# Licence Committee - minutes

## Centre 0324 (City Fertility) – Treatment (including embryo testing) and Storage Licence renewal application

Thursday, 8 September 2016

HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

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| Committee members | Lee Rayfield (Chair)<br>Margaret Gilmore<br>Ruth Wilde<br>Kate Brian<br>Anita Bharucha | |
| Members of the Executive | Ian Brown<br>Trent Fisher | Head of Corporate Governance<br>Secretary |
| Legal Adviser | Graham Miles | Blake Morgan LLP |
| Observers | None | |

## Declarations of interest:

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

## The committee had before it:

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

## The following papers were considered by the committee:

- renewal inspection report
- application form
- licensing minutes from the last three years

## 1. Consideration of application

**1.1.** The committee noted that the City Fertility (0324) has held a Treatment (including embryo testing) and Storage Licence with the HFEA since 2012 and provides a full range of fertility services. The executive is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

**1.2.** The committee noted the centre provided 248 cycles of treatment (excluding partner intrauterine insemination) in the 12 months leading to 31 May 2016. In relation to activity levels, this is considered to be a medium sized centre.

**1.3.** The committee noted that for IVF and ICSI, the HFEA held register data for the 12 months ending in February 2016 which shows the centre's success rates are in line with national averages.

**1.4.** The committee noted that for the 12 months ending in February 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 21 percent, this represents performance that is not likely to be statistically different from the 10 percent multiple live birth rate target.

**1.5.** The committee noted that the centre's current licence is due to expire on 28 November 2016.

**1.6.** The committee noted that at the time of the centre's renewal inspection, 15 June 2016, the executive found 8 areas of non-compliance including three major and five other.

**1.7.** The committee further noted that since inspection, the PR has fully implemented two of the executive's recommendations. The PR has also provided assurance that the remaining recommendations will be implemented within the required time scales.

**1.8.** The committee expressed some concern at the number of areas of non-compliance found at the time of inspection. However, the committee noted that the PR seems fully engaged with the executive and encourages the centre to continue the engagement particularly on the non-compliance in relation to 'Safeguarding'. The committee notes the significance of safeguarding within a clinic setting and emphasised the importance training in safeguarding to the clinic.

**1.9.** The committee had regard to its decision tree. The committee was satisfied that the application was submitted in the form required and contained the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid. The committee noted that the application was made by the Person Responsible (PR) for the centre.

**1.10.** The committee was satisfied that the PR possesses the required qualifications and experience and that the character of the PR is such as is required for supervision of the licensed activities. It was further satisfied that the PR will discharge their duties under section 17 of the Act. The committee noted that the inspectorate was satisfied that the PR had satisfactorily completed the PR entry programme.

**1.11.** The committee noted that the executive recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without any additional conditions.

## 2. Decision

**2.1.** The committee decided to renew the Treatment (including embryo testing) and Storage licence at centre 0316 for a period of 4 years with no additional conditions.

## 3. Chair's signature

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

### Signature

### Name

Lee Rayfield

### Date

27 September 2016

# 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 Licence Committee (LC) 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:** 14 – 15 June 2016.

**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:** Dr Douglas Gray, Mrs Gill Walsh, Dr Victoria Lamb, Mr Neil McComb.

**Date of Licence Committee:** 8 September 2016

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| **Centre name** | City Fertility |
| **Centre number** | 0324 |
| **Licence number** | L/0324/2/d |
| **Centre address** | 16, St John Street, London, EC1M 4NT, United Kingdom |
| **Person Responsible** | Mr Shaun Rogers |
| **Licence Holder** | Mr Matej Stejskal |
| **Date licence issued** | 29/11/2014 |
| **Licence expiry date** | 28/11/2016 |
| **Additional conditions applied to this licence** | None |

# Contents

# Section 1: Summary report

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

City Fertility has held a treatment and storage licence since 2012, including embryo testing from 2015, and provides a full range of fertility services.

The centre provided 284 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2016. In relation to activity levels this is a medium sized centre.

The current licence has been varied to reflect the following changes:

- March 2015 – change of Person Responsible (PR) from Jane Holman to Vivienne Hall;
- August 2015 – change of PR from Vivienne Hall to Shaun Rogers; and
- November 2015 – the addition of embryo testing as a licensed activity.

