# Executive Licensing Panel - minutes

## Centre 0367 (The Evewell)

## Interim Inspection Report

Tuesday, 26 November 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Clare Ettinghausen (Chair)<br>Yvonne Akinmodun<br>Laura Riley | Director of Strategy and Corporate Affairs<br>Head of Human Resources<br>Head of Regulatory Policy |
| 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 Evewell is located in London and has held a treatment (including embryo testing) and storage licence with the HFEA since 2018. The centre provides a full range of fertility services, including embryo testing.

**1.2.** The panel noted that, in the 12 months to July 2019, the centre had provided 145 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small sized centre.

**1.3.** The panel noted that, HFEA register data, between May 2018 and 31 April 2019, show the centre's 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 reported 12 cycle of partner insemination, with no pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

**1.5.** The panel noted that, between May 2018 and April 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to produce a multiple live birth rate statistically different from the 10% multiple live birth rate target.

**1.6.** The panel noted that an unannounced inspection took place on 24 September 2019.

**1.7.** The panel noted that, at the time of inspection, there were three major areas of non-compliance concerning medicines management, premises and facilities and legal parenthood. There were also two 'other' area of non-compliance regarding the website and emergency equipment. Since the inspection, the Person Responsible (PR) has fully implemented the recommendations concerning premises and facilities and the website. The PR has given a commitment to implement the recommendations relating to medicines management, legal parenthood and emergency equipment.

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

## 2. Decision

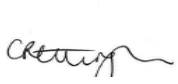
**2.1.** The panel noted that the centre's renewal inspection was due to be conducted in 2020 and hoped that evidence of progress, in the areas of non-compliance identified in the interim report, would have been made.

**2.2.** The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued,

## 3. Chair's signature

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

**Signature**



**Name**

Clare Ettinghausen

## Date

4 December 2019

# Interim Licensing Report

**Centre name:** The Evewell
**Centre number:** 0367
**Date licence issued:** 17 September 2018
**Licence expiry date:** 16 September 2020
**Date of inspection:** 24 September 2019
**Inspectors:** Louise Winstone and Polly Todd
**Date of Executive Licensing Panel:** 26 November 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.

Newly licensed centres usually receive a licence to operate for two years and are subjected to an unannounced interim inspection after one year, to assess whether they are operating in a compliant manner. If the licence is renewed, it can be awarded 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 current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

## Summary for the Executive Licensing Panel

### Summary for licensing decision

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

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

Since the inspection visit, the following recommendations have been fully implemented:

**Major areas of non compliance:**

- The PR should ensure that the centre's premises and facilities are safe for staff and patients.

**'Other' areas of practice that require improvement:**

- The PR should ensure that the centre's website is compliant with guidance.

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

**Major areas of non compliance:**

- The PR should ensure that medicine management practice and procedures are compliant with statutory requirements and best practice guidance.
- The PR should ensure that the processes for obtaining legal parenthood consents are robust and in line with regulatory requirements.

**'Other' areas of practice that require improvement:**

- The PR should ensure that emergency resuscitation equipment is checked as per practice guidance.

## Information about the centre

The Evewell is located in London and has held a licence with the HFEA since 2018.

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

The centre provided 145 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to July 2019. In relation to activity levels this is a small 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 May 2018 to April 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported twelve cycles of partner insemination with no pregnancies. This is likely to be in line with the national average.

#### Multiple births[2]

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

Between May 2018 and April 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be statistically different from 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 following laboratory activities were observed in the course of the inspection: embryo biopsy. The procedure observed was witnessed in accordance with HFEA requirements. The inspection team also discussed witnessing with staff and reviewed witnessing in patient records. 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.

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[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

On inspection, the 'bring-forward' system, the accuracy of storage consent records and the plans for audit were discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

### Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

### Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures 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.

As the centre only opened in September 2018, it was not required that audits of all critical activity should have been undertaken by the time of the inspection. The inspection team was however able to assess the effectiveness of the centre's QMS by reviewing the reports of the following audits: witnessing. The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- leadership
- patient support
- consent
- imports of gametes and embryos from outside the EU/EEA
- data submission to the HFEA
- the use of CE marked medical devices
- the content of the centre's website
- HFEA Clinic Focus articles regarding screening requirements.

The centre has been effective in ensuring compliance with guidance issued by the HFEA, with the exception of the centre's website. The website is not compliant with guidance because:

- The success rates listed for each group of patients is represented as a percentage and does not state the number of patients treated. Given that this is a new centre, this information is essential in groups comprising less than 50 treatments per year.

