Interim Licensing Report

Centre name: London Women's Clinic, Darlington
Centre number: 0075
Date licence issued: 1 April 2011
Licence expiry date: 31 March 2015
Additional conditions applied to this licence: None
Date of inspection: 15 November 2012
Inspectors: Gill Walsh (Lead), Sara Parlett
Date of Executive Licensing Panel: 1 March 2013

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 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 inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note: the progress made by the centre in meeting the HFEA multiple birth rate targets, the high level of compliance with the HFEA code of practice demonstrated by the centre team and the positive comments made by patients in relation to their experiences.

The team have no recommendations for improvement following this inspection.

Information about the centre

The London Women's Clinic, Darlington is located in Darlington, County Durham and has been licensed by the HFEA since 1992. The centre's current licence was issued on 1 April 2011 for a period of four years with no additional licence conditions.

The centre provides a full range of fertility services.

The centre provided 244 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2012. 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]

HFEA held register data for the year ending October 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2011 the centre reported one cycle of partner intrauterine insemination with no pregnancy. This is in line with the national average.

Multiple births[2]

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

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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.

[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.

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 31%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to April 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%: this also represents performance that is not likely to be statistically different from the 15% live birth rate target.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple 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.

There were no procedures being conducted in the laboratory on the day of inspection therefore witnessing practice could not be directly observed.

The inspection team was able to discuss witnessing procedures with the laboratory team and conduct a review of records that were present in 10 sets of patient notes and concluded that compliant records of manual witnessing are maintained.

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 records of consent to disclosure to researchers given by 10 patients and their partners were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in all of the records reviewed.

Consent: To the storage of cryopreserved material

A review of the centre's records of consent to storage of gametes and embryos showed that all gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period.

The storage period for three sets of embryos as recorded on the centre's database was cross checked against the consenting decisions made by the gamete providers as recorded in the gamete provider's primary record. The storage period had been accurately recorded in all cases.

Staffing

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

There was little patient activity on the day of inspection and no laboratory procedures were taking place and so it was difficult to assess staffing levels during periods of high activity. Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival and the atmosphere in the clinic appeared calm at all times. The staff stated the team work flexibly to accommodate fluctuations in patient and laboratory activity by grouping patient treatments where possible. The laboratory staff stated that they 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 we spoke to two patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further four patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback overall was very positive with two of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received during treatment.

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 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

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

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in October 2010 recommendations for improvement were made in relation to one area of critical non-compliance, six areas of major non-compliance and five 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

The on-going monitoring of the centre's success rates for 2012 has demonstrated that the centre's performance is consistently in line with the national average. The centre has not been issued with any performance alerts in 2012.

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 register team of the HFEA report that the quality of data submitted by the centre to the HFEA is good and that the centre has a good record of compliance with data submission requirements.

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			

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			

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			

Additional information from the Person Responsible
On behalf of the team I thank the inspectors for conducting the unannounced inspection with such sensitivity and professionalism. It was greatly appreciated.

HFEA Executive Licensing Panel Meeting

1 March 2013

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

Minutes – Item 3

Centre 0075 – (London Women's Clinic, Darlington) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Jasper Squire – Computer Programmer David Moysen – Head of IT	Rebecca Loveys

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also 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 this is a small centre which provides a full range of fertility services, and has been licensed since 1992.

2. The Panel noted that the centre's current licence is due to expire on 31 March 2015.

3. The Panel noted that in the 12 months to 31 October 2012 the centre provided 244 cycles of treatment (excluding partner intrauterine insemination).

4. The Panel noted that the twelve recommendations made by the Inspectorate in its last renewal inspection report were evidenced as completed.

5. The Panel congratulated the centre on having no recommendations for improvement following this inspection in November 2012.

6. The Panel noted the centre's high level of compliance.

7. The Panel noted the positive patient feedback received by the centre.

Decision

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

Signed:  Date: 11 March 2013

Mark Bennett (Chair)