Executive Licensing Panel - minutes

Centre 0007 (Hewitt Fertility Clinic)

Interim Inspection Report

Thursday, 16 August 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Anna Quinn Laura Riley	Head of Intelligence Scientific Policy Manager Head of Regulatory Policy
Members of the Executive	Richard Chamberlain	Temporary Committee Clerk
External adviser		
Observers	Catherine Burwood	Senior Governance 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 considered the papers, which included an interim inspection report, and licensing minutes for the last three years:

- 17 November 2017 – licence variation for change of PR
- 24 March 2017 – licence variation for change of PR
- 4 November 2016 – renewal inspection progress report
- 30 October 2015 – renewal inspection report

1.2. The panel noted that the Hewitt Fertility Centre (Centre 0007) is located in the Liverpool Women's Hospital and has held a Treatment (including embryo testing) and Storage licence with the HFEA since 1992. It provides a full range of fertility services including embryo testing.

1.3. The panel noted that the centre's current licence was varied in March and November 2017 to reflect two changes of Person Responsible (PR).

1.4. The panel noted that in the 12 months to 31 May 2018, the centre reported 2,886 cycles of partner insemination (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.5. The panel noted that IVF and ICSI (intracytoplasmic sperm injection) HFEA held register data for the period 1 March 2017 to 28 February 2018 shows that the centre's success rates are in line with the national averages with the following exception: clinical pregnancy rates following ICSI in patients aged less than 38 years are lower than average at a statistically significant level.

1.6. The panel noted that between 1 March 2017 and 28 February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6.4%. This represents performance that is statistically lower than the 10% multiple live birth rate target.

1.7. The panel noted that at the time of the latest inspection on 12 June 2018 there were no areas of critical non-compliance, and two areas of major non-compliance regarding pregnancy success rates and medicines management.

1.8. The panel noted that there were three 'other' areas of non-compliance regarding the centre's website, infection control and staffing.

1.9. The panel noted that further action was required regarding all of the non-compliances.

2. Decision

2.1. The panel had regard to its decision tree. The panel had no serious concerns although noted that all areas of non-compliance required further engagement with the executive, with audits expected to be received.

2.2. The panel were encouraged by the range of actions undertaken by the centre to investigate ICSI success rates in patients under 38 years of age and hopes that this will continue so that improvements can be seen.

2.3. The panel congratulated the centre for its low rate of multiple pregnancies.

2.4. The panel agreed with the executive that the clinic's Treatment (including embryo testing) and Storage licence should continue until expiry in October 2020 subject to recommendations being implemented within the prescribed timescale.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

3 September 2018

Interim Licensing Report

Centre name: Hewitt Fertility Centre
Centre number: 0007
Date licence issued: 1 November 2016
Licence expiry date: 31 October 2020
Additional conditions applied to this licence: None
Date of inspection: 12 June 2018
Inspectors: Louise Winstone (lead), Grace Lyndon
Date of Executive Licensing Panel: 16 August 2018

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 (SLCs).

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 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

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 at the time of the inspection there were a number of areas of practice that required improvement, including two major and three 'other' areas of non-compliance.

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non-compliance:

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

'Other' areas of practice that require improvement:

- The PR should review the centre's website to ensure that success rates are published in accordance with guidance.
- The PR should ensure that infection control measures and practices are compliant with regulatory requirements and best practice.
- The PR should ensure the local procedures for lone working are fully documented.

Information about the centre

The Hewitt Fertility Centre is located in Liverpool and has held a Treatment (including embryo testing) and Storage licence with the HFEA since 1992.

The centre provides a full range of fertility services including embryo testing.

The centre provided 2886 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2018. In relation to activity levels this is a large centre.

The centre's current licence was varied in March and November 2017 to reflect two changes of Person Responsible (PR).

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 1 March 2017 to 28 February 2018 show the centre's success rates are in line with national averages with the following exception:

- clinical pregnancy rates following ICSI in patients aged less than 38 years are lower than average at a statistically significant level (see recommendation 1).

In 2017, the centre reported 22 cycles of partner insemination with no clinical pregnancies. This is likely to represent 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.

Between 1 March 2017 to 28 February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6.4%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target.

[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%.

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 transfer 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.

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 interim inspection took place on a day that the centre had reduced activity due to the air handling unit being replaced in the laboratory and it was therefore not possible to observe if there were sufficient numbers of staff for the activities of the centre. Centre staff were however able to assure the inspection team that current staffing levels in the clinic are suitable for the activities being carried out.

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, consents including consent to legal parenthood, infection control and medicines management.

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 use of CE marked medical devices

- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles regarding: screening requirements, knowledge of new legal requirements on the importation and coding of gametes and embryos and awareness of consultation on HFEA Code of Practice update.

The centre is effective in ensuring compliance with guidance issued by the HFEA with exception to the following:

- The centre's website does not provide information on live birth rates (see recommendation 3).

