# Executive Licensing Panel - minutes

## Centre 0076 (NURTURE Fertility)

## Interim Inspection Report

Friday, 28 July 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

| | | |
|---|---|---|
| Panel members | Hannah Verdin (Chair)<br>Anna Coundley<br>Anjeli Kara | Head of Regulatory Policy<br>Information Access and Policy Manager<br>Regulatory Policy Manager |
| Members of the Executive | Bernice Ash | Secretary |
| External adviser | | |
| Observers | | |

## 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 NUTURE Fertility is based in Nottingham and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services except for embryo testing and is part of The Fertility Partnership group.

**1.2.** The panel noted that in the 12 months prior to 28 February 2017, the centre had provided 1,114 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a large sized centre.

**1.3.** The panel noted that the inspection took place on 31 March 2017.

**1.4.** The panel noted that at the time of the inspection on 31 March 2017, two major areas of non-compliance or poor practice were identified concerning multiple births and medicines managements. The panel noted that since the inspection, the Person Responsible (PR) had provided assurances that both recommendations have been fully implemented. The panel noted that the PR will provide a summary of the proposed audit, with regards to medicines management, by 30 September 2017.

**1.5.** The panel noted that between December 2015 and November 2016 the centre's multiple pregnancy 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.

**1.6.** The panel noted that the centre provided a review of their multiple clinical pregnancy rate in advance of the inspection and this, along with their proposed actions were discussed during the inspection. The centre's own data shows that multiple clinical pregnancy rates in patients receiving fresh IVF are likely to be within target and that the centre has upward of 95% uptake of elective single embryo transfer (eSET) for this group of patients. The centre has however identified recent improvements to their success rates following frozen embryo transfer which are likely to have contributed most to their high multiple pregnancy rate.

**1.7.** The panel noted that the inspection team is satisfied that the PR and his team are fully engaged in this process and are committed to reducing the incidence of multiple clinical pregnancies and the consequent risks to both mother and babies. In particular, the inspection team notes the efforts being taken to ensure consistency across the team, and how the message is communicated to patients.

**1.8.** The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence, noting that the centre's success rates for women aged under 38 years having fresh cycles of IVF and under 39 years having frozen embryo transfer (FET) are above the national average at a statistically significant level. However, the centre's clinical multiple pregnancy rate represents performance above the 10% live multiple birth rate target. The PR is encouraged to continue to use the Quality Management System (QMS) to monitor and reduce the multiple live birth rate.

## 2. Decision

**2.1.** The panel was satisfied the centre was fit to have its treatment and storage licence continued, noting a summary of the proposed audit, with regards to medicines management, is due by 30 September 2017.

## 3. Chair's signature

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

**Signature**

**Name**

Hannah Verdin

**Date**

4 August 2017

# Interim Licensing Report

**Centre name:** NURTURE Fertility
**Centre number:** 0076
**Date licence issued:** 01 June 2015
**Licence expiry date:** 31 May 2019
**Additional conditions applied to this licence:** None
**Date of inspection:** 31/03/2017
**Inspectors:** Gill Walsh and Douglas Gray
**Date of Executive Licensing Panel:** 28 July 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 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 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 and notes; that the centre's success rates for women aged under 38 years having fresh cycles of IVF and under 39 years having frozen embryo transfer (FET) are above the national average at a statistically significant level. However, the centre's clinical multiple pregnancy rate represents performance above the 10% live multiple birth rate target. The PR is encouraged to continue to use the Quality Management System (QMS) to monitor and reduce the multiple live birth rate.

The Executive Licensing Panel is asked to note that at the time of the inspection there are recommendations for improvement in relation to two major area of non-compliance or poor practice as follows:

**'Major' areas of non-compliance:**

- The PR should keep the effectiveness of the centre's multiple birth minimisation strategy and its implementation under review to ensure that the no greater than 10% multiple live birth rate is not exceeded.

- The PR should ensure that medicines management practices are in accordance with guidance.

Since the inspection the PR has provided assurance that both recommendations have been fully implemented. It remains that the PR should provide a summary of the proposed audit by 30 September 2017.

