HFEA Executive Licensing Panel Meeting

21 March 2014

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

Minutes – Item 1

Centre 0057 – (Wessex Fertility Limited) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard (Chair) – Interim Director of Strategy	Dee Knoyle
Rachel Hopkins – Head of HR	**Observing:**
Matthew Watts – Regulatory Policy Manager	Sam Hartley – Head of Governance and Licensing

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 this is a medium-size centre, licensed by the HFEA since 31 July 1992, and providing a full range of fertility services including embryo testing.

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 29 January 2014.

4. The Panel noted that in the 12 months to 31 December 2013, the centre provided 604 cycles of treatment (excluding partner intrauterine insemination). The centre's clinical pregnancy rate is in line with national averages.

5. The Panel noted that for the year 2013, the centre reported 34 cycles of partner insemination with two pregnancies. This is in line with the national average.

6. The Panel noted that between 1 April 2011 and 30 September 2012, the centre's multiple live birth rates for all IVF, ICSI and FET cycles for all age groups was 20%. This represented performance that was not likely to be statistically different from the 15% maximum multiple live birth rate target for this period.

7. The Panel noted that between 1 October 2012 and 30 September 2013, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 22%. This represents performance that is likely to be statistically greater than the 10% maximum multiple live birth rate target for this period. The Panel urged the centre to monitor their multiple live birth rates.

8. The Panel noted that there were no areas of non-compliance or poor practice identified and commended the centre for this.

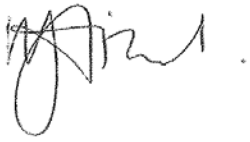
9. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

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

Decision

11. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Treatment (including embryo testing) and Storage licence continued.

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



Signed: Date: 27 March 2014

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Wessex Fertility Limited
Centre number: 0057
Date licence issued: 21/08/2013
Licence expiry date: 31/07/2016
Additional conditions applied to this licence: None
Date of inspection: 29/01/2014
Inspectors: Mrs Bhavna Mehta; Lynne Nice
Date of Executive Licensing Panel: 21 March 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 their feedback in relation to their experiences at the centre.

The Executive Licensing Panel is asked to note that there are no recommendations for improvement.

Information about the centre

The Wessex Fertility Limited is located in Southampton and has held a licence with the HFEA since 31 July 1992.

The centre provides a full range of fertility services.

The centre provided 604 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/12/2013. In relation to activity levels this is a medium 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 31 December 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2013 the centre reported 34 cycles of partner insemination with two pregnancies. This is in line with the national average. As the activity rate is below 50 cycles no percentage rates are provided.

Multiple births[2]

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

Between 1 April 2011 and 30 September 2012, the centre's multiple live birth rates for all IVF, ICSI and FET cycles for all age groups was 20%: this represented performance that was not likely to be statistically different than the 15% multiple live birth rate target for this period.

Between 1 October 2012 and 30 September 2013, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 22%: this represents performance that is likely to be statistically greater than the 10% multiple live birth rate target for this period.

[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. The MLBR target of 10% (from October 2012) is calculated as equivalent to a 13% MCPR.

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; thawing of gametes 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 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 ten patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in all of the records reviewed.

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 and gametes as recorded on the centre's database were cross checked against the consent given by the gamete providers. In the records checked, the embryos and gametes were being stored in accordance with the patient's 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 five of patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further three patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with all individuals providing written feedback to the HFEA commenting that they have compliments about the care that they 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;
- 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, no non-compliances were identified by the inspection team.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in February 2012 recommendations for improvement were made in relation to two areas of major non-compliance.

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

On-going monitoring of centre success rates

The centre has not been issued with any performance 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 centre is broadly compliant with register submission requirements. The HFEA Register team note some other minor outstanding data related issues that are being followed up separately by them.

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. 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
2. None			

‘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
3. None			

Additional information from the Person Responsible