HFEA Executive Licensing Panel Meeting

2 May 2014

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

Minutes – Item 5

Centre 0293 – (Andrology Solutions) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
David Moysen – Head of IT	**Also in attendance:**
Nick Jones – Director of Compliance & Information	Sam Hartley – Head of Governance & Licensing
	Sue Gallone – Director of Finance & Resources

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 Andrology Solutions is located in London and has held a licence with the HFEA since August 2007. The centre provides insemination and storage services.

2. The Panel noted that the centre is currently on a four-year licence, due to expire on 31 July 2016.

3. The Panel noted that the inspection took place on 11 February 2014.

4. The Panel noted that in the 12 months to 31 January 2014 the centre provided 13 cycles of donor insemination treatment. The centre also provided 159 cycles of partner insemination treatment in 2013. In relation to activity levels this is a small centre.

5. The Panel noted that for the year 2013 the centre reported 159 cycles of partner insemination with 19 pregnancies. This equates to a 12% pregnancy rate which is in line with the national average.

6. The Panel noted that in 2013, one of the 19 pregnancies resulting from partner insemination treatment at the centre was a multiple pregnancy.

7. The Panel noted that at the time of inspection one major area of non-compliance and one other area of non-compliance were identified. The Panel noted the commitment of the Person Responsible to fully implement the recommendations within the prescribed timescales.

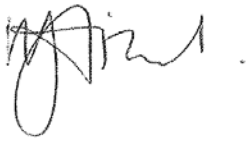
8. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

9. The Panel noted that the Inspectorate recommends the continuation of the centre's licence.

Decision

10. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Treatment (insemination using partner/donor sperm) and Storage licence continued.

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



Signed: Date: 19 May 2014
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Andrology Solutions
Centre number: 0293
Date licence issued: 1 August 2012
Licence expiry date: 31 July 2016
Additional conditions applied to this licence: None
Date of inspection: 11 February 2014
Inspectors: Dr Victoria Lamb; Dr Karen Conyers (HFEA observer)
Date of Executive Licensing Panel: 2 May 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 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 there are recommendations for improvement in relation to one 'major' area of non-compliance and one 'other' area of non-compliance.

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

'Major' area of non compliance:

- The PR should review the procedures for checking and submitting consent to disclosure decisions to the HFEA to ensure that consent to disclosure decisions made by the patient are accurately reflected on the HFEA register.

'Other' area of non-compliance:

- The PR should review witnessing procedures and take action to ensure that witnessing is completed and fully recorded at the time the clinical or laboratory process takes place.

Information about the centre

Andrology Solutions is located in London and has held a licence with the HFEA since August 2007.

The centre provides insemination and sperm storage services.

The centre provided 13 cycles of donor insemination treatment in the 12 months to 31 January 2014. It also provided 159 cycles of partner insemination treatment in 2013. 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

For the year 2013 the centre reported 159 cycles of partner insemination with 19 pregnancies. This equates to a 12% 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 2013, only one of the 19 pregnancies resulting from partner insemination treatment at the centre was a multiple pregnancy.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. Removal of frozen sperm from storage was observed in the course of the inspection. The procedure observed was witnessed in accordance with HFEA requirements using a manual system. The inspection team was also able to review records that were present in the laboratory and concluded that records of manual witnessing are maintained. However, although witnessing checks are completed at the time the relevant clinical or laboratory process takes place, they may be documented afterwards and the time recorded is that when witnessing checks are documented rather than when they are made. Additionally, in two cases reviewed the time of a witnessing check was not recorded and, in one further case, the time and date of a witnessing check was not recorded (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 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 three patients were reviewed in the course of the inspection. The consents were completed correctly and reported to the HFEA accurately in one of the records, however in one of the other records one patient had not completed a consent to disclosure to researchers form, while in the other a patient had given consent to disclosure to researchers on the consent form but the data submitted to the HFEA indicated that consent had been withheld (see recommendation 1).

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that gametes currently in store are being stored within their consented storage period. The storage period for one set of gametes as recorded on the centre's database was cross checked against the consent given by the gamete provider. In the record checked, the gametes were being stored in accordance with the consenting decision.

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 patient who provided feedback on their experiences and observed interactions between centre staff and other patients, both face to face and on the phone. A further three patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive in all cases.

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 additional non-compliances.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2012 recommendations for improvement were made in relation to five '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 the last year the centre has not received any alerts regarding 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 information team consider that the centre is compliant with requirements for register submissions.

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			

‘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. In one of the three sets of patient records reviewed, one patient had not completed a consent to disclosure to researchers form. In another record a patient had given consent to disclosure to researchers using the consent form but the data submitted by the centre to the HFEA indicated that consent to disclosure had been withheld. General Directions 0007.	The PR should correct those submissions that were incorrect and review the procedures for checking and submitting consent to disclosure decisions to the HFEA to ensure that consent to disclosure decisions made by patients are accurately reflected on the HFEA register. The PR should perform an audit of consent to disclosure decisions against those recorded at the HFEA. The PR should inform the HFEA of the audit results by 11 May 2014.	Audit on all DI patients will be performed. Patient records will be checked to ensure CD form response matches the record on the EDI system. Results to be communicated by 11 May	The inspector will review the audit results and ensure that they include a review of the procedures for checking and submitting consent to disclosure decisions to the HFEA.

‘Other’ area 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. Witnessing checks are completed at the time the relevant clinical or laboratory process takes place, but the witnessing documentation may be completed afterwards, and the time of completion of the witnessing documentation is recorded rather than the time of the witnessing check. Additionally, in two cases reviewed, the time of a witnessing check was not recorded and in one further case the time and date of a witnessing check was not recorded. SLC T71 and CoP 18.8.	The PR should take immediate action to ensure that witnessing is completed and fully recorded at the time the clinical or laboratory process takes place. The HFEA should be advised of the measures taken to ensure that this happens by 11 April 2014. The PR should review witnessing procedures. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 11 May 2014. The PR should provide monthly updates to the HFEA on progress in implementing corrective actions.	Procedures have been reviewed at a meeting with staff on 21st march 2014. IUI patients are asked to witness samples just prior to insemination as the doctor is preparing to inseminate the patient, which has made it difficult to ask the patient to sign at the same time. TESE patient identification occurs when the patient is brought into theatres and again it is not always convenient to sign documentation at the time of witnessing. Staff are now ensuring that the times of all witnessing procedures will be recorded accurately. SOPs for witnessing procedures will be reviewed and staff will be reminded of measures they need to take. PR will introduce a review of all witnessing procedures at the end of the day to ensure	The PR has provided the inspector with confirmation of measures taken to ensure compliance with SLC T71 and CoP 18.8. This was done by 11 April 2014. The PR has also confirmed that she will provide the inspector with a summary report of the review findings including corrective actions and the timescale for their implementation by 11 May 2014. The query regarding the monthly report has been clarified with the PR and the inspector will maintain dialogue with the PR to ensure this recommendation is complied with.

		contemporaneous witnessing and recording on all documents is carried out. A monthly report will be submitted to the HFEA with regard to the PR review. However, this does feel rather excessive given that this is not considered to be a major area of non-compliance. Furthermore, there was no limit given to this request by the HFEA. Please advise.	

Additional information from the Person Responsible