Executive Licensing Panel - minutes

Centre 0067(St Mary's Hospital) Interim Inspection Report

Thursday, 6 April 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Ian Peacock Joanne Anton	Director of Strategy & Corporate Affairs Systems Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash Siobhain Kelly	Secretary Senior Governance Manager
External adviser		
Observers	Anna Quinn	Scientific Policy Manager

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 the St Mary's Hospital is located in Manchester and has held a licence with the HFEA since April 1992. The centre provides a full range of fertility services.

1.2. The panel noted that in the 12 months to 31 December 2016, the centre provided 1738 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.3. The panel noted that the inspection took place on 2 February 2017.

1.4. The panel noted that at the time of the interim inspection there were one major area of non-compliance concerning the controlled drug register and one 'other' area of non-compliance regarding the nitrogen generator. The PR had given a commitment to implement both recommendations made.

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

2. Decision

2.1. The panel noted the non-compliances, acknowledging the PR's commitment to addressing them.

2.2. The panel was satisfied that the centre was fit to have its 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

18 April 2017

Interim Licensing Report

Centre name: St Mary's Hospital
Centre number: 0067
Date licence issued: 01/08/2015
Licence expiry date: 31/07/2019
Additional conditions applied to this licence: None
Date of inspection: 02/02/2017
Inspectors: Vicki Lamb, Gill Walsh, Nick Jones (observer)
Date of Executive Licensing Panel: 07/04/2017

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 ELP is asked to note that at the time of the inspection there was one major and one 'other' area of non-compliance.

The PR has given a commitment to implement both these recommendations:

Major area of non-compliance:

- The PR should review how entries and corrections are made in the controlled drugs register to ensure compliance with Trust requirements and Misuse of Drugs regulations.

'Other' areas of practice that require improvement:

- The PR should obtain evidence to demonstrate that the nitrogen generator produces a suitable quality product.

Information about the centre

St Mary's Hospital is located in Manchester and has held a licence with the HFEA since April 1992. The centre provides a full range of fertility services.

The centre provided 1738 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 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 period December 2015 – November 2016 show the centre's success rates are in line with national averages with the following exception:

- The clinical pregnancy rate following FET in women aged under 40 years are lower than average at a statistically significant level

In 2015, the centre reported 19 cycles of partner insemination with one pregnancy.

Multiple births[2]

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

Between December 2015 and November 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure 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: two egg collections and freezing embryos. All of the procedures observed were witnessed using appropriate 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, the ‘bring-forward’ system was discussed with staff and the storage spreadsheet was 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 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 and infection prevention and control.

The centre’s procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic’s processes for implementing learning are effective. 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 of samples in storage and the ‘bring-forward’ system;
- the centre’s audit of multiple pregnancies;
- 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’s audit of legal parenthood;
- HFEA Clinic Focus articles regarding screening requirements.

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 partially compliant with guidance. In some instances the time and amount of a drug administered to the patient, or the amount that was wasted, was not recorded as per Trust

requirement and controlled drug management requirements. Not all corrections in the controlled drug register were made in accordance with guidance and in several instances it was not clear what the original entry was or who made the correction (see recommendation 1).

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

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, we reviewed infection control practices and found them 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 the following medical devices was reviewed in the course of the inspection: freezing straws, four-well dishes, 1ml pipettes, culture dishes, ICSI holding and injection pipettes. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, we spoke to two patients about their experiences at the centre. Six patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with two of the individuals providing written feedback giving compliments about the care 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 non-compliant with the following HFEA requirement:

- The PR is assured that the nitrogen generator produces a suitable quality product, but he was not able to produce evidence to support this (see recommendation 2).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2015, recommendations for improvement were made in relation to one critical, three major and eight 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

The success rates for FET in women aged under 40 years are currently below the national average and these were discussed at the time of the inspection. The PR has provided a commitment to keep these success rates under review, and the executive will continue to monitor this.

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

Where a couple to be treated with donated gametes or embryos is 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, 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 sent the report of the audit to the HFEA within the required timeframe. The audit showed that one couple was affected by legal parenthood consent anomalies. This case was concluded in June 2016 following a declaration of parenthood being made by the Family Division of the High Court.

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 this consent; and that effective audit procedures are in place to ensure on-going compliance with consent

taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

Inspectors visited the centre in September 2016, the focus of which was learning from legal parenthood consent anomalies. As part of that visit, the inspection team reviewed 27 patient records where consent to legal parenthood may be required. One anomaly which could pose a challenge to effective consent to legal parenthood was identified and is being addressed by the centre and through monitoring by the HFEA.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and the offer of counselling was seen to be in place prior to consent and treatment in four cases. In one case, the signature on the WP form was dated with the correct day and month but with the year that corresponded to the woman's year of birth. No pregnancy resulted from the treatment and therefore there was no implication for legal parenthood.

In summary, the inspection team considers the processes used to obtain legal parenthood consent at this centre to be broadly compliant with HFEA requirements. This issue will be dealt with through the ongoing monitoring relating to the legal parenthood visit conducted in September 2016, therefore no recommendation is made here.

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
1. In some instances the time and amount of a drug administered to the patient, and amount that was wasted, was not recorded as per Trust requirement and controlled drug management requirements. Not all corrections in the controlled drug register were made in accordance with guidance and in several instances it was not clear what the original entry was or who made the correction. SLC T2 and Misuse of Drugs Regulations 2001,	The PR should review how entries and corrections are made in the controlled drugs register to ensure compliance with Trust requirements and Misuse of Drugs regulations. A summary of the findings of this review, any corrective actions and timescales for implementation should be provided to the centre's inspector by 2 May 2017.	I informed Angela Williams, Theatre Matron and Preoperative Services, on the findings and forwarded her the interim inspection report. Her initial response was to inform the anaesthetic lead for IVF and the Team Manager for gynaecology theatres of the report. A full investigation will be completed including regular audits. The findings of the investigation and subsequent audits will be submitted to the centre's inspectors by the 2nd of May 2017.	The inspector is confident the summary of the review findings will be forwarded by the required date.

schedule 20 (c)			

‘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
2. The PR is assured that the nitrogen generator produces a suitable quality product, but he was not able to produce evidence to support this. SLC T24	The PR should obtain evidence to demonstrate that the nitrogen generator produces a suitable quality product. This evidence should be submitted to the centre’s inspector by 2 May 2017.	I have attached the Nitrogen generator data sheet which presents the nitrogen purity the machine should provide us with. However going forward when the machine is next serviced a portal will be introduced into the line so that the purity can be analysed and reported at that and at subsequent services.	The PR has provided evidence that the nitrogen generator should produce a suitable quality product. The inspector will follow up with the PR on the actual quality of the product when the portal has been introduced into the line.

Additional information from the Person Responsible
I would like to thank the inspectors for a thorough inspection and acknowledge the findings submitted in this report. I appreciate and welcome the many positive remarks you gave us in the feedback session at the end of the inspection and it was nice to be able to pass these comments on to the whole Department. I am confident that there will be no recurrence in our Major area of non-compliance - Controlled drug management.