At the time of City Fertility's last licence renewal in 2014, Licence Committee granted a licence for two years due to the nature and severity of the non compliances noted at the inspection. The Committee requested and received progress updates at their meetings in March and May 2015, and at their meeting in November 2015 the Committee considered the outcome of a focused interim inspection. At the November meeting the Committee required the renewal report for this centre to be put to Licence Committee, and not delegated to the Executive Licensing Panel.

## Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period March 2015 – February 2016 show the centre's success rates are in line with national averages.

In 2015, the centre reported 16 cycles of partner insemination with two pregnancies. Although data for 2015 have not yet been analysed, this represents a clinical pregnancy which 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 March 2015 – February 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 21%: 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 their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The Licence Committee is asked to note that at the time of the inspection there were three major areas of non-compliance and five 'other' areas resulting in the following recommendations that the PR has committed to implementing:

Major areas of non compliance:

- Written information on intralipids should make clear the reasons for prescribing this medicine off-label when there is little evidence to support its use. This recommendation has been fully implemented.
- The PR should investigate missing welfare of the child assessments from one set of medical records, provide a summary of his findings.
- The centre's nominated safeguarding lead and relevant staff, should receive adequate training in safeguarding; and, an SOP covering safeguarding procedures should be developed.

'Other' areas that require improvement:

- The centre's Controlled Drugs Accountable Officer (CDAO) should be registered with the Care Quality Commission; and, the waste portion of controlled drugs in vials should be routinely recorded.
- For patients meeting the centre's criteria for eSET that receive a multiple embryo transfer, an appropriate record should be made in their medical records.
- Audits should make use of relevant quality indicators; and, there should be an SOP that adequately covers the provision of information to patients relating to their proposed treatment.
- Third party agreements with laboratories that test patients' bloods or biopsied cells should describe how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.
- The procedures used to submit licensed treatment data should be reviewed to identify and address reasons for delays in submissions.

## Recommendation to the Licence Committee

The centre has no critical areas of concern but does have three major of areas of concern. The inspection team notes that the success rates are consistent with the national average and the centre's multiple clinical pregnancy rate suggests it will meet the live birth rate target. The inspector will continue to monitor the centre's performance.

The inspectors would particularly like the Committee to note the cooperation of the PR since the last inspection, and that significant improvements have been made. Whilst some actions are required to implement the recommendations made, the inspectors are satisfied that practices are suitable. The centre has a quality management system (QMS) in place and the PR is encouraged to use it to best effect to monitor and improve the service provided.

The inspection team recommends the renewal of the centre's licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

# 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)**
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic

siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this 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 an environment that is fit for purpose.

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

The premises of the centre's 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 for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

**Medicines management**
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

**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 processes for administering and monitoring patients during intralipid infusion were reviewed and considered to be suitable but the information provided to patients concerning intralipid therapy was not fully compliant.

**Pre-operative assessment and the surgical pathway**
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This 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 broadly 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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos 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 in place 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 do not have satellite or transport arrangements.

**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 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**

**Medicines management**
The centre's Controlled Drugs Accountable Officer (CDAO) is not registered with the Care Quality Commission (Section 10 of the Controlled Drugs (Supervision of Management and Use) Regulations, 2013; recommendation 4).

A review of the centre's controlled drugs book showed that the waste portion of a drug vial remaining after part has been administered to a patient is not routinely recorded or witnessed (Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)', 2007; recommendation 4).

**Prescription of intralipid 'off label'**
The centre's written information on intralipid therapy does not make clear the reasons for prescribing this medicine off-label when there is little evidence to support its use in fertility treatment (SLC T58; recommendation 1).

**Multiple births (Guidance note 7; General Direction 0003)**
When multiple embryos are transferred to a patient who meets the criteria for single embryo transfer, notes are not made in the medical record providing a clear explanation of the reasons for transferring more than one embryo or documenting that the risks associated with multiple pregnancy have been fully discussed with the patient. The centre has a form to be used to collect this information but it is rarely used (General Direction 0003; recommendation 5).

