Interim Licensing Report

Centre name: South East Fertility Clinic
Centre number: 0208
Date licence issued: 01/05/2009
Licence expiry date: 30/04/2014
Additional conditions applied to this licence: None
Date of inspection: 28/11/2012
Inspectors: Ms Janet Kirkland (Lead), Dr Andrew Leonard
Date of Executive Licensing Panel: 08/02/2013

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 (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 centre's effective process for seeking patient feedback and evaluating patient satisfaction.
- The positive comments made by patients in feedback questionnaires submitted to the HFEA.

The Executive Licensing Panel is asked to note that at the time of inspection there were recommendations for improvement in relation to one 'critical', one 'major' and two 'other' areas of non-compliance.

The PR has since the inspection provided evidence and assurances that the following recommendation has been complied with:

'Other' areas of non-compliance or poor practice that require improvement:

- The PR should ensure either that the tubes at egg collection are appropriately labelled and that transfers between tubes and dishes are witnessed or that the risks of the current practice of not labelling or witnessing at egg collection are assessed and appropriate risk control measures are documented, implemented and recorded.

The PR has committed to comply with the following non-compliances within the documented timescale.

Critical areas of non- compliance:

- **The Person Responsible (PR) should ensure that no gametes or embryos are kept in storage for longer than the consented period.**

Major areas of non- compliance:

- The PR should ensure that witness checks are performed and documented in a manner compliant with HFEA requirements.

'Other' areas of non-compliance or poor practice that require improvement:

- The PR should audit a sample of patient and partner consents to disclosure of identifying information to researchers documented in patient records, against the consent decisions recorded in the HFEA Register, to determine whether the consent discrepancies between these sources noted on inspection are isolated occurrences or are more prevalent.

Information about the centre

The South East Fertility Clinic is located in Tunbridge Wells and has held a licence with the HFEA since 2007. The centre provides a full range of fertility services.

The centre provided 482 cycles of treatment in the 12 months to 30 September 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 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 30 June 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2012 the centre reported 53 cycles of partner insemination with eight pregnancies.This indicates a 15% success rate which is consistent with the national average.

Multiple births[2]

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

For the time period 1 April 2010 to 31 March 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%. This represented performance that was not likely to be statistically different from the 20% multiple live birth rate target.

For the time period 1 July 2011 to 30 June 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 25%. This also represents performance that is not likely to be statistically different from 15% multiple live birth rate target for this time period.

While it is acknowledged that the centre's clinical multiple pregnancy rate indicates performance not likely to be different from the relevant targets, it is recommended that the centre review the current multiple birth rate minimisation strategy in consideration of the 10% live birth rate target that became effective on 1 October 2012.

Witnessing

Good witnessing processes are vital to ensure 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 provider ID check: sperm

[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.

preparation; embryo transfer. All of the procedures were manually witnessed and checks were made and documented in accordance with HFEA requirements, with some exceptions discussed below.

The inspection team was able to review witness check sheets that were present in the laboratory and in 10 sets of patient records provided by centre staff. From this we could conclude that accurate records of manual witnessing are maintained, with two exceptions discussed below.

The following non-compliances were observed:

- The tubes used during egg collection to transfer follicular fluid containing eggs to the laboratory were not labeled with patient identifiers, so the transfer of follicular fluid from the tubes to dishes could not be witnessed. This could lead to a risk of misidentification if unmarked tubes from one patient are inadvertently left in a critical work area when a second egg collection commences. To mitigate the risks, staff ensure that the eggs of only one patient are present within the procedure room and laboratory critical work areas at any time. The process of clearing and cleaning these areas after each egg collection was observed on inspection (see recommendation 3).

- The time when the witnessed identification check of the sperm provider is performed is not documented (see recommendation 2).

- A signature was missing from two witnessed identification checks in the records audited on inspection (see recommendation 2).

- The centre does not perform witnessed identification checks of sperm samples at their disposal after use in treatment (see recommendation 2).

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 on the HFEA register 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 register 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 20 patients and partners were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately for 14 of them. Discrepancies were noted in six consents: One couple had not been registered on the EDI system the other two couples had, according to the consents reviewed on inspection, consented to disclosure to researchers while the entry on the EDI system indicated that they had not consented.

Consent: To the storage of cryopreserved material

Discussions with the laboratory manager and a review of the centre's records of consent to storage of gametes and embryos indicated that the centre does not have effective consent to storage for one set of cryopreserved embryos (see recommendation 1).

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: 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 were unable to speak to patients directly however we had the opportunity to discuss the centre's process for obtaining patient feedback and evaluating the level of patient satisfaction. The centre manager explained that patient satisfaction surveys are analysed on a monthly basis and reviewed at a centre management meeting. Any issues arising are identified and corrective actions taken. An annual review of patient satisfaction is also performed. We were provided with the last month's patient satisfaction survey which indicated high levels of patient satisfaction.

Thirty nine patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was primarily positive. Negative comments were minimal and were discussed with the PR during the inspection visit.

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 queries by telephone and e-mail.

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 and discussions during the visit to the centre, the inspection team did not identify any additional non-compliances other than those listed elsewhere in this report.

Compliance with recommendations made at the last inspection

Following the interim inspection in 2010, recommendations for improvement were made in relation to one major area of non-compliance and three 'other' areas 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 2012, the centre has not received any alerts from the HFEA concerning success rates.

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 HFEA register team report that information submission by the centre to the HFEA is generally compliant: The quality of data submitted is good and, when necessary, staff work proactively with the HFEA staff to resolve issues.

