Executive Licensing Panel - minutes

Centre 0201 (Edinburgh Assisted Conception Unit)

Interim Inspection Report

Tuesday, 10 December 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Howard Ryan Helen Crutcher	Director of Finance and Resources Data Analyst 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 that the Edinburgh Assisted Conception Unit, also known as the Edinburgh Fertility and Reproductive Endocrinology Centre, is located at the Royal Infirmary of Edinburgh. The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services, including embryo testing. Other licensed activities at the centre include storage of gametes and embryos.

1.2. The panel noted that, in the 12 months to 31 July 2019, the centre provided 999 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre.

1.3. The panel noted that, HFEA register data, for the year ending 31 May 2019, show the centre's multiple pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages.

1.4. The panel noted that, in 2018, the centre provided 12 cycles of partner inseminations, with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

1.5. The panel noted that, for the year ending 31 May 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target.

1.6. The panel noted that an unannounced inspection took place on 17 September 2019.

1.7. The panel noted that at the time of inspection there were two 'other' areas of non-compliance concerning equipment and materials and premises and facilities. Since the inspection, the Person Responsible (PR) has provided evidence that the recommendation concerning premises and facilities has been implemented, and has committed, where required, to audit the effectiveness of these actions, within the required timescales. The PR has given a commitment to fully implement the recommendation in relation to equipment and materials.

1.8. 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 expressed concern regarding the low numbers of patient feedback, provided by patients through use of the 'Choose a Fertility Clinic' facility, available on the HFEA's website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.

2.2. The panel congratulated the centre on its low multiple birth rate.

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

Richard Sydee

Date

17 December 2019

Interim Licensing Report

Centre name: Edinburgh Assisted Conception Unit
Centre number: 0201
Date licence issued: 1 March 2018
Licence expiry date: 28 February 2022
Additional conditions applied to this licence: None
Date of inspection: 17 September 2019
Inspectors: Janet Kirkland (Lead), Victoria Brown and Lesley Brown
Date of Executive Licensing Panel: 10 December 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 – post review of draft by PR

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

The ELP is asked to note that this report makes recommendations for improvement in relation to two 'other' areas of non compliance or poor practice.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

'Other' areas of non compliance:

- The PR should ensure that gas cylinders are secured in accordance with compressed gas safe storage guidance.

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

'Other' areas of non compliance:

- The PR should ensure that CE marked medical devices are used where possible.

Information about the centre

The Edinburgh Assisted Conception Unit is also known as the Edinburgh Fertility and Reproductive Endocrinology Centre and is located at the Royal Infirmary of Edinburgh.

The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing. Other licensed activities of the centre include storage of gametes and embryos.

The centre provided 999 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2019. In relation to activity levels this is a medium centre.

The centre's current licence was varied in 2018, after an inspection in August 2018, in response to an application to vary the centre's licence to create a new cryostore and change the current cryostore into an andrology laboratory.

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]

[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 $p \leq 0.002$.

For IVF and ICSI, HFEA held register data for the year ending 31 May 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported 12 cycles of partner insemination with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 May 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be 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. The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and review the centre's most recent audits of practice. 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, the 'bring-forward' system was discussed with staff and reports of audits of all stored gametes and embryos, and storage records were reviewed. These activities indicated that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: The reception area was very busy upon arrival and the inspection team was informed that there were several members of staff on leave. The inspection team left the clinic and returned after an hour, when a senior member of staff became available. On return, the atmosphere in the clinic appeared calm, staff mix and numbers appeared reasonable for the scheduled activities of the centre and staff in the laboratory were able to carry out their activities without distraction. In addition, staff were very accommodating with their contribution to the inspection.

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

[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%.

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; legal parenthood; witnessing; consent to storage; patient support.

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
- counselling
- extension of storage consent
- screening
- the use of the Single European Code

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 compliant with guidance.

Prescription of intralipid 'off label'

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

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the

safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: culture media, culture dishes, tubes, pipettes used to handle gametes and embryos, vitrification devices and specimen containers used to collect semen samples. We found the centre to be broadly compliant with HFEA requirements to use CE marked medical devices wherever possible because specimen containers used to collect semen samples used at the centre are not CE marked to the appropriate level. Appropriately CE marked specimen containers were already in stock at the centre however were not routinely used (see recommendation 1).

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 two patients have provided feedback in the last 12 months, giving an average four 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 reviewed. The inspection team noted many positive comments from patients, especially regarding support.

On the basis of the clinic's own 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 not compliant with the following HFEA requirement:

During the inspection, four small cylinders in the gas cylinder cupboard were not adequately secured. Brackets and chains were in place however these were not fit for the purpose of securing cylinders of this size. In addition, one large cylinder was not secured to the wall despite an appropriate bracket and chain being present. The inspection team notes that the unsecured large gas cylinder was immediately secured by clinic staff upon identification (see recommendation 2).

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 four major and four 'other' areas of non compliance.

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

Following the licence variation inspection in 2018, recommendations for improvement were made in relation to one major and one 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in September 2017 the centre has not received any performance related risk tool alerts.

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. There are currently no significant data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 16 January 2019**.**

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 September 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. 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

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 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 partly 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			

‘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.

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
1. Equipment and materials The specimen containers used to collect semen samples used by the centre are CE marked for invitro diagnostic use only. SLC T30.	The PR should ensure that medical devices CE marked to an appropriate level are used where possible. We would not recommend precipitous changes that might impact on the quality of treatment; however, the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used. The PR should inform the centre’s inspector when appropriately CE marked specimen pots are in use, no later than 17 December 2019.	Red topped, CE 0089 marked Semen Collection Containers by REPROMED will be used for any semen samples which are collected with the intention of being used for IVF treatment. The CE marking on Semen Collection Containers by REPROMED is identified in Directive 93/42/EEC for Medical devices and states that the notified body responsible for "MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)" is BSI Assurance UK Ltd. The centre is familiar with the semen collection containers by REPROMED as they are used for toxicity testing the Sterilin sample	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has confirmed that appropriately CE marked devices will be used by the centre. The PR should inform the centre’s inspector when appropriately CE marked specimen pots are in use, no later than 17 December 2019. **Further action required.**

		pots. The Sterilin pots will only be used for collecting semen samples which will not be used in treatment. Protocols associated with the collection of semen for use in any ART related treatment will be updated prior to the introduction of the pots into general use.	
2. **Premises and facilities** Gas cylinders were not adequately secured. Department of Health (2006) 'Medical Gases Health Technical Memorandum (HTM) 02- 01: Medical gas pipeline systems; Operational management. SLCs T2, T17.	The PR should take immediate action to ensure that medical gases are stored appropriately, ensuring that all cylinders are appropriately secured from falling over. The PR should inform the centre's inspector of the actions taken to comply with this recommendation when responding to the inspection report.	After investigation into the root cause of the non-compliance, it was identified that the gas cylinders were correctly secured by the person delivering the cylinders to the centre but not by the embryologist connecting them for use. All staff involved in the handling of gas cylinders were reminded of their responsibility to ensure that cylinders are stored securely, in line with current guidance. Additional guidance will be added to the appropriate protocols and alert signs have been placed both above the cylinders and on the inside of the door as a visual prompt. The Consultant Embryologist has also introduced a witnessing step	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that staff have been reminded of their responsibilities and a witnessing step has been introduced to ensure cylinders are appropriately secured once connected for use. The PR has confirmed the small cylinders that were not adequately secured have now been removed from the gas storage cupboard, as they are no longer in use at the centre. **No further action required.**

		for the safe connection and storage of gas cylinders to their log book.	

Additional information from the Person Responsible