Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
21 August 2015

Minutes – item no. 2

Centre 0287 (Ayrshire Fertility Unit) – Interim Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Joanne Anton Policy Manager Ian Peacock Analyst Programmer
Members of the Executive in attendance:	Dee Knoyle Committee Secretary

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:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of application

1. The panel noted that Ayrshire Fertility Unit has held a licence with the HFEA since 2007. The centre provides partner intrauterine insemination (IUI) only.

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

3. The panel noted that the inspection took place on 1 July 2015.

4. The panel noted that in 2014, the centre reported 74 cycles of partner insemination with eight pregnancies. This represented a clinical pregnancy rate of 11% which was in line with the national average. In relation to activity levels this is a small centre.

5. The panel noted that at the time of the interim inspection on 1 July 2015, one major and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to fully implementing all of the recommendations within the prescribed timescales.

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

7. The panel noted that the inspectorate recommends that the licence is allowed to continue.

Decision

8. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment licence continued.

Signed: Date: 24 August 2015
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Ayrshire Fertility Unit
Centre number: 0287
Date licence issued: 01 November 2013
Licence expiry date: 31 October 2017
Additional conditions applied to this licence: None
Date of inspection: 01 July 2015
Inspectors: Susan Jolliffe (Lead) Lesley Brown
Date of Executive Licensing Panel: 21 August 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 a short notice interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. 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 comments made by patients.

The ELP is asked to note that there are recommendations for improvement in relation to one major and two 'other' area of non-compliance or poor practice.

Since the inspection the PR has given a commitment to fully implementing all the following recommendations within the prescribed timescales.

'Major' areas of non-compliance:

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

'Other' areas of practice that require improvement:

- The PR should ensure that a witnessing audit is performed every two years.
- The PR should ensure that the style and design of the sink, taps and flooring in the procedure room are appropriate for the environment to promote the prevention and control of infection.

Information about the centre

Ayrshire Fertility Unit has held a licence with the HFEA since 2007. The centre provides basic partner services, intra uterine insemination (IUI) to National Health Service (NHS) patients.
The centre provided 46 cycles of partner insemination in 2014, in relation to activity levels this is a very small 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

In 2014, the centre reported 74 cycles of partner insemination with eight pregnancies. This represents a clinical pregnancy rate of 11% which is in line with the national average.

Witnessing

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 during the inspection but was able to discuss witnessing with staff and to review witnessing in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The centre does not provide any storage of gametes and embryos.

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 were seen promptly on arrival, the atmosphere in the clinic appeared calm and staff were able to carry out their activities without distraction.

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 evaluating the centre's audit of procedures. The inspection team considered that the centre's audit practices are broadly compliant with requirements; the witnessing audit had not been completed in the last two years (see 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 the most recently issued HFEA consent form versions;
- the HFEA reports of adverse incidents from 2013 to 2015;
- knowledge of the HFEA Clinic Focus articles.

The centre has been broadly effective in ensuring compliance with guidance issued by the HFEA although it is noted (below) that the centre had failed to implement guidance on the use of CE marked medical devices.

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 administration of medicines were reviewed and were found to be compliant.

Infection Control

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

During the inspection, we reviewed infection control practices and found them to be broadly compliant with guidance. The following non compliance was noted:

- the procedure room has hand operated taps. The taps should be operated either by the persons elbow, or by a sensor to allow them to be easily turned on and off without recontamination on the operator's hands (see recommendation 3).
- The procedure room floor had cracks in the surface material and the central join was missing sealant in an area by the door. Maintenance is critically important in the prevention and control of infection, avoiding cracks and tears in finishes where dirt can build up (see recommendation 3).

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: syringes, media, specimen containers, serological pipettes. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical devices are not CE marked: serological pipettes (10ml) used for measuring the volume of semen samples during the assessment

process, and serological pipettes (2ml) used for the transfer of semen when setting up tubes and removing the sample that will be used for insemination (see recommendation 1).

Patient experience

During the inspection, we spoke to two patients about their experiences at the centre and 31 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 26 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 staff who are supportive, friendly and professional,
- maintains an effective system for responding to patient phone calls,
- has respect for the privacy and confidentiality of patients in the clinic.

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 and the pre-inspection assessment indicate that the centre is compliant with standard licence conditions (with the exceptions noted in this report).

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 four major and two 'other' area(s) 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 May 2013 the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

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

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. **CE marked medical devices** The following medical device used by the centre is not CE marked: serological pipettes size 10ml and 2ml. All medical devices should be CE marked. SLC T30. Clinic Focus April 2013	The PR should conduct a review of all medical devices currently in use to identify where products are not CE marked and take action to source alternatives. Where devices are not CE marked then the PR should indicate the proposed timescale for sourcing alternatives by 01 October 2015.	I already have had discussions within our departmental meetings to take this forward and hopefully will try and implement this soon.	The Executive acknowledges the PR’s responses and his commitment to fully implementing the recommendation. 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
2. **Audit** The witnessing audit had not been completed in the last two years. Centres must audit processes authorised by their licence at least every two years. SLC T36	The PR should review their audit programme to ensure that activities carried out in the process of providing treatment services are compliant with regulatory requirements. A witnessing audit should be performed. A summary of the findings of the review and the witnessing audit including any corrective actions identified and timescales for implementation should be provided to the centre's inspector by 01 October 2015.	We have a rolling independant audit process carried out by the Clinical Governance team which inspects all the systems according to QMS prescribed by HFEA. We will ensure that the witnessing audit is completed by October 2015.	The Executive acknowledges the PR’s response and his commitment to fully implementing the recommendation. Further action is required.
3. **Infection Control** The procedure room had hand operated taps SLC T17 and Standard Infection	The PR should ensure that the procedure room is suitable for the licensed activities, or other activities carried out for the purpose of providing treatment	We will conduct a risk assessment with the infection control team and keep HFEA informed. However, sanction of funds and major works as	The Executive acknowledges the PR’s response and his commitment to fully implementing the recommendation.

Control Precautions (SICPs) : Hand Hygiene Hand washing in the hospital setting by Health Protection Scotland (HPS) (page 20) The procedure room floor had cracks in the surface material and sealant missing in the join. SLC T17 and Health Building Note 00-10: Part A – Flooring (Page 3)	services to IUI patients at the centre. The PR should complete a risk assessment with the infection control lead. The findings and a corrective action plan including implementation dates should be provided to the centre's inspector by 01 October 2015.	proposed by the inspection team will take some time before it is fully implemented.	Further action is required.

Additional information from the Person Responsible
I would like to thank the HFEA team for carrying out the inspection and agree to the concerns raised. I am currently on sick leave and will try my best to implement the proposed changes within the scheduled dates as far as possible.