HFEA Executive Licensing Panel Meeting

24 April 2014

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

Minutes – Item 3

Centre 0259 – (Epsom & St Helier NHS Trust) – 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 Epsom and St Helier NHS Trust is located in Carshalton, Surrey and has held a licence with the HFEA since 2007. The centre provides treatment (insemination using partner sperm) and also provides transport IVF services to The Bridge Centre (centre 0070) and ACU Kings College Hospital (centre 0109) for approximately 200 patients per annum.

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 10 December 2013.

4. The Panel noted that in the 12 months to 31 December 2012, the centre reported 17 cycles of partner insemination with one pregnancy, which is in line with national averages.

5. The Panel noted that during 2012 there were no multiple pregnancies reported as a result of IUI treatment provided at this centre.

6. The Panel noted that at the time of inspection there were two 'other' areas of non-compliance identified. The Panel noted the steps the PR had taken to address the non-compliances and her commitment to fully implement both recommendations within the prescribed timescales.

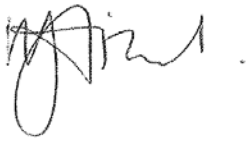
7. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

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: Epsom and St Helier NHS Trust
Centre number: 0259
Date licence issued: 01/07/2012
Licence expiry date: 30/06/2016
Additional conditions applied to this licence: None
Date of inspection: 10/12/2013
Inspectors: Parvez Qureshi (Lead) and Gill Walsh
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 (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. In particular we note the positive comments made by patients in their feedback in relation to their experiences at the centre.

The Executive Licensing Panel is asked to note that there were no recommendations for improvement in relation to 'critical' and 'major' areas of non-compliance but recommendations were made in relation to two 'other' areas of non-compliance at the time of the inspection:

In providing feedback on this report the Person Responsible (PR) has given a commitment to fully implement the following recommendations:

'Other' areas of practice that require improvement:

- The PR should review the process for seeking consent to disclosure to in consideration of which elements of consent to disclosure apply to different patient groups. Staff seeking consent to disclosure must ensure patients providing their consent are properly informed and that the forms completed accurately reflect this.

Subsequent to the review of the report by the PR it was agreed that the following recommendation requires no further action by this centre but is for the primary centre's for which this centre acts as a provider of transport IVF to implement;

- The PR should audit a sample of consent to disclosure forms completed by transport IVF patients to assess whether the inspection observations represent a common failure to document consent decisions consistently. A report of the audit findings including corrective actions and the timescale for their implementation should be provided to the HFEA.

The HFEA will liaise with the relevant primary centres in relation to the implementation of this recommendation.

Information about the centre

The Epsom and St Helier NHS Trust is located in Carshalton, Surrey and has held a licence with the HFEA since 2007.

The centre provides partner intrauterine insemination (IUI) treatment to NHS and self funded patients. The centre also provides transport IVF services to The Bridge Centre (centre 0070) and ACU Kings College Hospital (centre 0109) for approximately 200 patients per annum.

The centre provided 17 cycles of partner IUI in the 12 months to 31 December 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]

For the year 2012 the centre reported 17 cycles of partner insemination with one pregnancy; 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. There were no multiple pregnancies reported for 2012 as a result of IUI treatment provided at this centre.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and identification errors do not occur. At the time of this inspection no laboratory procedures were taking place therefore no witnessing activities were observed in the course of the inspection. However, a discussion held with centre staff and a review of the centre's witnessing standard operating procedure showed that the centre has a robust witnessing procedure in place in accordance with HFEA requirements.

The inspection team 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.

A review of six patient records was conducted on inspection to review the consents taken to the disclosure of information to researchers.

The audit showed that patients having IUI treatment were being asked to consent to disclosure of their treatment information to researchers. The HFEA does not hold any information about patients' IUI treatments and so these sections of the consent forms are not relevant to this patient group.

The audit also showed that consents to disclosure provided by patients having transport IVF treatment were not completed accurately: there were alterations and discrepancies between the consent provided by partners. This meant that it was sometimes difficult to clearly understand the patients' consent decisions.

