Executive Licensing Panel - minutes

Centre 0033 (Manchester Fertility) Additional Inspection Report

Friday, 10 February 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Howard Ryan Jessica Watkin	Director of Strategy & Corporate Affairs Report Developer Policy Manager
Members of the Executive	Bernice Ash	Secretary
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 Manchester Fertility has held a licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The panel noted that the additional inspection took place on 29 November 2016.

1.3. The panel noted that in the 12 months to 31 October 2016, the centre provided 1574 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.4. The panel noted that at the time of the inspection, there had been a recommendation for improvement in one 'other' area of non-compliance concerning SOPs. Since the inspection, this recommendation had been fully implemented.

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

2. Decision

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

21 February 2017

Additional Inspection Report

Centre name: Manchester Fertility
Centre number: 0033
Date licence issued: 01/05/2014
Licence expiry date: 30/04/2018
Additional conditions applied to this licence: None
Date of inspection: 29/11/2016
Inspectors: Vicki Lamb, Susan Jolliffe
Date of Executive Licensing Panel: 10 February 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 a targeted, scheduled, additional inspection completed following concerns raised at an interim inspection in November 2015. The aim of this report 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 a recommendation for improvement in relation to one 'other' area of practice as follows:

'Other' area of non-compliance:

- The PR should ensure that SOPs reflect practices at the centre.

Since the inspection visit this recommendation has been fully implemented.

Information about the centre

Manchester Fertility has held a licence with the HFEA since 1992 and provides a full range of fertility services. The centre provided 1574 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/10/2016. In relation to activity levels this is a large centre.

At the centre's last inspection in November 2015, recommendations were made in two critical and three major areas of non-compliance and one 'other' area of practice. The inspection team recommended an additional inspection should take place in 2016 in order to fully assess the continued effectiveness of corrective actions taken in response to these two critical recommendations:

- The PR should ensure that a suitably trained and competent controlled drugs accountable officer (CDAO) is appointed. The PR should review practices relating to the management of medicines, including controlled drugs, to ensure that accurate and complete records are maintained and that medicines are administered and disposed of in accordance with legislation and best practice guidance.

- The PR should ensure that effective consent to legal parenthood is obtained.

This is the report of that additional inspection.

Details of Inspection findings

Quality of Service

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 August 2015 to 31 July 2016 show the centre's success rates are in line with national averages.

Multiple births[2]

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

Between 1 August 2015 and 31 July 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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.

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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%.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed. With reference to the observations made in 2015, the inspectors concluded:

- the PR is the controlled drugs accountable officer and showed commitment to the role;
- clinical staff have received training in medicines management;
- the dose of controlled drug administered to patients is clearly recorded in the controlled drugs register and on the anaesthetic record in the patient notes;
- the disposal of any unused portion of a controlled drug is witnessed, and the amount disposed of is recorded in the controlled drug register;
- recording 'carry over' of controlled drug stock from one page of the register to the next is witnessed by a second person;
- staff clearly record the date of the stock check of emergency drugs on the resuscitation trolley.

The inspectors were therefore satisfied the actions taken by the PR in response to the 2015 interim inspection were effective.

Overall, the clinic's processes for medicines management were found to be compliant with guidance with one exception:

- the controlled drug SOP does not reflect practices at the centre (see recommendation 1).

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 recommendations made at the time of the last inspection

Following the interim inspection in 2015, recommendations for improvement were made in relation to two critical, three major and one 'other' area of non-compliance. The PR has provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last interim inspection in November 2015 the centre has not received any performance related risk tool alerts.

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 and took appropriate action with respect to the issues identified by the audit. Evidence was provided by the PR that she considered the revised practices put in place for obtaining consent to legal parenthood were robust.

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.

However, during the interim inspection at this centre in November 2015 three errors on legal parenthood consent forms were noted in the five sets of patient records that were reviewed. In one set of notes, the patient's date of birth was missing from the sticker placed on the form containing the patient's identifying information; on a second form the patient's date of birth on the sticker was different to that handwritten by the patient; and in the third, the patient had written their date of birth instead of the date they signed the form. The PR addressed these issues quickly and constructively.

On this inspection the team reviewed 30 sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. In all cases, identifying information was visible and correct, effective consent to legal parenthood was in place and the offer of counselling was seen to be in place prior to consent and treatment. The inspectors were therefore satisfied the actions taken by the PR in response to the 2015 interim inspection were effective.

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. The controlled drug SOP does not reflect practices at the centre (T33b).	The PR should ensure that all SOPs reflect practices at the centre. The revised controlled drug SOP should be provided to the centre’s inspector by 28 January 2017.	The Controlled Drug SOP, OP-NR-63 Management of Controlled Drugs has been revised in accordance with the Inspector’s advice.	The revised SOP was submitted by the PR on 13 December 2016. The SOP now reflects practice at the centre. No further action required.

Additional information from the Person Responsible
Updated document OP-NR-63 Management of Controlled drugs has been sent to our Inspector.