# Executive Licensing Panel - minutes

## Centre 0354 (IVI London (Wimpole Street))

## Renewal Inspection Report

Thursday, 16 August 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

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|---|---|---|
| Panel members | Caylin Joski-Jethi (Chair)<br>Anna Quinn<br>Laura Riley | Head of Intelligence<br>Scientific Policy Manager<br>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 a completed application form, a renewal inspection report, an email confirmation from the Person Responsible (PR) wishing to renew the Treatment (including embryo testing) and Storage licence, and licensing minutes for the last three years.

**1.2.** The panel noted that IVI London of 83 Wimpole Street, London W1G 9RQ has held a Treatment (including embryo testing) and Storage licence with the HFEA since 2016.

**1.3.** The panel noted that up until April 2018, the centre has been unable to report any activity to the HFEA due to problems with setting up the EDI system since the centre varied their licence from an IUI centre to a treatment (including embryo testing) and storage centre. Therefore, the centre's pregnancy and multiple pregnancy rates since August 2017, have not been reported and the register team are unable to determine the centres effectiveness in this area of practice as they do not have the centre data to undertake comparisons.

**1.4.** Based on the data provided to the inspector, the centre provided 90 cycles of treatment (excluding partner insemination) in the 12 months to 31 December 2017. In relation to current activity levels this is a very small centre.

**1.5.** The panel noted that at the time of the inspection, the centre reported that in the 12 months to 31 December 2017, it had provided 90 cycles of treatment (excluding partner intrauterine insemination) resulting in 41 pregnancies. This is likely to be in line with national averages. There had been one multiple pregnancy resulting from treatments carried out in 2017. Based on this information, this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

**1.6.** The panel noted that this current licence has been varied to reflect a change of PR in 28 July 2017.

**1.7.** The PR has submitted an application for the renewal of a Treatment and Storage licence. This is an error and the PR has confirmed to the centre's inspector, that he wishes to apply for a Treatment (including embryo testing) and Storage licence. Written confirmation of this was provided with this report.

**1.8.** An inspection was carried out at the centre on 5 and 6 June 2018.

**1.9.** The panel noted that at the time of the inspection, there were no critical areas of non-compliance and three major areas of non-compliance covering safety and suitability of premises and facilities, medicines management, and surrogacy. The Executive acknowledged the PR's response and commitment to implementation and confirmed that no further action was required beyond a submission of an audit of medicines management and pre-operative assessment by 5 December 2018. There were also three 'other' non-compliances concerning pre-operative assessment, the QMS, and Third Party Agreements (TPAs).

**1.10.** The panel noted that no further action was required other than submission of an audit of medicines management and pre-operative assessment practice due by 5 December 2018, and submission of copies of completed, compliant TPAs due by 5 December 2018.

**1.11.** The panel noted the inspectorate comment that the centre has no critical areas of concern and would continue to monitor the centre's performance.

**1.12.** The inspection team recommended the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions.

## 2. Decision

**2.1.** The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

**2.2.** The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

**2.3.** The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

**2.4.** The panel noted that the inspectors found that the centre had no serious areas of concern, no critical non-compliances, and on other 'major' and other areas of non-compliance the executive was satisfied with the responses of the PR, noting that no further action was required other than the submission of an audit of pre-operative assessment and medicines management by 5 December 2018.

**2.5.** The panel was pleased how the centre had developed an effective QMS which would help ensure patient safety.

**2.6.** The panel endorsed the inspectorate's recommendation to renew the centre's Treatment (including embryo testing) and Storage licence for a period of four years, without additional conditions, subject to the inspector's recommendations being implemented within the prescribed timescales.

## 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

# Inspection Report

## Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

**Date of inspection:** 5 and 6 June 2018

**Purpose of inspection:** Renewal of a licence to carry out Treatment (including embryo testing) and Storage

**Inspection details:** The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

**Inspectors:** Polly Todd, Sara Parlett, Kathryn Mangold, Julie Katsaros (observer)

**Date of Executive Licensing Panel:** 16 August 2018

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|---|---|
| **Centre name** | IVI London (Wimpole Street) |
| **Centre number** | 0354 |
| **Licence number** | L/0354/1/b |
| **Centre address** | 83, Wimpole Street, London, W1G 9RQ, United Kingdom |
| **Person Responsible** | Mr Joseph Enda McVeigh |
| **Licence Holder** | Ms Janet Talbot |
| **Date licence issued** | 28 November 2016 |
| **Licence expiry date** | 27 November 2018 |
| **Additional conditions applied to this licence** | None |

# Contents

# Section 1: Summary report

### Brief description of the centre and its licensing history:

IVI London has held a Treatment (including embryo testing) and Storage licence with the HFEA since 2016 and provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos.

Up until April 2018, the centre has been unable to report any activity to the HFEA. Based on data provided to the centre's inspector at the inspection, the centre provided 90 cycles of treatment (excluding partner insemination) in the 12 months to 31 December 2017. In relation to current activity levels this is a very small centre.

The Person Responsible (PR) has submitted an application for the renewal of a Treatment and Storage licence. This is an error and the PR has confirmed to the centre's inspector, that he wishes to apply for a Treatment (including embryo testing) and Storage licence. Written confirmation of this is provided with this report.

This current licence has been varied to reflect a change of PR in 28 July 2017.

### Pregnancy outcomes[1]

Based on the information provided to the centre's inspector, at the inspection, the centre provided 90 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2017, resulting in 41 pregnancies. This is likely to be in line with national averages.

At the time of the inspection there was no information relating to cycles of partner insemination available, due to the aforementioned issues with data submission. The centre has been in close liaison with the HFEA to rectify this problem and the PR has committed to providing this information in response to this report. As the issues with data submission were beyond the centre's control, no non-compliance has been cited at this time. The Executive will continue to monitor the centre's data submission to ensure that actions implemented are effective in achieving compliance with General Direction 0005.

### Multiple births[2]

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

At the time of the inspection, the centre reported that there had been one multiple pregnancy resulting from treatments carried out in 2017. Based on this information, this represents performance that is not likely to be statistically different from 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 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

## Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

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

Since the inspection visit, the following recommendations have been fully implemented. Where required, and by the dates specified, the PR will provide an update or summary of audits conducted to ensure that the corrective actions taken, have been effective.

Major areas of non compliance:

- The PR should ensure that equipment on the emergency resuscitation trolley is fit for purpose and within a specified expiry date and that new staff members receive practical life support training.
- The PR should ensure that medicines management procedure and practice is in line with statutory and regulatory requirements.
- The PR should ensure that all patients undergoing assisted fertility treatments, including surrogates and their partners (if they have one) have a welfare of the child assessment.

'Other' areas that requires improvement:

- The PR should ensure that the assessment of patients undergoing surgical procedures is in line with practice guidance.
- The PR should ensure that there are standard operating procedures (SOPs) for all activities authorised by this licence and other activities carried out in the course of providing treatment services, that do not require a licence.
- The PR should ensure that all core requirements are included in any third-party agreement.

## Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern.

Based on the information provided to the inspection team, the centre's success rates are likely to be consistent with national average.

The centre has an effective quality management system (QMS) in place. The PR is encouraged to continue to use the QMS to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance.

The inspection team recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions.

# Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

## 1. Protection of the patient and children born following treatment

### Witnessing and assuring patient and donor identification

**What the centre does well**

**Witnessing (Guidance note 18)**
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

**What the centre could do better**
Nothing identified at this inspection.

### Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

**What the centre does well**

**Screening of donors (Guidance note 11)**
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

**Payments for donors (Guidance note 13; General Direction 0001)**
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

**Donor assisted conception (Guidance note 20)**
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to

access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

**What the centre could do better**
Nothing identified at this inspection.

**Suitable premises and suitable practices**
Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

**What the centre does well**

**Safety and suitability of premises and facilities (Guidance note 25)**
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are partially compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

**Laboratory accreditation (Guidance note 25)**
The centre's laboratories and/or third-party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

**Infection control (Guidance Note 25)**
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

**Medicines management (Guidance Note 25)**
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially 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.

**Pre-operative assessment and the surgical pathway (Guidance Note 25)**
The centre has policies and procedures in place that are broadly compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. It is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

**Multiple births (Guidance note 7; General Direction 0003)**
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

**Procurement of gametes and embryos (Guidance note 15)**
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

**Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)**
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;

- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

**Receipt of gametes and embryos (Guidance note15)**
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

**Imports and exports (Guidance note 16; General Direction 0006)**
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

**Traceability (Guidance note 19)**
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

**Quality management system (QMS) (Guidance note 23)**
The centre has a QMS that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

**Third party agreements (Guidance note 24)**
The centre's third party agreements are broadly compliant with HFEA requirements.

