Executive Licensing Panel - minutes

Centre 0057 (Wessex Fertility Limited)

Interim Inspection Report

Tuesday, 10 April 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Caylin Joski-Jethi (Chair) Clare Ettinghausen Anna Quinn	Head of Intelligence Director of Strategy and Corporate Affairs Scientific Policy Manager
Members of the Executive	Nana Gyamfi	Secretary
External adviser		
Observers	Catherine Burwood Kathleen Sarsfield Watson Bernice Ash	Senior Governance Manager Communications Manager Committee Officer

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 Wessex Fertility Limited is located in Southampton and has held a licence with the HFEA since July 1992. The centre provides a full range of fertility services.

1.2. The panel noted that, in the 12 months to 31 December 2017, the centre reported 993 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels, this is a medium sized centre.

1.3. The panel noted that between 1 October 2016 and 30 September 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is below the 10% multiple live birth rate target.

1.4. The panel noted that the inspection took place on 6 February 2018.

1.5. The panel noted that at the time of the inspection, one critical area of non-compliance or poor practice was identified, concerning the safety and suitability of premises and facilities. As a similar non-compliance, relating to the safe securing of cylinders in the laboratory was identified at the last renewal inspection, this non-compliance was escalated from 'major' to 'critical'. One 'other' area of non-compliances was also identified regarding the Quality Management System (QMS).

1.6. The panel noted that since the inspection, the Person Responsible (PR) has provided evidence that actions had been taken to implement the recommendation in relation to the critical non-compliance, and has committed to audit the effectiveness of these actions within the prescribed timescales. The PR has given a commitment to implementing the recommendation concerning the QMS, within the prescribed timescales.

1.7. The panel noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting 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.

2. Decision

2.1. The panel complimented the centre on their low multiple birth rate alongside overall birth rates which are in line with the national average, which ensures patients receive high quality and safe clinical care.

2.2. The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued, subject to recommendations being implemented within the required timescale, and in particular, the audit of effectiveness of the corrective actions taken to address the critical non-compliance.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

16 April 2018

Interim Licensing Report

Centre name: Wessex Fertility Limited
Centre number: 0057
Date licence issued: 01/08/2016
Licence expiry date: 31/07/2020
Additional conditions applied to this licence: None
Date of inspection: 06/02/2018
Inspectors: Vicki Lamb, Polly Todd, Janet Anderson-Pearce (observer)
Date of Executive Licensing Panel: 10 April 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 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. 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 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 this report makes recommendations for improvement in relation to one critical and one 'other' area of non-compliance or poor practice.

The PR has provided evidence that actions have been taken to implement the following recommendation and has committed to audit the effectiveness of those actions within the required timescale:

Critical area of non-compliance:

- **The PR should ensure that all gas cylinders are properly secured as per regulatory requirements.**

Since the inspection visit the PR has given a commitment to implement the following recommendation within the prescribed timescale:

'Other' area of practice that requires improvement:

- The PR should ensure that audits are conducted every two years.

Information about the centre

Wessex Fertility Limited is located in Southampton and has held a licence with the HFEA since July 1992. The centre provides a full range of fertility services.

The centre provided 993 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2017. 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 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 IVF and ICSI, HFEA held register data for the period 1 October 2016 – 30 September 2017 show the centre's success rates are in line with national averages.

In 2016 the centre reported 17 cycles of partner insemination with two pregnancies, which is in line with the national average.

Multiple births[2]

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

Between 1 October 2016 and 30 September 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is below the 10% multiple live birth rate target.

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: thawing of embryos; preparation for embryo transfer. All of the procedures observed were witnessed using an electronic witnessing system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos 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 and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and embryos and consent records were reviewed, and the 'bring-forward' system was discussed with staff. These activities

[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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

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: 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; medicines management and infection control.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements; an infection control audit was last performed in December 2015, which is more than two years ago (see recommendation 2).

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, storage expiry dates and patient ratings.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

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 and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: centrifuge tubes; egg collection tubes; pipettes and culture media. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience
During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Fifty-two patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with almost all of the individuals providing written feedback giving compliments about the care received.

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, with the exceptions noted 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 four major and three 'other' areas of non-compliance.

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

However, in the course of this interim inspection a gas cylinder was stored in a corridor leading to a fire exit and the cylinder was not secured sufficiently to ensure that it remained in an upright position (see recommendation 1). The safe securing of cylinders at a different location in the centre was a non-compliance at the previous renewal inspection.

On-going monitoring of centre success rates

Since the last renewal inspection in February 2016 the centre has received four risk tool alerts related to performance, to which the PR has responded appropriately, providing evidence and information that the issues have been addressed

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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in February 2016, legal parenthood consenting processes were found to be robust.

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 consent audits. Four 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.

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 noncompliance 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.

A critical area of noncompliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
1. Safety and suitability of premises and facilities A gas cylinder was stored in a corridor leading to a fire exit and the cylinder was not secured sufficiently to ensure that it remained in an upright position. A similar non-compliance related to the safe securing of cylinders in the laboratory was seen at the last renewal inspection. This	The PR should ensure that all gas cylinders are properly secured as per regulatory requirements. The PR should investigate why this non-compliance has occurred again. This should include a review of processes for gas cylinder storage and staff training requirements.	A gas cylinder cage has now been fitted to store cylinders ensuring compliance with this recommendation. Changes were made following the last inspection with additional storage support but a cage was not purchased to store the cylinders and this is now in place. An audit will be undertaken and supplied as	The PR has taken action to ensure that there is now sufficient space to store all gas cylinders in compliance with regulatory requirements. A summary report of the audit is due by 5 July 2018. Further action required.

non-compliance has therefore been escalated to ‘critical’. SLC T17, Health Technical Memorandum 02-01: medical gas pipeline systems part B: Operational management	A summary report of this review with corrective actions should be provided to the centre’s inspector when responding to this report. Three months after the implementation of corrective actions, the PR should audit the storage of gas cylinders to ensure that corrective actions taken have been effective. A summary report of this audit should be provided to the centre’s inspector by 5 July 2018.	requested. The laboratory manager and the PR will meet to discuss the best way to provide the audit to the inspection team.	

‘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
None			

‘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	Executive review
2. **QMS** An infection control audit was last performed in December 2015, which is more than two years ago. SLC T36	The PR should ensure that audits are conducted every two years. The PR should ensure that the infection control audit is completed and provide a summary report of the findings to the centre’s inspector by 5 May 2018.	A new infection audit will be supplied by 5 May 2018.	The PR has agreed to supply the audit by 5 May 2018. Further action required.

Additional information from the Person Responsible