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
5 June 2015

Minutes – item no. 4

Centre 0021 (Hull IVF Unit) – Interim Report

Members of the Panel:	**Juliet Tizzard** Director of Strategy & Corporate Affairs (Chair) **David Moysen** Head of IT **Hannah Verdin** Head of Regulatory Policy
Members of the Executive in attendance:	**Sam Hartley** Head of Governance & Licensing

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 Hull IVF Unit has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

2. The panel noted that the centre's licence is due to expire on 30 September 2017.

3. The panel noted that the inspection took place on 14 April 2015.

4. The panel noted that in the 12 months to 28 February 2015, the centre provided 444 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

5. The panel noted that for IVF and ICSI, HFEA-held register data for the year ending 30 November 2014 showed the centre's success rates were in line with national averages.

6. The panel noted that in 2014, the centre performed one cycle of IUI with one pregnancy. This was consistent with the national average.

7. Between 1 December 2013 and 30 November 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

8. The panel noted that at the time of the interim inspection on 14 April 2015, there were no areas recommended for improvement

9. The panel noted that the inspection team recommended the continuation of the centre's licence and noted the positive comments made by patients.

Decision

10. 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 that there were no areas requiring improvement, and commended the centre in its adherence to the HFEA's regulatory regime. In particular, the panel commended the centre on its low multiple pregnancy rate, and the positive patient feedback received.

Signed: Date: 15 June 2015

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Hull IVF Unit
Centre number: 0021
Date licence issued: 01 October 2013
Licence expiry date: 30 September 2017
Additional conditions applied to this licence: None
Date of inspection: 14 April 2015
Inspectors: Andrew Leonard (lead), Janet Kirkland
Date of Executive Licensing Panel: 5 June 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 that the centre's multiple live birth rate is not likely to be statistically different from the 10% target, and the positive comments made by patients about the treatment they received at the centre.

The ELP is asked to note that there are no recommendations for improvement.

Information about the centre

The centre is located within the Hull and East Yorkshire (HEY) Women and Children's Hospital. The Hull IVF Unit has been licensed by the HFEA since 1992.

The centre offers a full range of fertility treatment to NHS and private patients. It provided 444 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2015. In relation to activity levels this is a smalll 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 year ending 30 November 2014 show the centre's success rates are in line with the national averages.

For the year 2014 the centre reported one cycle of partner insemination with one pregnancy. This is in line with the national average.

Multiple births[2]

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

Between 1 December 2013 and 30 November 2014 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This means that the centre's multiple live birth rate is not likely to be statistically different from 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 inspection team was not able to observe any laboratory activities during the inspection but was able to have discussions about witnessing with staff. Witnessing procedures described are compliant with HFEA requirements.

Consent to the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics as it can enable patients to undergo further fertility treatment without further invasive procedures being performed 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.

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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 1.3 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

On inspection, the centre provided recent reports of audits of all stored gametes and embryos and of the accuracy of all storage logs and records, including consent forms. The audits showed that there is effective consent for all gametes and embryos being stored.

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 observed in the course of the inspection 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.

Quality Management System (QMS)

It is important that clinics 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.

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

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 correct HFEA consent form versions.

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 centre'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

Having suitable arrangements in place to ensure that patients experience care in a clean environment is important, as well as ensuring that both patients and staff are protected from acquiring infections.

During the inspection, we assessed compliance with infection control guidance by observation and found that the centre's procedures were 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 and 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: culture media; vitrification kits; tubes used during egg collection. The centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Nineteen patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 14 of the individuals providing written feedback that they have compliments about the care they had 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 and observations during the visit to the centre, indicate that the centre is fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in May 2013, recommendations for improvement were made in relation to one major and three 'other' areas of non-compliance. The PR 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 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. This information is held in the HFEA Register.

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

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
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
None			

Additional information from the Person Responsible