## Information about the centre

NURTURE Fertility has been licenced by the HFEA since 1992 and provides a full range of fertility services except for embryo testing. The centre is part of The Fertility Partnership group.

NURTURE Fertility was last inspected for a licence renewal in January 2015 and for a variation of the licence to reflect a change of centre name and premises in February 2015.

The centre provided 1114 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. In terms of activity, this is a large centre.

The centre has a satellite agreement in place with Burton Fertility, Burton on Trent.

## 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 December 2015 to November 2016 show the centre's success rates are in line with national averages with the following exceptions:

- the clinical pregnancy rate following IVF in women aged under 38 years are higher than average at a statistically significant level and;
- the clinical pregnancy rate following frozen embryo transfer (FET) in woman under 39 years is higher than average at a statistically significant level.

In 2016, the centre reported seven cycles of partner insemination with no pregnancies, this is in line with national average.

### Multiple births[2]

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

Between December 2015 and November 2016, the centre's multiple pregnancy 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 (see recommendation 1).

The centre provided a review of their multiple clinical pregnancy rate in advance of the inspection and this, along with their proposed actions were discussed during the inspection. The centre's own data shows that multiple clinical pregnancy rates in patients receiving fresh IVF are likely to be within target and that the centre has upward of 95% uptake of

[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%.

elective single embryo transfer (eSET) for this group of patients. The centre has however identified recent improvements to their success rates following frozen embryo transfer which are likely to have contributed most to their high multiple pregnancy rate.

The inspection team is satisfied that the PR and his team are fully engaged in this process and is committed to reducing the incidence of multiple clinical pregnancies and the consequent risks to both mother and babies. In particular, the inspection team notes the efforts being taken to ensure consistency across the team, and how the message is communicated to patients.

### 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 during the inspection: egg collection. All the procedures observed were witnessed using a manual 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 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 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 effectiveness of the centre’s QMS was assessed by reviewing the reports of the following audits: witnessing and consent to storage, infection control, medicines management, controlled drugs and legal parenthood. 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 regarding the following:

- the centre's audits of infection control and medicines management;
- 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 HFEA reports of adverse incidents from 2010-2012 and 2013, and
- HFEA Clinic Focus articles regarding:
    - the introduction of the new posthumous birth registration (PBR) consent form;
    - updates to the Code of Practice and;
    - guidance on zika and ebola virus.

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 partially compliant with guidance because:

- the medicines fridge contained two pathology samples (blood and urine) awaiting collection. The samples were however contained within a sealed plastic bag;
- a small amount of unused medicines that patients had returned to the centre for disposal were placed with current stock available for supply and;
- during surgical procedures, several controlled drugs had been drawn up ahead of use. Although appropriately labelled, the syringes were not stored in a controlled environment until required.

(See recommendation 2)

### 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, infection control practices were found 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 all plastic ware, reagents and media was reviewed in the course of the inspection. The centre was 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 has they were undergoing egg collection that day. We did however discuss the mechanism employed by the centre for obtaining feedback from service users and how that information informs actions for improvement. The results of the centre's most recent satisfaction survey were also reviewed. It was noted that a high proportion of those responding gave compliments about the care 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;
- 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 there are no further areas of non-compliance.

## 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 four 'other' areas of non-compliance.

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

## On-going monitoring of centre success rates

Since the last renewal inspection in January 2015 the centre has received eight HFEA automated risk based risk assessment tool (RBAT) alerts, all relating to high multiple clinical pregnancy rates (discussed above). The PR has responded appropriately.

## 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. The register team of the HFEA currently report no issues of concern regarding the quality or timeliness of the data submitted 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 sent the report of this audit to the HFEA within the required timeframe. The audit showed that four couples were affected by legal parenthood consent anomalies.

At the licence renewal inspection in January 2015 this audit was reviewed and found to have been performed per the method specified by the HFEA and that appropriate actions had been taken in response to the audit findings. All couples were informed of the anomalies and had been provided with support and advice in accordance with the expectations of the HFEA. There are no ongoing actions regarding these couples.

