Executive Licensing Panel - minutes

Centre 0017 (Newcastle Fertility Centre at Life) Interim Inspection Report

Friday, 20 May 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Howard Ryan Anjeli Kara	Director of Strategy & Corporate Affairs Technical Report Developer Regulatory Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that Newcastle Fertility Centre at Life has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing.

1.2. The panel noted that the centre's licence is due to expire on 31 July 2018.

1.3. The panel noted that the inspection took place on 8 March 2016.

1.4. The panel noted that in the 12 months to 31 January 2016, the centre provided 1051 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.5. The panel noted that in 2015 the centre reported 27 cycles of partner insemination with one pregnancy. The national average pregnancy rate for 2015 following partner insemination has not yet been calculated.

1.6. The panel noted that for the year ending 31 October 2015 HFEA-held register data for IVF and ICSI, showed the centre's success rates were in line with national averages.

1.7. The panel noted that for the year ending 31 October 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 13%. This means that the centre's multiple live birth rate is likely to meet the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the interim inspection on 8 March 2016, one other area of non-compliance was identified and has been addressed.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's licence

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel were reassured by the inspectorate's report that the centre only had one area of non-compliance which has been addressed.

2.3. The panel was satisfied that the centre was fit to have its treatment (including embryo testing) and storage licence continued.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Juliet Tizzard

Date

3 June 2016

Interim Licensing Report

Centre name: Newcastle Fertility Centre at Life
Centre number: 0017
Date licence issued: 01 August 2014
Licence expiry date: 31 July 2018
Additional conditions applied to this licence: None
Date of inspection: 08 March 2016
Inspectors: Douglas Gray (Lead), Janet Kirkland MacHattie
Date of Executive Licensing Panel: 20 May 2016

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 2015-2017 the focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

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

The inspection team recommends the continuation of the centre's licence. The Panel is asked to note that a recommendation is made to address a non compliance in one 'other' area of practice;

'Other' areas of practice:

- The PR should consider whether a revision to their screening policy and/or further staff training is required to reflect their current practice for screening partners before treatment.

The PR has fully addressed this non-compliance in their response to this report.

Information about the centre

The Newcastle Fertility Centre at LIFE is located in Newcastle upon Tyne and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

The centre provided 1051 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2016. 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 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 31 October 2016 show the centre's success rates are in line with national averages.

In 2015 the centre reported 27 cycles of partner insemination with one pregnancy. The national average pregnancy rate for 2015 following partner insemination has not yet been calculated.

Multiple births[2]

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

For the year ending 31 October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%: this means that the centre's multiple live birth rate is likely to meet the 10% multiple live 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, or discussed with staff, in the course of the inspection: egg collection, sperm preparation, and freezing of embryos. All of the procedures observed are witnessed using manual and electronic witnessing in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

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[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%.

On inspection, reports of audits of stored gametes and embryos were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: 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.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following prescribed standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, consent to storage, consent to legal parenthood, medicines management and infection control. The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

The clinic's processes for implementing learning were also considered. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the centre's audits identified above
- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, infection control practices were reviewed and found to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of all medical devices was reviewed and they were all appropriately CE marked.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Seven patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with five patients giving compliments about the care 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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- 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

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is fully compliant with HFEA requirements, with the following exception:

- Before the gametes of a person are processed for their own treatment or for treatment with their partner, blood samples must be taken to be screened for certain viral infections (SLC T50 and T51). These blood samples must be taken within three months before gametes are first donated for their partners' use. These screening results are valid for subsequent treatment cycles for a period of two years. In two sets of medical records reviewed, the patients' blood samples were taken approximately five months in advance of their treatment. Staff told the inspectors that their screening policy did not include a requirement that bloods are taken within three months before the donation and some staff seemed unclear of the requirement (recommendation 1).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2014, recommendations for improvement were made in relation to five 'other' areas of practice that required improvement. Evidence was provided that all of the recommendations were fully implemented within the timescales.

On-going monitoring of centre success rates

Since the last inspection the centre has received one risk tool alert related to success rates in patients aged <38 receiving IVF using their own eggs. The centre responded appropriately to this alert, and during the inspection, staff committed to keeping success rates in this group under review.

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 information is held in the HFEA Register. The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

When a couple to be treated with donated gametes are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to us and to respond to those findings. The centre reported their findings to HFEA within the required timeframe. Eight couples were identified in which the effectiveness of the consent provided could be questioned. The PR has taken appropriate action to provide information and support to the affected couples, and has fully engaged with the Executive.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take consent to legal parenthood; and that effective audit procedures to ensure on-going compliance with consent taking requirements are in place. The PR provided confirmation of this.

During the inspection the centre's audit of consent to legal parenthood was reviewed. The review confirmed that the audit had been performed according to the method specified by the HFEA and that actions had been taken in response to the audit findings.

To provide further assurance of the effectiveness of the centre's procedures, the inspectors reviewed five sets of medical records in which treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood may be required. Effective consent to legal parenthood and documentation of an offer of counselling prior to the consent being taken, were seen in all cases to be in place prior to treatment.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA 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 areas 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;
- which can comprise 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
None			

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate 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
1. Screening Blood samples for viral screening of patients and their partners are not, in some cases, taken within the timeframe specified by the Authority. (SLC T51)	The PR was not available during this inspection but has since explained that on occasion bloods may be taken beyond the required three months, but in such circumstances the risks of not repeating the blood borne viral screening for those patients are considered by the multi disciplinary team and repeat screening would be performed if considered necessary. During this inspection, the centre’s screening policy and competency of staff in relation to screening requirements were not reviewed by the inspectors. Given that some staff seemed unclear of the timing of patient / partner screening requirements and how they are implemented at	Our patient pathway policy for BBV screening is that when the decision is made to proceed to treatment ie – when the consent clinic appointment is set up, viral screen is undertaken. This obviates the need to "remember" to do it since it is routine. Hence the staff may appear to be less clear on the requirements. It would only be undertaken earlier in a couple where there was a known significant risk. The consent clinic is when dates are given to start treatment (egg collection date established). Our view is that if there is going to be an issue ie an unexpected positive result we should know that before dates are given to the patients since it would be extremely	The PR has provided suitable assurance that in the occasional circumstances in which bloods for screening are taken outside of the required timeframe, the clinical team consider whether repeat screening is necessary based upon risk. The PR has also confirmed by email that staff have been reminded of the centre’s screening policy. We anticipate further guidance on screening will be available later this year and we are therefore satisfied that no further action is required at this time.

	the centre, the PR should consider whether a revision to their screening policy and/or further staff training is required to reflect their current practice and ensure consistency. The PR should provide confirmation any actions to be taken by 8 June 2016.	disappointing to them and disruptive for us to pick it up after that point (Surely that is the purpose of screening after all). On occasion that means that delays occur such that the screening sample is indeed taken more than 3 months before the start of first treatment. At our MDM all new starter treatments are discussed and for each one the screen result and date of screening are positively reviewed. Thus whilst we do not have a policy of routinely repeating the bloods if the gap is larger this gives an opportunity for risk assessment. For later treatments we will for example repeat screening at that point if it is more than 2 yrs. We would repeat a first test for a couple if we considered them to be at risk (this would be an extremely rare occurrence) but would not where that risk was not considered significant for cost and time efficiency reasons.	

		We understand that the HFEA may be further considering the assessment of partner screening requirements and therefore before reconsidering our policy we will wait for further guidance.	

Additional information from the Person Responsible