HFEA Executive Licensing Panel Meeting

30 May 2014

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

Minutes – Item 3

Centre 0162 – (Queens Medical Centre Fertility Unit) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Rachel Hopkins – Head of HR (Chair)	Dee Knoyle
David Moysen – Head of IT	**Observing:**
Matthew Watts – Regulatory Policy Manager	Sam Hartley – Head of Governance and Licensing

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:

- 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 Queen's Medical Centre Fertility Unit is located in Nottingham within the Queen's Medical Campus which is part of Nottingham University Hospitals NHS Trust and has held a licence with the HFEA since 1992. The centre provides treatment (insemination using partner/donor sperm) and storage.

2. The Panel noted that the centre is currently on a four-year licence, due to expire on 30 June 2016.

3. The Panel noted that the inspection took place on 5 March 2014.

4. The Panel noted that in the 12 months to January 2014, the centre provided 71 cycles of donor insemination treatment (excluding partner intrauterine insemination).

5. The Panel noted that for the year 2013 the centre reported 271 cycles of partner insemination with 30 pregnancies; this equates to a clinical pregnancy rate of 11%. The national average for 2013 was not available for comparison.

6. The Panel noted that HFEA-held register data for the year ending October 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

7. The Panel noted that for IUI treatment during 2013 the centre reported four multiple pregnancies.

8. The Panel noted that at the time of inspection there were two major and three 'other' areas of non-compliance identified. The Panel noted in particular the non-compliances in relation to the submission of information to the HFEA, quality indicators and audits. The Panel noted that the Person Responsible (PR) has addressed one 'other' area of non-compliance and has committed to fully implementing all of the outstanding recommendations within the prescribed timescales.

9. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

10. The Panel noted that the Inspectorate recommends the continuation of the centre's licence.

Decision

11. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Treatment (insemination using partner/donor sperm) licence continued. The Panel urged the centre to work hard to fully address all the recommendations made in this interim inspection report within the prescribed timescales, in particular quality indicators and audits raised at the last inspection.

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

13. The Panel is in support of the Inspectorate monitoring the centre's progress closely and reporting any delays in implementing the recommendations to a licensing committee.

Signed: Date: 12 June 2014
Rachel Hopkins (Chair)

Interim Licensing Report

Centre name: Queens Medical Centre Fertility Unit
Centre number: 0162
Date licence issued: 01/07/2012
Licence expiry date: 30/06/2016
Additional conditions applied to this licence: None
Date of inspection: 05/03/2014
Inspectors: Parvez Qureshi (lead), Karen Conyers (observing)
Date of Executive Licensing Panel: 30/05/2014

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 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 positive comments made by patients in their feedback in relation to their experiences at the centre.

The Executive Licensing Panel is asked to note that there were no recommendations for improvement in relation to 'critical' areas of non-compliance but recommendations were made in relation to two 'major' areas and three 'other' areas of non-compliance at the time of the inspection: Since the inspection visit the following recommendation has been implemented:

Other' areas of practice that require improvement:

- The PR should ensure that assessments of staff competency to perform their designated tasks are documented.

The PR has given a commitment to fully implement the following recommendations:

'Major' areas of non compliance:

- The Person Responsible (PR) should ensure that written consent to disclosure to researchers is taken whenever appropriate and records of this are retained in the patients file.
- The PR should establish quality indicators (QIs) or objectives relevant to all activities and conduct regular audits for the procedures identified during the inspection.

'Other' areas of practice that require improvement:

- The PR should ensure that witnessing checks are completed and recorded at the time the procedure takes place and a record retained in the patient's medical records.
- The PR should investigate the current barriers to the centre being able to submit information via the EDI system and work with the Trust IT department, and that of the HFEA to ensure that this issue is resolved without further delay.

In consideration that the PR gave a commitment to implement recommendations relating to the development of QIs and the conduct of relevant audits and also in consideration of the serious implications of the centre being unable to record treatments to the HFEA in line with the requirements of Directions the Executive undertakes to monitor the centre's progress closely and to refer any delays in implementing the recommendations to a licensing committee.

