Interim Licensing Report

Centre name: **Salisbury Fertility Centre**
Centre number: **0197**
Date licence issued: **1 May 2011**
Licence expiry date: **30 April 2015**
Additional conditions applied to this licence: **None**
Date of inspection: **26 March 2013**
Inspectors: **Mr Wil Lenton (Lead); Mr Parvez Qureshi**
Date of Executive Licensing Panel: **7 June 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 progress made by the centre in meeting the HFEA multiple birth rate targets and the positive comments made by patients in relation to their experiences.

The ELP is asked to note that at the time of the inspection there were two major areas of non-compliance that required improvement.

Since the inspection visit the PR has given a commitment to fully implement the following recommendations within the specified time-frames:

'Major' areas of non compliance:

The Person Responsible (PR) should review procedures for submitting patients' consent to disclosure to researchers to the HFEA.

The PR should ensure that the documented validation of all critical equipment is completed and evidence of this be provided to the centre's inspector.

Information about the centre

The Salisbury Fertility Centre (SFC) is located in Salisbury District Hospital, Odstock Road, Salisbury, and has held a licence with the HFEA since 2002. The centre provides a full range of fertility services and provided 553 treatment cycles (excluding partner intrauterine insemination) in the twelve months to 28 February 2013. In relation to activity levels this is a medium sized 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 December 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exceptions:

- clinical pregnancy rates following frozen embryo transfer in patients aged less than 37 years are lower than the national average at a statistically significant level.

The centre has reviewed its current embryo freezing and thawing practices and staff have also attended the Association of Clinical Embryologists (ACE), 'Best Practice' workshop as part of this review. The laboratory manager will continue to monitor laboratory freeze/thaw quality indicators (QIs) going forward.

For the year 2011 the centre reported 68 cycles of partner insemination with six pregnancies. This equates to a 9% pregnancy rate which is in line with the national average.

Multiple births[2]

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

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 28%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

[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.

For the time period April 2011 to September 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%: this also represents performance that is not likely to be statistically different from 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. The following laboratory activities were observed in the course of the inspection: egg collection and sperm preparation. All of the procedures observed were witnessed in accordance with HFEA requirements using a manual system.
The inspection team was able to review records that were present in the laboratory and concluded that 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 80% of the records reviewed. (see recommendation 1).

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. The storage periods for two sets of embryos as recorded on the centre's database were cross checked against the consent given by the gamete providers. In the two sets of records checked, the embryos were being stored in accordance with those consenting decisions.

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 spoke to one couple who provided feedback on their experiences at the centre. We also observed interactions between centre staff and patients on the day of the inspection. A further four patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally good with 75% of respondents commenting that they were satisfied with the care that they had received. A review of 10 patient questionnaires received at the centre also indicated that patients were generally happy with the quality of service provided at the centre.

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 no further non-compliances.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2011 recommendations for improvement were made in relation to three areas of major non-compliance and three 'other' areas of non-compliance.

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

The following recommendation has not been fully implemented:

- Documentation relating to critical equipment validation has not been finalised. (see recommendation 2).

On-going monitoring of centre success rates

The centre has not been issued with any performance alerts in the last six months.

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 confirmed prior to inspection that presently there are no outstanding data issues concerning this centre.

Annex 1

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
Nothing 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. Two out of ten consents to research reviewed were found to have been reported inaccurately to the HFEA. General Direction 0005	The PR should review procedures for submitting patients' consent to disclosure to researchers to the HFEA. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the HFEA. To be submitted by 26 July 2013 Three months after the implementation of corrective actions the centre should audit a random sample of ten sets of patient records to ensure that consent to disclosure to researchers taken from patients has been correctly transferred to the HFEA register. The records audited should have had this consent completed within the previous three months. This audit should be submitted to the HFEA for cross reference against the records held by the HFEA.	The issue raised around the consent to disclosure for research is being investigated. An action plan is in place to firstly identify if the issue is historic or on-going and then processes will be reviewed as needed and corrective actions completed. This will be done by 26 July 2013 and a second audit planned for October 2013.	The Executive acknowledges the prompt action taken by the PR in response to this recommendation. The inspector will continue to monitor this issue and await the final report from the centre. **Further action required**.

2. Documentation relating to some critical equipment validation has still not been finalised~~.~~. SLC T24 This was an issue at the previous inspection in January 2011.	The PR should ensure that the documented validation of all critical equipment is completed and evidence of this be provided to the centre's inspector. To be submitted by 26 July 2013.	The validation and documentation of critical equipment is underway and this will be completed by 26 July 2013.	As this was an issue at the previous inspection the PR is asked to submit an action plan and time-line giving details of each piece of critical equipment and specifying when each was fully validated. The inspector will continue to monitor this issue and await final confirmation from the PR that all actions have been completed. **Further action required.**

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
Nothing noted.			

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

7 June 2013

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

Minutes – Item 1

Centre 0197 – (Salisbury Fertility Centre) – Interim Inspection

Members of the Panel: Juliet Tizzard – Head of Policy and Communications (Chair) Jasper Squire – Computer Programmer Matthew Watts – Regulatory Policy Manager	Committee Secretary: Rebecca Loveys Observing: Terence Dourado

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 medium sized centre which provides a full range of fertility services.

2. The Panel noted that the centre has held an HFEA licence since 2002.

3. The Panel noted that in 2012 the centre's clinical pregnancy rates were in line with the national average. This excludes clinical pregnancy rates following frozen embryo transfer in patients aged less than 37 years, which are lower than the national average at a statistically significant level.

4. The Panel noted that for the time period April 2011 to September 2012 the centre's multiple clinical pregnancy rate for IVF, ICSI and FET cycles for all age groups was 23%, which represents performance that is unlikely to be statistically different from the 15% live multiple birth rate target.

5. The Panel noted that in 2011 the centre reported 68 cycles of partner insemination with six pregnancies, which equates to a 9% pregnancy rate which is in line with the national average.

6. The Panel noted that the centre's current licence is due to expire in April 2015.

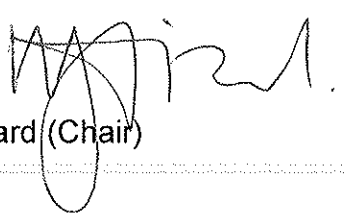
7. The Panel noted that at the time of the inspection, which took place on 26 March 2013, two major areas of non-compliance were identified.

8. The Panel noted that the area of non-compliance, regarding documentation relating to some critical equipment validation having not been finalised, was identified at the centre's last inspection.

Decision

9. The Panel had regard to its decision tree. It was satisfied that there were no issues preventing the continuation of the centre's licence.

10. The Panel endorsed the Inspectorate's recommendations and agreed to continue the centre's licence with no additional conditions.

Signed: 
Juliet Tizzard (Chair)

Date: 11 June 2013