Interim Licensing Report

Centre name: **The James Cook University Hospital**
Centre number: **0055**
Date licence issued: **01/02/2012**
Licence expiry date: **31/01/2016**
Additional conditions applied to this licence: **None**
Date of inspection: **15/05/2013**
Inspectors: **Victoria Lamb (Lead), Susan Jolliffe**
Date of Executive Licensing Panel: **02/08/2013**

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 (ELP) 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.

The team made recommendations for improvement in relation to one 'major' area of non-compliance and three 'other' areas of non-compliance. The Person Responsible (PR) has provided evidence that the following recommendations have been implemented:

'Other' areas of practice that require improvement:

- The PR should consider the risks of not labelling the tubes used during egg collection. The HFEA should be informed of any actions taken to mitigate the risks of misidentification as a result of this practice by the time this report is considered by the ELP.

- The findings of the counselling audit should be documented and appropriate action taken. Evidence that the audit has been documented should be sent to the inspector.

- The PR should ensure that the process for when a woman being treated withdraws her consent to a nominated second parent being the legal parent, or consents to a different person being the legal parent of any child born is documented in a standard operating procedure (SOP), and this SOP should be provided to the inspector.

The PR has agreed to implement the following recommendation within the prescribed timescale:

'Major' areas of non compliance:

- Three months after the inspection the PR should audit a random sample of ten sets of patient records, to ensure that consent to disclosure to researchers taken from patients has been correctly transferred for entry on to the HFEA register.

Information about the centre

The James Cook University Hospital is located in Middlesbrough and has held a licence with the HFEA since July 1992.

The centre provides a full range of fertility services.

The centre provided 416 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/03/2013. In relation to activity levels this is a small 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 December 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2012 the centre reported 14 cycles of partner insemination with no pregnancies. This is in line with the national average.

Multiple births[2]

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

Between 1 April 2010 and 31 March 2011 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 26%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period 1 April 2011 to 30 September 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 24%: this also represents performance that is not likely to be statistically different from the 15% live birth rate target.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target.

[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.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. Three egg collections were observed in the course of the inspection. All of the procedures observed were witnessed in accordance with HFEA requirements using a manual system.

The inspection team was able to review five sets of records that were present in the laboratory and concluded that records of manual witnessing are maintained, and all witnessing steps were present.

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 10 patients and their partners were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in nine of the records reviewed. In one set of records the patient and her partner had consented to disclosure to researchers but this had not been reported to the HFEA. See recommendation 1.

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that two sets of embryos in store were being stored beyond the expiry of the consented storage period by approximately two months. Although the bring forward system appeared robust and centre staff were aware of these embryos, they had not been discarded, or further consent obtained, by the time of the inspection. Two days after the inspection the PR contacted the lead inspector with further information on these embryos, which were the only ones being stored beyond the consented storage period. One set of embryos had been discarded in line with the patients' wishes and consent for extended storage was obtained for the other set of embryos. The PR has put in place new procedures to ensure this situation does not reoccur. No recommendation is required.

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: 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 one patient who provided feedback on her experiences and observed interactions between centre staff and patients. A further 20 patients also provided feedback directly to the HFEA in the time since the last inspection. Eleven of the individuals providing feedback commented that they had compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides appropriate information on the availability of counselling.

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-compliances:

- 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 identifier. See recommendation 2.
- The findings of the counselling audit have not been documented. See recommendation 3.
- There is no standard operating procedure for staff to follow should a woman being treated withdraw her consent to a nominated second parent being the legal parent, or consent to a different person being the legal parent of any child born. See recommendation 4.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2011, recommendations for improvement were made in relation to one area of critical non-compliance, seven areas of major non-compliance and six 'other' areas of non-compliance.

Following the inspection the PR provided information and evidence that all of the recommendations were fully implemented.

On-going monitoring of centre success rates

In 2012, the centre did not receive any alerts from the HFEA regarding the provision of treatment.

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.