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 non-compliant with guidance because:

- There were a number of sections in the controlled drugs register that were incomplete, such as signatures, dates, times, documentation of the amount of drug administered and discarded. Following a thorough examination of the controlled drugs register, it was clear that there were no missing drugs but that this represented poor record keeping.
- One anaesthetist had signed the register by the use of brackets for a group of patients. It was therefore unclear if the signature referred to each patient individually or had been signed at the time of drug administration;
- Medication such as 'Viagra' was dispensed to patients by cutting off a single tablet from the blister pack. The full name of the medication, the strength, the expiry date or the batch number was therefore not available to the patient receiving the drug, this is not in accordance with regulatory requirements and best practice.

See recommendation 2.

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 broadly compliant with guidance because:

- Boxes of consumables were stored on the floor of the store room, this was an area of practice requiring action that was identified in the centre's own recent infection control audit that had not yet been actioned;

- The temporary closures on the sharps bins in the clinical areas were not in use. It is best practice to use the temporary closures on the sharps bins to prevent spillage, for infection control and to prevent needle stick injuries.

See recommendation 4.

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

During the inspection no patients were available to speak with the inspectors about their experiences at the centre. The centre's most recent patient feedback, collected between April 2017 and March 2018, was reviewed. All feedback was positive. A further five patients had provided feedback to the HFEA via the HFEA website. This feedback reflects that in the centre's own survey.

Based on 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 compliant with HFEA requirements with the following exception: the centre's 'lone worker' policy is not detailed enough and does not include the procedures for all staff including the counsellors who are in the centre after normal working hours. Staff could describe the procedures, but these had not been documented (see recommendation 5).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in June 2016, a recommendation for improvement was made in relation to one critical, six major and two 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in June 2016, the centre has received five risk tool alerts related to performance, to which the PR has responded appropriately, providing evidence and information that the issues have been addressed. However, clinical pregnancy rates following ICSI in patients aged less than 38 years remain lower than average at a statistically significant level. This was discussed with staff during the inspection who provided a commitment to keep success rates in this group of patients under review (see recommendation 1).

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 centre currently has a large number of missing outcome forms and late submitted forms. This was discussed with centre staff during the inspection who were aware of this issue. A plan had already been put into place to rectify the missing outcome forms and it was evident during the inspection that the team were working hard to correct this. Therefore, no further action is required and progress with this will continue to be monitored.

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 June 2016, legal parenthood consenting processes were found to be robust.

To provide assurance of the compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures and the legal parenthood consenting audits with staff. Five 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.

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. Pregnancy success rates The centre’s success rates for ICSI treatments involving fresh embryos in women under 38 years old are lower than the national average at a statistically significant level.	The PR should seek to improve the pregnancy success rates for ICSI treatments involving fresh embryos in women under 38 years old. The PR should provide the centre’s inspector with a review of the centre’s success rate for ICSI in patients under 38 when responding to the report. Following this, the PR should provide quarterly updates on the actions taken to address the success rate for ICSI in	A full investigation of the ICSI success rates is in progress. A procedural audit has been carried out and no areas of concern were raised with regards to this (1.1). The investigation revealed 224 missing outcomes, these are in the process of being completed with 84 still outstanding. However, 64 of these are from a satellite centre. HFC are working with them to get this resolved. See attached current report (1.2).	The executive acknowledges the PR’s response and commitment to investigate and improve the success rates for ICSI treatments involving fresh embryos in women under 38 years old. The executive awaits the quarterly update from the PR by 28 September 2018 with the goal of improving this success rate by 12 December 2018. Further action is required.

	patients less than 38, with a goal of improving this success rate by 12 December 2018.	A new system has been developed to ensure these results are obtained in a timely manner in future. The Quality Assistant has been sending out a monthly report to the department leads at HFC to highlight all missing data, HFEA forms and errors. An email is also sent to the satellite centres requesting their missing outcomes. This has been in place since May 2018 and we have seen a marked improvement as it has made staff more aware of the requirements (1.3/1.4). Collating the data with the newly submitted outcomes, cancelled/freeze all cycle data is in progress. An investigation to look at individual ICSI practitioner results in detail and procedures associated with ICSI is planned. An external company attended to test the pH of culture media in the lab and found it to be approx 7.4. We predict this is	

		due to the 'traffic' in and out of the incubators. With immediate effect, we have increased the level of oil in our dishes to ensure complete coverage of the media drops. We have also started to systematically raise the CO2 in our incubators and retest the media to bring the pH down to a more appropriate level. The time between stripping the oocytes and injection has been reduced to a minimum to avoid the denuded oocytes being in potentially suboptimal media in regards to pH for longer than necessary. The current ICSI data is attached (1.5) please note that it includes patients aged 39. Table 2 highlights the clinical preg rates including an update for March and April, where an increase can be seen. Approximately 22% of patients are not receiving an ET. We will audit the reasons for this	

