# Licence Committee - minutes

## Centre 0005 (Fertility Exeter) Interim

Thursday, 7 September 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

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| Committee members | Andy Greenfield (Chair)<br>Lee Rayfield<br>Ruth Wilde<br>Kate Brian<br>Anita Bharucha | |
| Members of the Executive | Dee Knoyle | Secretary |
| Legal Adviser | Dawn Brathwaite | Mills & Reeve LLP |
| Specialist Adviser | | |
| Observers | | |

## Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item.

## The committee had before it:

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

## The following papers were considered by the committee:

- Interim inspection report
- Update provided by PR on 4 August 2017.
- Licence Committee minutes, 4 May 2017, Executive update
- Copy of Executive update papers submitted to Licence Committee, 4 May 2017
- Licence Committee minutes, 12 January 2017, renewal inspection report
- Copy of papers submitted to Licence Committee,12 January 2017
- Executive update submitted to Licence Committee, 12 January 2017, in addition to papers shortly before the committee met

## 1. Background

### Renewal inspection - September 2016

**1.1.** The inspectorate carried out a renewal inspection at Fertility Exeter, centre 0005 in September 2016 and identified one critical, nine major and three other areas of non-compliance; five of the non-compliances were identified at the previous inspection. There were concerns raised about the centre's persistently low success rates for IVF in patients under the age of 38 years. The Licence Committee considered the centre's renewal application at its meeting on 12 January 2017 and agreed to renew the centre's treatment and storage licence for a period of three years, instead of the usual four years, with no additional conditions. The Licence Committee requested to see the outcome of an external review of the centre's clinical and laboratory practices and procedures that could impact on success rates and an action plan to implement the recommendations made as a result of the review. The Licence Committee also endorsed the inspectorate's recommendation to carry out an interim inspection within 12 months of the renewal inspection, focussing on the quality management system, surgical pathway and pregnancy success rates. The Licence Committee requested a report of the outcome of the interim inspection.

### Executive Update - May 2017

**1.2.** The Licence Committee was provided with an Executive update and considered the progress on the implementation of the recommendations of the renewal inspection at its meeting in May 2017. The inspectorate was satisfied with the progress made. The recommendations had been addressed within the timescales specified, an external review had been performed and the action plan was in development. The Licence Committee requested another update at its meeting in July 2017, however, an interim inspection had to be performed at the centre on 25 July 2017, focussing on the implementation of the recommendations of the renewal inspection. Therefore, it was agreed that the report of the interim inspection was to be presented to the Licence Committee in September 2017, to allow the inspection team to provide a more comprehensive report, based on evidence observed on the interim inspection visit.

## 2. Consideration of Application

### Interim Inspection – 25 July 2017

**2.1.** The committee noted that Fertility Exeter is located in Devon and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services.

**2.2.** The committee noted that in the 12 months to 31 May 2017, the centre provided 510 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small to medium-sized centre.

**2.3.** The committee noted that for IVF and ICSI, HFEA-held register data for the year ending 30 April 2017 showed the centre's success rates were in line with national averages with the following exceptions:

- clinical pregnancy rates following IVF in patients aged less than 38 years were below average at a statistically significant level;
- clinical pregnancy rates following FET (frozen embryo transfer) in patients aged less than 38 years were below average at a statistically significant level.

**2.4.** The committee noted that for the year 2016 the centre reported 162 cycles of partner insemination with 18 clinical pregnancies. This represented a clinical pregnancy rate of 11%, which is comparable to the national average.

**2.5.** The committee noted that HFEA-held register data for the year ending April 2017 showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 18%. This represents performance that is not likely to be significantly different to the 10% maximum multiple live birth rate target for this period.

**2.6.** The committee noted that the centre's interim inspection took place on 25 July 2017 and there were no areas of non-compliance identified.

**2.7.** The committee noted that the inspectorate is satisfied that compliance has been achieved and maintained.

**2.8.** The committee noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

## 3. Decision

**3.1.** The committee was satisfied that considerable improvement had been made by the centre, following engagement with the inspectorate and continuous monitoring of the implementation of the recommendations. The committee noted, in particular, that the issues relating to legal parenthood and low success rates for IVF in patients under the age of 38 years had been addressed over time. The committee agreed that it was too early to assess the full results of the centre's actions and asked that the inspectorate shares with it future data from the centre for reassurance that improvements in the centre's practices are permanent.

