HFEA Executive Licensing Panel Meeting

24 April 2014

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

Minutes – Item 2

Centre 0278 – (Assisted Conception Unit, Leigh Infirmary) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair) David Moysen – Head of IT Joanne Anton – Policy Manager	Dee Knoyle

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 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 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 Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the Assisted Conception Unit, Leigh Infirmary is part of the Obstetric and Gynaecology Directorate of Wrightington, Wigan and Leigh NHS Trust and has been licensed by the HFEA since 2007. The centre provides treatment (insemination using partner sperm) and also provides in vitro fertilisation (IVF) satellite services for CARE Manchester (centre 0185) and St Mary's Hospital NHS Trust (centre 0067). Patients who require IVF are treated up to the point of egg collection and then referred to either centre 0185 or 0067 for completion of their treatment.

2. The Panel noted that the centre is currently on a four-year licence, due to expire on 30 June 2016.

3. The Panel noted that the inspection took place on 30 January 2014.

4. The Panel noted that in the 12 months to 31 December 2013, the centre reported 207 cycles of partner insemination with 28 pregnancies. This equates to a clinical pregnancy rate of 13%, which is in line with national averages.

5. The Panel noted that during 2013 the centre had four multiple pregnancies.

6. The Panel noted that there were no areas of non-compliance or poor practice identified and commended the centre for this.

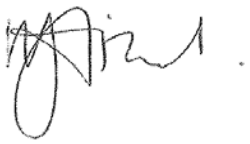
7. The Panel noted in particular the positive comments made by patients in relation to their experience of the centre.

8. The Panel noted that the Inspectorate recommends the continuation of the centre's licence.

Decision

9. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Treatment (insemination using partner sperm) licence continued.

10. The Panel approved the Inspectorate's recommendation to continue the centre's licence with no additional conditions.



Signed: Date: 8 May 2014

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Assisted Conception Unit Leigh Infirmary
Centre number: 0278
Date licence issued: 01/07/2012
Licence expiry date: 30/06/2016
Additional conditions applied to this licence: None
Date of inspection: 30/01/2014
Inspector: Mr Parvez Qureshi
Date of Executive Licensing Panel: 24/04/2014

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 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

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 with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspector to form a conclusion on the continuation of the centre's licence. The inspector recommends the continuation of the centre's licence. In particular the inspector notes the implementation of recommendations made at the time of the last inspection and the positive comments made by patients in their feedback in relation to their experiences at the centre.

The ELP is asked to note that there are no recommendations for improvement resulting from this inspection.

Information about the centre

The Assisted Conception Unit, Leigh Infirmary is part of the Obstetric and Gynaecology Directorate of Wrightington, Wigan and Leigh NHS Trust and has held a licence with the HFEA since 2007 for basic partner treatment services. A fee paying service is available to those patients who do not fulfil the National Health Service (NHS) criteria for Intrauterine Insemination (IUI) treatment.

The unit provides in vitro fertilisation (IVF) satellite services for CARE Manchester (centre 0185) and St Mary's Hospital NHS Trust (centre 0067). Patients who require IVF treatment are treated up to the point of egg collection and then referred to either centre 0185 or 0067 for completion of their treatment.

The centre provided 207 cycles of partner IUI in the 12 months to 31 December 2013. In relation to activity levels this is a small centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

For the year 2013 the centre reported 207 cycles of partner insemination with 28 pregnancies; this equates to a clinical pregnancy rate of 13%. The centre's clinical pregnancy rate is in line with national averages.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy. During 2013 the centre reported four multiple pregnancies.

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 activity was observed in the course of the inspection: sperm preparation. All of the procedures observed were witnessed in accordance with HFEA requirements using a manual system.

The inspector was able to review five sets of patient notes and concluded that appropriate records of manual witnessing are maintained.

[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.
[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The HFEA does not hold information, including records of intentions relating to consent to disclosure, about patients having IUI treatment. Therefore the centre is not required to collect and report consents for disclosure to researchers.

Consent: To the storage of cryopreserved material

This inspection theme is not relevant as the centre does not offer storage of cryopreserved material.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: there was an IUI clinic running at the time of this inspection and patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times. A discussion held with staff confirmed that staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit the inspector spoke to two patients who provided feedback on their experiences. A further eight patients (both IUI and IVF satellite) also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive from the majority of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they 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;
- gives prospective and current patients sufficient, accessible and up-to-date information.

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

From the information submitted by the centre in their self-assessment questionnaire and from observations during the visit to the centre no additional non-compliances were identified.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in January 2012 recommendations for improvement were made in relation to one area of major non-compliance and one 'other' area of non-compliance.

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

On-going monitoring of centre success rates

This centre is not subject to on-going monitoring through the HFEA risk tool and has not therefore been issued with any performance 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 centre provided its annual IUI treatment return for 2013 within the required timescale.

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’ area 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			

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Centre name & number: Assisted Conception Unit Leigh Infirmary 0278

‘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
- 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 noted			

‘Other’ areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non compliance, but which indicates 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