Executive Licensing Panel - minutes

Centre 0033 (Manchester Fertility)

Interim Inspection Report

Tuesday, 11 February 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Yvonne Akinmodun Helen Crutcher	Director of Strategy and Corporate Affairs Head of Human Resources Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing 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:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted Manchester Fertility is located in Cheadle in Greater Manchester and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

1.2. The panel noted that, in the 12 months to 31 August 2019, the centre had provided 1947 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the period June 2018 to May 2019, show the centre's success rates are in line with the national averages, with the following exception:

- Clinical pregnancy rates following FET in patients aged less than 40 years are above average at a statistically significant level.

1.4. The panel noted that, in 2018, the centre reported 29 cycles of partner insemination, with four pregnancies This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, between April 2018 and May 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target for this period.

1.6. The panel noted that an unannounced inspection took place on 6 November 2019.

1.7. The panel noted that at the time of inspection there was one major area of non-compliance concerning medicines management. Since the inspection visit, the Person Responsible (PR) has given a commitment to fully implement the recommendation made in the report.

1.8. The panel noted that the centre is well led and provides a good level of patient support.

1.9. The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence.

2. Decision

2.1. The panel congratulated the centre on its low multiple birth rate and noted that the clinical pregnancy rates following FET in patients aged less than 40 years are above average at a statistically significant level.

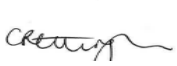
2.2. The panel noted that, between June 2018 and May 2019, 25 patients had provided feedback through means of the centre's own patient survey, and comments were generally positive. Three patients had been spoken to during the inspection, also giving positive feedback. However, only thirty patients had provided feedback on their experience of the centre, in the last 12 months, through the 'Choose a Fertility Clinic' facility available on the HFEA website. The panel suggested that the centre should actively encourage patients to provide feedback through their own patient survey and the 'Choose a Fertility Clinic' facility, located on the HFEA website.

2.3. The panel was satisfied 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

Clare Ettinghausen

Date

13 February 2020

Interim Licensing Report

Centre name: Manchester Fertility
Centre number: 0033
Date licence issued: 01 May 2018
Licence expiry date: 30 April 2022
Additional conditions applied to this licence: None
Date of inspection: 06 November 2019
Inspectors: Julie Katsaros and Louise Winstone
Date of Executive Licensing Panel: 11 February 2020

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. The current foci for an interim inspection are:

- **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

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence.

The centre is well led and provides a good level of patient support.

The ELP is asked to note that this report makes recommendations for improvement in relation to one major area of non-compliance or poor practice.

The Person Responsible (PR) has given a commitment to fully implement the following recommendation:

Major area of non-compliance

- The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements.

Information about the centre

Manchester Fertility is located in Cheadle in Greater Manchester and has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services.

The centre provided 1947 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2019. 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 June 2018 to May 2019 show the centre's success rates are in line with national averages with the following exception:

- Clinical pregnancy rates following FET in patients aged less than 40 years are above average at a statistically significant level.

In 2018, the centre reported 29 cycles of partner insemination with four clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

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

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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%.

Between April 2018 and May 2019 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This represents performance that is likely to be statistically lower than 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. During the course of the inspection an egg collection was observed. The procedure observed was witnessed using an electronic witnessing system 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.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs were reviewed and the 'bring-forward' system was discussed with staff. 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: patients attending for consultations 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.

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 (SOP) 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: medicines management; infection control; legal parenthood; consent to storage and witnessing.

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:

- leadership
- patient support
- information provision
- implications of treatment and consent
- counselling
- extension of storage consent
- consent
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood

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 because:

- there were numerous entries in the controlled drug register where the supply, administration and discard of controlled drugs was not recorded by either the person administering the drug or a witness;
- there were numerous entries in the controlled drug register where the time of supply, administration or discard of controlled drugs was not recorded by either the person administering the drug or a witness;
- there were numerous entries in the controlled drug register where the unit of drug either supplied or administered was not recorded;
- during an audit of the records of five patients who had recently undergone procedures, the dose of controlled drug administered to all five patients was not recorded;
- entries recorded in the controlled drug register for four patients on a given date were partially completed with a note indicating that they were written in error and subsequently rewritten on a different page, this indicates to the inspection team that the centre's staff are pre populating the controlled drug register for procedural lists;
- the inspection team observed a member of staff completing the witnessing sections of the controlled drug register after the mornings theatre procedural list had ended and not contemporaneously with each procedure undertaken;
- a member of the centre's theatre staff regularly accessed the controlled drug key store to retrieve the keys, which was contrary to the centre's SOP which stated that the keys must be signed in and out by the registered nurse in charge;
- audits undertaken by an independent consultant pharmacist employed by the centre to oversee the centre's management of medicines and the centre's staff failed to identify any of the findings highlighted by the inspection team;

- a recent incident at the centre where an ampoule of a controlled drug was found open and empty was discovered by centre staff during a routine controlled drug stock check. The PR immediately took appropriate remedial actions as per the centre's SOP and controlled drug regulations. The inspection team were assured that the centre has a robust system for the reporting of incidents, however, the inspection team were not assured that robust corrective and preventative actions were implemented following the incident and that a similar incident could not happen again (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 all media and laboratory medical devices was reviewed in the course of the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures compliant with HFEA guidance.

Patient feedback

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only 30 patients have provided feedback in the last 12 months, giving an average three star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes.

For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The centre's own most recent patient survey responses were therefore reviewed. During the period June 2018 to May 2019, 25 patients provided feedback. Feedback received was generally positive.

During the inspection the inspectors spoke to three patients who also provided positive feedback on their experiences.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

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 exception noted elsewhere in the report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to two major and one 'other' area 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

Since the last renewal inspection in November 2017, the centre has received three risk tool alerts related to performance, to which the PR has responded appropriately, providing evidence and information that the issue has been addressed.

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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in November 2017, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Three sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Annex 1

Areas of practice that require the attention of the Person Responsible

This 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 made.

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 non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

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;
- 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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Medicines management A number of issues relating to medicines management practices were noted by the inspection team. These are described in the body of the report. SLC T2. The Misuse of Drugs Regulations 2001 20(c). DH (2007) ‘Safer Management of Controlled	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements. The PR should review practices and procedures relating to medicines management, taking into consideration but not limited to the findings of this report. A summary report of this review, including any corrective actions, staff training, with timescales, should be	Following on from the inspection I can confirm that steps have already been taken to change practices and procedures relating to medicines management and our report will be forwarded to you by 6th February 2020 as requested. We were disappointed your findings were not highlighted during our audit of medicine management and accept that improvements are needed. Plans are already in place to change our	The executive acknowledges the PR’s response and commitment to fully implement the recommendation. Further action is required.

Drugs; A guide to good practice in secondary care (England)'. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'.	provided to the centre's inspector by 6 February 2020. The PR should review the centre's audit of medicine management practices and procedures to ensure that they are audited against compliance with regulatory requirements and their own approved protocols and quality indicators and that staff undertaking audits are suitably trained and competent. A summary report of this review, including any corrective actions, staff training, with timescales, should be provided to the centre's inspector by 6 February 2020. Three months after the implementation of corrective actions the PR should audit medicines management practice and procedures to ensure that corrective actions implemented, have been effective in achieving compliance. A summary report of this audit should be	audit process. Once the changes identified are put into place, a follow up audit as requested will be carried out three months later and the report forwarded to you.	

	provided to the centre's inspector by 6 May 2020.		

'Other' areas of practice that requires improvement

Other 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.

An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

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
I would like to thank the Inspector's for their useful feedback and comments. We accept all the findings and have begun to work with them to enable us to improve our service.