HFEA Executive Licensing Panel Meeting

15 November 2013

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

Minutes – Item 2

Centre 0019 – (Aberdeen Fertility Centre) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
Joanne Anton – Policy Manager	**Observing:**
David Moysen – Head of IT	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 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, licensed by the HFEA since 1992, which provides a full range of fertility services.

2. The Panel noted that the centre is currently on a four-year licence, due to expire on 31 January 2015.

3. The Panel noted that the inspection took place on 25 October 2012. The Panel noted that there had been a significant delay in submitting the inspection report to the Panel for consideration, and expressed its disappointment and regret at this delay. The Panel were assured that processes are now in place to ensure such an error would not recur.

4. The Panel noted that for the year ending July 2012, HFEA held register data show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

5. The Panel noted that for the year 2011, the centre reported 44 cycles of partner insemination with three pregnancies. This is consistent with the national average.

6. The Panel noted that in 2010/11, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%. This represented performance that was not likely to be statistically different from the 20% multiple live birth rate target.

7. The Panel noted that for the time period 1 April 2011 to 13 July 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%. This also represents performance that is not likely to be statistically different from the 15% multiple live birth rate target.

8. The Panel noted that at the time of inspection, two major and two other areas of non-compliance were identified. The Panel noted that the PR has fully implemented all recommendations.

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

Decision

10. The Panel had regard to its decision tree. Based on the report of the inspection on 25 October 2012 the Panel was satisfied that the centre was fit to have its treatment and storage licence continued.

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

Signed: Date: 28 November 2013

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Aberdeen Fertility Centre
Centre number: 0019
Date licence issued: 01 February 2011
Licence expiry date: 31 January 2015
Additional conditions applied to this licence: None
Date of inspection: 25 October 2012
Inspectors: Gill Walsh (Lead) and David Gibbon
Date of Executive Licensing Panel: 15 November 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 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 and the very positive comments made by patients in relation to their experiences.

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major areas of non-compliance and two 'other' areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and provided evidence that the following recommendations have been fully implemented:

'**Major' areas of non compliance:**

- The PR should ensure that the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms.

- The PR should ensure all treatment data required by the HFEA is submitted within the timeframe required by Direction 0005.

'Other' areas of practice that require improvement:

- The PR should ensure that for all manual witnessing steps the witness records their signature for each step witnessed.

- The PR should ensure that the assessment of staff competence to conduct witnessing procedures is documented.

Information about the centre

The Aberdeen Fertility Centre is located within Aberdeen Maternity Hospital and is part of Aberdeen University. The centre has held a licence with the HFEA since 1992. The centre's current licence was granted on 1 February 2011 for a period of four years with no additional licence conditions.

The centre provides a full range of fertility services and provided 609 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2012. In relation to activity levels this is a medium sized 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 July 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2011 the centre reported 44 cycles of partner insemination with three pregnancies. This is consistent with the national average.

Multiple births[2]

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

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%: this represented performance that was not likely to be statistically different from the no greater than 20% multiple live birth rate target.

For the time period 1 April 2011 to 13 July 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%: this also represents performance that is not likely to be statistically different from the no greater than 15% multiple live 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.

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.

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: preparation for embryo transfer. All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing system.

The inspection team was able to review records that were present in the laboratory and concluded that records of both manual and electronic witnessing are maintained.

Of the 10 witnessing records reviewed on inspection it was noted in one record seen that one witnessing signature was absent at the time of embryo transfer (see recommendation 3).

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 five cases (see recommendation 1).

Consent: To the storage of cryopreserved material

A review of the centre's records of consent to storage of gametes and embryos showed that all gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period.

The storage period for three sets of embryos as recorded on the centre's database was cross checked against the consenting decisions made by the gamete providers as recorded in the gamete provider's primary record. 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: 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.

The PR stated that she felt there are sufficient staff currently of an appropriate skill mix to accommodate the current level of activity. A full staffing and material resources review has recently been conducted as part of a scoping exercise to determine the resources required to meet likely increase in activity over the next year to 18 months as a result of waiting list initiatives.

Patient experience

During the inspection visit we spoke to three patients and their partners who provided feedback on their experiences and observed interactions between centre staff and patients. A further 29 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with 16 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 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.

