Executive Licensing Panel - minutes

Centre 0254 (The Agora Gynaecology and Fertility Centre) Interim

Friday, 17 June 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 considered the papers, which included an inspection report and licensing minutes for the last three years.

1.2. The panel noted that Agora Gynaecology and Fertility Centre, centre 0254 has held a licence with the HFEA since 2007. The centre provides a full range of fertility services.

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

1.4. The panel noted that the inspection took place on 21 January 2016.

1.5. The panel noted that in the 12 months to 31 December 2015, the centre provided 672 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

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

1.7. The panel noted that in 2015, the centre reported 72 cycles of partner insemination with eight pregnancies which represents a clinical pregnancy rate of 11%. This is likely to be consistent with the national average.

1.8. Between October 2014 and September 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 20%. This means that the centre's multiple birth rate is likely to be higher than the 10% maximum multiple live birth rate target for this period.

1.9. The panel noted that at the time of the interim inspection on 21 January 2016, two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has fully implemented the recommendations to address these non-compliances.

1.10. The panel noted that there was positive feedback from patients in relation to their treatment at the centre.

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 was encouraged to see significant improvement at the centre since the last renewal inspection.

2.3. The panel 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

30 June 2016

Interim Licensing Report

Centre name: The Agora Gynaecology and Fertility Centre
Centre number: 0254
Date licence issued: 01/02/2015
Licence expiry date: 31/01/2018
Additional conditions applied to this licence: None
Date of inspection: 21/01/2016
Inspectors: Mrs Gill Walsh, Dr Victoria Lamb
Date of Executive Licensing Panel: 17/06/2016

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 positive engagement of the centre team in effectively implementing the recommendations of the last inspection and the compliments made by patients about the care they have received.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to two 'other' areas of practice.

Since the inspection the PR has provided assurance that both of the following recommendations have been fully implemented.

'Other' areas of practice that require improvement:

- The PR should review the information displayed on the centre's website against the requirements of Chair's letter CH(11)02 and CoP guidance 4.5 and make any necessary adjustments to the website information to ensure compliance with the 'responsible use of websites' guidance provided in that letter.

- The PR should inform the centre's inspector when CE marked tubes are brought into use. This should be no later than 21 May 2016.

Information about the centre

The Agora Gynaecology and Fertility Centre is located in Brighton and Hove and has held a treatment and storage licence with the HFEA since 2007 and provides a full range of fertility services to self-funded and NHS patients.

The centre was last inspected for licence renewal in October 2014. The report of this inspection was considered by Licence Committee (LC) rather than an ELP as there were a significant number and range of non compliances identified. The LC endorsed the Executive's recommendation to grant a licence for three years (with no additional conditions) rather than the usual four and also required the Executive to conduct an unannounced inspection within one year of the licence coming in to force. This is the report of that inspection visit.

There has been no application to vary this licence since it was granted in February 2015.

The centre provided 672 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2015. In relation to activity levels this is a medium sized centre.

The centre is also registered with Care Quality Commission (CQC) and was last inspected by them in December 2013. All standards inspected against were met on that occasion.

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 October 2014 to September 2015 show the centre's success rates are in line with national averages.

In 2015 the centre reported 72 cycles of partner insemination with eight pregnancies. This represents a clinical pregnancy rate of 11%. National data for 2015 has yet to be analysed but this is likely to be consistent with the national average.

Multiple births[2]

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

Between October 2014 and September 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%: this meant the centre's multiple birth rate is likely to be higher than the 10% multiple live birth rate target.

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[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%.

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: two embryo transfers. All of the procedures observed were witnessed using an electronic witnessing system and manually where necessary 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 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 and consent to storage, controlled drugs and general medicines management.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the centre's audits of witnessing, consent to storage and medicines management;
- 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;
- HFEA Clinic Focus articles regarding: screening requirements, equipment failure, medicines management and the prescribing of intralipid 'off label'.

The centre is broadly effective in implementing learning from their audits and/or guidance from the HFEA because:

- the centre's website is not compliant with guidance issued in Chair's letter CH(11)02 (recommendation 1);
- not all products in use are CE marked (recommendation 2).

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

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'.

The CE mark status of medical devices in use 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 with one exception. 5 ml tubes are not CE marked, however the laboratory manager confirmed that a CE marked alternative has been sourced and will be phased into use shortly (recommendation 2).

Patient experience

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

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

- has respect for the privacy and confidentiality of patients in the clinic;

- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients 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 compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in October 2014, recommendations for improvement were made in relation to two critical, 10 major and four 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the agreed timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in October 2014 the centre has received one risk tool alert in December 2015 relating to high multiple pregnancy rates. This was discussed on inspection. The centre's multiple birth minimisation strategy was last revised in September 2015. The PR described that multiple pregnancy rates are monitored closely and that a further revision of the multiple birth minimisation strategy is anticipated with the introduction of 'embryoscope' which is currently going through validation. The PR gave a commitment to keep the centre's multiple clinical pregnancy rates under close review. No formal recommendation is considered to be necessary at this time.

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. The register team of the HFEA currently have no concerns regarding the timeliness and accuracy of data provided by the centre.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is 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 and took appropriate action with respect to the issues identified by the audit.

The centre's legal parenthood audit was reviewed at the renewal inspection in October 2014 and showed that the audit had been performed according to the method specified by the HFEA and that actions had been taken in response to the audit findings.

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 this consent; 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 further assurance of the effectiveness of the centre's procedures, the inspection team reviewed six sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood may be required. Effective consent to legal parenthood and the offer of counselling was seen to be in place prior to consent and treatment in all cases.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None			

‘Major’ area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. **Responsible use of websites** The centre’s website displays data which is over three years old and does not display the live birth rate per treatment cycle.	The PR should review the information displayed on the centre’s website against the requirements of Chair’s letter CH(11)02 and make any necessary adjustments to the website information to ensure	The updated statistical information required and patient information to make the website compliant will be uploaded to the website before 21st April 2016	The PRs response and action to implement this recommendation is acknowledged. The centre’s website has been updated accordingly.

CH(1102 CoP guidance 4.5	compliance with the 'responsible use of websites' guidance provided in that letter. The PR should provide a summary of actions taken to the centre's inspector by 21 April 2016.		No further action is required.
2. Use of CE marked devices 5ml tubes used at the centre are not CE marked. It is however acknowledged that CE marked alternatives are to be phased in shortly. SLC T30	The PR should inform the centre's inspector when the CE marked tubes are brought into use. This should be no later than 21 May 2016.	CEmarked 5mls tubes sourced from Hunter Scientific	The PRs response and action to implement this recommendation is acknowledged. On 11 May 2016 the centre confirmed that this product is now in use. No further action is required.

Additional information from the Person Responsible