HFEA Executive Licensing Panel Meeting

5 September 2014

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

Minutes – Item 4

Centre 0119 – (Birmingham Women's Hospital) – Interim Treatment (including embryo testing) & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Director of Strategy & Corporate Affairs David Moysen – Head of IT Rachel Hopkins – Head of Human Resources	Dee Knoyle

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

1. The Panel noted that the Birmingham Women's Hospital has held an HFEA licence since 1992. The centre provides a full range of fertility services, including embryo testing.

2. The Panel noted that the centre's licence is due to expire on 30 November 2016.

3. The Panel noted that the inspection took place on 11 June 2014.

4. The Panel noted that in the 12 months to 30 April 2014, the centre provided 1007 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

5. The Panel noted that in 2013, the centre reported 135 cycles of partner insemination with 17 pregnancies. This equates to a 13% clinical pregnancy rate which is consistent with the national average.

6. The Panel noted that for IVF and ICSI, HFEA-held register data for the year ending January 2014 show the centre's success rates are in line with national averages.

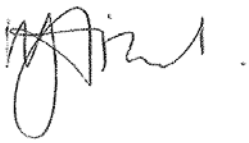
7. Between 1 February 2013 and 31 January 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represented performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

8. The Panel noted that at the time of the interim inspection on 11 June 2014, two major and one other area of non-compliance were identified. The Panel noted that the Person Responsible is committed to fully implement the recommendations made by the Inspectorate.

9. The Panel noted that the Inspectorate recommended the continuation of the centre's licence.

Decision

10. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment (including embryo testing) and storage licence continued.



Signed: Date: 15 September 2014

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Birmingham Women's Hospital
Centre number: 0119
Date licence issued: 01/12/2012
Licence expiry date: 30/11/2016
Additional conditions applied to this licence: None
Date of inspection: 11/06/2014
Inspectors: Sara Parlett (lead), Janet Kirkland, Karen Conyers (observing)
Date of Executive Licensing Panel: 05/09/2014

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 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 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. In particular we note the progress made by the centre in meeting the HFEA multiple birth rate targets.

The ELP is asked to note that the report makes recommendations for improvement in relation to two major and one 'other' areas of non-compliance. Since the inspection, the Person Responsible (PR) has given a commitment to implement the following recommendations within the specified timescales:

'Major' areas of non compliance:

- The PR should review the procedures for checking and submitting consent to disclosure decisions to the HFEA and ensure that patients are given sufficient information to complete the consent to disclosure form clearly and accurately.
- The PR should ensure that wherever possible only CE marked consumables are used.

The PR has provided evidence that the following recommendation has been fully implemented:

'Other' areas of practice that require improvement:

- The PR should consider the risks of not labelling the containers used during egg collection.

Information about the centre

The assisted conception unit at Birmingham Women's Hospital has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services, including embryo testing.

The centre provided 1007 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30/04/2014. In relation to activity levels this is a large 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.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending January 2014 show the centre's success rates are in line with national averages.

In 2013, the centre reported 135 cycles of partner insemination with 17 pregnancies. This equates to a 13% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

Between 01/02/2013 and 31/01/2014 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

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, sperm thaw and embryo freeze. All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing system.

The inspection team was able to review witnessing records that were present in five sets of patient notes and concluded that records of witnessing are accurately maintained.

[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%.

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 01/10/2009, 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 were reviewed in the course of the inspection. The following issues were noted:

- Four of the consent decisions documented in the patient's files did not correspond to those recorded on the HFEA register. In three cases the disclosure consent form in the patient files indicated that consent had been given but the data submitted to the HFEA register recorded that it had been withheld. In one case, the patient had not consented to contact research but the data submitted to the HFEA register recorded that consent had been given.
- In three of the records reviewed it was apparent that the instructions on the completion of the consent form by the patient had not been adhered to. This would result in centre staff inputting the data to the HFEA register having to use an element of judgement in determining the decision of the patient. This issue raised concern that the completion of the consent form and the implications of the consent decision are not being explained effectively to patients (see recommendation 1).

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, with one exception; one set of embryos were being stored for the permitted "cooling off" period after one gamete provider had withdrawn consent to storage. The storage period for one set of embryos as recorded on the centre's database was cross checked against the consent given by the gamete providers. In the set of records checked, the embryos 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 three patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further seven patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with four of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received. The patients interviewed also provided positive feedback on their experiences.

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;
- maintains an effective system for responding to patient phone calls.

The centre conducts patient satisfaction surveys and the most recent survey results from April – June 2014 were provided on inspection. Positive feedback was received.

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 unique identifier or a uniquely identifying donor code (see recommendation 3).
- Serological pipettes used in the laboratory are not CE marked. Glass Pasteur pipettes in use in the laboratory did not appear to be CE marked. It is the inspection team's understanding that CE marked equivalents are available (see recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2012 recommendations for improvement were made in relation to two major and four '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

No risk tool alerts have been received by the centre in relation to success rates or multiple pregnancy rates in the last twelve months.

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 compliant with register submission related 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.			

‘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. Four of the consent to disclosure decisions documented in the patient’s files did not correspond to those recorded on the HFEA register. In addition it was apparent that the instructions on the completion of the consent form had not been adhered to. This raises concerns that the completion of the consents and the implications of the consent decisions are not being explained effectively to patients. General Directions 0005	The PR should ensure that the submissions that have been identified as being incorrect are corrected. The PR should review systems and processes to ensure that in future, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms. This should include ensuring staff are trained and competent in obtaining effective consent and submitting consent to disclosure decisions to the HFEA. A summary report of	An initial review of the process suggests that problems in completion of the forms have lead to ambiguities which have lead to the inaccuracies in the data submitted. The standard operating procedure for staff and and the information sheet for patients has been revised to include more detailed information on completion of these forms. These have been submitted to our inspector. A training sessionfor staff has been organised to reinforce the process. Corrections of the errors identified is underway.	The PR has submitted a detailed SOP and patient information. The lead inspector acknowledges the PR’s response and this will be subject to on-going monitoring.

and SLC T58.	the findings of the review, including corrective action and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 11 September 2014. Three months after the implementation of corrective action, the centre should perform an audit of a random representative sample of patient records to ensure that these corrective actions are effective. This audit should be submitted to the centre's inspector by 11 January 2015.		
2. Serological pipettes in use in the laboratory are not CE marked. Glass Pasteur pipettes in use did not appear to be CE marked. SLC T30.	The PR should ensure that wherever possible CE marked medical devices are used. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this, the PR should provide the centre's inspector with a list of all	A source of CE marked serological pipettes has been identified and these have been ordered. The centre is already using CE marked Pasteurs. The list of medical devices will be submitted within the timescale.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

	medical devices (consumables and reagents) currently in use in the clinic. The list should document the CE mark status of each device and where devices are not CE marked, the list should document either the anticipated time by which a CE mark is expected to be obtained or the action that will be taken to ensure compliance within the next year. This list should be submitted by 11 September 2014.		

‘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. 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.	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 and dishes 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 11 September 2014.	The standard operating procedures for the laboratory and theatre which document the procedures for ensuring that all unlabelled tubes and dishes are disposed of after the completion of one case and before the commencement of the next, have been submitted. As this is a dedicated theatre facility with only one case taking place at a time there should be no unlabelled material that might give rise to a risk of misidentification.	The lead inspector acknowledges the PR’s response. The PR has also confirmed that a record of the completion of this check step will be made in the patient notes. No further action is required.

Additional information from the Person Responsible