HFEA Executive Licensing Panel Meeting

25 July 2014

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

Minutes – Item 3

Centre 0196 – (Jessop Fertility) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Paula Robinson (Chair) – Head of Business Planning Nick Jones – Director of Compliance & Information Ian Peacock – Analyst Programmer	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

1. The Panel noted that Jessop Fertility is located in Sheffield and has held a licence with the HFEA since 2001. 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 2016.

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

4. The Panel noted that in the 12 months to 31 March 2014, the centre provided 1104 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

5. The Panel noted that in 2013, the centre reported 256 cycles of partner insemination with 31 pregnancies, two of these were twin pregnancies. This equates to a 12% clinical pregnancy rate which represents performance that is not considered likely to be statistically different from the 10% maximum live birth rate target that has been in place since October 2012.

6. The Panel noted that for IVF and ICSI, HFEA-held register data for the year ending 31 March 2014 show that the centre's success rates are not likely to be statistically different from the national averages, with the following exceptions:

    - clinical pregnancy rates for FET cycles using IVF or ICSI in patients aged 16-39 are lower than average at a statistically significant level.

    - clinical pregnancy rates by cycle for ICSI treatments using fresh embryos in patients aged 16-37 are lower than average at a statistically significant level.

    - clinical pregnancy rates by cycle for IVF treatments involving fresh embryos in patients aged 16-37 are lower than average at a statistically significant level.

7. However, analysis of the data shows that there was a marked decrease in success rates during a particular period of time that correlates with a grade A incident that was caused by a faulty oxygen sensor in one of the centre's incubators. It is therefore likely that this incident is directly responsible for the centre's success rates being lower than the national average for the year ending 31 March 2014.

8. During the inspection, the PR provided assurance that their own analysis of data (too recent to be available to the HFEA) shows that success rates are returning to a level consistent with those achieved before the incident.

9. Between 1 February 2013 and 31 January 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%: this represents performance that is not likely to be statistically different from

the 10% maximum live birth rate target that has been in place since October 2012.

10. The Panel noted that at the time of inspection one major and one other area of non-compliance were identified. The Panel noted that both recommendations for improvement have been implemented.

11. The Panel noted that, in consideration of the information provided by the centre documenting the corrective actions taken, the Inspectorate concluded that the PR has taken steps to ensure the use of suitable practices in compliance with the HF&E Act 1990 (as amended), Section 17 (1)(d). The Inspectorate therefore, considers it proportionate not to make any recommendations concerning regulatory action in relation to success rates at this time. However the centre's success rates will continue to be closely monitored by the HFEA.

Decision

12. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued.

13. The Panel noted the information about success rates, and the circumstances in which this had occurred, and was in support of the Inspectorate monitoring the centre's success rates closely, as planned.

Signed: Date: 31 July 2014
Paula Robinson (Chair)

Interim Licensing Report

Centre name: Jessop Fertility
Centre number: 0196
Date licence issued: 1 October 2012
Licence expiry date: 30 September 2016
Additional conditions applied to this licence: None
Date of inspection: 30 April 2014
Inspectors: Mrs Susan Jolliffe (Lead), Dr Douglas Gray
Date of Executive Licensing Panel: 25 July 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 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 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 (ELP) 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.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to one 'major' area of non-compliance and one 'other' area of practice that requires improvement.

In providing feedback on this report the PR provided evidence that the following recommendation has been implemented;

'Other' areas of practice that require improvement:

- The PR should ensure that all licensed treatment activity is reported accurately to the HFEA within the timeframes required.

The PR has provided assurance that the following recommendation will be implemented.

'Major' areas of non-compliance:

- The PR should continue with their plan of action to gain CPA accreditation for the laboratory that carries out diagnostic semen analysis.

Information about the centre

Jessop Fertility is located in Sheffield and has held a licence with the HFEA since 2001.

The centre provides a full range of fertility services to National Health Service (NHS) and self funding patients.

The centre provided 1104 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2014. In relation to activity levels this is a large 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.

Pregnancy outcomes[1]

In 2013, the centre reported 256 cycles of partner insemination with 31 pregnancies, two of these were twin pregnancies. This equates to a 12% clinical pregnancy rate which represents performance that is not considered likely to be statistically different from the 10% live birth rate target that has been in place since October 2012.

For IVF and ICSI, HFEA held register data for the year ending 31 March 2014 show that the centre's success rates are not likely to be statistically different from the national averages with the following exceptions;

- clinical pregnancy rates for FET cycles using IVF or ICSI in patients aged 16-39 are lower than average at a statistically significant level.

- clinical pregnancy rates by cycle for ICSI treatments using fresh embryos in patients aged 16-37 are lower than average at a statistically significant level.

