# Executive Licensing Panel - minutes

## Centre 0354 (IVI, London)

## Interim Inspection Report

Friday, 16 February 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

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| Panel members | Caylin Joski-Jethi (Chair)<br>Helen Crutcher<br>Anna Coundley | Head of Intelligence<br>Risk & Business Planning Manager<br>Information Access & Policy Manager |
| Members of the Executive | Bernice Ash<br>Dan Howard<br>Nana Gyamfi | Secretary<br>Chief Information Officer (Observing)<br>Licensing Information Officer (Observing) |
| External adviser | | |
| Observers | | |

## Declarations of interest

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

## The panel had before it:

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

## 1. Consideration of application

**1.1.** The panel noted that IVI, London is located in central London and has held a treatment (including embryo testing) and storage licence with the HFEA since 2016. The centre provides a full range of fertility services.

**1.2.** The panel noted that the centre is currently unable to report treatment activity to the HFEA. However, based on data provided by the centre to the inspector for treatments in the year to 24 November 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is not likely to be significantly different from the 10% multiple live birth rate target.

**1.3.** The panel also noted that, based on data provided to the inspector, the centre had performed 12 partner insemination treatments, leading to one pregnancy, in the year to 24 November 2017. This is a pregnancy rate which is likely to be in line with the national average.

**1.4.** The panel noted that although the centre has been unable to report treatment activity to the HFEA, this is due to a delay implementing the HFEA's new data submission system and the inspection team has therefore not raised this as a non-compliance. The centre has been engaged with the HFEA since before it was licensed and will report treatment data as soon as a reporting system is available to them.

**1.5.** The panel noted that the inspection took place on 28 November 2017.

**1.6.** The panel noted that at the time of the inspection on 28 November 2017, one major area of non-compliance or poor practice was identified, concerning the Quality Management System (QMS), alongside three 'other' areas of non-compliance regarding equipment and materials, screening and traceability. The panel noted that since the inspection, the Person Responsible (PR) has committed to implementing all the recommendations made in the report.

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

## 2. Decision

**2.1.** The panel encouraged the PR to ensure that the traceability and screening audit summary reports are provided to the inspectorate within the prescribed timescales.

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

## 3. Chair's signature

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

### Signature

### Name

Caylin Joski-Jethi (Chair)

### Date

21 February 2018

# Interim Licensing Report

**Centre name:** IVI London
**Centre number:** 0354
**Date licence issued:** 28 November 2016
**Licence expiry date:** 27 November 2018
**Additional conditions applied to this licence:** None
**Date of inspection:** 28 November 2017
**Inspectors:** Shanaz Pasha (lead); Andrew Leonard; Mhairi West (observer)
**Date of Executive Licensing Panel:** 16 February 2018

## Purpose of the report

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

Newly licensed centres usually receive a licence to operate for two years and are subjected to an unannounced interim inspection after one year, to assess whether they are operating in a compliant manner. If the licence is renewed, it can be awarded for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLCs).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. For 2015-2017 the foci of an interim inspection are:

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

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

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

## Summary for the Executive Licensing Panel

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

The ELP is asked to note that recommendations for improvement are made in relation to one major and three 'other' areas of non-compliance or poor practice.

Since the inspection visit the PR has given a commitment to implementing the following recommendations within the prescribed timescales:

Major areas of non-compliance:

- The Person Responsible (PR) should ensure that the quality management system is robust generally and, notably, in the areas of concern identified in the report.

'Other' area of non-compliance:

- The PR should ensure that documentation is present supporting 'validation or specific certification' of all medical devices.
- The PR should ensure either that egg collections tubes are appropriately labelled, or that a risk assessment of the current practice of not labelling the tubes is documented, including appropriate risk control measures.
- The PR should ensure with immediate effect that patients, their partners and donors are assessed for possible past or present Ebola virus exposure or infection.

## Information about the centre

IVI London is located in central London and has held a licence with the HFEA since 2016. The centre provides a full range of fertility services.

The centre is currently unable to report treatment activity to the HFEA. Based on data provided by the centre to the inspector, the centre provided 173 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 24 November 2017. In relation to activity levels, this is a small centre.

The centre's licence was varied in August 2017 to reflect a change of PR.

## Details of Inspection findings

## Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

### Pregnancy outcomes

The centre is currently unable to report treatment activity to the HFEA, therefore the centre's pregnancy rates overall and the multiple pregnancy rate cannot be calculated using register data.

Based on data provided by the centre to the inspector, the centre's pregnancy rates for the year to 24 November 2017 are likely to be in line with national averages.

Based on data provided by the centre to the inspector, the centre has performed 12 partner insemination treatments leading to one pregnancy in the year to 24 November 2017, a pregnancy rate which is likely to be in line with the national average.

### Multiple births[1]

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

Based on data provided by the centre to the inspector for treatments in the year to 24 November 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represents performance that is not likely to be significantly different from the 10% multiple live birth rate target.

### Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection team observed witnessing practices associated with vitrification and thawing of embryos, discussed witnessing procedures with staff and reviewed witnessing documentation in patient records.

These activities indicate that witnessing procedures are compliant with HFEA requirements.

[1]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%.

## Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, the centre's storage records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective. The centre will perform their first audits of stored gametes and embryos in early 2018, which is in line with the timeframe required by licence condition T36.

## Staffing

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

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

## Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, traceability, welfare of the child, consent to disclosure, patient paperwork records, medicines management and infection control.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements (recommendation 1) because:

- The centre's audits of ten patient paperwork records in May and October 2017, noted that approximately half of the ten patient records audited on each occasion contained non conformances. These were generally minor but on all occasions the records had been erroneously signed off at the end of the treatment cycle as complete; this raises concerns regarding the accuracy of this check. A senior embryologist discussed the corrective and preventative actions taken but none were recorded in the audit reports. The repeated non conformances in October 2017 suggest the corrective actions in May 2017 were not effective.
- The traceability audit also recorded that the batch records were inaccurate for seven of 81 items reviewed. The senior embryologist reassured the inspection team that the batch records had been corrected. Again, however no corrective and preventative actions were recorded in the audits.

The senior embryologist explained that corrective and preventative actions are recorded and monitored by the quality manager at the IVI group head office but could provide no evidence of this. The inspection team is concerned that the failure to record corrective and preventative actions and their implementation in audit reports held at the centre, may lead to centre staff not effectively addressing non compliances and non conformances in their activities found through audit. The repeated non conformances seen in the patient paperwork records in May 2017 and October 2017 provide evidence that this may be the case.

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

- the collection of patient feedback, including to the HFEA;
- the use of tissue establishment coding;
- register data verification;
- information for trans and non-binary patients;
- screening for Zika and Ebola viruses;
- use of CE marked medical devices;
- the use of the most recently issued HFEA consent form versions;
- the bring forward system

The centre has been partially effective in ensuring compliance with guidance issued by the HFEA (recommendation 1). This is because the centre has not:

- fully implemented the use of the HFEA PBR form on which a married or civil partner can record their consent to posthumous registration;
- changed donor and patient screening practice so that it includes consideration of the potential for past or current Ebola virus exposure or infection when screening patients and donors (and recommendation 4).

### Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

### Prescription of intralipid 'off label'

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

### Infection Control

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

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

### Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices in use in the laboratory was reviewed during the inspection, including culture medium, vitrification and thawing medium, culture dishes and other plasticware used to culture and manipulate gametes and embryos. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

It was noted that two medical devices – pipette tips and a six well culture plate used in vitrification were not CE marked. There are however no other suitable CE marked products which could be used in their place and the senior embryologist described effective rationales for their safe use. The inspection team notes however that documentation supporting 'validation or specific certification' of these two devices, which should contain this rationale, is not present (recommendation 2).

All equipment has been validated and is regularly cleaned, well maintained and subject to appropriate servicing arrangements.

## Patient experience

During the inspection, we spoke to one patient couple about their experiences at the centre and they were very positive about the care they had received.
The centre has implemented a patient feedback process but feedback analysis has not yet been prepared. This is acceptable given the centre has been open only one year, the analysis is planned for early 2018, and because individual feedback is reviewed when received and is generally good and is acted upon if necessary.

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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions; and
- maintains an effective system for responding to patient phone calls.

## Monitoring of the centre's performance

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

### Compliance with HFEA standard licence conditions

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

- The inspection team noted that egg collection tubes are not labelled with patient identifiers or electronic tags. This practice has been risk assessed and appropriate risk control measures to mitigate any risks have been implemented, but the risk assessment has not been documented nor is the completion of a key risk control measure – the clean up and physical checks of all critical work areas between egg collections – documented in patient records when completed (recommendation 3).
- Centre staff make no consideration of the potential for past or current Ebola virus exposure or infection when screening patients and donors (recommendation 4).

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

Following the initial licensing inspection in November 2016, no recommendations for improvement needed to be made.

### On-going monitoring of centre success rates

Since the initial licensing inspection in November 2016, the centre has not been able to report treatment data and outcomes 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.

### Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is not compliant with requirements to submit information to the HFEA as there are a large number of treatments which have not been reported. This is not raised as a non compliance in this report by the inspection team, because the centre has been engaged with the HFEA since before it was licensed, so that the HFEA might install an electronic data interface (EDI) device at the centre, via which the centre could submit treatment data to the HFEA register. The HFEA is currently implementing an alternative to the EDI system and has therefore not installed an EDI device at this centre. This alternative is delayed, hence treatments being performed for a year without being reported by the centre. 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 report the treatment data when the alternative reporting system is implemented by the HFEA.

## Legal parenthood

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

While the focus on legal parenthood consenting has been in place since February 2014, this centre only opened in November 2016. The centre's proposed legal parenthood consenting practices were considered compliant at the time of licensing.

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 the most recent legal parenthood consenting audit. Six 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, with the exceptions noted elsewhere in the report are compliant with HFEA requirements.

**Annex 1**

## Areas of practice that require the attention of the Person Responsible

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

### Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical 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 identified | | | |

### ‘Major’ area of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

| Area of practice and reference | Action required and timescale for action | PR Response | Executive review |
|---|---|---|---|
| **1) The quality management system**<br>The inspection team was concerned that the QMS is not robust because:<br>• