Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at
Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF
on
30 January 2015

Minutes – item no. 1

Centre 0321 (NewLife Fertility Centre) – (Interim Inspection Report)

Members of the Panel:	Juliet Tizzard **Director of Strategy & Corporate Affairs (Chair)** Nick Jones **Director of Compliance & Information** Hannah Verdin **Head of Regulatory Policy**
Observing:	
Committee Secretary:	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 the 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 the 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 the publication of Authority and committee papers

Consideration of Application

1. The Panel noted that NewLife Fertility Centre has held a licence with the HFEA since August 2011. The centre is located in Epsom, Surrey and provides a full range of fertility services including embryo testing.

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

3. The Panel noted that the inspection took place on 12 November 2014.

4. The Panel noted that in the 12 months to 30 September 2014, the centre provided 215 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

5. The Panel noted that for IVF and ICSI HFEA-held register data for the period August 2013 to July 2014 showed the centre's success rates were in line with national averages.

6. The Panel noted that in 2013 the centre reported 48 cycles of partner insemination with five pregnancies which was in line with the national average.

7. Between August 2013 and July 2014, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 29%. This represented performance that was likely to be significantly higher than the 10% maximum multiple live birth rate target for this period.

8. The Panel noted that at the time of the interim inspection on 12 November 2014, one major area of non-compliance was identified. The Panel noted the Inspectorate's recommendation that the Person Responsible (PR) should review the effectiveness of the centre's multiple births minimisation strategy and their compliance with this strategy and provide a summary of the findings to the HFEA. The Panel noted that the PR has committed to continue to monitor the pregnancies resulting from treatment at the centre and to review the elective single embryo transfer policy accordingly.

9. The Panel noted the progress the centre has made towards compliance through implementing the recommendations identified at the previous inspection.

10. The Panel noted the positive comments received from patients in relation to their experience at the centre.

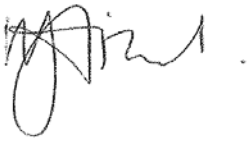
11. The Panel noted that the Inspectorate recommended the continuation of the centre's licence.

Decision

12. The Panel was concerned about the major non-compliance relating to multiple births and the PR's lack of awareness of the centre's performance. A multiple pregnancy is the single biggest risk of fertility treatment. The Panel agreed that the major non-compliance relating to multiple births requires action from the PR to mitigate future potential risks and urged the PR to engage with the Inspectorate and address this matter urgently.

13. The Panel endorsed the Inspectorate's recommendation that the PR should review the effectiveness of the centre's multiple births minimisation strategy and their compliance with this strategy and provide a summary of the findings to the HFEA. The Panel agreed that the if Inspectorate is not satisfied with the centre's progress in addressing this non-compliance and has further concerns, it should return to the ELP or or take further regulatory action, in line with the Compliance and Enforcement Policy.

14. 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: 12 February 2015
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: NewLife Fertility Centre
Centre number: 0321
Date licence issued: 03/08/2013
Licence expiry date: 02/08/2016
Additional conditions applied to this licence: None
Date of inspection: 12/11/2014
Inspectors: Ms Janet Kirkland (Lead) and Andrew Glew
Date of Executive Licensing Panel: 30/01/2015

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. In particular we note the progress made by the centre's team towards compliance through implementing the recommendations identified at the previous inspection and the positive comments received at the HFEA from patients in relation to their experience at the centre.

The Executive Licensing Panel is asked to note that at the time of the inspection there was one recommendation for improvement in relation to a major area of non-compliance.

Major area of non-compliance:

The PR should review the effectiveness of the centre's multiple births minimisation strategy and their compliance with this strategy. The PR should provide a summary of the findings to the HFEA. The summary should include any actions the PR intends to take in order to ensure that the centre does not exceed a multiple live birth rate of 10%.

The PR has in responding to the report committed to continue to monitor the pregnancies resulting from treatment at the centre and to review the eSET policy accordingly.

Information about the centre

The NewLife Fertility Centre is located in Epsom, Surrey and has held a licence with the HFEA since August 2011.

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

The centre performed 215 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30/09/2014. In relation to activity levels this is a small centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: They are 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 period August 2013 - July 2014 show the centre's success rates are in line with national averages.

In 2013 the centre reported 48 cycles of partner insemination with five pregnancies. This equates to a 10% 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 August 2013 and July 2014, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 29%: This represented performance that was likely to be significantly higher than the 10% multiple live birth rate target for this period.

