Executive Licensing Panel – minutes

Centre 0006 (Lister Fertility Clinic) 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 Lister Fertility Clinic, centre 0006 is located within the Lister Hospital in central London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services

1.2. The panel noted that the centre's licence is due to expire on 28 February 2018.

1.3. The panel noted that the inspection took place on 3 September 2015.

1.4. The panel noted that in the 12 months to 31 July 2015, the centre provided 2,845 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.5. The panel noted that in the 12 months to April 2015, HFEA-held register data for IVF and ICSI showed the centre's success rates were in line with national averages with the following exceptions:

- the clinical pregnancy rates following IVF in women aged under 38 years are higher than the national average at a statistically significant level.

1.6. The panel noted that in 2014, the centre reported 262 cycles of partner insemination with 37 pregnancies. This represented a clinical pregnancy rate of 14% which was consistent with the national average.

1.7. Between May 2014 and April 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 14%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% maximum multiple live birth rate target.

1.8. The panel noted that at the time of the interim inspection on 3 September 2015, three major and one other area of non-compliance were identified. The panel noted that before the inspection visit was concluded, the centre had confirmed that the recommendation to ensure that the theatre's controlled drugs cabinet was securely fixed, had already been implemented. The panel noted that the Person Responsible (PR) has committed to fully implementing the outstanding recommendations.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

2. Decision

2.1. The panel noted the non-compliances and urged the centre to address them within the prescribed timescales.

2.2. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment 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: The Lister Fertility Clinic
Centre number: 0006
Date licence issued: 01/03/2014
Licence expiry date: 28/02/2018
Additional conditions applied to this licence: None
Date of inspection: 03/09/2015
Inspectors: Sara Parlett (Lead), Susan Jolliffe, Grace Lyndon (HFEA Observer) and Gill Laver (HFEA Observer)
Date of Executive Licensing Panel: 15/01/2016

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. In particular we note the centre's clinical pregnancy rates following IVF in women aged under 38 years are higher than the national average at a statistically significant level.

The ELP is asked to note that there were recommendations for improvement in relation to three major and one 'other' areas of non compliance.

Before the inspection visit was concluded, the centre confirmed that the following recommendation had already been implemented:

'Major' area of non compliance:

- The PR should ensure that the theatre's controlled drugs cabinet is securely fixed to the wall.

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

'Major' areas of non compliance:

- The PR should assess any associated risk presented by conducting phlebotomy in clinical rooms where handwashing facilities are not readily available. The PR should seek advice on the integrity of the flooring in clinical areas to determine whether this poses an infection risk.
- The PR should ensure that audits assess compliance with regulatory requirements.

'Other' areas of non compliance:

- The PR should review practices to ensure that sharps containers are used in accordance with manufacturer's instructions and professional body guidance, and do not pose a risk to patients or staff.

Information about the centre

The Lister Fertility Clinic is situated within the Lister Hospital in central London and has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services.

The centre provided 2,845 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/07/2015. In relation to activity levels this is a large 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 in the 12 months to April 2015 show the centre's success rates are in line with national averages with the following exceptions:

- the clinical pregnancy rates following IVF in women aged under 38 years are higher than the national average at a statistically significant level.

In 2014, the centre reported 262 cycles of partner insemination with 37 pregnancies. This represents a clinical pregnancy rate of 14% which is consistent with the national average.

Multiple births[2]

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

Between May 2014 and April 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring 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: sperm preparation, thawing of embryos and preparation for embryo transfer. All of the procedures observed were witnessed using an electronic witnessing system in accordance with HFEA requirements.

[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, 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 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: 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, consent to storage, medicines management and infection control.

It is noted that the centre's own audits of infection control and medicines management failed to identify non compliance with regulatory requirements. On this basis it is concluded that the centre's procedures for auditing are partially compliant with requirements (recommendation 2).

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 use of CE marked medical devices;
- the content of the centre's website;
- the use of the most recently issued HFEA consent form versions;
- the centre's audit of legal parenthood;
- the HFEA reports of adverse incidents from 2010-2012 and 2013;
- HFEA Clinic Focus articles regarding equipment failures.

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.

On inspection it was noted that the controlled drugs cabinet in the centre's theatre was not secured to the wall. Clinic staff were unaware of this until it was brought to their attention. Action was taken to rectify this before the inspection was concluded (recommendation 3).

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 partially compliant with guidance.

The type of flooring in some clinical areas appeared to be textured and unsealed. Flooring met directly with the skirting and at corners creating sharp angles which are difficult to clean (recommendation 1).

There are no hand washing facilities in five of the nine rooms currently used for phlebotomy (recommendation 1).

Sharps containers in use in the anaesthetic room and theatre were filled beyond the recommended safe level (recommendation 4).

It is acknowledged that the centre has reported no incidence of infection.

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: embryo culture media, vitrification kits and plastic ware. The centre is compliant with the requirement to use CE marked medical devices wherever possible.

Patient experience

During the inspection, we spoke to three patients and their partners about their experiences at the centre. Eight patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was largely positive, with three of the individuals providing written feedback giving compliments about the care they 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 and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

The centre's own patient satisfaction survey results were discussed on inspection. They take corrective action based on any negative trends. The results of these surveys are carefully considered and demonstrated a learning culture at the centre.