As part of the HFEA's ongoing activities relating to 'legal parenthood' in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the executive.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed seven sets of records where treatment with donor sperm had recently been provided. Consent to legal parenthood was required in three instances. Effective consent to legal parenthood and the 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 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 |
|---|---|---|---|
| 1. Multiple births.<br><br>The centre’s current multiple clinical pregnancy rate is 22% which is likely to be higher than the 10% multiple live birth rate target at a statistically significant level.<br><br>COP 7.1, SLC T2, General Directions 0003. | The PR should keep the effectiveness of the centre’s multiple birth minimisation strategy and its implementation under review to ensure that the no greater than 10% multiple live birth rate is not exceeded.<br><br>It was agreed that the PR would continue with their scheduled audits and that he would send copies to his inspector. It was agreed that data for a period of six months would likely be required to show any significant effect.<br><br>The audits should be broken down by patient group and | We are happy with the report and recognise we have a problem with our multiple birth rates. This primarily stems from our FET cycles. There is a difference of 15%, so SET 45% v’s DET 60% CPR/ET but also a 45% MPR We have amended our eSET policy for FER.<br><br>An email was sent to all staff:<br><br>Following on from our recent HFEA inspection we have to significantly reduce our Multiple Pregnancy Rate (MPR) for FER patients. The HFEA have given us a deadline of November 2017 | The executive acknowledges the PRs response and actions taken to reduce the MPR rate.<br><br>No further action is required at this point. The centre’s MPR will be monitored |

| | | | |
|---|---|---|---|
| | treatment type and should include detail of any revision to the current strategy where required.<br><br>The centre's inspector will continue to monitor the centre's progress. Should no progress be evident in the centre's CUSUM plots by 31 November 2017, the inspectorate will consider whether further action is necessary in accordance with the Compliance and Enforcement Policy. | for us to demonstrate a significant reduction in MPR for FER patients. We do have an eSET policy for FER patients but compliance is low as many patients specify they want two embryos back despite our advice and the risks. At present we provide the information to patients and allow them to choose.<br><br>Having reviewed our data we have found a group of patients that is at particularly high risk of Multiple Pregnancy (50% MPR), these As such, we have decided to perform single embryo transfer in all patients in this category. When we are consulting/consenting this group of patients who are having an FER we will make them aware that if they meet the eSET policy we will be performing a single embryo transfer. This patient group will have an estimated 45% chance of pregnancy with a single embryo transfer. | |

| | | | |
|---|---|---|---|
| | | This policy will come into effect for all patients having consultation from 15th May 2017 | |
| 2. Medicines management<br><br>a) The medicines fridge contained samples of blood and urine.<br><br>b) A small amount of medication returned by patients for disposal was present with current stock and therefore potentially available to be re-issued to another patient.<br><br>c) Controlled drugs for more than one patient were prepared at the same time but not stored securely until required.<br><br>SLC T2 | The PR should ensure that medicines management practices are in accordance with guidance.<br><br>The PR should review procedures currently in place to:<br>a) ensure that only medicines are kept in the medicines fridge;<br>b) unused medicines returned to the centre are consistently disposed of promptly and not returned to stock;<br>c) if, as requested by the attending anaesthetist, controlled drugs are prepared for more than one patient at a time, there are measures in place to ensure that the prepared drugs are held securely until required. | We have revised our practices accordingly in line with the inspection recommendation. All staff have beeen informed of the changes required. The audit will be provided by the due date. | The executive acknowledges the PRs response and action to implement this recommendation.<br><br>No further action is required other than to provide a summary of the scheduled audit by 30 September 2017. |

| | | | |
|---|---|---|---|
| | The PR should provide an update and a summary of actions to taken to address these areas of concern when responding this report.<br><br>The PR should provide evidence that the proposed actions have been implemented by 31 June 2017.<br><br>Three months after the implementation of an actions the PR should audit these areas of practice to demonstrate whether the corrective actions have been effective. A summary of these audits should be provided to the centre's inspection by 30 September 2017. | | |

### '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 |
|---|---|---|---|
| 3. None | | | |

| Additional information from the Person Responsible |
| --- |
| We are happy with the report and recognise we have a problem with our multiple birth rates. Many thanks for the feedback after the inspection, it was much appreciated. |