- There is no reference to the HFEA as the source of national information for comparison purposes.

See 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 and were found to be partially compliant with guidance because:

- There were several illegible entries in the controlled drugs (CD) register.
- There was an alteration in the CD register that was completely obliterated; this is not in line with regulatory requirements or the centre's own protocols.
- The amount of controlled drug given was not recorded in all instances and there were several entries where just numbers had been written, for example 100 or 1000 rather than 100mgs or 1000mcg.
- The centre's CD register does not facilitate the recording of supply and wastage of controlled drugs, therefore the discard and witnessing of controlled drugs could not be recorded. It is reliant on the practitioner making additional entries in the register to record the supply, administration and discard of the CD, which was only done in a small number of entries. A number of pages in the CD register were not labelled at the top of the page to indicate which drug the entries on the page related to.
- The carry-over of drugs from one page to another was not recorded or witnessed.

See recommendation 1.

### Prescription of intralipid 'off label'

Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was not reviewed during this inspection due to a focus on legal parenthood consenting processes. However, this area of practice will be a focus during the centre's renewal inspection.

The PR has been provided with information to enable the centre to audit the information provided to patients offered intralipid therapy.

### 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 5-star rating to the clinic. This was discussed with the PR who was asked to consider ways to promote the use of this facility. This will be followed up at the next inspection.

The centre's own most recent patient survey responses were therefore reviewed. During the period June 2019 to August 2019, 40 patients provided feedback. Feedback was positive, complimenting the service received.

During the inspection there were no patients available to speak to the inspectors.

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

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

## Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

### Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is non-compliant with the following HFEA requirements:

- There is no safety signage on the exterior of the cryostore room describing the potential health and safety risks to personnel entering. This was discussed during the centre's initial inspection and the inspectors were advised that the signage had been ordered and would be in place prior to the centre opening (see recommendation 2).
- There were three large gas cylinders in the medical gas storage room that were not secured to the wall (see recommendation 2).
- The checklist for the resuscitation trolley in the procedure room identified items that had been used and needed replacement but there was no indication that the required actions had been completed. The centre's procedure is that the resuscitation trolley should be checked on a weekly basis, but it had not been checked between 29 August and 17 September 2019. The Resuscitation Council (UK) recommendations are that resuscitation trolleys should be checked at least daily (see recommendation 5).

### Compliance with recommendations made at the time of the last inspection

Following the initial licence inspection in 2018, no recommendations for improvement were made.

### On-going monitoring of centre success rates

Since the initial licence inspection in 2018, 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.

### 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.

While the focus on legal parenthood consenting has been in place since February 2014, this centre only opened in 2018. The centre's proposed legal parenthood consenting practices were considered compliant at the time of licensing in 2018.

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. Three sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are partially compliant with HFEA requirements due to the following:

- The centre has a blanket policy of completing the WP and PP legal parenthood consent forms for all patients where legal parenthood consent applies. This causes concern to the inspection team about what information is being provided to patients when completing a form which does not apply to their situation. It also raises concerns that staff do not fully understand the requirements of legal parenthood consent.
- In one record where the patient's marital status could not be ascertained from the records, a WP and a PBR form had been completed. In this case the centre's own protocols had not been followed to complete both WP and PP forms and it can only be assumed that the patient was married by the presence of a PBR consent form.
- For patients that record their marital status as single/cohabiting the centre does not ensure they are not legally married/civil partnered to anyone else. Similarly, for couples that report they are not married to each other, the centre does not check that they are not married to someone other than the person with which they present for treatment.
- In two of the records audited the patients had completed their legal parenthood consents on the same day that the offer of counselling was made. This causes concern that patients may not have had a suitable period of time to consider their options.
- It was difficult to ascertain the marital status of the patients in the records audited.

See recommendation 3.

