Executive Licensing Panel - minutes

Centre 0170 (Gateshead Fertility Unit) – Interim Inspection Report

Friday, 30 October 2015

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

Panel members	Juliet Tizzard (Chair) Hannah Verdin David Moysen	Director of Strategy & Corporate Affairs Head of Regulatory Policy Head of IT
Members of the Executive	Dee Knoyle	Secretary
External adviser	None	
Observers	None	

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 Gateshead Fertility Unit, centre 0170, has held a licence with the HFEA since 1996 and provides a full range of fertility services.

1.2. The panel noted that the centre's licence is due to expire on 31 December 2017.

1.3. The panel noted that the inspection took place on 4 August 2015.

1.4. The panel noted that in the 12 months to 30 June 2015, the centre provided 667 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.5. The panel noted that HFEA-held register data for the period April 2014 to March 2015 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2014, the centre reported 17 cycles of partner insemination with two pregnancies. This represented performance which was in line with the national average.

1.7. Between April 2014 and March 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 21%. This means that the centre's multiple live birth rate is likely to be higher than the 10% maximum multiple live birth rate target. The panel noted that the centre had identified this and taken positive steps to address this issue, including a change of clinician job plans to allow Saturday working and transfer of single day five blastocysts and an introduction of time lapse imaging to aid identification of embryos with a higher implantation potential. The centre has recently undertaken a review of their multiple births minimisation strategy in order to identify patients who may be more at risk of a multiple birth, and had evidence that the impact of all the changes implemented by April 2015 had reduced its multiple birth rate dramatically.

1.8. The panel noted that at the time of the interim inspection on 4 August 2015, one major and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has implemented the inspectorate's recommendations for the two other areas of non-compliance and has committed to fully implementing the major area of non-compliance within the prescribed timescales. The panel noted that in consideration of the centre's engagement and action, no recommendations were made in respect of the clinic's multiple births minimisation strategy, however the centre's multiple pregnancy rates will be kept under review.

1.9. The panel noted that there were positive comments made by patients.

1.10. 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 and was satisfied that the centre was fit to have its treatment and storage licence continued. The panel noted the progress the centre has made in reducing its high multiple birth rate and encouraged the centre to continue making progress in this area.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

10 November 2015

Interim Licensing Report

Centre name: The Gateshead Fertility Unit
Centre number: 0170
Date licence issued: 01 January 2014
Licence expiry date: 31 December 2017
Additional conditions applied to this licence: None
Date of inspection: 04 August 2015
Inspectors: Susan Jolliffe, Lesley Brown.
Date of Executive Licensing Panel: 30 October 2015

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 success rates in line with national averages, and the positive comments made by patients.

The ELP is asked to note that at the time of the inspection, there were three recommendations for improvement in relation to one major and two 'other' area of practice that required improvement.

The PR has implemented the following recommendations:

'Other' areas of practice that require improvement:

- The PR should review the storage of oxygen cylinders at the centre, taking into consideration potential health and safety risks.

- The PR should ensure that the standard operating procedure (SOP) that incorporates action to be taken if staff encounter a clinical emergency during a surgical procedure, is reviewed regularly.

The PR has given a commitment to fully implement the following recommendation;

'Major' areas of non compliance**:**

- The PR should ensure that CE marked medical devices are used wherever possible.

Information about the centre

Gateshead Fertility Unit is located within the Queen Elizabeth Hospital in Gateshead and has held a licence with the HFEA since 1996.

The centre provides a full range of fertility services to both NHS and self-funded patients.

The centre provided 667 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2015. In relation to activity levels this is a medium size 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 April 2014 to March 2015 show the centre's success rates are in line with national averages.

In 2014, the centre reported 17 cycles of partner insemination with two pregnancies. This is in line with the national average.

Multiple births[2]

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

Between April 2014 and March 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 21%: This means that the centre's multiple live birth rate is likely to be higher than the 10% multiple live birth rate target.

The centre had identified this and taken positive steps to address this issue. This includes change of clinician job plans to allow Saturday working and transfer of single day five blastocysts and an introduction of time lapse imaging to aid identification of embryos with a higher implantation potential.

The centre has recently undertaken a review of their multiple birth minimisation strategy in order to identify patients who may be more at risk of a multiple birth, and had evidence that the impact of all these changes implemented by April 2015 had reduced the multiple birth rate dramatically. In consideration of this engagement and action, no recommendation has been made in respect of the clinic's multiple births minimisation strategy but the centre's multiple pregnancy rates will be kept under review.

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 inspection team was not able to observe any laboratory activities but centre staff were able to describe the witnessing procedures that are undertaken. From these discussions the inspection team was able to evaluate that the centre's procedures are witnessed in accordance with HFEA requirements using an electronic witnessing system.

