2022
Additional conditions applied to this licence: None
Date of inspection: 26 November 2019
Inspectors: Sandrine Oakes (Lead) and Lesley Brown
Date of Executive Licensing Panel: 28 January 2020

Purpose of the report

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

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

This is a report of a short notice interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The 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.

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 major and one 'other' area of non-compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major area of non-compliance:

- The PR should ensure that the centre's facilities are suitable for patients and staff.

'Other' area of practice that requires improvement:

- The PR should ensure compliance with infection prevention and control regulations.

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 samples storage facilities. The centre holds a treatment (insemination using partner/donor sperm) and storage licence.

The centre currently does not provide treatments with donor sperm; however, this licence type is the most suitable for the centre's range of activities.

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 2018, the centre reported 26 cycles of partner insemination with four pregnancies, which is in line with the national average.

Multiple births

The single biggest risk of fertility treatment is a multiple pregnancy. In 2018, the centre reported no multiple births.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of sperm samples and that identification errors do not occur. There were no procedures on the day of the inspection, however the centre's witnessing practices were discussed, and the centre's own witnessing audit was reviewed. The centre's witnessing practices were considered compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of sperm samples is an important service offered by fertility clinics. It enables patients 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 sperm samples are stored in accordance with the consent of the sperm providers.

On inspection, the centre's report of the audit for all cryopreserved sperm samples, the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing sperm samples 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.

On the day of inspection, the centre did not have any procedures taking place and there was a small number of staff on duty at the time. Staffing levels were discussed with the PR and the laboratory manager. The inspection team considered levels to be 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.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing; consent to storage; traceability; infection control.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements with the exception noted in the infection control section of this report.

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
- extension of storage consent
- the use of CE marked medical devices

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

Medicines management

The centre does not keep medicines as part of its licensed activities therefore this area of practice is not relevant at this inspection.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Infection Control
It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be broadly compliant with guidance because:

- the only infection control audit performed in the last two years focussed on hand hygiene. This is too narrow in scope to demonstrate that general infection control practices at the clinic are compliant with best practice guidelines;
- one speculum in its sterile packaging had an expiry date of November 2018.

See recommendation 2.

Equipment and Materials
It is important that products (known as medical devices) that come into contact with sperm samples are approved for the provision of fertility treatment, to ensure the safety of sperm samples and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of all medical devices was reviewed in the course of the inspection. 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 centre. There was no patient feedback in the last 12 months, so there was no rating available for the centre. This is a small centre, however for the system to work well, it's important that every patient knows about the rating system. The inspection team discussed this with the PR. She felt the clinic was actively seeking patients' feedback and promoting the HFEA website. The inspection team was reassured that the PR is taking appropriate actions to remedy the low feedback rate.

The centre's own most recent patient survey responses (August 2019) were reviewed. Out of 22 responses, 95% of patients responded that they would be likely to recommend the centre to friends and family.

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 compliant with HFEA requirements with the exception of the following, where the inspection team found the centre to be partially compliant with HFEA requirements.

- The patients' toilet call alarm system near the reception is not routinely tested. On the day of the inspection, it was tested, and it was found that the alarm does not ring at the centre. Whilst the inspection team continued their tour of the premises, a member of staff from a different department on the 4th floor of the building enquired about an alarm ringing in their office. The inspection team was concerned that they did not know of the source of the alarm and would be unable to provide the required assistance.

See recommendation 1.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to four major and three 'other' areas of non-compliance.

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 December 2017, the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

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

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

Legal parenthood

This inspection theme is not relevant as the centre does not offer treatment services with donor sperm.

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’ 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	Executive review
1. Premises The patients’ toilet call alarm system near the reception is not routinely tested. On the day of the inspection, it was tested, and it was found that the alarm does not ring at the centre. Whilst the inspection team continued their tour of the premises, a member of staff from a different department on the 4th floor of the building enquired about an alarm ringing in their office. The inspection team was concerned that they did not know of the source of the alarm and would be unable to	The PR should ensure that the centre’s facilities are suitable for patients and staff. The PR should review the call alarm system for the patients and staff and inform the centre’s inspector of a plan of actions with timelines to address this non-conformance when responding to this report.	Trust Estates department has been informed to correct the alarm in patient toilet i.e. to ring with in fertility unit. Work in progress- will updated along with infection control audit [26th Feb 2020] All staff are aware of how to summon hospital security help in an emergency 777 and any staff subject to 'Lone working' are provided with a safety 'lone worker' device.	The executive notes the PR’s response and commitment to implementing this recommendation. No further action beyond submission of an update by 26 February 2020.

provide the required assistance. SLC T2. Department of Health - Health Technical Memorandum 00 Policies and principles of healthcare engineering (2014), section 3.29.			

‘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	Executive review
2. Infection Control On inspection, the following issues were identified: • the only infection control audit performed in the last two years focussed on hand hygiene. This is too narrow in scope to demonstrate that general infection control practices at the clinic are compliant with best practice guidelines; • one speculum in its sterile packaging had an expiry date of November 2018. SLC T36. CoP 25.20. Department of Health,	The PR should ensure compliance with infection prevention and control regulations. The PR should conduct an infection control audit which is sufficient to demonstrate that general infection control practices at the clinic are compliant with best practice guidance. A summary report of this audit should be provided to the centre’s inspector by 26 February 2020. The PR should review the process for ensuring that all consumables are within their expiry date. The PR should indicate which actions are being put in place to address	I assure that we will conduct an infection control audit and will forward the report in the time given to us. Prior to any use, expiry dates on all consumables will be checked. In addition, now we put in place a plan to check the trolley with consumables once every 3 months for expiry and	The executive notes the PR’s response and commitment to implementing this recommendation. No further action beyond submission of an infection control audit by 26 February 2020.

The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance (2015) sections 1.2 and 1.5.	this non-conformance when responding to the report.	this will be maintained on an continuous electronic record.	

Additional information from the Person Responsible