Interim Licensing Report

Centre name: **Sunderland Fertility Centre**
Centre number: **0096**
Date licence issued: **1 June 2009**
Licence expiry date: **31 May 2014**
Additional conditions applied to this licence: **None**
Date of inspection: **21 November 2012**
Inspectors: **Dr Victoria Lamb**
Date of Executive Licensing Panel: **8 February 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 positive comments made by patients in relation to their experiences.

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

Since the inspection visit the PR has given a commitment to fully implement all the recommendations.

'Critical' areas of non compliance:

- **The PR must obtain written effective consent to storage for all material in store and a medical practitioner's statement where relevant.**

'Major' areas of non compliance:

- The PR must ensure that annual returns are sent to the Authority in compliance with Directions 0005.

Information about the centre

The Sunderland Fertility Centre is located in Sunderland and has held a licence with the HFEA since 31 July 1992.

The centre provides insemination with partner and donor sperm.

The centre provided 0 cycles of donor insemination treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2012, and 96 cycles of partner insemination. In relation to activity levels this is a very 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

The centre has not performed any donor insemination treatments since the last inspection.

For the year 2011 the centre had not reported any partner insemination treatments. However, on the day of the inspection the inspector was provided with a report showing 96 cycles of partner insemination with 11 pregnancies. This equates to an 11% pregnancy rate. This pregnancy rate is in line with the national average.

Multiple births

This centre does not provide IVF or ICSI treatment, therefore this theme is not relevant.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur.

No laboratory activities were occurring on the day of the inspection, but the inspector was able to review records that were present in the laboratory and concluded that records of manual witnessing are maintained. All of the records seen were witnessed in accordance with HFEA requirements.

Consent: To disclosure to researchers

No treatments requiring consent to disclosure to researchers have been undertaken at the centre since the last inspection, therefore this theme is not relevant.

Consent: To the storage of cryopreserved material

The centre undertakes long term storage of sperm for patients undergoing treatment for cancer. A review of the centre's records of consent to storage of gametes showed that all except five samples of sperm currently in store are being stored in accordance with the consent of the gamete provider, are within the consented storage period and have a

medical practitioner's statement where relevant . The five samples are all in long term storage: in four cases the patients have given written consent to long term storage and the samples are within the consented storage period but the medical practitioner's statement has not been completed; in one case the patient has verbally expressed a wish to continue storing the sperm but no written consent is in place and the medical practitioner's statement has not been completed. 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 and staff in the laboratory were able to carry out their activities without distraction.

Patient experience

During the inspection visit we spoke to three patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further five patients also provided feedback directly to the HFEA. Feedback was positive with all of the individuals providing feedback commenting that they were satisfied with the privacy and cleanliness of the centre, and the information provided by the staff.

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 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 interim inspection in 2010 recommendations for improvement were made in relation to two areas of 'major' non-compliance and four 'other' areas of non-compliance.

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

Centre staff reported that they were working to resolve the final recommendation and at the time of inspection seven of the 12 cases where samples were being stored without effective consent and/or a medical practitioner's statement had been resolved. The inspector will work with the centre on this issue and is confident that it can be resolved within six months. See recommendation 1.

On-going monitoring of centre success rates

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 centre did not submit an annual return by 28 February 2012 reporting IUI treatments undertaken. 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
1. The centre does not have written effective consent for the storage of all cryopreserved sperm currently in store and does not have medical practitioner's statements in all relevant circumstances. (Human Fertilisation and Embryology Act 1990 (as amended) schedule 3, 8(1); Human Fertilisation and Embryology (statutory storage period for embryos and gametes) regulations	The PR must, as a matter of urgency, obtain written effective consent to storage for all material in store and a medical practitioner's statement where relevant. The PR should update the inspector when this issue is resolved or by 28 February 2013, whichever is the soonest. This was an issue at the last inspection and has been escalated to 'critical' due to the	There is one stored sample without written consent, the patient has expressed his wishes verbally to continue storing his sample and we are in the process of obtaining his written consent. Stored sperm samples that do not have an up to date medical practitioner's statement are being reviewed and statements are being obtained where relevant. All stored samples will have a medical	This is a satisfactory response. On 10 January 2013 the PR informed the inspector that the patient who has sperm in store without written consent has been contacted again to obtain written consent from him. The inspector looks forward to receiving an update when these issues are resolved or by 28 February 2013, whichever is the soonest.

2009, part 3 (4)). Four patients have consented to long term storage but the medical practitioner's statement was not present. One patient has verbally expressed a wish to continue storing the sperm but there was no written consent or medical practitioner's statement.	continuing nature of this issue. By 28 February 2013.	practitioner's statement by the end of 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. The PR did not submit an annual return to the Authority reporting IUI treatments for 2011. (Directions 0005.)	The PR must submit an annual return for 2011 and ensure that in future annual returns are sent to the Authority in compliance with Directions 0005. By 28 February 2013.	The Centre's SOP for "submission of Data to the HFEA" has been updated to ensure compliance with this requirement.	An annual return for 2011 has been submitted. The inspector is satisfied with this response.

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

HFEA Executive Licensing Panel Meeting

8 February 2013

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

Minutes – Item 2

Centre 0096 – (Sunderland Fertility Centre) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Joanne Anton, Policy Manager Jasper Squire, Computer Programmer	Neil McComb Observing: 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 1992 and provides intra uterine insemination (IUI) treatment using partner and donor sperm.

2. The Panel noted that the centre provided no cycles of donor insemination treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2012, and 96 cycles of partner insemination. In relation to activity levels this is a very small centre.

3. The Panel noted that the centre's current licence is due to expire on 31 May 2014.

4. The Panel noted that the centre was inspected in November 2012 and at the time of the inspection the Inspectorate identified one critical and one major area of non-compliance.

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

6. The Panel noted the lack of effective written consent for five samples of cryopreserved sperm.

7. The Panel noted that an annual return for 2011 had not, at the time of inspection, been submitted but recognised that the return has since been provided.

8. The Panel wished to acknowledge the positive feedback provided by patients of the centre.

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

Decision

10. 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)