Interim Licensing Report

Centre name: **Newcastle Fertility Centre at Life**
Centre number: **0017**
Date licence issued: **01/08/2011**
Licence expiry date: **31/07/2014**
Additional conditions applied to this licence: **None**
Date of inspection: **20/02/2013**
Inspectors: **Douglas Gray, Gill Walsh**
Date of Executive Licensing Panel: **10/05/2013**

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 inspection team has made recommendations for improvement and these should be implemented within the time specified.

ELP are asked to note that there are recommendations for improvement in relation to one 'major' area of non-compliance, and two 'other' areas of non-compliance as follows:

'Major' areas of non compliance:

- The Person Responsible (PR) should either obtain written consent to storage or, where the centre has followed its own procedures and determined that it is appropriate, should allow embryos to perish when the statutory storage period has been exceeded or if there is no effective consent to storage. This recommendation has been implemented.

'Other' areas of practice that require improvement:

- The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification. This recommendation has been implemented.
- The PR should ensure that gamete providers in all future surrogacy arrangements are appropriately screened as donors. The PR has provided a commitment to implement this recommendation and is developing procedures to ensure compliance.

Information about the centre

The Newcastle Fertility Centre is located in the Bioscience Centre at The International Centre for Life, Newcastle upon Tyne. The centre has held a HFEA licence since 31 July 1992. The centre provides a full range of fertility services including embryo testing.

The centre provided 952 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2012. In relation to activity levels, this is a medium sized centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on a number of 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 September 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 IVF in patients aged less than 38 years are lower than average at a statistically significant level.

For the year 2011 the centre reported 21 cycles of partner insemination with one pregnancy; this is consistent with the national average.

Multiple births[2]

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

From 1 April 2010 to 31 March 2011 the centre's multiple clinical pregnancy rate for all IVF, Intra Cytoplasmic Sperm Injection (ICSI) and Frozen Embryo Transfer (FET) cycles for all age groups was 26 %. This represents performance that is not likely to be statistically different from the 20 % live birth rate target.

From 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 centre introduced a new multiple births minimisation strategy in July 2012 and evidence was seen during the inspection that its effectiveness is being reviewed on a monthly basis.

[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. The following laboratory activities were observed in the course of the inspection: egg collection, sperm preparation, removing embryos from cryopreservation and disposing of embryos. All procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing system. An audit of electronic witnessing records for three sets of patients showed that critical steps were appropriately witnessed and recorded. Five sets of hard copy patient records were audited for evidence of traceability to electronic witnessing records held on the centre's database. Witnessing records were found to be fully traceable in each case.

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 during the inspection. The consent forms were completed and had been reported through EDI accurately.

Consent: To the storage of cryopreserved material

A review of the centre's records of consent to storage of sperm showed that all sperm currently in store was being stored in accordance with the consent of the sperm providers and was within the consented storage period. A review of the centre's records of consent to storage of embryos showed that two embryos for one pair of gamete providers were being stored outside the consented storage period (see recommendation 1).

The storage periods for three sets of embryos and three sets of sperm samples as recorded on the centre's database were cross checked against the consent given by the gamete providers on HFEA consent forms. The storage period had been accurately recorded in all cases.

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; 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 three patients and their partners who provided feedback on their experiences and observed interactions between centre staff and patients. A further 32 patients also provided feedback directly to the HFEA in the time since the last inspection. Written feedback was generally positive especially relating to the centre's staff who were described as friendly, helpful and professional.

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 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.

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 these additional non-compliances:

- Tubes used to collect follicular fluid which are transferred to the laboratory, and dishes into which the fluid is poured for egg collection were not labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code (including labelling in the form of electronic tags). See recommendation 2.
- Sperm to be used for surrogacy is not quarantined for a minimum of 180 days, prior to repeat screening of the donor. The donor's blood is not tested by the nucleic acid amplification technique (NAT) for HIV, HBV or HCV. Processing of gametes does not include a validated inactivation step for these viruses. See recommendation 3.

Compliance with recommendations made at the time of the last inspection

Following a renewal inspection in 2011, recommendations for improvement were made in seven areas of major non-compliance and six 'other' areas of non-compliance. During a follow-up visit, the PR provided information and evidence that all of the outstanding recommendations had been fully implemented.

On-going monitoring of centre success rates

From September 2012 to the time of inspection, the centre was issued with two performance alerts relating to the provision of IVF treatment in patients < 38 years old. The PR provided a commitment to keep success rates in this group of patients under review following the implementation of new policies and procedures.

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 centre is highly compliant with register submission 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 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 on inspection.			

