Executive Licensing Panel - minutes

Centre 0197 (Salisbury Fertility Centre) Executive Update

Friday, 24 March 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Howard Ryan Jessica Watkin	Head of Business Planning Report Developer Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The Salisbury Fertility Centre, centre 0197 is located in Salisbury. The centre provides a full range of fertility services and has been licensed by the HFEA since May 2002.

1.2. The Executive Licensing Panel considered the centre's interim inspection report at its meeting on 24 February 2017, noting that the report discussed the centre's multiple pregnancy rate of 22% and recommended 'The PR should undertake an audit of the progress and effectiveness of the multiple births minimisation strategy'.

1.3. The 24 February 2017 Executive Licensing Panel were concerned about the centre's performance around multiple births and decided to adjourn consideration regarding the continuation of the centre's licence until the inspectorate was able to report on the audit findings concerning multiple births, due for submission by 22 February 2017.

2. Consideration of application

2.1. The panel considered the papers, which included an executive update, inspection report and licensing minutes for the last three years.

2.2. The panel noted that the Executive had confirmed that the PR had submitted an audit of practice against the Multiple Births Minimisation Policy as evidence of the implementation of the recommendation made in the inspection report, on 23 February 2017.

2.3. The panel noted the Executive's review findings. The centre has provided good evidence that it has now implemented the recommendation made in the interim inspection report with respect to multiple births. In response to the audit, the PR has implemented changes to eSET criteria and associated embryo transfer practice, which should significantly reduce the centre's overall multiple pregnancy rate while maintaining satisfactory pregnancy rates. The inspectorate will continue to review the implementation of this recommendation through the risk tool and on-going monitoring system and to follow up with the PR on the implementation of the report's remaining recommendations which are due in May 2017.

2.4. The panel noted that the inspectorate was satisfied that the evidence submitted had addressed the recommendation made in the report and recommended the continuation of the centre's licence.

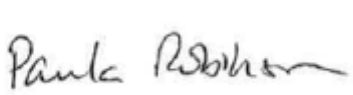
3. Decision

3.1. The Panel welcomed the additional information regarding multiple births and was satisfied the centre was fit to have its licence continued

4. Chair's signature

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

Signature



Name

Paula Robinson

Date

4 April 2017

Interim Licensing Report

Centre name: Salisbury Fertility Centre
Centre number: 0197
Date licence issued: 01/05/2015
Licence expiry date: 30/04/2019
Additional conditions applied to this licence: None
Date of inspection: 22/11/2016
Inspectors: Grace Lyndon (lead) and Louise Winstone
Date of Executive Licensing Panel: 24/02/2017

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of 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. For 2015-2017 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

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their treatment experiences.

The ELP is asked to note that there are five recommendations for improvement in relation to four major and one 'other' area of non compliance or poor practice.

The PR has made a commitment to work with the HFEA to complete the non-compliances within the given timeframe.

'Major' areas of non compliance:

- The PR should undertake an audit of the progress and effectiveness of the multiple births minimisation strategy.
- The PR should ensure that CE marked medical devices are used in licensed activities.
- The PR should be review the centre's record keeping practices and ensure that they are compliant with the confidentiality requirements.
- The PR should ensure compliance with medicines management regulations and best practice guidance.

'Other' areas of practice that require improvement:

- The PR should ensure that IUI data is submitted within the required timeframe.

Information about the centre

The Salisbury Fertility Centre is located in Salisbury and has held a licence with the HFEA since 2002.

The centre provides a full range of fertility services.

The centre provided 570 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30/09/2016. In relation to activity levels this is a medium centre.

An application to vary the centre's licence to reflect the change of Licence Holder to Salisbury NHS Foundation Trust was approved in November 2016.

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 July 2015 to June 2016 show the centre's success rates are in line with national averages.

The centre has yet to submit IUI data for 2015 (see recommendation 5).

Multiple births[2]

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

Between July 2015 and June 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%: This means that the centre's multiple live birth rate is likely to be statistically higher than the 10% multiple live birth rate target (see recommendation 1).

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: egg collection. The procedure observed was witnessed using a manual witnessing system and 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

[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%.

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.

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 prescribed 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 and consent to storage.

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 content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- the use of CE marked medical devices.

The centre has been effective in ensuring compliance with guidance issued by the HFEA, except regarding that related to the use of CE marked devices (see below and recommendation 4).

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. These processes were found to be partially compliant with guidance because records of the discard of controlled drugs were not consistently countersigned by two staff members (see recommendation 2). Staff considered that the signatures already present in the controlled drugs register, recording the removal of the drugs from the controlled drugs cupboard, would suffice.

Surgical Pathway
It is important that clinics follow best practice for surgical pathways to protect patients and ensure that patient confidentiality and dignity are protected.

During the inspection, we reviewed the pre-, peri- and post-surgical practices and found them to be compliant with guidance.

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'.

We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible, because the following medical devices used in treatment are not CE marked: 10ml, 5ml and 1ml serological pipettes; 50ml flasks; 13ml and 5ml tubes; and Hartmann's flush media used during egg collection (although this is only used occasionally as an extra flushing media if required). In addition, the pots used for the collection of sperm to be used in treatment were not CE marked at the appropriate level, i.e. they were CE marked for in vitro diagnostic use but not for use as class II medical devices (see recommendation 4).

Patient experience
During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Seven patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with four of the individuals providing written feedback giving compliments about the care received.

On the basis of this feedback and observations made in the course of the inspection, it was possible to assess that the centre has staff who are supportive and professional.