**3.2.** The committee acknowledged how small changes can have a positive impact on performance and encouraged best practice.

**3.3.** The committee was satisfied that the centre was fit to have its licence continued.

**3.4.** The committee also requested that the centre's future inspection report is considered by the Licence Committee.

## 4. Chair's signature

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

### Signature

### Name

Andy Greenfield

### Date

29 September 2017

# Interim Licensing Report

**Centre name:** Fertility Exeter
**Centre number:** 0005
**Date licence issued:** 01/03/2017
**Licence expiry date:** 28/02/2020
**Additional conditions applied to this licence:** None
**Date of inspection:** 25/07/2017
**Inspectors:** Janet Kirkland MacHattie, Lesley Brown
**Date of Licence Committee:** 7 September 2017

## 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 announced interim/additional inspection together with our assessment of the centre's performance based on other information. For 2015-2017 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.

This report represents an evaluation of the centre's performance based on the above in addition to an assessment of the centre's compliance with recommendations made following the renewal inspection in September 2016. The aim is to provide the Authority's Licence Committee with information on which to make a decision about the continuation of the licence.

## Summary for the Licence Committee

The inspection team recommends the continuation of the centre's licence. In particular we note the compliance achieved and maintained, relevant to the recommendations made in the renewal inspection report of September 2016.

The Licence Committee is asked to note that there were no non-compliances identified on this inspection visit.

## Information about the centre

Fertility Exeter is located in Devon and has held a Treatment and Storage licence with the HFEA since 1992. The centre provides a full range of fertility services.

The centre's ownership changed in 2014 from Peninsular Centre for Reproductive Medicine Ltd to Royal Devon and Exeter NHS Foundation Trust.

The centre provided 510 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2017. In relation to activity levels this is a small to medium sized centre. Other licensed activities of the centre include storage of gametes and embryos.

A renewal inspection performed at the centre in September 2016 identified one critical, nine major and three 'other' areas of non-compliance or poor practice. Such was the executives' concern, in particular about the centre's persistently low success rates for IVF in patients under the age of 38, that the report was presented in January 2017 to a Licence Committee rather than to an Executive Licensing Panel (ELP).

The Licence Committee renewed the centre's licence for a period of three years rather than the usual four. The committee requested to see the outcome of an external review of the centre's clinical and laboratory practices and procedures that could impact on success rates and an action plan to implement the review's recommendations. The Licence Committee also endorsed the inspectorate's recommendation to carry out an interim inspection within 12 months of the renewal inspection, focussing on the quality management system, surgical pathway and pregnancy success rates, and required that the report of that interim inspection be presented to them.

An update of actions taken to implement the recommendations of the renewal inspection was presented to the Licence Committee in May 2017, at which time the centre's inspector was satisfied with the progress being made; recommendations had been addressed within the timescales specified, an external review had been performed and the action plan was in development. The committee requested another update at their July meeting, however an interim inspection had to be performed at the centre on 25 July 2017, focussing on the implementation of the recommendations of the renewal inspection. It was decided, with the agreement of the licensing team, to present a report of the interim inspection to the September meeting of the committee, rather than an update report to the July meeting. This would allow the inspection team to provide a more comprehensive report based on evidence observed on an inspection visit. This is the report of that interim inspection.

## 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 year ending 30 April 2017 show the centre's success rates are in line with national averages with the following exceptions:

- clinical pregnancy rates following IVF in patients aged less than 38 years are below average at a statistically significant level;
- clinical pregnancy rates following FET in patients aged less than 38 years are below average at a statistically significant level;

For the year 2016 the centre reported 162 cycles of partner insemination with18 clinical pregnancies. This represents a clinical pregnancy rate of 11% which is comparable to the national average

### Multiple births[2]

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

HFEA held register data for the year ending April 2017 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate 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 inspection team was not able to observe full laboratory activity during the inspection but was able to discuss witnessing with staff and observe active verbal witnessing during part of an egg collection. The centre's audit of witnessing was reviewed by the inspection team in 2016 and no issues were identified

These activities indicated that witnessing procedures are compliant 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.