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. The centre did not have written effective consent for the storage of all cryopreserved embryos in store at the time of inspection. HF&E Act 1990 (as amended), Schedule 3 (8)(2)	The PR should continue to make progress to either obtain written consent to storage or, where the centre has followed its own procedures and determined that it is appropriate, should allow embryos to perish when the statutory storage period has been exceeded or if there is no effective consent to storage. The centre's inspector should be provided with monthly up-dates until consent issues for these embryos have been resolved.	This reference is to a SINGLE batch of two embryos which at the time of inspection were stored less than three weeks beyond the initial 5 year period of consent. Consent for a second batch remains within the time limit. A case could therefore be argued legally that we did have valid consent for embryo storage. We were already aware of the issue and that the couple have valid consent for a further batch of embryos in store in the Centre. Whilst we had attempted to see the couple to discuss either extension of consent or embryo disposal we had not yet managed to get them into the clinic for this. Within recent preceding months they indicated that they had wanted the embryos to be transferred but had failed to attend appointments. In these	The inspection team acknowledges the PR's comments relating to the difficult circumstances leading to this non-compliance and are pleased to hear that it has been resolved within an appropriate time scale. No further action is required.

		circumstances it was not considered in the patients' best interests to dispose of the embryos without discussion and this would potentially be open to legal challenge. At the time of the inspection we were specifically advised by the inspector that we were not being asked to dispose of the embryos until resolution. Appropriate extension to storage forms have now been completed.	

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. Not all dishes and tubes at egg collection were labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code (including labelling in the form of electronic tags). 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. The risk assessment and details of any action taken should be submitted to the centre's inspector by 20 May 2013.	A step has been added to our process and associated SOP to confirm that all tubes from the oocyte retrieval have been passed through to the laboratory before the theatre is cleared for the next patient. Documents submitted (NFC/SOP/Clinical/93).	No further action is required.
3. Sperm to be used for surrogacy is not quarantined for a minimum of 180 days, prior to repeat screening of the donor. The donor's blood is not tested by the nucleic acid amplification technique (NAT) for HIV, HBV or HCV. Processing of gametes does not include a validated inactivation step for these viruses. The PR has confirmed that	The PR should ensure that gamete providers in all future surrogacy arrangements are appropriately screened. The PR should amend relevant SOPs and a summary of any changes should be forwarded to the centre's inspector. If necessary, staff training should be provided to ensure the requirements of SLC	There is inconsistency in dealing with couples commissioning full surrogacy where embryos are transferred rather than insemination of semen/sperm undertaken, compared with other embryo donors where it is not expected that sperm is quarantined in advance. Quarantining sperm in this situation risks either long term storage of sperm which is not used if a surrogate is not identified or risk of losing a recruited surrogate when there is a delay for quarantining. In addition the infection risk from sperm	The inspection team acknowledges the PR's commitment to introduce NAT testing. Any modified SOPs should be forwarded to the centre's inspector.

there have been no surrogacy cases at the centre since the time of the last inspection and so there has been no 'significant risk of causing harm to patients'. The PR has also confirmed that the centre is currently working towards implementing NAT testing for surrogacy. SLC T53c	T53c are complied with. By 20 May 2013.	in this setting is umlikely to be any greater than that from an egg for which there is no quarantine requirement. In order however to satisfy the HFEA requirements the Centre will undertake NAT testing of the commissioning male in addition to standard viral screening prior to treatment. SOPs will be modified to reflect this.	

Additional information from the Person Responsible

Thank you.
Page 9. "Outcomes" whilst we acknowledge the data highlighted can we point out that this is unvalidated data both in relation to our returns to HFEA but also unvalidated with regard to national background data which is similarly not prepared for publication.

HFEA Executive Licensing Panel Meeting

10 May 2013

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

Minutes – Item 1

Centre 0017 – (Newcastle Fertility Centre at Life) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair) Nick Jones – Director of Compliance Ian Peacock – Analyst Programmer	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 has held an HFEA licence since 1992.

2. The Panel noted that in the 12 months to 31 December 2012, the centre provided 952 cycles of treatment (excluding partner intrauterine insemination).

3. The Panel noted that the inspection took place on 20 February 2013.

4. The Panel noted that, at the time of inspection, one major and two other areas of non-compliance were identified.

5. The Panel noted the outstanding area of non-compliance relating to sperm not being quarantined for a minimum of 180 days in surrogacy arrangements.

6. The Panel noted that all issues identified at the last inspection have since been addressed by the Person Responsible.

Decision

7. The Panel endorsed the Inspectorate's recommendations and agreed to continue the centre's licence with no additional conditions.

Signed:  Date: 15/5/13

Juliet Tizzard (Chair)