**Transport and satellite agreements (Guidance note 24; General Direction 0010)**
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

**Equipment and materials (Guidance note 26)**
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

**Process validation (Guidance note 15)**
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

**Adverse incidents (Guidance note 27)**
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

**What the centre could do better**
**Safety and suitability of premises and facilities (Guidance note 25)**
On inspection the following issues were noted:

- A laryngoscope on the emergency resuscitation trolley was out of date.
- A suction catheter had no expiry date on the packaging.
- Two drugs were out of date (adrenaline and amiodarone).
- Practical life support training was not provided for new staff. The centre is reliant on on-line training which is not in line with practice guidance.

SLC T2; T23. Resuscitation Council 2015. See recommendation 1.

**Medicines management (Guidance Note 25)**
On inspection the following issues were noted:

- Practitioners were observed removing controlled drugs from the controlled drugs cupboard before they had been prescribed to a patient.
- There was no master list of signatures for the controlled drugs register.
- Amendments in the controlled drugs register were not in line with regulatory or statutory requirements. Changes had been made by over-writing a previously made entry.

SLC T2; DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'; Misuse of Drugs (safe custody) Regulations 2001; NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. See recommendation 2.

**Pre-operative assessment and the surgical pathway (Guidance Note 25)**
The centre does not use a World Health Organisation (WHO) safety checklist or equivalent for the assessment of patients undergoing surgical procedures.

SLC T2; WHO 2009 'Surgical safety checklist'. See recommendation 4.

**Quality management system (QMS) (Guidance note 23)**
The centre does not have an SOP for the following activities:

- The provision of information to patients

- Record keeping

SLC T33(b). See recommendation 5.

**Third party agreements (TPA) (Guidance note 24)**
The following was noted on inspection:

- The TPA with The Doctor's Laboratory – does not specify how any tests/diagnostic results are relayed to the centre, including sign off and confirmation that the result applies to the correct sample.
- The TPA with Vitrolife did not provide full details of the third party or the identification of the person responsible for managing the arrangement between the centre and third party.

SLC T114 (a) (b) (f). See recommendation 6.

## Staff engaged in licensed activity

Person Responsible (PR)
Staff

**What the centre does well**

**Person Responsible (Guidance note 1)**
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

**Staff (Guidance note 2)**
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

**What the centre could do better**
Nothing identified at this inspection.

## Welfare of the child and safeguarding

**What the centre does well**

**Welfare of the child (Guidance note 8)**
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that

treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements with the exception noted in the surrogacy section of this report.

**Safeguarding (Guidance Note 25)**
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

**What the centre could do better**
Nothing identified at this inspection.

## Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

**What the centre does well**

The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

**What the centre could do better**
Nothing identified at this inspection.

## 2. The experience of patients

### Patient feedback

**What the centre does well**

During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. A further two patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with all the individuals providing written feedback commenting that they have compliments about the care that they 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 respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

**What the centre could do better**

Nothing identified at this inspection.

### Treating patients fairly

Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

**What the centre does well**

**Treating patients fairly (Guidance note 29)**

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

**Counselling (Guidance note 3)**

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent [and prior to consenting to legal parenthood].

**Egg [and sperm] sharing arrangements (Guidance note 12; General Direction 0001)**

This centre does not undertake egg (or sperm) sharing treatments therefore this area of practice is not relevant to this inspection.

**Surrogacy (Guidance note 14)**
The centre's procedures for treatment involving surrogacy are partially compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

**Complaints (Guidance note 28)**
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

**Confidentiality and privacy (Guidance note 30)**
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

**What the centre could do better**
**Surrogacy (Guidance note 14)**
The centre has conducted one treatment involving a surrogate woman but did not undertake a welfare of the child assessment of the surrogate woman. In addition, the centre's surrogacy SOP does not make provision for conducting welfare of the child assessments on surrogates and their partners (if they have one).

SLC T56; Code of Practice 8.4; 14.1. See recommendation 3.

## Information

**What the centre does well**

**Information (Guidance note 4; Chair's Letter CH(11)02)**
The centre's procedures for providing information to patients and donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

**What the centre could do better**
Nothing identified at this inspection.

## Consent and disclosure of information, held on the HFEA Register, for use in research

**What the centre does well**

**Consent (Guidance note 5;6)**
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

**Legal parenthood (Guidance note 6)**

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 was not licensed in 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in November 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.

**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**

It is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

As discussed above, up until April 2018, the centre has been unable to report any activity to the HFEA therefore it was not possible to fully assess the centre's compliance with this requirement.

