Interim Licensing Report

Centre name: NURTURE
Centre number: 0076
Date licence issued: 01/06/2011
Licence expiry date: 31/05/2015
Additional conditions applied to this licence: None
Date of inspection: 12/12/2012
Inspectors: Sara Parlett (lead), Dr Douglas Gray, Victoria Mills
Date of Executive Licensing Panel: 01/03/2013

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 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 centre's achievement in meeting the HFEA multiple pregnancy rate targets and the exceptionally positive comments made by patients in relation to their experiences.

The Executive Licensing Panel is asked to note that the report found no critical or major non-compliances, but recommendations for improvement were made in relation to two 'other' areas of non-compliance as follows:

'Critical' areas of non compliance:

None

'Major' areas of non compliance:

None

'Other' areas of practice that require improvement:

1. The Person Responsible (PR) should ensure that the time that procedures take place is recorded in the patient notes.
2. The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification.

Since the inspection, the PR has provided evidence which demonstrates that both recommendations have been implemented. However, the PR is asked to submit the documented risk assessment required under recommendation 2.

Information about the centre

NURTURE is located in Nottingham and has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services.

The centre provided 617 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2012. 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 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 July 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exceptions:

- clinical pregnancy rates following in vitro fertilisation (IVF) in patients aged under 38 years are above average at a statistically significant level.
- clinical pregnancy rates following frozen embryo transfer (FET) in patients aged under 40 years are above average at a statistically significant level.

For the year 2011 the centre reported five cycles of partner intrauterine insemination with two pregnancies. This is consistent with the national average.

Multiple births[2]

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

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. This represented performance that was not likely to be statistically different from the 20% live birth rate target. The inspection team congratulates the centre on this achievement.

For the time period 1 April 2011 to 13 July 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. This also represents performance that is not likely to be statistically different from the 15% live birth rate target.

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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.

[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 centre's achievement in meeting the multiple clinical pregnancy rate targets demonstrates that the centre has an effective strategy in place to meet the HFEA's multiple birth rate targets.

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 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 ten sets of patient notes and concluded that records of witnessing are accurately maintained, with one exception. It was noted that the time that one embryo transfer and one embryo freeze was performed was not recorded in the patient records (see recommendation 1).

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 20 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 three sets of embryos and three sets of gametes as recorded on the centre's database were cross checked against the consent given by the gamete providers. In the six sets of records checked, the material was being stored in accordance with those 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 ten patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 57 patients also provided feedback directly to the HFEA in the time since the last inspection. Forty eight of the 57 individuals providing written feedback to the HFEA commented that they have compliments about the care that they received. The comments made were exceptionally positive.

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. There were some comments received by the HFEA in the patient questionnaires regarding lack of privacy in the reception area. On inspection, centre staff confirmed that they were aware of this issue and corrective action has been taken to address it;
- 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, the inspection team identified the following non-compliance:

- At egg collection, not all containers used during the procurement of eggs are labelled with the patient's/donor's full name and a further unique identifier or a uniquely identifying donor code (see recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2010, recommendations for improvement were made in relation to five areas of major non-compliance and eight 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations have been fully implemented.

On-going monitoring of centre success rates

The centre has not been issued with any performance alerts in 2012.

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 quality of data submitted by this centre is good, submissions are generally timely and the centre works proactively with the HFEA to address register submission issues as they arise.

There are currently two live register submission issues. There are a number of:

- historic treatments in which donor gametes have been used where the donor appears to be unregistered (i.e. this could potentially impact on the ability of the Authority to fulfil statutory obligations to the donor conceived and donors); and

- outstanding form submissions involving a variety of form types (i.e. which could impact on the effectiveness of the Authority's clinical and multiple pregnancy monitoring mechanisms).

These are not significant enough in number to require a recommendation to be made. It is suggested that the centre continues to work proactively with the HFEA to resolve these issues.

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 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
None noted.			

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
None noted.			

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
1. The time of some procedures was not recorded in the patient records, which is non-compliant with CoP Guidance 18.7 (b).	The PR should ensure that the time that procedures take place is always recorded in the patient notes. This recommendation should be implemented immediately. It is recommended that, prospectively, this is included in the scope of the centre's witnessing audits. Confirmation of this should be provided to the inspector by 12 March 2013.	Recommendation has been implemented, all witnessing steps are time stamped and the time stamp is checked as part of the witnessing audit. A witnessing audit since the change has revealed a 100% compliance (Audit 40)	The inspection team is satisfied with the PR's response. No further action is required.
2. At egg collection not all containers (dishes, vials, ampoules, tubes etc) used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code. SLC T101.	The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification and take corrective action where appropriate. Action could include the introduction of a check step to confirm that critical work areas are cleared in between egg collection cases. The risk assessment and details of any action taken should be submitted to the inspector by 12 March 2013.	Recommendation has been implemented. In theatre - at the end of each egg collection a member of staff checks that the test tube rack is empty and all tubes have gone through to the lab and then signs for this check. In the lab, at the end of the egg collection the embryologist performing the procedure checks that all the tubes within the flowhood have	The inspection team acknowledges the PR's response. The PR is asked to submit a copy of the documented risk assessment by 12 March 2013.

		been checked and discarded and then signs for this check. Only after both checks have been performed does the next egg collection start. Audit scheduled for end of February 2013.	

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

1 March 2013

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

Minutes – Item 2

Centre 0076 – (NURTURE) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Jasper Squire – Computer Programmer David Moysen – Head of IT	Rebecca Loveys

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also 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-sized centre which provides a full range of fertility services, and has been licensed since 1992.

2. The Panel noted that the centre's current licence is due to expire on 31 May 2015.

3. The Panel noted that, in the 12 months to 31 October 2012, the centre provided 617 cycles of treatment (excluding partner intrauterine insemination).

4. The Panel noted that the centre was inspected on 12 December 2012, and that the Inspectorate identified two other areas of non-compliance.

5. The Panel noted the positive comments made by the Inspectorate about the centre meeting multiple birth rate targets.

6. The Panel noted the accuracy with which the centre recorded consents for disclosure to researchers. The Panel agreed that the centre and the HFEA should continue working together on two live register submission issues.

7. The Panel noted that all thirteen recommendations made by the Inspectorate in the centre's last renewal report have been reported and evidenced as completed.

8. The Panel noted the positive patient feedback received by the centre.

Decision

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

Signed:  Date: 1 c March 2013

Mark Bennett (Chair)