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 performs diagnostic semen analysis. Centre staff explained that they have chosen to apply for CPA accreditation of the andrology laboratory most likely in early 2013. Evidence was provided demonstrating the significant amount of work that has been undertaken in preparation for CPA requirements. In the course of the inspection it was noted that the centre has a quality management system; has validated procedures and equipment; staff are suitably qualified to perform and interpret the tests; and participates in the national external quality assessment scheme (NEQAS) for semen analysis. In consideration of this, the centre's semen analysis service is considered to have a status equivalent to that provided by CPA accreditation. In terms of HFEA requirements, no further action is required by the centre in relation to CPA accreditation.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in August 2010 recommendations for improvement were made in relation to two areas of major non-compliance and six 'other' areas of non-compliance.

The PR provided information and evidence that all but one of the recommendations were fully implemented within the prescribed timescales. It was noted on inspection that the assessment of competence to witness was not documented for one member of staff (see recommendation 4).

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.

This centre has a good record of data submission and of compliance with related regulatory requirements. The quality of data currently supplied to the HFEA contains a low level of error and the centre works proactively with the HFEA to correct errors. However, the registry department of the HFEA report that intention to treat forms (ITT) forms are not always submitted within the timeframe required by Direction 0005 and at the time of inspection a considerable number of forms remain outstanding. This is a recurrence of an issue noted at the last inspection (see recommendation 2).

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. The record of the consent to disclosure to researchers decision recorded on the HFEA register as submitted by the centre via the EDI system did not accurately reflect that recorded in the patient / partner's primary medical record held in the centre in five of the records reviewed. The consent decision recorded with the HFEA presented a risk of unauthorised consent to disclosure of information regarding treatment in two instances. Chair's letter CH(12)03	The centre should review its related systems and processes by which these consenting decisions are communicated to the HFEA. Where appropriate, the cause(s) of these discrepancies should be addressed. 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 communicated for entry on to the HFEA register.	We have gone over the notes that were reviewed at the time of inspection and have highlighted the discrepancies in red (attachment 1). The staff entering the data have had a tutorial. The database has been changed to exactly same language as is on CD form to avoid wrong interpretation. In addition audits have been put in place in Dec 2012 and January 2013 to check if new system is working. The report of these audits will be	The inspection team is satisfied with the PR's response. Evidence of training and correction of the consent decisions identified has been completed. An audit and evidence of corrective actions was provided by the PR by the due date. No further action is required.

	The records audited should have had this consent completed within the previous three months. This audit should be submitted to the HFEA by 28 February 2013. The HFEA may require the centre to perform an audit of individual consent records against the consent decision held by the HFEA in the future if an application is made by researchers for the release of that information.	submitted to HFEA in February 2013	
2. ITT forms are not always submitted within the timeframe required by Direction 0005 and at the time of inspection a considerable number of forms remain outstanding. This is a recurrence of a similar issue addressed following the last inspection report.	The PR should review the systems for the submission of ITT forms to ensure that treatment forms are submitted in a timely fashion in accordance with Directions and that the back log of submissions is addressed. By 25 January 2013	There is an operating protocol in place (OP-GN-0056) regarding data entry and areas of responsibility. Staff have been made aware of this and we have put a time aside in January to re-audit this process where timeline for each patient will be undertaken. On looking at clinical portal the number of late submissions have reduced dramatically over	The inspection team is satisfied with the PR's response. A revised SOP has been provided prior to the due date and the register team currently report that treatment data is submitted within acceptable timeframes. No further action is required.

		the last months and we will endeavour to continue to improve on this.	

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. It was noted in one record seen that one witnessing signature was absent at the time of embryo transfer. SLC T71	The PR should ensure that for all manual witnessing steps the witness records their signature for each step witnessed. Immediately	This was clarified when summary of inspection was presented -the electronic witness was in place and report available to see. This was during the introduction of the electronic witnessing and at this time both manual and electronic witnessing was taking place.	The inspection team is satisfied with the PR's response. No further action required.
4. Not all relevant staff can provide documented evidence of the assessment of their competence to witnessing. SLC T15a	The PR should ensure that the assessment of staff competence to conduct witnessing procedures is documented. By 25 January 2013	A new competency form has been designed (attachment 2). All relevant staff will have it signed by 25th January 2013.	The PR has provided evidence that this recommendation has been fully implemented. No further action is required.

Additional information from the Person Responsible