The inspection team considers the centre's non-compliance to be beyond their control and makes no recommendations, except to continue to engage with the HFEA and to ensure all data is submitted by the proposed deadline.

**What the centre could do better**

Nothing identified at this inspection.

## 3. The protection of gametes and embryos

### Respect for the special status of the embryo

**What the centre does well**
The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

**What the centre could do better**
Nothing identified at this inspection.

### Screening of patients and Storage of gametes and embryos

**What the centre does well**

**Screening of patients (Guidance note 15)**
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

**Storage of gametes and embryos (Guidance note 17)**
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

**What the centre could do better**
Nothing identified at this inspection.

## Use of embryos for training staff

**What the centre does well**

**Use of embryos for training staff (Guidance note 22)**
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

**What the centre could do better**
Nothing identified at this inspection.

## 4. Information management

### Record keeping and Obligations and reporting requirements

**What the centre does well**

**Record keeping and document control (Guidance note 31)**
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

**Obligations and reporting requirements (Guidance note 32; General Direction 0005)**
It is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.
The clinic is not compliant with requirements to submit information to the HFEA as there are a large number of treatments which have not been reported. The centre has been engaged with the HFEA since before it was licensed, to address problems with devices used to report treatments to the HFEA register. This matter was only resolved two weeks before this inspection and the centre has put procedures in place to address the backlog of data to be submitted and input live data, going forward. The PR has given a commitment that all treatment data will be submitted to the HFEA by 31 July 2018.

The inspection team considers the centre's non-compliance to be beyond the control of the centre and makes no recommendations, except that the PR continues to engage with the HFEA to ensure all data is submitted by the proposed deadline.

**What the centre could do better**
Nothing identified at this inspection.

## Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to one area of major non-compliance and three 'other' areas of non-compliance.

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

### On-going monitoring of centre success rates

The centre has had ongoing difficulties with data submission since November 2016 and has only recently been able to report treatment data to the HFEA register. The risk tool alerts system generally uses register data, so no alert emails concerning treatment outcomes have been issued to the centre since it started activity.

# Areas of practice requiring action

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, General 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 area 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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of 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 | Executive Review |
|---|---|---|---|
| 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 to a 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
- 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 | Executive Review |
|---|---|---|---|
| **1. Safety and suitability of premises and facilities:**<br>On inspection, the following issues were noted:<br>• A laryngoscope on the emergency resuscitation trolley was out of date<br>• A suction catheter had no expiry date on the packaging.<br>• Two drugs were out of date (adrenaline and amiodarone).<br>• Practical life support training was not provided for new staff. | The PR should ensure that equipment on the emergency resuscitation trolley is fit for purpose and within a specified expiry date, and that new staff members receive practical life support training.<br><br>The PR should inform the centre's inspector of the measures taken to address this non-compliance when responding to this report. | PO raised for replacement equipment 2906/18 (attached)<br><br>National supply issue with adrenaline and so drugs had been kept beyond expiry date. New drugs now in stock Amiodarone expires 30/10/19<br><br>On site BLS and ILS booked for 04th September. Admin | The Executive acknowledges the PR's response and commitment to implementing this recommendation.<br><br>No further action required. |

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| The centre is reliant on on-line training which is not in line with practice guidance.<br><br>SLC T2; T23.<br><br>Resuscitation Council 2015. | | and Lab staff will complete BLS, nursing and medical team will up date ILS | |
| **2. Medicines management:**<br>On inspection the following issues were noted:<br>• Practitioners were observed removing controlled drugs from the controlled drugs cupboard before they had been prescribed to a patient.<br>• There was no master list of signatures for the controlled drugs register.<br>• Amendments in the controlled drugs register were not in line with regulatory or statutory requirements. Changes had been made by over-writing a previously made entry.<br><br>SLC T2. | The PR should ensure that medicines management procedure and practice is in line with statutory and regulatory requirements.<br><br>The PR should review practices relating to the management of medicines to ensure compliance with regulatory and statutory requirements.<br><br>A summary report of this review including staff training requirements and corrective actions, with timescales, should be provided to the centre's inspector by 5 September 2018.<br><br>Three months after the review, the PR should audit medicines management practice and | Master list of Signatures for controlled drugs (attached)<br><br>SOP N1.2 relating to Medicines Management circulated to all staff to ensure read and understood (see attached signature list) | The Executive acknowledges the PR's response and commitment to implementing this recommendation.<br><br>No further action beyond submission of an audit of medicines management practice due by 5 December 2018. |

