# Executive Licensing Panel - minutes

## Centre 0276 (Bristol Reproductive Medicine Clinic) Interim Inspection Report

Thursday, 6 April 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Juliet Tizzard (Chair)<br>Ian Peacock<br>Joanne Anton | Director of Strategy & Corporate Affairs<br>Systems Manager<br>Head of Regulatory Policy |
| Members of the Executive | Bernice Ash<br>Siobhain Kelly | Secretary<br>Senior Governance Manager |
| External adviser | | |
| Observers | Anna Quinn | Scientific Policy Manager |

## 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 the Reproductive Medicine Clinic, Bristol is located within St. Michael's Hospital, which is part of University Hospital Bristol, NHS Foundation Trust. The centre has held a Treatment (Insemination using partner sperm) licence with the HFEA since 2007.

**1.2.** The panel noted that the centre provides partner intrauterine insemination treatment only. The centre does not have facilities on site for the analysis or preparation of semen for use in treatment and this service is provided by the Bristol Centre for Reproductive Medicine (HFEA licensed centre 0295) nearby. The male partner attends centre 0295 to produce a semen sample which is prepared for insemination. The sample is then transported by the male partner and/or patient to the Reproductive Medicine Clinic where the insemination is performed.

**1.3.** The panel noted that centre provided 33 partner intrauterine insemination cycles in 2015. In relation to activity levels, this is a very small centre.

**1.4.** The panel noted that the inspection took place on 7 February 2017.

**1.5.** The panel noted that at the time of the interim inspection there were no recommendations for improvement.

**1.6.** The panel noted that the inspectorate recommends the continuation of the centre's licence. In particular, the inspection team noted the detailed and clear patient records kept by the centre.

## 2. Decision

**2.1.** The panel congratulated the centre on having no non-compliances and was satisfied that the centre was fit to have its licence continued.

## 3. Chair's signature

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

**Signature**

**Name**

Juliet Tizzard

**Date**

18 April 2017

# Interim Licensing Report

**Centre name:** Reproductive Medicine Clinic, Bristol
**Centre number:** 0276
**Date licence issued:** 01/07/2015
**Licence expiry date:** 30/06/2019
**Additional conditions applied to this licence:** None
**Date of inspection:** 07/02/2017
**Inspectors:** Grace Lyndon (Lead), Sara Parlett
**Date of Executive Licensing Panel:** 24 March 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 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. 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.

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

The inspection team recommends the continuation of the centre's licence. In particular we noted the detailed and clear patient records that are kept by the centre.

The ELP is asked to note that there are no recommendations for improvement.

## Information about the centre

The Reproductive Medicine Clinic, Bristol is located within St. Michael's Hospital, which is part of University Hospital Bristol, NHS Foundation Trust. The centre has held a 'Treatment (Insemination using partner sperm)' licence with the HFEA since 2007.

The centre provides partner intrauterine insemination treatment only. The centre does not have facilities on site for the analysis or preparation of semen for use in treatment and this service is provided by the Bristol Centre for Reproductive Medicine (HFEA licensed centre 0295) nearby. The male partner attends centre 0295 to produce a semen sample which is prepared for insemination. The sample is then transported by the male partner and/or patient to the Reproductive Medicine Clinic where the insemination is performed.

The centre provided 33 partner intrauterine insemination cycles in 2015. 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 important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

#### Pregnancy outcomes

In 2015, the centre reported 33 cycles of partner insemination with five pregnancies. This is in line with the national average.

#### Multiple births

The single biggest risk of fertility treatment is a multiple pregnancy. No multiple pregnancies have been reported by the centre in the last two years.

#### 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 any laboratory activities during the inspection but was able to discuss witnessing with staff and review witnessing in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

#### Consent: To the storage of cryopreserved material

The centre does not store gametes.

#### 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 on the day of inspection. Staffing levels were also discussed

with the senior staff and matron during the inspection. The inspection team concluded that staffing arrangements at the centre are compliant.

## 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, welfare of the child assessment and infection prevention and control.

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 use of CE marked medical devices.
- The use of consent forms comparable to the most recently issued HFEA consent form versions. The centre uses its own consent form to recorded patient consent to insemination but key content is identical to that in the HFEA MGI consent form, since the centre has a process to ensure its consent form is updated when the MGI form is revised by the HFEA. The inspection team reminds the PR that, to maintain compliance, he must ensure that this process continues to function in an accurate and timely manner. If this cannot be guaranteed, the inspection team suggests that the HFEA MGI form is used.
- the centre's patient files were well presented. Despite staff routinely asking patients about their travel history, the response was not documented on the patient information form already in use or within the patient notes. This was discussed with the PR. A prompt for the question and space for the response to be documented will be added to the new adapted patient information form and will be placed in the patient notes.

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

## Medicines management

The centre does not administer or hold medication for patients, therefore this area of practice was not relevant.

## 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 IUI catheters used at the centre are CE marked. Sperm is processed at centre 0295. At the last HFEA inspection at centre 0295 in June 2016, the centre was compliant with 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. Eight patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive with five of the individuals providing written feedback giving compliments about the care received.

The centre undertakes quarterly patient surveys. Thirteen patients responded in the last quarter. The surveys were comprehensive and included a variety of questions from waiting times to understanding information given from centre staff. The responses were positive.

## 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 2015, recommendations for improvement were made in relation to three major and four 'other' areas of non compliance.

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

## On-going monitoring of centre success rates

As this centre only provides IUI partner treatment, their success rates are not subject to ongoing monitoring through the HFEA risk tool.

## 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 clinic provided its annual IUI treatment return for 2015 within the required timescale. The return for treatments in 2016 is not yet due.

## 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.

The centre undertakes partner intrauterine insemination only, therefore this area of practice is not applicable to this centre.

**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 identified | | We are delighted that this is the case | |

### ‘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 identified | | We are delighted that this is the case | |

## ‘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 identified | | We are delighted that this is the case | |

| Additional information from the Person Responsible |
| --- |
| We are very pleased that our centre is compliant, and recognise the effort across the board, by our very dedicated and caring nursing team that leads to this. Some minor points have been raised by our inspecting team and addressed along with this response. |