## 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 |
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| 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 |
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| **1. Medicines Management**<br>There were a number of issues identified during the inspection as detailed in the body of the report.<br><br>The Misuse of Drugs Regulations 2001, regulation 20a, 20c.<br><br>The Association of Anaesthetists of Great-Britain and Ireland (AAGBI) ‘Controlled Drugs in Perioperative Care’ 2019. | The PR should ensure that medicine management practice and procedures are compliant with statutory and practice guidance.<br><br>The PR should review current practice including, but not exclusive to, the issues identified in this report and provide a summary report of the review including staff training requirements and timeframes for implementation of corrective actions to the centre’s inspector by 24 December 2019. | Commuication with the lead anaesthetist for dissemination regarding the completion of the CD register specifically:<br>- ensuring that wastage is noted in the correct column;<br>- entries must be legible and nurses have been instructed not to countersign any entry that does not comply with the regulations on controlled drug recording. This has been entered into SOP-CLIN-004 Medicines Management.<br>- entries must not be obliterated but a single line | The executive acknowledges the PR’s response. The updated SOP-CLIN-004 has been received and the PR has committed to provide the summary of the review by 24 December 2019 and the follow up audit by 24 March 2020.<br><br>Further action is required. |

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| NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. | If the PR choses to deviate from practice guidance they should conduct a full risk assessment giving a clear rationale for the deviation, a copy of which should be provided to the centre's inspector.<br><br>Three months after the review, the PR should audit medicines management practice to ensure that any corrective actions implemented have been effective in achieving and maintaining compliance.<br><br>A summary report of this review should be provided to the centre's inspector by 24 March 2020. | drawn through and in brackets (written in error) recorded.<br>- A number of pages in the CD Register were noted not to have been labelled, this has been corrected and added into the SOP as above.<br>- The carry over of drugs from one page to another was not recorded or witnessed. This has been added explicitly to the SOP as above and discussed in the nurses meeting.<br>- All points as above will be discussed in the Management and Complaince Meeting and then disseminated to relevent departments for discussion at their department meetings.<br><br>Audit scheduled for three months time.<br><br>Summary of the review and audit will be provided by 24 December 2019 and the follow up audit by 24 March 2020. | |
| **2. Premises and facilities**<br>During the inspection, the following issues were noted: | The PR should ensure that the centre's premises and facilities are safe for staff and patients. | - Sign has been put in place on the door of the cryostore room.<br>- All cylinders now comply with requirement to be chained to the wall. | The executive acknowledges the PR's response and the actions taken to address this recommendation. |

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| The door to the cryostore room does not notify personnel of the potential health and safety risks upon entering.<br><br>There were three large gas cylinders in the medical gas storage room that were not secured to the wall with chains.<br><br>SLC T17 and Health Technical Memorandum 02-01: Medical gas pipeline systems Part B: Operational management. | The PR should fit appropriate safety signage to the exterior of the cryostore room and provide confirmation that this has been actioned when responding to this report.<br><br>The PR should ensure that all medical gases are kept secure at all times. When responding to the report, the PR should provide confirmation that immediate actions have been taken to address this. The PR should undertake a review to identify the factors that have led to this non-compliance. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. | Review of non-compliance (Cylinders):<br>Factors that led to the non-compliance - There was a delivery of cylinders that morning and the driver did not take all empty cylinders as required. CO not available due to inspection therefore cylinders left unsecured.<br>Corrective action - SOP-LAB-015 – information included to reflect that gas cylinders should always be secured to the wall using the chains provided.Laboratory staff have been made aware that should any delivery occur where there is insufficient space to securely store cylinders, the laboratory director must be notified asap. This has also been discussed at the laboratory meeting. | No further action is required. |
| **3. Legal Parenthood**<br>There were a number of issues identified during the inspection which raised concerns regarding the legal parenthood consenting process, as detailed in the body of the report. | The PR should ensure that the processes for obtaining legal parenthood consents are robust and in line with statutory and regulatory requirements.<br><br>The PR should ensure that the marital status of all patients is | Updated FM-CON-009 to capture marital/civil partnership status at point of acquiring donor sperm. Update patient registration form to ask specific questions regarding marital/civil | The executive acknowledges the PR's response and commitment to provide the review by 24 December 2019 and the follow up audit by 24 March 2020.<br><br>Further action is required. |