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| DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'.<br><br>Misuse of Drugs (safe custody) Regulations 2001.<br><br>NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. | procedure to ensure that any corrective actions implemented have been effective in achieving and maintaining compliance.<br><br>A summary report of this audit should be provided to the centre's inspector by 5 December 2018. | | |
| **3.Surrogacy:**<br>The centre has conducted one treatment involving a surrogate woman but did not undertake a welfare of the child assessment of the surrogate woman.<br><br>In addition, the centre's surrogacy SOP does not make provision for conducting welfare of the child assessments on surrogates and their partners (if they have one).<br><br>SLC T56.<br><br>Code of Practice 8.4; 14.1. | The PR should ensure that all patients undergoing assisted fertility treatments, including surrogates and their partners (if they have one) have a welfare of the child assessment.<br><br>The PR should ensure that there are documented procedures in place to ensure that welfare of the child assessments are conducted with surrogate women and their partners (where applicable).<br><br>The PR should provide the centre's inspector with a copy of the SOP which directs | Welfare of child assessment has been undertaken retrospectively<br><br>SOP N 6.9<br>Section 3 (vii) amended (attached)<br><br>Discussed with staff at clinical team meeting 28th June to ensure all potential surrogates | The executive acknowledges the PR's response and commitment to implementing this recommendation.<br><br>No further action required. |

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| | compliant practice for welfare of the child assessments and confirm that staff have been suitably trained, by 5 September 2018. | are sent welfare of child forms to complete and that staff carry out assessment | |

## Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates 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 | Executive Review |
|---|---|---|---|
| **4.Pre-operative assessment:** The centre does not use a World Health Organisation (WHO) safety checklist or equivalent for assessment of patients undergoing surgical procedures.<br><br>SLC T2.<br><br>WHO 2009 'Surgical safety checklist'. | The PR should ensure that the assessment of patients undergoing surgical procedures is in line with practice guidance.<br><br>The PR should review the centre's procedures for the assessment of patients undergoing surgical procedures and provide a summary report, including any corrective actions taken, to the centre's inspector by 5 September 2018.<br><br>Three months after the review, the PR should audit practice relating to the assessment of patients undergoing surgical procedures, to ensure that any corrective actions taken have | Following discussions with Anaesthetic lead - implementation of a modified safety checklist appropriate to conscious sedation. (attached) | The Executive acknowledges the PR's response and commitment in implementing this recommendation.<br><br>No further action required beyond submission of an audit of pre-operative assessment practice due by 5 December 2018. |

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| | been effective in achieving and maintaining compliance.<br><br>A summary report of this audit should be provided to the centre's inspector by 5 December 2018. | | |
| **5. QMS:**<br>The centre does not have an SOP for the following activities:<br>• The provision of information to patients<br>• Record keeping<br><br>SLC T33(b). | The PR should ensure that there are SOPs for all activities authorised by this licence and other activities carried out in the course of providing treatment services, that do not require a licence.<br><br>The PR should provide the centre's inspector with a copy of the SOPs identified in this report by 5 September 2018.<br><br>The PR should ensure that these areas of practice are appropriately audited in line with the centre's audit schedule to ensure that procedures have been embedded into practice.<br><br>A summary report of the audits should be forwarded to the centre's inspector by 5 December 2018. | | Prior to the report being reviewed by the PR, the PR submitted SOPs and audits for this area of practice, to the satisfaction of the Executive.<br><br>No further action required. |

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| **6.Third Party Agreements:**<br>The following issues were noted on inspection:<br>• The TPA with The Doctor's Laboratory – does not specify how any tests/diagnostic results are relayed to the centre, including sign off and confirmation that the result applies to the correct sample.<br><br>• The TPA with Vitrolife did not provide full details of the third party or the identification of the person responsible for managing the arrangement between the centre and third party.<br><br>SLC T114 (a) (b) (f). | The PR should ensure that all core requirements are included in any third-party agreement.<br><br>The PR should review all third- party agreements, to ensure they are compliant with SLCs and make the relevant amendments to the TPAs identified in this report.<br><br>A copy of the completed and compliant TPAs (identified in this report) should be provided to the centre's inspector by 5 December 2018. | All third party agreements reviewed and amendments made as required. Replacement TPAs sent to companies where required. | The Executive acknowledges the PR's response and commitment to implementing this recommendation.<br><br>No further action beyond submission of copies of the completed, compliant TPAs due by 5 December 2018. |

| Reponses from the Person Responsible to this inspection report |
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