Information about the centre

Queen's Medical Centre Fertility Unit has been licensed by the HFEA for treatment and storage of gametes since 1992. The centre is an NHS clinic which is located within the Queen's Medical Campus which is part of Nottingham University Hospitals NHS Trust.

The centre provides a service for the diagnosis and treatment of sub-fertility and insemination with partner or donor sperm. The centre also incorporates the andrology department which provides a service for those wishing to donate sperm and for those wishing to store their sperm for the preservation of fertility.

The centre provided 71 cycles of donor insemination treatment (excluding partner intrauterine insemination) in the 12 months to January 2014. In relation to activity levels this is a small centre.

An application to vary the centre's licence to change the PR was granted by an Executive Licensing Panel on 20 February 2014. The minutes confirming this decision were only available following this inspection.

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 October 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2013 the centre reported 271 cycles of partner insemination with 30 pregnancies; this equates to a clinical pregnancy rate of 11%. The national average for 2013 is not yet available for comparison.

Multiple births

The single biggest risk of fertility treatment is a multiple pregnancy. For IUI treatment during 2013 the centre reported four multiple pregnancies.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur.

[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.

The following laboratory activities were observed in the course of the inspection; IUI sperm sample preparation and insemination. Whilst activities were appropriately witnessed by a second person, the time of witnessing is not recorded. This was also noted during a review of witnessing records in five sets of patient notes. In addition some records of witnessing steps are not retained in the patient's records (see recommendation 4).

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. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The HFEA does not hold information, including records of intentions relating to consent to disclosure, about patients having IUI treatment with their partner's sperm. Therefore the centre is not required to collect and report consents for disclosure to researchers for this group of patients.

The records of consent to disclosure to researchers for four DI patients and their partners were reviewed in the course of the inspection. It was noted that written consent to disclosure had not been completed in any of the records seen. Staff stated that verbal consent had been taken and this was then recorded directly on to EDI (see recommendation 1).

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that gametes currently in store are being stored within their consented storage period. The storage periods for five sets of gametes as recorded on the centre's database were cross checked against the consent given by the gamete providers. In the five sets of records checked, the gametes were 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 five patients who provided feedback on their experiences. A further 17 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 12 of the individuals providing written feedback to the HFEA commenting that they have 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 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 the following non-compliances:

- The centre has not established (QIs) or quality objectives relevant to following procedures: consent, welfare of the child (WoC), traceability, data submission to the HFEA and confidentiality. The centre has not audited some of the procedures against compliance with the approved protocols, regulatory requirements and QIs in the last two years. This was identified as a non-compliance at the time of the centre's last inspection. See recommendation 2.
- Not all staff were able to provide documented evidence of the assessment of their competence to perform their designated tasks (see recommendation 3).
- The register team of the HFEA report that the centre has been unable to submit required treatment and donor information via the HFEA Electronic Data Interface (EDI) system for over four months. See recommendation 5.

Compliance with recommendations made at the time of the last inspection

Following a renewal inspection in February 2012 recommendations for improvement were made in relation to four areas of major non-compliance and three 'other' areas of practice that required improvement.

The PR provided information and evidence that six of the recommendations were fully implemented within the prescribed timescales.

Although the PR gave a commitment to implement the remaining recommendation, no evidence was available during our inspection to support this (see recommendation 2):

- The PR should establish QIs or objectives relevant to all activities and conduct regular audits for them.

On-going monitoring of centre success rates

In the last year, the centre has not been issued with any performance alerts relating to treatments with donor sperm.

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 register team of the HFEA report that the centre has been unable to submit required treatment and donor information via the HFEA Electronic Data Interface (EDI) system for over four months. The centre reports that this is due to yet unresolved issues with the Trust IT systems.