- clinical pregnancy rates by cycle for IVF treatments involving fresh embryos in patients aged 16-37 are lower than average at a statistically significant level.

Analysis of our data shows that there was a marked decrease in success rates during a period of time that correlates with a grade A incident caused by a faulty oxygen sensor in one of the centre's incubators. It is therefore likely that this incident is directly responsible for the centre's success rates being lower than the national average for the year ending 31 March 2014.

During the inspection, the PR provided assurance that their own analysis of data (too recent to be available to the HFEA) shows that success rates are returning to a level consistent with those achieved before the incident.

[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 $p \leq 0.002$.

In consideration of the information provided by the centre documenting the corrective actions taken, it is concluded that the PR has taken steps to ensure the use of suitable practices in compliance with the HF&E Act 1990 (as amended), Section 17 (1)(d). The inspection team considers it proportionate therefore not to make recommendations at this time concerning regulatory action in relation to success rates. The centre's success rates will continue to be closely monitored by the HFEA.

Multiple births[2]

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

Between 01 February 2013 and 31 January 2014 the multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 12% this represents performance that is not likely to be statistically different from the 10% live birth rate target that has been in place since October 2012.

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: egg collection, sperm preparation, donor sperm preparation and disposing of gametes. All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic or manual witnessing system. The inspection team was able to review records that were present in the laboratory and concluded that records of electronic and 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 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 database indicated that gametes and embryos currently in store are being stored within their consented storage period.

Staffing

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

[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%.

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; 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.

Patient experience

During the inspection visit we spoke to four patients (two couples) who provided feedback on their experiences and observed interactions between centre staff and patients. A further 20 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 11 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received, whilst three had complaints which were shared with the PR.

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, the inspection team identified the following non-compliance:

The centre's andrology laboratory that undertakes diagnostic sperm analysis for the purpose of licensed activities is not accredited by the CPA or another body accrediting to an equivalent standard (T21). (see recommendation 1). The PR provided assurance that appropriate preparatory activities are being taken ahead of an application for CPA accreditation later in 2014.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in May 2012 recommendations for improvement were made in relation to two 'other' area(s) 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

In the last twelve months, the centre has been issued with one performance alert in relation to success rates following ICSI with fresh embryo transfer.

The PR has kept the HFEA informed of actions taken in relation to the review of these procedures (see page 3 of this report).

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 is broadly compliant with data submission requirements. The centre has received four risk tool alerts in the last year for treatments using unregistered donor gametes. At the time of the inspection six treatments in which the gametes of apparently unregistered donors had been used had been reported to the HFEA. The PR checked these at the inspection and found that the clinic had registered the donors but there had been an error in their administrative work which resulted in the donors appearing not to be registered (see recommendation 2).

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			

‘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
1. The centre’s andrology s laboratory where diagnostic semen analysis is carried out is not accredited by the CPA (UK) or by another body accrediting to an equivalent standard. (SLC T21).	The inspection team acknowledge that the centre is seeking CPA accreditation for the andrology laboratory. Following discussion with the PR it is anticipated that accreditation will be achieved by 30 April 2015. The PR should inform the HFEA when accreditation is achieved, or if there is any change to the plan, or timeline.	The Andrology department has started the process of preparing for CPA accreditation. The centre has employed an external consultant to help with the project.	The centre has started to make progress towards CPA accreditation. Monitoring will continue to ensure that CPA accreditation is achieved within the agreed timescale.

‘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
2. The centre has had four risk tool alerts in the last year in relation to ‘treatments with unregistered donors’. The PR has not provided the information required by the Authority within the timescales required. (SLC T9(e) / T41) (General Directions 0005). **This was a non-compliance at the last inspection.**	At the time of writing six treatments in which the gametes of apparently unregistered donors have been used have been reported to the HFEA. The PR has agreed to work with the HFEA register team to provide the outstanding data by 30 May 2014. The PR should review the process for inputting data, and identify if this is a training issue for staff, and address any identified training needs. The outcome of this review and any actions taken should be shared with the lead inspector by 30 July 2014.	All outstanding queries have been dealt with. The problem arose because although RBAT Alerts are sent there is no way of finding out the forms which relate to the alert. It was agreed that in future the HFEA would send the details of the problem forms with the alert.	The centre currently has no outstanding corrections related to ‘treatments with unregistered donors’. No further action required.

Additional information from the Person Responsible

The report highlights the lower than expected pregnancy rates and the reason why this occurred (incident related to an incubator). All patients who had a compromised chance of a success pregnancy were fully informed and received further cycles funded by the unit.
The HFEA figures also do not take into account the cycles where elective freeze alls have taken place in recurrent implantation failure patients where there is mounting evidence that replacing frozen embryos may improve outcomes.
This year the centre has invested in new timelapse incubators which improve the stability of the culture environment and improved success rates are now being achieved.