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 following exception:

- Four out of the five patient's files reviewed on inspection did not contain the Day Surgery Unit anaesthetic and recovery record. This record is stored in the patient's general hospital notes and not within the centre's patient files, but it documents the licensed treatment provided under general anaesthetic – transvaginal egg collection – which is indicated as 'TVEC'. The inspection team considers this is a potential breach of the confidentiality requirements of the HF&E Act 1990 (as amended), because hospital staff who are not subject to the centre's licence have access to a record which identifies patients who have had licensed treatment activity (see recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2014, recommendations for improvement were made in relation to five major and five 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented, with exception to the use of CE marked devices (see recommendation 4).

On-going monitoring of centre success rates

Since the last renewal inspection in November 2014, the centre has received three risk tool alerts related to performance and the PR has responded.

During discussions at the time of the inspection, the PR provided a commitment to keep success rates in all the groups of patients under review. The PR is committed to review the multiple birth data from the past few months. This will be reviewed alongside the eSet policy and changes will be made as required. The multiple pregnancy rate is currently at 22%.

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 broadly compliant with requirements to submit information to the HFEA because the IUI treatment data for 2015 has not yet been submitted to the HFEA (see recommendation 5).

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and the offer of counselling was seen to be in place prior to consent and treatment in all cases.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None 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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Multiple Births The MPR for treatments in the most recent year is 22% and is significantly above the performance required to meet the 10% target. SLC T2.	The PR should undertake an audit of the progress and effectiveness of the multiple births minimisation strategy. A summary report of the audit findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 22 February 2017.	We have a births minimisation strategy in place. We are undertaking Audit of compliance. To be submitted to HFEA by 22 February 2017	The Executive thanks the PR for his response and looks forward to the summary report by 22 February 2017. **Further action required**
2. Medicines Management Records of the discard of controlled drugs were not consistently countersigned by two staff members in the controlled drugs register. Misuse of Drugs (Safe	The PR should ensure that the controlled drugs register is used appropriately and all entries are documented and signed by two staff members. A review of the use of the controlled drugs register	We have investigated the problem and it appears that the theatre recovery staff were using an old CD record book which only had one line for signatures. The Trust policy is that all CD drugs should be signed out and	The Executive notes the changes made and looks forward to the summary audit report by 22 May 2017. **Further action required.**

Custody) Regulations 1973 (as amended) regulation 27, 2001 regulations.	should be undertaken to ensure it is compliant with regulatory requirements. A summary of the review, including any changes to procedures, should be submitted to the HFEA by 22 February 2017. Three months after the implementation of any changes to procedures, the PR should audit the use of the controlled drugs register, to ensure the new process is compliant. A summary of this audit should be submitted to the HFEA by 22 May 2017.	disposals signed off by two members of staff. The CD record book has been replaced with a new CD record book which has three lines for signatures and staff given further training in processes and this will be discussed at their next departmental Governance Session. A review of the register will be made by the Person Responsible and Head of Day Surgery Unit in April 2017 and submitted to the HFEA by 22 May 2017.	
3. Confidentiality and privacy Day Surgery Unit anaesthetic and recovery records for patients treated at the centre, which document the licensed treatment activity provided to named patients, are held in the patient's general hospital notes and are available to all hospital staff. The inspection team considers this is a potential breach of the	The PR should be review the centre's record keeping practices and ensure that they are compliant with the confidentiality requirements of the HF&E Act 1990 (as amended), Section 33A. The PR should inform the centre's inspector of their proposed actions when responding to this report.	This has been discussed with the Day Surgery Unit team. No computerised record is kept of patient procedures for patients having licensed procedures in the DSU and agreed the notation for the procedure used on the anaesthetic record is essential for safety reasons (to demonstrate that an operation has been performed).	The Executive notes the discussion held with the surgical team. It is not clear that the risk to patient confidentiality has been addressed satisfactorily. The executive will correspond with the PR separately to address this point. **Further action required**

confidentiality requirements of the HF&E Act 1990 (as amended). HF&E Act 1990 (as amended), Section 33A.		Only clinical staff who work in the DSU and the Fertility Centre Team know that the agreed notation refers to a licensed procedure.	
4. CE Marked products The following medical devices were not CE marked at the appropriate level: 10ml, 5ml and 1ml serological pipettes; 50ml flasks; 13ml and 5ml tubes; Hartmann's flush media used during egg; pots used for the collection of sperm for use in treatment. The use of these non CE marked medical devices was cited as a non compliance in the previous inspection report. The centre is aware of their non CE marked status and are urged to source alternatives as soon as possible. SLC T30.	The PR should ensure that only medical devices which are CE marked at the appropriate level are used in treatment activities. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment provided; however the inspection team notes that this non compliance was reported at the last inspection. The PR should advise the centre's inspector when responding to this report, regarding the anticipated time by which a CE mark is expected to be obtained for these items or of the actions that will be taken to ensure that only CE marked medical devices are used in treatment	The centre has identified our non CE marked products and continues to watch for suitable replacements. Our product use is under constant review and we are replacing non CE marked materials with CE marked ones whenever they become available. We were told at ESHRE 2016 by Falcon that they intended to release CE marked products within the next year; therefore we will be implementing the changes as soon as they are available.	The Executive thanks the PR for his response and it is expected that suitable products will be in place by 22 May 2017. **Further action required**

	activities. It is expected that suitable products will be in place by 22 May 2017.		

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
5. Submission of IUI data The centre has not submitted IUI treatment and success rate data for treatments in 2015. General Direction 0005.	The PR should ensure that the IUI data for treatments in 2015 is submitted to the HFEA as soon possible. The PR should notify the centre’s inspector when this has been done.	The IUI data is available and will be submitted electronically as soon as the HFEA portal is opened.	The Executive awaits the submission of IUI data through the HFEA portal as soon as possible. **Further action required**

Additional information from the Person Responsible