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
1. The records of consent to disclosure to researchers for four DI patients and their partners were reviewed in the course of the inspection. It was noted that written consent to disclosure had not been completed in any of the records seen. Staff stated that verbal consent had been taken and this was then recorded directly on to EDI. Guidance supplementary to Chair’s Letter CH (10)05 and Direction 0007.	The PR should ensure that written consent to disclosure to researchers is taken whenever appropriate and records of this are retained in the patients file. The PR should audit consent to disclosure to researcher decisions to ensure the changes are effective and a summary report of the findings of the audit should be provided to the HFEA by 05 June 2014. The HFEA may require the centre to perform an audit of individual consent records against the consent decision held by the HFEA in the	We have now introduced that any new patient using donor gametes give their written consent to disclosure to researchers on the HFEA form. We have started using these forms and will provide the results of the audit	The lead inspector considers this to be an acceptable response. The PR to inform the centre inspector on completion of this action. Further action required.

	future if an application is made by researchers for the release of that information.		
2. The centre has not established QIs or quality objectives relevant to following procedures: Consent, WoC, Traceability, Data submission to the HFEA, and Confidentiality (SLC T35) The centre has not audited some of the procedures against compliance with the approved protocols, the regulatory requirements and QI in the last two years. (SLC T36) These were identified as areas for improvement at the time of the last inspection.	The PR should establish QIs or objectives relevant to all activities and conduct regular audits for the procedures identified during the inspection. The PR should provide the centre's inspector with a schedule documenting the anticipated timescale for completion of these audits by 05 June 2014 The PR should provide a copy of the final audit reports are to be provided to the centre inspector by 5 September 2104.	We are reviewing our procedures and pathways and plan to audit them. We plan to audit confidentiality by identifying any non-conformities relating to it and patient survey	The lead inspector considers this to be an acceptable response. The PR to inform the centre inspector on completion of this action. Further action required.

‘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
3. Not all staff were able to provide documented evidence of the assessment of their competency to perform their designated tasks. (SLC T15a)	The PR should ensure that an assessment of staff competency to perform their designated tasks is documented. This action should be implemented by 05 September 2014.	All nursing competencies are signed by the PR and included in the nursing portfolios.	The lead inspector considers this to be an acceptable response. No further action required.
4. No time of witnessing is recorded. In addition, records of witnessing steps are not retained in the patient’s records. (SLC T71)	The PR should ensure that witnessing checks are completed and recorded at the time the procedure takes place and a record retained in the patient’s medical records. The PR should review relevant documentation of procedures to reflect necessary changes that ensure the time of witnessing is recorded and appropriate records are kept. A copy of any amended documentation should be forwarded to the centre’s inspector by 05 June 2014.	We have started including times on the witnessing record sheets. We will include this in the forms as an amendment and audit it.	The lead inspector considers this to be an acceptable response. The PR to inform the centre inspector on completion of this action. Further action required.

	The PR should conduct an audit of witnessing records to ensure the changes are effective. The PR is to provide a summary report of this audit to the HFEA by 05 September 2014.		
5. The register team of the HFEA report that the centre has been unable to submit required treatment and donor information via the HFEA Electronic Data Interface (EDI) system for over four months. The centre reports that this is due to unresolved issues with the Trust IT systems. By not providing this information to the HFEA the Authority is at risk of not being able to fulfil its statutory function of maintaining an accurate register of treatment and donation or to provide information to the parents of the donor conceived. Directions 0005	The PR should investigate the current barriers to the centre being able to submit information via the EDI system and work with the Trust IT department, and that of the HFEA to ensure that this issue is resolved without further delay. The PR should provide the HFEA with a summary of her findings in response to this report. Subject to the findings of her preliminary investigation, the PR should provide an update on progress / resolution to the register team and to the centre's inspector by 5 May 2014 and weekly there after if the matter is not resolved.	The Trust IT has been liaised with regarding the EDI system and has been formally agreed by the Trust management. We await its implementation by our Trust IT services.	The lead inspector considers this to be an acceptable response. The PR to inform the centre inspector and the HFEA register team on completion of this action. Further action required.

Additional information from the Person Responsible
As advised, we have conducted the "Consent to Legal Parenthood" Audit. All of our unmarried/not in civil partnership couples that have had pregnancies/are pregnant have completed the forms making us 100% compliant. Consent to disclosure, Welfare of the Child and Consent to treatment forms were also looked at for all patients as per HFEA inspection. All sets of notes had all consent forms present. Please let me know if the committee wished to see the detailed data on this audit.

Trim Reference: 2014/006824
Centre name & number: Queens Medical Centre Fertility Unit 0162