In October 2014, the centre received a Risk Tool alert in relation to their multiple pregnancy rate. This was discussed on inspection and there appeared to be an element of confusion as to the calculation of the multiple pregnancy rate, since the centre had calculated it to be 5.1% and had therefore not taken any action. Post inspection, the inspector reviewed the centre's response to the Risk Tool alert and the figures that they had used in their calculation. The inspector noted that the centre had calculated their multiple pregnancy rate as a percentage of the total cycles performed rather than of the number of clinical pregnancies produced by those treatment cycles. The PR has been advised of this error (see recommendation 1).

[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%.

Witnessing
Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection was unannounced and the inspection team was not able to observe any activities in the laboratory. The scientific inspector did however have the opportunity to go into the laboratory with the laboratory manager and talk through the witnessing practices at the centre. The inspector considered that witnessing is performed in accordance with HFEA requirements using an electronic witnessing/manual 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.

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 ten 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 and the results of the centre's audit of stored material performed in June 2014 indicated that gametes and embryos currently in store are being stored within their consented storage period.

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 were discussed in the course of the on-site inspection and appeared to be suitable for the activities being carried out.

Patient experience
During the inspection visit there were no patients available to talk to the inspection team regarding their experiences however 12 patients had provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 11 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 did not identify any additional non-compliances.

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in February 2014, recommendations for improvement were made in relation to seven areas of major non-compliance.

The Executive at that time carefully considered whether it was appropriate to recommend continuation of the centre's licence and the ELP directed that the centre be inspected again within a 12 month period.

The centre team has worked closely with the HFEA and has provided evidence and documentation when required in order to demonstrate that all of the recommendations from the previous inspection have been implemented and are effective.

On-going monitoring of centre success rates

Since the previous inspection in February 2014 the centre team has received one performance related alert. This was in relation to their multiple pregnancy rate and is discussed in the body of the report (see recommendation 1).

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 at the HFEA reported that the centre provides information to the register in a compliant manner.

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 in order 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 those findings. The centre's legal parenthood audit was performed and submitted to the HFEA in the required manner and actions have been taken in response to the audit 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 identified			

‘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
Between August 2013 and July 2014, the centre’s multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 29%. This represented performance that was likely to be significantly higher than the10% multiple live birth rate target for this period. General Direction 0003 and SLC T2.	The PR should review the effectiveness of the centre’s multiple births minimisation strategy and their compliance with this strategy. The PR should provide a summary of the findings to the HFEA. The summary should include any actions the PR intends to take in order to ensure that the centre does not exceed a multiple live birth rate of 10%. The report should be provided by 12 January 2014.	MNewlife feels strongly that it is in the best interests of its patients to individualise their care from point of initial consultation and investigation up to embryo transfer. This includes consideration of previous fertility history and treatment outcome when counselling a patient on number of embryos to transfer, rather than implementing a blanket policy defined by age and morphological embryo grade alone. Newlife reviews its MBMS annually to identify any trend in MPR and has changed eSET criteria previously as a result. Whilst previous audits have looked at MPR per treatment	The inspector notes that the PR has provided reassurance that eSET criteria have recently been changed. In relation to activity levels this is a small centre and the impact of these changes is likely to take some time to have an effect but the centre’s progress will continue to be monitored. It is also noted that clinic staff attended the recent multiple births workshops which indicates engagement on this matter. The PR asserts that there has been no increase in multiple clinical pregnancy rate in 2014 but for the time period reported in this report (August 2013 to July 2014) the HFEA’s data

		cycle rather than per pregnancy, there has been no significant increase in MPR in 2014 compared to previous years. In fact the MPR for fresh IVF / ICSI is lower in 2014 vs 2013 (19.4% VS 22.2%). It is also important to note that due to the relatively low cycle numbers at Newlife, very few multiple pregnancy events can skew the overall percentage MPR above the desired level. Newlife has reviewed each of the cases of multiple pregnancy as a result of fresh IVF / ICSI and FET in 2014 and feels that in each case the management and number of embryos transferred was appropriate. We will continue to monitor MPR and eSET policy and review criteria accordingly in order to give our patients the best possible chance of a successful treatment and achieving their dream of a healthy family. Copy of audit submitted	shows that the clinic's clinical multiple pregnancy rate is 29%. However, the PR has quoted the multiple clinical pregnancy rate for fresh cycles only and is reminded that the HFEA target relates to all cycles, including frozen cycles. It remains a concern that the PR does not seem to have acknowledged that the clinic is failing to meet the current target at a statistically significant level. Further action required and the executive will continue to liaise closely with the PR.

‘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
None identified			

Additional information from the Person Responsible
The PR and centre staff are pleased that this report reflects the hardwork and effort that has gone into improving consent documentation and all previous findings. Our detailed response to the MBRS and the audit completed, illustrate that this is a result of small cycle numbers. The centre does have a policy to deal with multiple birth rate and we do work towards the 10% target., whilst considering the best outcome for each patient.