**Quality management system (QMS) (Guidance note 23)**

The centre has established quality indicators and completes a full range of audits regularly, however audits do not include a review of the process against the relevant quality indicators (SLC T36; recommendation 6).

**Third party agreements (Guidance note 24)**
The centre's third party agreements with laboratories that test patients' bloods or biopsied cells do not describe how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample (SLC T114(f); recommendation 7).

## 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 biological sciences 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 treatment is provided, the welfare of any child who may be born as a result of the licensed treatment and of any other child who may be affected by that birth, are partially compliant with HFEA requirements.

**Safeguarding**
The centre's procedures are partially 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**

**Welfare of the child (Guidance note 8)**
In one set of medical records reviewed during the inspection there were no documented welfare of the child assessments although treatments had been provided (SLCs T46(e) and T56; see recommendation 2). The inspectors do not believe this represented a wider problem in the taking and recording of welfare of the child assessments, since such assessments were found in all other medical records reviewed and the centre's regular audits of welfare of the child assessment have identified no concerns.

**Safeguarding**
The centre's nominated safeguarding lead and some relevant staff have not received adequate training in safeguarding. There is also no SOP in place to direct staff in the event that a safeguarding concern arises (SLCs T12, T15 and T33(b); CoP Guidance 25.33 and 25.35; recommendation **Error! Reference source not found.**).

## Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

**What the centre does well**

**Preimplantation genetic screening (Guidance note 9);**
**Embryo testing and sex selection (Guidance note 10)**
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 inspectors spoke to one patient who provided feedback on her experiences. A further 16 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with all of the individuals providing written feedback to the HFEA 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)**
Treatments involving egg and sperm sharing are not offered.

**Surrogacy (Guidance note 14)**

The centre's procedures for treatment involving surrogacy are 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**
Nothing identified at this inspection.

## Information

**What the centre does well**

**Information (Guidance note 4)**
It is important to ensure that centres give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions. The centre's procedures for providing information to patients and / or donors are broadly compliant with HFEA requirements.

**What the centre could do better**
Whilst the centre had an SOP for 'the provision of information', it did not cover the procedures and requirements relating to the provision of information to prospective patients about the nature of their proposed treatments (SLC T33(b); recommendation 6).

## 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 its effectiveness and, in some cases, it may be

necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, 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. On this inspection, inspectors reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

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 four 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 with a prior offer of counselling was in place before treatment in all cases.

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

**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements. This is important to ensure that HFEA holds an accurate record of patients' consent, so that it only releases the patient identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing, and those born following, licensed treatments.

**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). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- 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
### Storage of gametes and embryos

**What the centre does well**

**Screening of patients (Guidance note 17)**

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 (Guidance note 22)

**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**
**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)**
The centre's procedures for submitting information about licensed activities to the Authority are broadly compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

**What the centre could do better**

**Obligations and reporting requirements (Guidance note 32; General Direction 0005)**
Some problems were found with the timeliness and accuracy of the centre's submission of donor insemination treatments to the Register; 2% (2/91) of the IVF and 42% (5/12) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005 (recommendation 8).

# Section 3: Monitoring of the centre's performance

Following an interim inspection in August 2015, recommendations were made to address one critical non compliance, four major non compliances and two 'other' areas of poor practice. The PR provided information and evidence that all of the recommendations were fully implemented within the agreed timescales.

## On-going monitoring of centre success rates

Since the 2015 inspection the centre was asked in August and September 2015 to review procedures in relation to their multiple pregnancy rates. The PR responded to the request and during discussions at the time of the inspection, provided a commitment to keep their multiple pregnancy rate under review. The Committee should note that since this time, the centre's multiple pregnancy rate has reduced to 21%, which represents performance that is not likely to be statistically different from the 10% multiple live birth rate target; progress is therefore being made. A recommendation has been made in this report to further facilitate compliance with the requirements of General Directions 0003.

# 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 Direction 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.

| 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.

