Executive Licensing Panel - minutes

Centre 0293 (Andrology Solutions)

Interim Inspection Report

Friday, 22 June 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Lisa Whiting Niamh Marren	Director of Strategy and Corporate Affairs Data and Insights Analyst Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Karen Conyers	Inspector

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that Andrology Solutions shares a premise with The Doctors Laboratory in a building located at 75-76 Wimpole Street, London. Although now one building, it retains two entrances adjacent to each other and patients visiting both The Doctors Laboratory and Andrology Solutions use the door at 75 Wimpole Street. The centre has held a licence with the HFEA since 2007.

1.2. The panel noted that, in the 12 months to December 2017, the centre provided six cycles of intrauterine insemination using donor sperm. In relation to activity this is a small sized centre.

1.3. The panel noted that, for the year January to December 2017 the centre reported 224 cycles of partner insemination with 23 pregnancies. This represents a clinical pregnancy rate of 10%, which is in line with the national average.

1.4. The panel noted that, between January and December 2017, the centre's multiple live birth rate for all IUI cycles for all age groups is 2%; this represents performance that is not likely to be statistically different from the 10% live birth target for this period.

1.5. The panel noted that the inspection took place on 21 March 2018.

1.6. The panel noted that at the time of the inspection, one major area of non-compliance was identified concerning the Quality Management System (QMS). Since the inspection, the Person Responsible (PR) has fully resolved the recommendation regarding the QMS.

1.7. The panel noted that the inspectorate recommends the continuation of the centre's treatment (insemination using partner/donor sperm) and storage licence, particularly noting the positive feedback provided by patients.

2. Decision

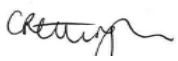
2.1. The panel commended the centre on addressing the one non-compliance regarding the QMS, identified at the interim inspection, encouraging this good practice to continue through to the centre's renewal.

2.2. The panel was satisfied the centre was fit to have its treatment (insemination using partner/donor sperm) and storage licence continued.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Clare Ettinghausen

Date

26 June 2018

Interim Licensing Report

Centre name: **Andrology Solutions**
Centre number: **0293**
Date licence issued: **01 August 2016**
Licence expiry date: **31 July 2020**
Additional conditions applied to this licence: **None**
Date of inspection: **21 March 2018**
Inspectors: **Janet Anderson-Pearce (Lead) Susan Jolliffe, Vicki Lamb**
Date of Executive Licensing Panel: **22/06/2018**

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. The focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

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

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the positive feedback made by patients to their experience.

The ELP is asked to note that this report makes one recommendation for improvement in relation one major area of non-compliance or poor practice.

Following the inspection this non-compliance has been resolved.

'Major' area of non compliance.

- The PR should ensure that the audits for consent, witnessing and storage have corrective and preventative action documented and implemented.

Information about the centre

Andrology Solutions has held a Treatment and Storage licence with the HFEA since 2007.

The centre shares a premise with The Doctors Laboratory in a building located at 75-76 Wimpole Street London. Although now one building, it retains two entrances adjacent to each other and patients visiting both The Doctors Laboratory and Andrology Solutions use the door at 75 Wimpole Street.

The centre provided six cycles of intrauterine insemination using donor sperm in the 12 months up to December 2017 and 224 cycles using partner sperm during 2017. 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.

Pregnancy Outcomes[1]

For the year January to December 2017 the centre reported 224 cycles of partner insemination with 23 pregnancies. This represents a clinical pregnancy rate of 10%, which is in line with the national average.

Multiple births[2]

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

Between January and December 2017, the centre's multiple live birth rate for all IUI cycles for all age groups is 2% this represents performance that is not likely to be statistically different from the 10% live birth target for this period.

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: sperm preparation and freezing. All of the procedures observed were witnessed using a manual system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes are stored in accordance with the consent of the gamete providers.

[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 10% MLBR target is calculated as equivalent to a MCPR of 13%.

On inspection, reports of audits of all stored gametes and of the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and in line with the consent of the gamete providers are effective (but see also Quality Management System section).

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations 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.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, consent to storage and legal parenthood.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements because three out of the four audits did not show any corrective or preventative action, see details below (recommendation 1).

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding: screening requirements, equipment failures.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Infection Control
It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials
It is important that products (known as medical devices) that come into contact with gametes are approved for the provision of fertility treatment, to ensure the safety of gametes and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of sperm pots, serological pipettes, centrifuge tubes, 5ml tubes and media were reviewed in the course of the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience
During the inspection, we spoke to one patient about his experience at the centre. No patients provided feedback directly to the HFEA in the time since the last inspection. The centre provided feedback from patients for the inspection team to review. The feedback was all positive.

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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- 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
Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the

centre is fully compliant with HFEA requirements, except in those areas identified elsewhere in this report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016, recommendations for improvement were made in relation to two major and four 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in February 2016 the centre has not received any performance related risk tool 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. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

At the inspection in February 2016 we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. Action had been taken in response to the audit findings.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

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 made.

Critical areas 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 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;
- which can comprise 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.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Quality Management System Three out of four audits seen at the inspection; Consent Witnessing and Storage had no corrective or preventative actions. (SLC T36)	The PR should ensure that the audits for consent, witnessing and storage have corrective and preventative action documented and implemented. The PR should send the updated audit summary showing the corrective and preventative action to the lead inspector by 21 June 2018.	All audits for consent, witnessing and storage have been updated to include corrective and Preventative Action. Updated Audit summaries emailed separately.	The Executive acknowledges the PR response, all noncompliance's resolved, no further action required.

'Other' areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

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