HFEA Executive Licensing Panel Meeting

28 November 2014

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

Minutes – Item 3

Centre 0077 – Regional Fertility Centre, Belfast – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard (Chair) Director of Strategy & Corporate Affairs Ian Peacock – Analyst Programmer Joanne Anton – Policy Manager	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 Regional Fertility Centre, Belfast has held an HFEA licence since 1992. The centre provides a full range of fertility services.

2. The Panel noted that the centre's licence is due to expire on 28 February 2017.

3. The Panel noted that the inspection took place on 10 September 2014.

4. The Panel noted that in the 12 months to 31 July 2014, the centre provided 1159 cycles of treatment (excluding partner intrauterine insemination) in. In relation to activity levels this is a large centre.

5. The Panel noted that HFEA-held register data for the year ending April 2014 showed the centre's success rates in terms of clinical pregnancy rates were in line with national averages with the following exceptions:

    - Clinical pregnancy rates following IVF treatment in patients aged 16 to 37 years are lower than average at a statistically significant level.
    - Clinical pregnancy rates following ICSI treatment in patients aged 16 to 37 years are lower than average at a statistically significant level.

6. The Panel noted that for the year 2013, the centre reported 62 cycles of partner insemination with two pregnancies. This equates to a 3% pregnancy rate which was consistent with the national average.

7. Between 1 June 2013 and 31 May 2014 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

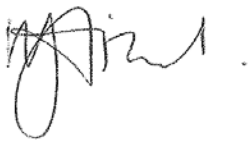
8. The Panel noted that at the time of the interim inspection on 10 September 2014, one major and one other area of non-compliance were identified. The Panel noted that the Person Responsible (PR) has committed to implement the outstanding recommendation within the prescribed timescale.

9. The Panel noted the relatively high proportion of negative feedback made by patients in relation to their experience of the centre, though acknowledged the PR was being proactive in addressing the issues raised by patients and that the Inspectorate will liaise closely with the centre to monitor patient feedback.

10. The Panel noted that the Inspectorate recommended 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 and storage licence continued.



Signed: Date: 3 December 2014

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Regional Fertility Centre, Belfast
Centre number: 0077
Date licence issued: 1 March 2013
Licence expiry date: 28 February 2017
Additional conditions applied to this licence: None
Date of inspection: 10 September 2014
Inspectors: Mrs Lisa Beaumont (Lead) and Mrs Sara Parlett
Date of Executive Licensing Panel: 28 November 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 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 Executive Licensing Panel is asked to note that the report makes recommendations for improvement in relation to one major and one 'other' areas of non-compliance. Since the inspection, the Person Responsible (PR) has implemented the following recommendation:

'Other' areas of practice that require improvement:

- the PR should assess the risks of not labelling the tubes and dishes used during egg collection and should take action to mitigate any risks identified.

The PR has given a commitment to implement the following recommendation within the specified timescale:

Major areas of practice that require improvement:

- the PR should ensure that welfare of the child assessments are completed and audit processes are reviewed to ensure they are robust.

Information about the centre

The Regional Fertility Centre, Belfast has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services.

The centre provided 1159 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 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]

HFEA held register data for the year ending April 2014 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 treatment in patients aged 16 to 37 years are lower than average at a statistically significant level.
- Clinical pregnancy rates following ICSI treatment in patients aged 16 to 37 years are lower than average at a statistically significant level.

Refer to page 6 of this report for further details.

For the year 2013 the centre reported 62 cycles of partner insemination with two pregnancies. This equates to a three per cent pregnancy rate which is consistent with the national average.

Multiple births[2]

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

Between 1 June 2013 and 31 May 2014 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. 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

[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%.

observed in the course of the inspection: sperm preparation and egg collection. All of the procedures observed were witnessed in accordance with HFEA requirements using a combination of electronic and manual witnessing systems.

The inspection team reviewed records that were present in five sets of patient notes and concluded that records of manual and electronic witnessing are accurately maintained.

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 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 with two exceptions: two sets of embryos were being stored for the permitted 'cooling off' period after one gamete provider had withdrawn consent to storage.

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 couples who provided feedback on their experiences, and we observed interactions between centre staff and patients. All three couples gave consistent, positive feedback on the care they had received. Two couples commented that the temperature of the waiting room can get too high and that a water dispenser would be appreciated.

A further 42 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was fairly negative overall with 25 individuals commenting that they had a complaint and 17 individuals commenting that they have compliments about the care that they received.

The negative feedback relates to the following areas:

- staff in the administration team are rude and unhelpful;
- patients have difficulty getting through to reception;
- long waiting list causing a delay in treatment;
- appointments delayed / cancelled.

The inspection team discussed this feedback in detail with the centre, and notes the following actions have been taken:

- staff in the administration team have recently attended training on complaints management and handling difficult phone calls;
- from October 2014 a new phone system will be installed which will provide options for callers to enable calls to be streamed and answered more efficiently. There will also be dedicated direct numbers to contact the nursing team and the waiting list management team;
- NHS patient treatment is locally commissioned to start within 12 months of referral, but the centre is currently offering treatment to commence within 6 months because it has the capacity to do so, and believes this is in the best interests of the patients;
- a new system was introduced in November 2013 enabling the centre to contact patients more efficiently and therefore start treatment more quickly. This has had a positive impact on the number of complaints related to treatment delays.