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| **1. Intralipid**<br><br>Written information on intralipid does not make clear the reasons for prescribing this off-label where there is little evidence to support its use.<br><br>(SLC T58; HFEA Clinic Focus, July 2015) | The PR should review and revise the written information provided to patients on intralipid therapy to ensure it is compliant with guidance provided by HFEA.<br><br>A copy of the amended information was received from the PR 19 July 2016 and therefore no further action is required. | N/A | |
| **2. Welfare of the child**<br><br>In one set of notes reviewed during the inspection there were no documented welfare of the child assessments although treatments had been provided. | The PR should investigate this observation and provide a summary of his findings by 15 September 2016. The PR should confirm when their next scheduled audit of welfare of the child forms is due and a copy of this should be | A further audit will be completed as part of the standard audit schedule on the 5th September, these details will be sent to the authority by the 15th September, along with the findings of the investigation of the individual | The PR has forwarded a copy of a further audit completed since the inspection that identifies no errors. We await the outcome of the PR's investigation by 15 September. |

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| (SLC T56; SLC T46(e)) | forwarded to their inspector. | missing WoC form. | |
| **3. Safeguarding**<br><br>The centre's nominated safeguarding lead and some relevant staff have not received adequate training in this area of practice, and there is no SOP in place to guide staff in the event of safeguarding concerns.<br><br>(SLC T12, T15 and T33(b); CoP Guidance 25.33 and 25.35) | All relevant staff should be trained in safeguarding to the required level for their post.<br><br>A timeframe for the provision of training in safeguarding to relevant staff should be provided to the centre's inspector, alongside an SOP that adequately covers safeguarding procedures by 15 September 2016. | Training in place for Safeguarding officer to level three safeguarding adults and children. All staff have completed level 1 safeguarding adults and children. See the accompanying Safeguarding SOP | The PR has provided confirmation that staff are, or will be, trained to a level required for their post. We request confirmation once the safeguarding officer has completed their training. A suitable SOP covering safeguarding has been submitted. |

## 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.

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
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| **4. Medicine management**<br><br>The centre's Controlled Drugs Accountable Officer (CDAO) is not registered with the Care Quality Commission<br><br>(Section 10 of the Controlled Drugs (Supervision of Management and Use) Regulations, 2013)<br><br>The waste portion of controlled drugs in vials is not routinely recorded.<br><br>(Department of Health guidelines ('Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)', 2007) | Confirmation that the CDAO is registered with the CQC should be provided to the centre's inspector by 15 September 2016.<br><br>The PR should review procedures (including documented SOPs) to ensure the waste portion of controlled drugs is recorded. Relevant staff should receive training in the up-dated procedures. Confirmation of these actions should be sent to the centre's inspector by 15 September 2016. Three months after, an audit should be completed to provide evidence of compliance with the revised procedures, and a copy sent to the centre's inspector by 15 December 2016. | All current nursing staff will complete Medication Awareness training, the centre's Controlled Drugs Accountable Officer and witness will complete this training as well. New nursing staff will complete this learning module as part of a revised orientation program compiled by the QM team, details of which can be made available by the 15th September, if required<br><br>In house training and reflection on our Medicine Management Policy and the relevant procedures to be completed on the 8th September<br><br>Audit schedule modified to include quarterly additional control drug audits. The findings of the audit in the final quarter of 2016 will be | Confirmation was received 1 August 2016 that an application had been submitted to CQC to register the centre's CDAO. No further action is required on this point.<br><br>The PR has taken suitable steps to train staff. A revised SOP has been submitted. We await the audit due December 2016. |

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| | | submitted as requested by the 15th December.<br><br>See attached modified SOP and evidence from the controlled drug register to demonstrate the change in practice. | |
| **5. Multiple births**<br><br>For patients meeting the centre's criteria for eSET that receive a multiple embryo transfer, a record is not always made in their medical records providing;<br>• a clear explanation of the reasons for transferring more than one embryo in that particular case; and,<br>• confirmation that the risks associated with multiple pregnancy have been fully discussed with the patient.<br><br>(General Direction 0003) | The PR should ensure that the information required by General Direction 0003 is consistently recorded in the patient records. A summary of actions taken to ensure this should be provided by 15 September 2016.<br><br>Six months after the implementation of these actions, an audit should be completed to provide evidence that the required information is being recorded consistently. A copy of the audit report should be sent to the centre's inspector by 15 March 2017. | Consent to transfer two embryos form reviewed to ensure that the required information is included.<br><br>Audit schedule has been modified to include half yearly additional audits specific to the modified practice. The findings of the audit will be provided to the authority on the 15th March 2017. | We await the outcome of the audit due March 2017. |
| **6. Quality management**<br><br>Audits do not utilise set quality | The PR should review the centre's audit process to ensure that they audit against | KPI schedule modified to include quarterly reviews and added to the QM audit | The PR has provided a summary of actions taken to ensure audits are linked to |