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[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%.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed, the 'bring-forward' system was discussed with staff and storage records were reviewed. These activities 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: 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 Person Responsible (PR) has, over the previous ten months, performed a full review of the quality management system. Several audits of the centre's activities have been provided to the HFEA in compliance with recommendations made in the renewal inspection report, including audits of:

- confidentiality and privacy
- welfare of the child
- infection control
- medicines management

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

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 centre's audits, as above;
- 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.

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.

### Pre-operative assessment and the surgical pathway
This visit provided an opportunity to review patient records and discuss the pre and post-operative procedure for monitoring patients undergoing egg collection. From this it was assessed that the centre's procedures are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

### 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, introduced since the renewal inspection, was reviewed: round bottom 5ml tubes and one step 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. Two patients provided feedback directly to the HFEA in the time since the last inspection.

The centre's process for obtaining and acting on feedback was discussed with the PR and examples of patient feedback was on display in the patient waiting area.

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.

### 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 one critical, nine major and three 'other' areas of non-compliance.

The PR provided information and evidence that all but two of the recommendations were implemented within the required timescales. The PR and the centre's inspector agreed on amended timescales for the final two recommendations and these have now been implemented.

### On-going monitoring of centre success rates

The centre's success rate for IVF treatments involving fresh embryos in women under 38 years old, has been consistently lower than the national average at a statistically significant level. Following the renewal inspection in 2016, it was recommended that the PR commission an independent expert review of all clinical and laboratory practices and procedures that could impact on this success rate. The review was to include an action plan identifying the corrective actions necessary to address the poor success rate along with a schedule for their implementation.

The PR complied with this recommendation and the inspection visit provided an opportunity to discuss the review, action plan and corrective actions where identified.

The clinical and scientific inspector were satisfied that the PR and the centre team had fully engaged with the process of review and the development of the action plan. Several of the actions have been completed and others are being implemented.

The PR monitors the treatment results carefully and is confident that the success rate for patients under the age of 38 is improving. The centre has data to support this from very recent treatments but this data is yet to be validated at the HFEA.

The PR has committed to keep treatment results under constant review and they will be carefully monitored by the centre's inspector using the HFEA Risk Tool.

In summary, the PR has complied with all of the recommendations in the report of the renewal inspection in September 2016 and has provided comprehensive and timely updates as required by the Licence Committee.

## 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.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre reported the findings of the audit to the HFEA within the required timeframe.

On inspection in 2014, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA . In 2016 in re-visiting the audit results, it was noted that two anomalies had been identified in the original audit which the previous PR had considered minor; further action such as contacting the patients had not been taken.

The current PR has, since the renewal inspection visit in September 2016 and in compliance with a recommendation in the inspection report, reviewed the relevant patient records and ascertained that one of the couples affected had been married at the time of the treatment and therefore no further action was needed. The PR has met with the other affected couple and informed them of the anomalies identified in their consent to legal parenthood. The PR informed the inspection team at this inspection that the Trust will cover the cost of any legal proceedings that the couple may wish to pursue. The PR will keep the centre's inspector informed of any further developments in this case.

To provide assurance of the ongoing effectiveness of the centre's procedures with regards to consent to legal parenthood, the inspection team reviewed two sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and an offer of counselling was seen to be in place prior to consent and treatment in all cases.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be 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 carried out.

### 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 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;
- 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.

| 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.

| 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

The PR welcomes this interim inspection report and is pleased that the inspectors have acknowldged the centre's commitment to delivering a high quality service to its patients. The PR is satisfied that the report reflects that the centre's team have fully engaged with addressing the non-compliances, engaging with the advice of the external review, developing and implementing an action plan and implementing changes to improve pregnancy rates for all patients including the women aged ,38 years having fresh IVF.

The PR and centre's team are fully committed to provding a high quality service, putting patient safety at the centre of all treatments and coninually improving the patient experience in all aspects of treatment.

The PR welcomes the on going support of the centre's inspector and will provide the quarterly updates as requested.