Executive Licensing Panel - minutes

Centre 0344 (Hewitt Fertility Centre, Knutsford)

Interim Inspection Report

Tuesday, 21 May 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Howard Ryan Yvonne Akinmodun	Director of Strategy and Corporate Affairs Report Developer Head of Human Resources
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 that the Hewitt Fertility Centre, Knutsford has held a treatment and storage licence with the HFEA since July 2015. The centre provides a full range of licensed fertility treatments (excluding embryo testing), to NHS and self-funded patients.

1.2. The panel noted that, in the 12 months to 31 January 2019, the centre had provided 876 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the period December 2017 to November 2018, show the centre's success rates are in line with the national averages with the following exception:

- The clinical pregnancy rate following IVF and FET in women aged under 38 years old are lower than average at a statistically significant level.

1.4. The panel noted that, in 2018, the centre reported 3 cycles of partner insemination with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

1.5. The panel noted that, HFEA register data, between December 2017 and November 2018, 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 significantly lower to the 10% multiple live birth rate target for this period.

1.6. The panel noted that the inspection took place on 12 March 2019.

1.7. The panel noted that at the time of inspection there were two major areas of non-compliance concerning medicines management and pregnancy success rates. There was also one 'other' area of non-compliance regarding staffing. Since the inspection, the Person Responsible (PR) has given a commitment to fully implement all the recommendations made in the report, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence, particularly commending the centre in achieving and maintaining a significantly low multiple birth rate.

2. Decision

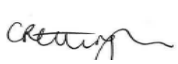
2.1. The panel particularly noted the non-compliance relating to pregnancy success rates, concerning IVF and FET in women aged under 38 years old, and looked forward to receiving a further progress update, following the renewal inspection to be conducted in 2021, encouraging the PR's continued engagement with the inspectorate on this issue.

2.2. The panel was satisfied 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

Clare Ettinghausen

Date

28 May 2019

Interim Licensing Report

Centre name: Hewitt Fertility Centre, Knutsford
Centre number: 0344
Date licence issued: 21 July 2017
Licence expiry date: 20 July 2021
Date of inspection: 12 March 2019
Inspectors: Louise Winstone and Katie Best
Date of Executive Licensing Panel: 21 May 2019

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. In particular, we commend the centre in achieving and maintaining a significantly low multiple birth rate.

The ELP is asked to note that this report makes recommendations for improvement in relation to two major and one 'other' area of non-compliance.

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

Major areas of non-compliance:

- The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance.
- The PR should seek to improve the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years old and FET treatments in women under 38 years old.

Other areas of non-compliance:

- The PR should ensure that all staff are adequately orientated and inducted to the premises.

Information about the centre

The Hewitt Fertility Centre, Knutsford has held a Treatment and Storage licence with the HFEA since July 2015.

The centre provides a full range of licensed fertility treatments (excluding embryo testing), to NHS and self-funded patients.

The centre provided 876 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2019. In relation to activity levels this is a medium sized 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 2017 to November 2018 show the centre's success rates are in line with national averages with the following exceptions:

- The clinical pregnancy rate following IVF and FET in women aged under 38 years are lower than average at a statistically significant level.

See recommendation 2.

In 2018, the centre reported three cycles of partner insemination with no pregnancies, which is in line with the national average.

Multiple births[2]

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

Between December 2017 and November 2018, 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. An embryo warming procedure was observed during this inspection. The observed procedure was witnessed using an electronic witnessing system, along with manual witnessing steps, in accordance with HFEA requirements. The centre's own witnessing audit was also reviewed. These activities indicated that witnessing procedures are compliant with HFEA requirements.

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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 multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 10% MLBR target is calculated as equivalent to a MCPR of 13%.

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 and consent records 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.

At the centre's last inspection in March 2017, there were concerns regarding inadequate staffing levels. The inspectors spoke at length with staff in all departments at this inspection and were assured that staffing levels have improved, are now stable and are suitable for the activities being carried out. It was noted however, that staff from the Hewitt Fertility Centre, Liverpool are required to cover staff shortages at the Knutsford site. The inspectors were concerned that there is no orientation or induction programme for staff to the premises at Knutsford.

See recommendation 3.

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: medicines management; infection control; legal parenthood; witnessing; consent to storage and traceability.

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
- counselling
- imports of gametes and embryos from outside the EU/EEA

- the use of the Single European Code
- data submission to the HFEA
- the use of CE marked medical devices
- the content of the centre's website
- HFEA Clinic Focus article 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 because:

- Staff could not locate the controlled drugs cupboard keys. These were later found in the embryology office. Keys for the controlled drugs cupboard should be kept secure and only accessible to staff with authorised access.
- There were several entries in the controlled drugs register that had not been witnessed by two members of staff and the carry-over of drugs from one page to another was not signed by two members of staff.
- There is no SOP to direct staff for the dispensing of 'top up' medicines to patients for self-administration and staff competencies in this area have not been assessed. This was cited as a non-compliance at the centre's last inspection.

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 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

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 one patient has provided feedback in the last 12 months, giving an average five-star rating to the clinic. For the system to work well, it's important that every patient knows about the rating system. The PR was asked to consider ways to promote the use of this facility, the inspectors were informed that this will be immediately acted upon and the PR is considering ways to encourage patients to provide feedback directly to the HFEA. One suggestion is to provide an iPad for patients to use while at the clinic. Improvement in this area will be followed up at the next inspection.

The centre's own most recent patient survey responses were therefore reviewed. Between July 2018 and January 2019, 39 patients had provided feedback directly to the clinic. All of this feedback was positive.