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
1. The centre does not have effective consent to storage for one set of cryopreserved embryos. HF&E Act 1990 (as amended), Schedule 3, 8 (1)	The PR has, since the inspection, informed the inspectors that following the approval of their ethics committee the embryos stored beyond their consented storage period have been allowed to perish. The PR should ensure that effective consent to storage is present for all cryopreserved embryos stored at the centre. The PR should also perform a		The inspector has received email confirmation from the PR that the situation has been corrected and the bring forward system has been reviewed and is functioning effectively. The inspector looks forward to receiving a copy of the review of the storage records and bring forward system by 28 February 2013. Further action required.

	review of the storage records and bring forward system to ensure they will prevent future storage without consent. A copy of the review should be forwarded to the HFEA by 28 February 2013.		

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
2. Witnessing Review of the witnessed identification checks documented in ten sets of patients records indicated that: a) The disposal of prepared sperm after its use to inseminate oocytes is not witnessed; b) The time of the witnessed check of the sperm provider's identity is not recorded because the witnessing record sheets do not require it; c) The signatures of a witness had not been recorded appropriately at two witness checks of the approximate 80 witness	The PR should ensure that all required witnessed identification checks are performed and are documented in the records in a manner compliant with HFEA requirements. The witnessing SOP and record sheets should be reviewed and revised to ensure they support compliant practice. Relevant staff should be provided with any necessary update training in the revised witnessing processes and their documentation. This recommendation should be implemented by 28 February 2013. Evidence for its implementation should be provided to the inspector by this		13 December 2012: An updated witnessing SOP was provided by the PR which addressed the inspectors' concerns regarding the witnessing of disposal of sperm samples and the recording of the time of the sperm provider's identity check. The Inspector looks forward to receiving evidence of staff training in the revised witnessing processes by 28 February 2013 in addition to the audit report of witnessing practices by 27 August 2013.

checks reviewed. SLC T71	date. The PR should also ensure witnessing practices are audited after revised processes and documentation are released, to verify that witnessing is being compliantly performed and documented. The audit report should be provided to the inspector by 27 August 2013.		

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
3. The tubes used during egg collection to transfer follicular fluid to the laboratory are not labelled, so the transfer of oocytes from those tubes to dishes cannot be witnessed. SLC T71 and T101	The PR should ensure either that the tubes at egg collection are labelled and that transfers between tubes and dishes are witnessed or that the risks of the current practice of not labelling or witnessing at egg collection are assessed and appropriate risk control measures are documented, implemented and recorded each time they are implemented. This action should be implemented by 28 February 2013. Actions taken to implement it should be advised to the lead inspector by this date.		13 December 2012: An updated SOP was provided by the PR which addressed the inspectors' concerns. No further action.
4. The consents to disclosure to researchers given by 20 patients and partners was audited against the consent decisions provided via the EDI system to the HFEA. Four patients had consented	The PR should audit a sample of patient and partner consents to disclosure to researchers documented in patient records, against the consent decisions recorded in the HFEA Register, to determine whether the consent		The inspector has received email confirmation from the PR that a further audit of the Consent to Disclosure for Research will be performed and a summary of the outcome submitted to the HFEA by 28

to disclosure but the EDI entry recorded that they had not consented.	discrepancies between these sources noted on inspection are isolated occurrences or are more prevalent. The audit report should be submitted to the HFEA by 28 February 2013 to assess whether further actions are required.		February 2013. Further action required

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

8 February 2013

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

Minutes – Item 3

Centre 0208 – (South East Fertility Clinic) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair)	Neil McComb
Joanne Anton, Policy Manager	Observing:
Jasper Squire, Computer Programmer	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 the centre has been licensed since 2007 and provides a full range of fertility services.

2. The Panel noted that in the 12 months to 20 September 2012, the centre provided 482 cycles of IVF/ICSI treatment. In relation to activity levels this is a small centre.

3. The Panel noted that the centre's current licence is due to expire on 30 April 2014.

4. The Panel noted that for the year ending 30 June 2012, the centre's IVF/ICSI success rates were in line with national averages.

5. The Panel noted that for the time period 1 April 2010 to 31 March 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%, and that this represented performance that was not likely to be statistically different from the 20% live birth rate target.

6. The Panel noted that for the time period 1 July 2011 to 30 June 2012, the centre's multiple pregnancy rate for IVF, ICSI and FET cycles for all age groups was 25%, and that this represented performance not likely to be statistically different from the 15% multiple live birth rate target. The Panel also noted, however, the Inspectorate's recommendation that the centre review its multiple births minimisation strategy in consideration of the 10% live birth rate target that came into force on 1 October 2012.

7. The Panel noted that the centre was inspected in November 2012 and at the time of the inspection the Inspectorate identified one critical, one major and two other areas of non-compliance.

8. The Panel noted that, since the inspection, the PR has provided evidence to the Inspectorate that one of the other area of non-compliance has been addressed.

9. The Panel noted that the PR has given a commitment to implement the one critical, one major and one other area of non-compliance that remain outstanding within the prescribed timeframes highlighted in the report.

10. The Panel noted the positive feedback provided by patients of the centre.

11. The Panel noted that the Inspectorate recommended the continuation of the centre's licence without additional conditions.

Decision

12. The Panel urged the centre to address the remaining non-compliance identified by the inspectorate.

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

Signed: Date: 19 February 2013
Juliet Tizzard (Chair)