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| Section 44(1) of Part 2 of the HF&E Act 2008, CE(14)01, 'Consent forms: A Guide for Clinic Staff', HFEA (2019). | obtained and clearly documented in the records.<br><br>Where patients report they are single, the PR must assure themselves that the patient is not legally married or in a civil partnership to anyone else.<br><br>The PR should stop the practice of completing all forms for all patients and ensure that only the legal parenthood consent forms relevant to the patient's circumstances, are completed.<br><br>The PR should review the current legal parenthood consent procedures. This should include current protocol and practice, records review, staff training requirements and auditing processes. A copy of this review with timeframes for corrective actions should be provided to the centre's inspector by 24 December 2019.<br><br>Three months after this review the PR should audit legal parenthood consents to ensure | partnership status at the point of first attendence at clinic.<br>Update donor sperm consent FM-CON-004 form to include questions on marital/civil partnership status.<br>SOP<br>Staff who undertake consenting in relation to Legal Parenthood have been made aware that the practice of completing all parentage forms for patients is to cease immediately.<br><br>Legal parentage champions in the laboratory and on the nursing staff are to be nominated and to receive training in relation to legal parentage, consent and implications. All treatments involving donor gametes are to involve the legal parentage champions going forward.<br><br>We will undertake regular audits on all treatments involving donated gametes to ensure 100% compliance.<br><br>Training session 21.11.2019 arranged for all staff to attend | |

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| | that corrective 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 24 March 2020.<br><br>It is acknowledged that the centre is new in their licensing history and there may not be any records to audit for legal parenthood purposes in three months' time. In this event the PR should audit records as the occasion arises and provide a summary report of the audit to the centre's inspector by 24 June 2020. | on legal arentage with James Lawford Davis.<br><br>'Completeness check' undertaken by senior nurse or nurse director by the start of stimulation on all patients, with a focus on legal parentage and consent.<br><br>'Completeness check' to be undertaken by senior embryologist or laboratory director before egg collection with a focus on legal parentage and consent.<br><br>Review to follow by 24 December 2019. Follow up audit will be provided to HFEA by 24 March 2020. | |

## ‘Other’ areas of practice that require improvement

An ‘other’ area of practice that requires 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 |
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| **4. Website**<br>The centre’s website is not compliant with guidance as detailed in the main body of the report.<br><br>CoP guidance 4.8. | The PR should ensure that the centre’s website is compliant with guidance.<br><br>When responding to this report, the PR should provide an action plan and time scales for ensuring compliance. It is expected that the centre’s website will be compliant by 24 October 2019. | Refer to attached initial website audit tool outcome and the associated action plan and timeframes for completion.<br><br>In addition to the update of the success rates section of the website we have added the following to explain our PGS results:<br>"PGS success rates are more influenced by other factors affecting fertility rather than simply age. There should be little difference in PGS success rates in all the age groups once normal embryos are transferred. Our view is that breaking the rates down by age is not necessarily a true indicator of success. PGS cycles may be better | The executive acknowledges the PR’s response. The PR has confirmed by email that the draft of changes has now been uploaded to the centre’s website.<br><br>No further action is required. |

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| | | presented as a percentage across all ages."<br><br>see draft of changes to be uploaded attached. | |
| **5. Emergency equipment**<br>The following issues were identified:<br>• The checklist for the resuscitation trolley in the procedure room identified items that had been used and needed replacement but there was no indication that the required actions had been completed.<br>• The centre's procedure is that the resuscitation trolley should be checked on a weekly basis, but it had not been checked between 29 August and 17 September 2019. The Resuscitation council recommendations are that resus trolleys should be checked at least daily<br><br>SLC T2; Resuscitation Council 'Keeping resuscitation drugs locked away November 2016'. | The PR should ensure that emergency resuscitation equipment is checked as per practice guidance.<br><br>The PR should review current procedures for checking and stocking the emergency resuscitation trolley and provide a risk assessment detailing a clear rationale if there is any deviation from practice guidance.<br><br>A summary report of this review with timescales for implementing any corrective actions should be provided to the centre's inspector by 24 December 2019.<br><br>Three months after the review the PR should audit the resuscitation trolley checking procedures to ensure that any corrective actions implemented have been effective in | Risk assessment completed and further discussion held with Resus council trainer - continue weekly resus trolley check and a full recheck to occur if medical emergency occurs.<br>See attached risk assessment.<br>No corrective actions taking place regarding timing of checklist.<br>regular audits undertaken to ensure that the weekly check is being performed. Audit by 24 December 2019 to check that weekly checks are occuring.<br>The follow up audit will be provided by 24 March 2020. | The executive acknowledges the PR's response and the actions taken to address this recommendation. The PR has committed to provide the audit by 24 December 2019 and the follow up audit by 24 March 2020.<br><br>Further action is required. |

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| | achieving and maintaining compliance.<br><br>A summary report of this review should be provided to the centre's inspector by 24 March 2020. | | |

| Additional information from the Person Responsible |
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