No patients were available to speak to inspectors during this visit.

On the basis of the centre's own patient 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.

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 critical, three major and three 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all the recommendations were fully implemented in the required timescales. However, the inspection team notes that the non-compliance related to the dispensing of medicines has reoccurred (see recommendation 1).

On-going monitoring of centre success rates

Since the last renewal inspection in March 2017, the centre has received 12 risk tool alerts related to performance, to which the PR has responded appropriately. However, clinical

pregnancy rates following IVF and FET in patients aged less than 38 years remain lower than average at a statistically significant level. This was discussed with the PR and key members of staff during the inspection who provided a commitment to keep success rates in this group of patients under review. See recommendation 2.

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.

Feedback received from the Registry team at the HFEA prior to this inspection reported that 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 the inspection in March 2017, legal parenthood consenting processes were found to be robust with exception to the observation that couples are asked to provide consent at the same appointment as they receive implications counselling. It was considered that couples do not have sufficient time to reflect before providing consent. The PR subsequently provided evidence to demonstrate that this had been addressed.

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. Four 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.

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			

‘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 Staff could not locate the controlled drugs cupboard keys. These were later found in the embryology office. There were several entries in the controlled drugs register that had not been witnessed by two members of staff and the carry-over of drugs from one page to another was not signed by two members of staff. There is no SOP to direct staff for the dispensing of ‘top up’	The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance. The PR should review the centre’s security procedures for the controlled drugs cupboard keys. A copy of the summary of the review should be sent to the centre’s inspector when responding to this report. The PR should review medicines management practices in relation to the	A review of the medicines management practice has been performed by the PR and the Consultant Nurse (attached). Following the review a robust system has been introduced to ensure security of controlled drugs. A locked room holds the keys to all secure areas of centre 0344. A small safe is located within the room, this safe holds prescription pads, controlled drugs keys and non-controlled drugs keys. The key pad code to gain	The executive acknowledges the PR’s response and commitment to implementing this recommendation. The PR has provided a review of medicines management practice including security procedures for the controlled drugs cupboard keys and staff training requirements. The PR has provided a commitment via email to submit an update on medicines management practices, including the SOP to direct staff for the dispensing

medicines to patients for self-administration and staff competencies in this area have not been assessed. This was cited as a non-compliance at the centre's last inspection. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'.	non-compliances identified in this report and this should include staff training requirements. A summary report of the review with corrective actions should be provided to the centre's inspector by 12 June 2019. Three months after this review the PR should audit medicines management practice to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this review should be provided to the centre's inspector by 12 September 2019.	access to the safe is known by trained nursing staff only. The nurse in charge of recovery now performs a CD book check with the ODP at the start and at completion of every theatre list. The carryover of drugs from one page to another in the CD book is completed each day and signed by two members of the nursing team. A 'shift team lead' check list and an 'egg collection safety checklist' have been introduced to confirm these actions are completed each day (see attached). A competency for dispensing of 'top-up' medicines has been created and is awaiting approval from pharmacy before introduced (see attached).	of 'top up' medicines, by 12 June 2019 and a follow up audit by 12 September 2019. Further action is required.
2. Pregnancy success rates The centre's success rates for IVF treatments involving fresh	The PR should seek to improve the pregnancy success rates for IVF treatments involving fresh	A process review of the IVF process has been performed (see attached) in response to recent RBATs. Work is	The executive acknowledges the PR's response.

embryos in women under 38 years old and FET treatments in women under 38 years old are lower than the national average at a statistically significant level.	embryos in women under 38 years old and FET treatments in women under 38 years old. The PR should provide the centre's inspector with a review of the centre's success rates for the groups of patients identified above when responding to the report. Following this, the PR should provide the centre's inspector quarterly updates on the actions taken to address the success rates, with a goal of improving the success rates by 12 September 2019.	ongoing to improve practice in the areas highlighted. In response to the major non-compliance raised in this inspection please find attached a comprehensive review of current success rates, improvements to practice, and areas of ongoing monitoring (see attached). An update will be provided on 12th June and again on 12th September 2019.	The PR has provided a review of the centre's success rates for IVF treatments involving fresh embryos in women under 38 years old and FET treatments in women under 38 years old. The PR is to continue to provide quarterly updates on the actions taken to address the success rates. Further action is required.

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement is 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
3. Staffing There is no orientation or induction to the premises for staff from the Hewitt Fertility Centre, Liverpool who are required to cover staff shortages at the Knutsford site. SLC T12 and T15a.	The PR should ensure that all staff are adequately orientated and inducted to the premises. The PR should inform the centre’s inspector of the actions taken to address this non-compliance when responding to this report.	QMS-SOP-15 'Orientation Programme' has been amended to include an information pack for centre 0344 (attached to email). This will be provided to all new staff. Confirmation that the member of staff has read and understood this information will be signed for at the end of the orientation program. All existing staff now have this 'competency' added to their competency matrix to be reviewed biannually by their line manager.	The executive acknowledges the PR’s response and commitment to implementing this recommendation. The orientation programme for all Hewitt Fertility Centre staff to the Knutsford site has been provided. No further action is required.

Additional information from the Person Responsible
As Person Responsible I would like to share my diappointment that non-compliance with the medicines management policy is a recurring non-compliance from the previous inspection. I am unhappy that we have failed in the same area twice as this is not something I am comfortable with. I will ensure the team work hard in this area to achieve continued compliance and I look forward to a positive outcome from the controlled drugs audit on 31st May 2019.