The inspection team considers that the PR is being proactive in addressing the issues raised by patients and does not consider a recommendation is proportionate, however the centre's inspector will liaise closely with the centre to monitor patient feedback going forward.

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

- is proactive in addressing a lot of the issues related to patient complaints;
- 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.

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:

- In two of five sets of notes reviewed, the welfare of the child assessment had not been completed by centre staff. In one of these sets of notes, the assessment had also not been fully completed by the patients. A recent welfare of the child audit did not identify that the forms had not been completed by the centre, which raises concern that the

centre's audit processes are not suitably robust. The PR explained that these errors occurred during a transition phase from doctor to nurse led consent sessions for welfare of the child. The PR was confident that the issue has since been resolved but committed to giving consideration to the wider co dependencies when making any change to a patient pathway process and to reviewing the audit process accordingly to ensure it is more robust. See recommendation 1.

- The tubes and dishes used during the procurement of eggs are not labelled with the provider's full name and a further 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 September 2012, recommendations for improvement were made in relation to seven areas of major non-compliance and four 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales; however it is noted that non-compliance related to welfare of the child assessment was observed at this inspection indicating that corrective action implemented after the last inspection has not been effective. See recommendation 1.

On-going monitoring of centre success rates

The centre has received four performance alerts within the last 12 months relating to success rates for ICSI and IVF in patients aged under 38 years. The centre provided brief responses to these alerts, concluding that the drop in success rates was due to a high number of patients failing to reach embryo transfer stage and that changes have been made to the stimulation regime. There has been a subsequent improvement in the success rates and the inspection team considers that no further regulatory action would be proportionate at this time. The centre's success rates will continue to be the subject of on-going monitoring.

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 HFEA requirements in relation to the submission of information to the HFEA and whilst it is noted that improvements could be made in the timeliness of data submissions, this issue is not considered significant enough to warrant a recommendation.

Legal parenthood audit

The partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born to become the legal parent. In February 2014, the HFEA asked all centres to audit their practices in this area to

ensure they are suitable, to report the findings of the audit to the HFEA and to respond to them. On this inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that appropriate actions had been taken in response to the audits findings.

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 two of five sets of notes reviewed, the welfare of the child assessment had not been completed by centre staff. In one of these sets of notes, the assessment had also not been fully completed by the patients. A recent welfare of the child audit did not identify that the forms had not been completed by the centre, which raises concern that the centre’s audit processes are not robust enough. The PR explained that these errors occurred during a transition phase from doctor to nurse	The PR should review audit processes to take account of any co dependencies identified as a result of a change to a patient pathway process, to ensure audit processes are more robust. The PR should conduct an audit of welfare of the child assessment in three months time, to confirm that the changes made in implementing nurse led welfare of the child assessment have been effective in ensuring that these assessments are fully completed by patients, are reviewed by centre staff and that the review and any	Our audit carried out immediately after the inspection (attached) has demonstrated that our previous procedures for WOC assessments were not identifying that assessments were being completed correctly in all cases. Following a change in practice from consents being medical led to nurse led, we failed to recognise the potential impact this could have on the review of WOC assessments. Current practice is for the WOC assessment to be made by medical staff before any patient is placed on a	The Executive acknowledges the PR’s comments and the corrective actions identified from the centre’s own audit which will be implemented to ensure that welfare of the child assessments will be completed as per regulatory requirements. Further action is required in relation to the completion of a further audit.

led consent sessions for welfare of the child. The PR was confident that the issue has since been resolved but committed to giving consideration to co dependencies when making any change to a patient pathway process and to reviewing the audit process accordingly to ensure it is more robust. (SLC T46) **This was an issue at the last inspection.**	decision is documented. A summary report of the audit findings should be provided to the HFEA by 10 December 2014.	treatment waiting list. In addition, at the nurse led consent appointment a further check is made to ensure correct procedure has been followed. If not the case is brought to the attention of medical staff, who complete the assessment, a non conformance is recorded for later analysis by the management team. We will now monitor the immediate impact of future changes in practice and we will carry out a further audit of our WOC assessment compliance and forward the summary results to the HFEA by the 10/12/14	

‘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. The tubes and dishes used during the procurement of eggs are not labelled with the provider’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 assess the risks of not labelling the tubes and dishes used during egg collection. The HFEA should be provided with evidence of the assessment undertaken, and any actions taken to mitigate the risks of misidentification as a result of this practice, by 10 December 2014.	A risk assessment was carried out after the inspection (attached). As a result, both the manual and electronic witnessing protocols (Docs no. 298 & 970 respectively) were amended to state that 'The Embryologist must ensure that the flow cabinet used for the egg collection and the heated test tube racks within the lab and treatment room are clear of all affected consumables at the end of the egg collection procedure’. The witnessing signing sheets (Docs no. 299 &1004) have been amended to reflect this change. This check is double witnessed. The amendments are highlighted.	The Executive acknowledges receipt of the risk assessment and that the PR has implemented additional check steps. No further action is required.

Additional information from the Person Responsible