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, with the exceptions noted elsewhere in this report.

Compliance with recommendations made at the time of the last inspection

Following the licence renewal inspection in September 2013, recommendations for improvement were made in relation to three major and eight '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

The centre has not received any HFEA automated risk tool alerts in the last year. However, alerts relating to multiple clinical pregnancy rates should have been triggered in October 2014, January 2015 and March 2015. The centre did not receive these alerts due to technical problems with the HFEA risk tool which have since been resolved.

The centre audits its multiple pregnancy rate frequently, was aware of the negative trend and has taken appropriate corrective action. The centre's current multiple clinical pregnancy rate is 14% which indicates that the multiple live birth rate is likely to be consistent with the current target.

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 centre has a number of data submission issues that the HFEA register team is working with the centre to address. However, these matters are not serious and it is not considered proportionate to categorise them as a non compliance at this stage.

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order 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. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. On inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. No issues were noted for which corrective action was required.

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
1. Infection control There are no hand washing facilities in five of the nine rooms currently used for phlebotomy. National Institute for Health and Care Excellence (2012) Infection: Prevention and control of healthcare-associated infections in primary and community care. Page 70. SLC T17. The type of flooring in some clinical areas appeared to be textured and unsealed. Flooring met directly with the skirting and at corners creating	The PR should assess any associated risk presented by conducting phlebotomy in clinical rooms where handwashing facilities are not readily available. The PR should seek advice on the integrity of the flooring in clinical areas to determine whether this poses an infection risk. The outcome of this assessment and detail of any action subsequently taken should be provided to the centre’s inspector by 3 February 2016.	An additional treatment room with sink has been installed, two further sinks are to be fitted and the remaining rooms are not used for phlebotomy only patient consultation. We have requested for the flooring to be changed with coving between the floor and the walls. The work will be completed by the end of the year. Alcohol gel is currently available in all rooms.	The PR’s response is acknowledged. The PR is requested to provide an update to the centre’s inspector by 3 January 2016. Further action is required.

sharp angles. Health Building Note 00-09: Infection control in the built environment (page 20). SLC T17.			
2. Quality Management system: The centre's own audit practices failed to identify significant areas of poor practice in infection control and medicines management. SLC T36	The PR should conduct a review of the centre's audit process to ensure that audits are performed against regulatory requirements. The outcome of the review and an action plan with timescales for the implementation of any changes should be provided to the centre's inspector by 3 January 2016.	The audit of the CD cabinet is a facility wide audit which is carried out quarterly. This template has been updated to include checking the integrity of the CD cabinet which includes secure fixings. The hospital is satisfied that regular internal and external audit of sharps management is robust. They are based on IPS audit tools used nationally. Monthly internal unannounced audits will now occur for a set period to review sharps management in theatres. The hospital had already identified the treatment room issues and had scheduled renovation works to take place at the end of the year which included replacement of flooring and installing two sinks. Our regular Infections control	The PR's response is acknowledged. The PR is requested to provide an update on progress with the scheduled works by 3 February 2016. Further action is required

		audits ensured that flooring was visibly clean, impervious to moisture and in a good state of repair. These will be updated to ensure that flooring is coved and non textured.	
3. Medicines management The controlled drugs cabinet in theatre was not secured to the wall. The Misuse of Drugs (Safe Custody) Regulations (1973) regulation 3.3. SLC T2.	Action was taken to rectify this before the inspection was concluded. However, the PR and the CDAO should ensure the security of the controlled drugs cupboard and the controlled drugs.	The PR and CDAO have ensured that the cabinet is properly secured. Quarterly audits are performed in all appropriate clinical areas using the attached audit tool in line with regulation. The Lister hospitals CD policy is attached which outlines our practices and processes are in line with regulations. The Lister Hospital also has a Home Office CD licence in line with regulation. The CDAO completes quarterly reports and updates.	The PR response is acknowledged. No further action is required

‘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
4. Infection control Sharps containers in use in the anaesthetic room and theatre were filled beyond the recommended safe level. National Institute for Health and Care Excellence (2012) Infection: Prevention and control of healthcare-associated infections in primary and community care. Page 101. SLC T2 and T23.	The PR should review practices to ensure that sharps containers are used in accordance with manufacturer’s instructions and professional body guidance and do not pose a risk to patients or staff. The PR is to provide confirmation of this when responding to this report. Three months after the implementation of any corrective action the centre should perform an audit to ensure that these corrective actions have been effective. A summary of the audit should be provided to the centre’s inspector by 3 February 2016.	A hospital wide policy is in place regarding sharps management. All staff receive annual mandatory training on use and correct disposal of sharps. Every department has a sharps audit performed quarterly. In addition an external company audits sharps management annually, this is an unannounced audit. Sharps management is also included in the Bi-annual waste audit. The Theatre Manager reviewed practice relating to sharps containers. This was reiterated to all theatre staff at their department meeting on 16.9.15. A routine audit was also carried out which found compliance of all areas.	The PR’s response is acknowledged. The PR is to provide the scheduled audit by 3 February 2016. Further action is required

Additional information from the Person Responsible