The inspection team were concerned that this may indicate that staff did not fully understand the nature of the consent they were seeking and that as a result, patients may not have received accurate information about the implications of giving the consent. See recommendation 1.

The records of consent to disclosure to researchers provided by three transport IVF patients whose records were audited were submitted to the HFEA by the primary centres (0070 and 0109) completing the treatment of patients initiated at Epsom and St Helier NHS Trust. The consent decisions reported to the HFEA did not match those in the patient records in all cases. While it is acknowledged that the reporting of these consent decisions is not the responsibility of Epsom and St Helier NHS Trust, there is a responsibility to ensure that the forms passed to the primary centres can be accurately interpreted. See recommendation 2.

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 no IUI clinic running at the time of this inspection, however transport IVF 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 we spoke to six patients who provided feedback on their experiences. A further 36 patients (both IUI and transport IVF) also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 25 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 by the inspection team.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in December 2011 no recommendations for improvement were made.

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 2012 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.			

‘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
1. A review of the records of six patients showed that patients having IUI treatment were being asked to consent to disclosure of their treatment information to researchers. The HFEA does not hold any information about	The PR should review the process for seeking consent to disclosure to in consideration of which elements of consent to disclosure apply to different patient groups. Staff seeking consent to disclosure must ensure patients providing their consent are properly informed and that the forms completed accurately reflect this.	As from 10th December 2013 Consent to Disclosure form part 1 is now being used for all IUI patients. Training session with team was conducted on 11th December 2013 regarding the use of the CD forms. We will set up an audit to monitor CD form completion immediately for both IUI and	The PR’s response is noted. No further action required.

	patients' IUI treatments and so these sections of the consent forms are not relevant to this patient group.	The PR should inform the lead inspector of the outcome of this review and any changes in practice implemented as a result by 10 March 2014.	transport IVF activity and re audit as appropriate.	
2.	The records of consent to disclosure to researchers provided by three transport IVF patients were not completed accurately: there were alterations and discrepancies between the consent provided by partners. This meant that it was sometimes difficult to clearly understand the patients' consent decisions. The inspection team were concerned that this may indicate that staff did not fully understand the nature of the consent they were seeking and that as a result, patients may not have received accurate information about the	The PR should audit a sample of consent to disclosure forms completed by transport IVF patients to assess whether the inspection observations represent a common failure to document consent decisions consistently. A report of the audit findings including corrective actions and the timescale for their implementation should be provided to the HFEA. While it is acknowledged that the reporting of these consent decisions is not the responsibility of Epsom and St Helier NHS Trust, there is a responsibility to ensure that the forms are completed accurately and can be accurately interpreted by the primary centres.	As the PR of 0259 I am not the PR for 0070 & 0109 so unable to compare to the HFEA data. We will make available our audits to the PRs of these units and the HFEA directly.	The PR's response is acknowledged. Further action is required in relation to the submission of the audit of the accuracy of completion of these consent forms and any corrective actions implemented as a result. The HFEA will liaise with the primary centres to ensure records of consent to disclosure to researchers provided by transport IVF patients are reported accurately to the HFEA.

implications of giving the consent. The subsequent submission of these records by the primary centres (0070 and 0109) to the HFEA through EDI were not reported accurately in all cases.			

Additional information from the Person Responsible
The interim inspection for our IUI licence has for understandable reasons encompassed inspection of our transport IVF activity. I acknowledge the discrepancies found with regard to completion of the CD form and have already instigated training and audit of this activity. However as the transport IVF activity is not covered by the IUI licence I have no jurisdiction with regard to the data submitted to the HFEA for unit 0070 & 0109 as I am sure the panel is aware. I have also not been able to discuss the issue as yet with the PRs of the above units as the Interim report is strictly confidential. Clarification of actions that are my responsibility as PR for the unit at St Helier (0259 IUI licence) should be clearly separated from actions required of me on behalf of the PR's in units 0070 & 0109