		and update the HFEA accordingly. The PR will provide an update by 28th September 2018 to inform them of any changes we have seen.	
2. Medicines Management The following issues were noted in the controlled drugs register: • missing signatures, dates and times; • missing documentation of the amount of drug administered and discarded; • in some cases, the anaesthetist had signed by the use of brackets for groups of patients. It was therefore unclear if the signature referred to each patient individually or had been signed at the time of drug administration. Medication such as 'Viagra' was dispensed to patients by	The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance. The PR should review the causes of the non-compliances identified in this report. A summary report of the review including corrective actions and timescales for implementation should be provided to the centre's inspector by 12 September 2018. Three months after the implementation of corrective actions, the PR should audit medicines management practice to ensure that actions implemented have been effective in achieving and maintaining compliance.	The findings of this report have been formally sent by the HFC Clinical Director to the Clinical Director of Anaesthetics for actioning (2.1). All Anaesthetists and ODP's who work at the HFC will be asked to sign MED FORM 21, a signature sheet to say they understand the importance of accurately recording the prescription/use of controlled drugs (2.2). This will be audited in November. Issuing Viagra for male HFC patients has been discussed amongst the senior nurses. Viagra is only ever given to the patient to be taken on the unit. However, although this hasn't happened to date, there could be a need in the future for the patient to take this medication home. HFC are	The executive acknowledges the PR's response. A follow up audit for medicines management practices is due by 12 December 2018. Further action is required.

cutting off a single tablet from the blister pack. The full name of the medication, the strength, the expiry date or the batch number was therefore not available to the patient receiving the drug. SLC T2. 'Controlled Drugs in Perioperative Care' 2006. Misuse of Drugs (safe Custody) Regulations 2001, NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. NMC standard for practice of administration of medicines section 4 standard 8 WHO Ensuring good dispensing practice. Chapter 30.	A summary report of this audit should be provided to the centre's inspector by 12 December 2018.	therefore arranging for two pre labelled packs of viagra to be available should this be required. An email has been sent to staff (2.3) to inform them of the issue.	

‘Other’ areas of practice that require 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.

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. Website The centre’s website does not provide information on live birth rates. Code of Practice 4.12.	The PR should review the centre’s website to ensure that success rates are published in accordance with guidance. It is understood that the centre has plans to review the contents of the website. The PR should audit the centre’s website against regulatory requirements and make the necessary corrections. The PR should inform the centre’s inspector, when the required corrections have been made so that a subsequent review for compliance can be undertaken. It is expected that the centre’s website will be fully compliant	This information will be added to the website. All aspects of the Code of Practice pertaining to website inclusion will be audited October/November 2018.	The executive acknowledges the PR’s response and awaits the website audit to be conducted in October/November 2018.

	with regulatory requirements by 12 December 2018.		
4. Infection control The following non-compliances were identified in relation to infection control: • Boxes of consumables were stored on the floor of the store room, this was an area of practice requiring action that was identified in the centre's own recent infection control audit; • The temporary closures on the sharps bins in the clinical areas were not in use. SLC T2. Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105. Healthcare-associated infections: prevention and control in primary and	The PR should ensure that infection control measures and practices are compliant with regulatory requirements and best practice. The PR should review the non-compliances identified in this report and provide the centre's inspector with a summary of the actions taken, including staff training, to ensure these have been addressed when responding to this report. Three months after the implementation of corrective actions, the PR should audit infection control practices to ensure that actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 12 December 2018.	Boxes of consumables were removed instantly and email of high importance was circulated to all staff regarding this (4.1). Signs have been placed in the stock rooms (4.3). An email was sent to all clinical staff with regards to the closing over of all sharps boxes inbetween use (4.1/4.2). Audit scheduled for October/ November 2018	The executive acknowledges the PR's response. A follow up audit for infection control practices is due by 12 December 2018. Further action is required.

community care 2017, section 1.1.4.4.			
5. Staff The centre's 'lone worker' policy is not detailed enough and does not include the procedures for all staff including the counsellors who are in the centre after normal working hours. SLC T17.	The PR should ensure the local procedures for lone working are fully documented. The PR should review the centre's 'lone worker' policy and forward a copy of the updated document to the clinic's inspector by 12 September 2018.	The department follows trusts Lone Working Policy (5.1) in respect of safety. The department does not have a specific policy although the principles are applied. If there are patients on the department more than two member of staff are here until the patients leave. Counselling patients are not routinely seen after working hours and another member of staff is present on the unit for their last appointment at 17:00. Communication between staff members working late needs to be looked in to and local policies updates and distributed to all staff members. The PR will feedback to the HFEA.	The executive acknowledges the PR's response and awaits an updated 'lone worker' policy by 12 September 2018. Further action is required.

Additional information from the Person Responsible