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.

During the inspection we evaluated the centre's processes for storing gametes and embryos and these were compliant with HFEA requirements. The centre has a bring-forward system to ensure that all samples are stored in line with the gamete provider's consent.

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 told us they 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 SOPs 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 witnessing and consent to storage audits.

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 use of the most recently issued HFEA consent form versions
- the centre's audits of storage and witnessing

- the centre's audit of legal parenthood
- guidance issued in 2012 related to the use of non CE marked medical devices.

The centre is partially effective in implementing learning from guidance from the HFEA; they had not fully implemented guidance issued in 2013 in relation to the use of CE marked medical devices (see below and recommendation 1).

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 compliant with guidance.

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 CE mark status of medical devices was reviewed. The centre is partially compliant with HFEA requirements to use CE marked medical devices. The centre uses a non CE marked saline solution as a flush medium during egg collection. The centre's audit documented this as a non compliance and advice had been sought from the Trust pharmacy department (see recommendation 1).

Patient experience

During the inspection visit we spoke to three patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 36 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 30 of the individuals also providing written feedback commenting that they had compliments about the care that they received, and felt that staff were friendly, supportive and professional.

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;
- 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 broadly compliant with HFEA requirements; the inspection team identified the following non-compliances:

- One full oxygen cylinder was in the room adjacent to a procedure room, the cylinder was not in use and appeared to be stored in the room. The cylinder was not secured and there was no health and safety signage. Medical gas cylinders should be kept in a purpose built cylinder store that allows the cylinders to be kept safe, accessible and well ventilated, external storage is available at the centre within wire mesh cages to store medical gases safely (recommendation 2).
- The centre's SOP for responding to clinical emergencies during a surgical procedure was due to be reviewed in May 2013. There was no evidence that this critical SOP had been reviewed, revised as necessary or reapproved (see 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 three major and six '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 July 2013 the centre has received two risk tool alerts related to performance, in January and March 2015, both were due to an increase in the multiple pregnancy rates. On both occasions the PR responded to the alert and has taken appropriate action, no further alerts have been issued.

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 centre is compliant with data submission requirements.
In the last 12 months the centre has been issued with two risk tool alerts from the Register team, in February and April 2015, both have been addressed satisfactorily.

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 and that no actions had been necessary as a result of the findings.

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
1. The following medical device used by the centre is not currently CE marked: flush medium used during egg collections (SLC T30). The PR had taken action with respect to guidance provided in 2013 on expectations with respect to the use of CE marked medical devices, however the corrective actions taken as part of the audit did not fully address the non compliance. The inspection team are satisfied that all other medical devices were considered.	The PR should take action to source alternative CE marked flush medium. The PR should provide the centre inspector with an action plan indicating the proposed timescale for the introduction of an alternative product by 4 November 2015.	After discussion with our pharmacy we have arranged to source CE marked flushing medium. Three manufacturers have been identified and we are currently sourcing quotes to identify additional costings. When an appropriate supplier has been identified, the CE marked medium will be used with immediate effect.	Further action required. The inspector acknowledges the PR’s response. Further action is required and the PR is requested to provide an update to the centre’s inspector on 4 November 2015.

‘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
2. The centre had one full oxygen cylinder stored in a room on the fourth floor. When designing a gas cylinder store a risk assessment should be carried out to ensure that the location meets regulatory requirements. BCGA guidance note 2 guidance for the storage of gas cylinders in the workplace revision 5: 2012. Health Technical Memorandum.02-01: Medical gas pipeline systems Part B: Operational management.	The PR should ensure safe storage of all medical gases. The PR should complete a risk assessment for the suitability of the medical gas store. The completed risk assessment and findings, with a corrective action plan and implementation dates should be provided to the centre's inspector by 4 November 2015.	The gas cylinder in question was a size E oxygen cylinder which was stored in a wall mounted holder. This is a back up oxygen cylinder for the resuscitation policy. This has now been removed form the unit and is now stored with other medical gases in a locked cage outside of the building in line with Trust policy	The PR has assured the inspector that the oxygen cylinder is now stored safely. No further action.
3. The centre has an SOP that incorporates action to be taken if staff encounter a clinical emergency during a surgical procedure. The document control showed it was due for	The PR should provide the centre's inspector with confirmation that a robust system is in place to ensure that SOPs are reviewed, revised and reapproved at a	The SOP has been reviewed and updated accordingly - please see attached	The requested SOP has been provided. No further action.

review in May 2013. HFEA Code of Practice 31.6.	frequency that ensures they remain fit for purpose. The identified SOP should be reviewed and provided to the centre inspector by 4 November 2015.		

Additional information from the Person Responsible