There are currently no data submission issues with 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’ 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			

‘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
1. In one case the records of consent to disclosure to researchers had been incorrectly reported to the HFEA. General Directions 0005	Three months after the inspection the PR should audit a random sample of ten sets of patient records to ensure that consent to disclosure to researchers taken from patients has been correctly transferred for entry on to the HFEA register. The records audited should have had this consent completed within the previous three months. This audit should be submitted to the HFEA by 30 September 2013. The HFEA may require the centre to perform an audit of individual consent records	The PR will conduct an audit (with the assistance of two members of the senior nursing staff) of a random sample of ten sets of patient records mid-August 2013, selected from patient group undergoing treatment May-August 2013. They will report their findings (checking individual consent forms against data entry on the HFEA EDI system) and will submit the results of the audit to you by mid-September 2013.	The inspector considers this to be a suitable response.

	against the consent decision held by the HFEA in the future if an application is made by researchers for the release of that information.		

‘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
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. SLC T101	While it is acknowledged that only one egg collection takes place at a time, the PR should consider the risks of not labelling the tubes used during egg collection. The HFEA should be informed of any actions taken to mitigate the risks of misidentification as a result of this practice by the time this report is considered by the ELP.	Embryologists to amend current SOP to include the changes required to mitigate the risks of misidentification pending HFEA approval of the attached document.	The PR has provided information of actions taken to mitigate the risks of misidentification at this stage - dishes and tubes at egg collection will now be labelled and witnessed. This is a suitable response.
3. The findings of the counselling audit have not been documented. SLC 36	The findings of the counselling audit should be documented and appropriate action taken. Evidence that the audit has been documented should be sent to the inspector by 31 August 2013.	The findings of the counselling audit have been documented and appropriate action taken. Relevant documentation is attached to this email.	Documented audit received with no corrective actions required. This is a suitable response.
4. Although the centre has a process in place to ensure that where a woman being treated withdraws her consent to a nominated	The PR should ensure that the process is documented in a SOP, and this SOP should be provided to the inspector by 31 August 2013.	A SOP for this scenario has been documented, along with the three related standard letters required. All four documents (1 x SOP, 3 x	Suitable documentation has been provided. This is a suitable response.

second parent being the legal parent, or consents to a different person being the legal parent of any child born, that the nominated second parent is informed of the change in writing, this process is not documented. SLC T33		standard letters) are attached.	

Additional information from the Person Responsible
I trust that the actions we have taken are acceptable to you, and that our report will be presented to the Executive Licensing Panel in an amended format.

HFEA Executive Licensing Panel Meeting

2 August 2013

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

Minutes – Item 3

Centre 0055 – (The James Cook University Hospital) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Nick Jones – Director of Compliance and Information Rachel Hopkins – Head of HR	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 small centre which provides a full range of fertility services, which has been licensed since 1992.

2. The Panel noted that the centre currently has a four-year licence due to expire January 2016.

3. The Panel noted that in the 12 months to 31 March 2012 the centre provided 416 cycles of treatment (excluding partner intrauterine insemination).

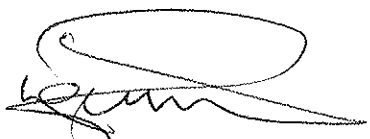
4. The Panel noted that, for the year ending December 2012, the centre's success rates in terms of clinical pregnancy rates were in line with national averages.

5. The Panel noted that, from 1 April 2011 to 30 September 2012, the centre's multiple clinical pregnancy rate for all cycles and all age groups was 24%, which represents performance that is not likely to be statistically different from the 15% live birth rate target for this period.

6. The Panel noted that, at the time of inspection, one major and three other areas of non-compliance were identified, and that the Person Responsible (PR) has since provided evidence that the three other areas of non-compliance have been addressed.

Decision

7. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence with no additional conditions. The Panel agreed with the recommendations and timescales for resolving the non-compliances within the report.

Signed:  Date: 7 August 2013

Mark Bennett (Chair)