Executive Licensing Panel - minutes

Centre 0068 (Leicester Fertility Centre) Interim Inspection Report

Friday, 6 May 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Howard Ryan	Director of Strategy & Corporate Affairs Head of Regulatory Policy Technical Report Developer
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

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 Leicester Fertility Centre 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 30 September 2018.

1.3. The panel noted that the inspection took place on 1 March 2016.

1.4. The panel noted that in the 12 months to 31 January 2016, the centre provided 507 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-size centre.

1.5. The panel noted that for the period November 2014 to October 2015, HFEA-held register data for IVF and ICSI showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2015, the centre reported 236 cycles of partner intrauterine insemination with 27 pregnancies. This represents a clinical pregnancy rate of 11% which is likely to be in line with national averages.

1.7. Between November 2014 and October 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 22%. This means that the centre's multiple live birth rate is likely to be statistically higher than the 10% maximum multiple live birth rate target.

1.8. The panel noted that the centre's multiple live birth rate was 9% between 2012 and 2013. The centre's multiple pregnancy rate has therefore increased.

1.9. The panel noted that the centres' procedures are compliant with the HFEA multiple births minimisation strategy requirements.

1.10. The panel noted that at the time of the interim inspection on 1 March 2016, two major areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to fully implementing the recommendations to address these non-compliances.

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

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel encouraged the PR to make every effort to lower the centre's multiple birth rate to previous levels.

2.3. The panel was satisfied that the centre was fit to have its treatment and storage licence continued, subject to the outstanding recommendation being fully implemented within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

19 May 2016

Interim Licensing Report

Centre name: Leicester Fertility Centre
Centre number: 0068
Date licence issued: 1 October 2014
Licence expiry date: 30 September 2018
Additional conditions applied to this licence: None
Date of inspection: 1 March 2016
Inspectors: Susan Jolliffe (Lead) Vicki Lamb
Date of Executive Licensing Panel: 6 May 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 that the centre had been awarded 'team of the year' from the University Hospitals of Leicester in February 2016.

The Executive Licensing Panel is asked to note that at the time of the inspection, there were two recommendations for improvement in relation to two major areas of non compliance.

Major areas of non compliance:

- the PR should undertake a review of medicines management procedures and review information presented on the centre's website.
- the PR should undertake an audit of the effectiveness of the centre's multiple births minimisation strategy, and determine whether there are barriers to the effective implementation of the strategy for all patients provided with licensed treatment at the centre.

The PR has given a commitment to fully implement these recommendations in the prescribed timescales.

Information about the centre

The Leicester Fertility Centre has held a licence with the HFEA since 1992.

The centre provides a full range of licensed treatments.

The centre provided 507 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2016. In relation to activity levels this is a medium 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 November 2014 to October 2015 show the centre's success rates are in line with national averages.

In 2015, the centre reported 236 cycles of partner insemination with 27 pregnancies. This represents a clinical pregnancy rate of 11%. National data for this year has not yet been analysed but it is likely to be in line with national averages.

Multiple births[2]

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

Between November 2014 and October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%. This means that the centre's multiple live birth rate is likely to be statistically higher than the 10% multiple live birth rate target.

The most recent data available to HFEA show the centre's multiple live birth rate was 9% between 2012-13. However, the centres multiple pregnancy rate has increased suggesting that the centre have changed practices that mean the centre will not meet the 10% target and require review (see recommendation 2).

The centres' procedures are compliant with the HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

Witnessing

[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%.

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: thawing of gametes and an embryo transfer. All of the procedures observed were witnessed using manual and electronic witnessing systems 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 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. 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, infection control and medicines management.

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: use of revised HFEA consent forms released on 1 April 2015; the content of the centre's website, learning from adverse incidents throughout the sector including failures of laboratory alarms; the most recent legal parenthood and medicines management audit; and implementing guidance on zika virus.

The centre is partially effective in implementing learning from their audits and guidance from the HFEA (see recommendation 1) because the centre has:

- not completed corrective actions identified in their medicines management audit dated 12 January 2016.
- not ensured compliance with guidance regarding the use of websites; there is no live birth rate per treatment cycle shown, and the multiple birth rate target shown is incorrect.

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 because; on eight out of 51 occasions since the last medicines management audit in January 2016, at which time it had been identified as a problem, the controlled drug register had no record of the second signatory witnessing the administration or disposal of a controlled drug (Alfentanyl) (see recommendation 1).

After discussion with the PR and staff, it was clear that a second signatory was available in theatre, and the medicines management SOP for the centre does state that when a controlled drug is administered or wasted that a second signatory is required. The reason given for not having the second signatory on the eight occasions was that there was some confusion amongst the theatre team regarding whose role this was.

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 infection control practices were reviewed and were found to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and 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, reagents and consumables. The centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, the inspectors spoke to two patients. A further two patients provided feedback directly to the HFEA in the time since the last inspection; feedback was discussed with the PR. The centre's own patient satisfaction survey results were discussed on inspection. They have a good response rate to these surveys and take corrective action where any negative trends are identified.

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;
- 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, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is fully compliant with HFEA requirements, with the two exceptions noted elsewhere in this report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in March 2014, recommendations for improvement were made in relation to one major and nine '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

In the last year, the centre has received one alert in September 2015 relating to multiple pregnancy rates. The centre responded within the requested timescale stating that they were committed to reducing the multiple birth rate and carry out regular reviews of their Multiple Birth Minimisation Strategy to assess its effectiveness. Multiple pregnancy data are reviewed every six months by the centre (see recommendation 2).

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

When a couple to be treated with donated gametes are 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.

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 provided the report of the audit to the HFEA within the required timeframe, showing there were no legal parenthood concerns.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take consent to legal parenthood; and that effective audit procedures to ensure on-going compliance with consent taking requirements are in place. The PR provided confirmation of this.
To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of patient notes, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required, no concerns were identified. It was noted that in accordance with Trust solicitors recommendations all couples using donor gametes, regardless of relationship status sign both the WP and PP form; following discussion with the Counsellor and the PR the rationale for this was to ensure that legal parenthood is discussed and understood by all couples.

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 noted			

‘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. QMS The centre’s register of controlled drugs showed that on eight occasions since 12 January 2016, a controlled drug had been administered or disposed of without a second signature being recorded in the register, as evidence that the procedure was witnessed. The inspection team acknowledges that the drugs could all be accounted for but was concerned that the record keeping had not been	The PR should ensure compliance with medicines’ management regulations. The PR should undertake a review of medicines management procedures and in particular consider why the changes in January had not been implemented. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre’s inspector by 1 June 2016. Within three months, the	The PR and senior clinical nurse have met with the UHL Chief Pharmacist to review the medicines management policy. An audit of the procedures and corrective actions will be supplied to the HFEA within the timescales required	The Executive acknowledges the PR’s response and her commitment to fully implementing the recommendation. Further action is required

maintained in accordance with regulations, despite this being identified at the centre's last controlled drug audit on 12 January 2016. SLC T36. The Misuse of Drugs Regulations, 2001. The centre's website does not meet the requirements of Chairs' letter: CH(11)02 Responsible use of websites: the duty of centres. Code of Practice 4.5	centre should carry out an audit of controlled drugs to ensure that corrective actions have been effective in ensuring compliance. A summary report of the audit should be submitted to the centre's inspector by 1 September 2016. The PR should review the website content against the Chair's letter and update it to reflect the recommendations by 1 June 2016.	The website has been updated and the most recent live birth rates added	The executive acknowledges the PR's response and can confirm that the website is now compliance with guidance No further action is required
2. Multiple Pregnancy Rate The centre is unlikely to meet the current multiple birth rate target General Directions 0003	The PR should undertake an audit of the effectiveness of the centre's multiple births minimisation strategy and determine whether there are barriers to the effective implementation of the strategy for all patients provided with licensed treatment at the centre.	The centre is continuing to monitor its MBMS and a copy of the most recent report including corrective actions will be submitted to the HFEA within the timescales requested	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. Further action is required

	A summary report of the audit findings including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 1 June 2016.		

'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
None noted			

Additional information from the Person Responsible