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| indicators and therefore it is difficult to establish whether a predetermined standard has been met.<br><br>(SLC T36)<br><br>Whilst the centre had an SOP for 'the provision of information', it does not cover the procedures and requirements relating to the provision of information to prospective patients about the nature of their proposed treatments.<br><br>(SLC T33(b)) | established relevant quality indicators.<br><br>A summary of actions taken to ensure this, including a sample of recent audits which have been linked to quality indicators, should be sent to the centre's inspector by 15 September 2016.<br><br>An SOP should be established that adequately covers the provision of information to patients relating to their proposed treatment. A copy of the new/amended SOP should be forwarded to the centre's inspector by 15 September 2015. | schedule notification system.<br><br>Details of the next KPI review will be provided to the authority after the next scheduled KPI meeting on the 18th August. Details of the quarterly KPI meetings will be provided to the authority throughout 2016/2017 to demonstrate compliance<br><br>A modified SOP/POLICY31 Provision of Patient Information will be prepared covering the provision of information to single patients and couples, to ensure that the verbal information that is provided in consultation and one to one interactions are also available in a written form. The NurseSOP8 Provision of Patient Information will also be reviewed to detail the documentation of information and provision of information from and in the electronic patient record system, at clinical and nurse consultations. The revised SOP/POLICY will be sent to | quality indicators. We await the outcome of their next KPI review and submission of example audits due 15 September 2016.<br><br>We await submission of the revised SOP due 15 September 2016. |

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| | | the inspector before the 15th September. | |
| **7. Third party agreements**<br><br>The centre's third party agreements with laboratories that test patients' bloods or biopsied cells do not describe how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.<br><br>(SLC T114(f)) | Relevant third party agreements should include information required by relevant standard licence conditions. Confirmation that these actions have been taken, alongside a copy of the additional information requested should be sent to the centre's inspector by 15 September 2016. | The generic third party agreement has been reviewed and modified to include a confirmation of procedures relating to sample processing and handling to ensure the named companies consider and demonstrate evidence of good practice. The PR has performed a second party audit of processes in the GENNET Letna genetic testing facility to ensure that SOP's and processes are sufficient. The modified agreement has been reviewed and sent to GENNET Prague, General Manager and TDL, the companies who provide services for testing blood samples and biopsied cells.<br><br>Once the documents are returned after a legal review they will be made available for the inspector, before the 15th September 2016. | The PR has taken appropriate action to satisfy themselves of the ability of their third party to meet the regulatory requirements. We await the revised TPA due September 2016. |
| **8. Obligations and reporting requirements** | The procedures used to submit licensed treatment data should | A review of patient information and process for donor | The PR has taken appropriate action and we await a |

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| Some problems were found with the timeliness and accuracy of the centre's submission of donor insemination treatments to the Register.<br><br>(General Direction 0005) | be reviewed to identify and address the reasons for delayed submissions. The outcome of this review should be forwarded to the centre's inspector by 15 September 2016.<br><br>The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to their inspector by 15 March 2017. | registration performed. Staff training obtained for registering donors on City electronic record software and subsequent submission of registration forms. Specific embryology team member to act as a patient/staff liaison for single patients and couples who require donor sperm to ensure compliance with relevant procedures. Audit of changes to be performed September/October 2016 to assess whether compliance has been achieved. | summary of their audit due March 2017. |

| Reponses from the Person Responsible to this inspection report |
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| The City Fertility team strive to work with the authority to constantly review and improve our practices, to ensure that the centre performs at the optimum level, which will enable us to ensure that the patient journey is as smooth as possible. We acknowledge that the points detailed in the inspection show areas where our processes need a review. The centre has made some immediate changes to our procedures and will implement all of the recommendations and provide the require information to the authority to demonstrate our compliance to the Code of Practice and guidance. |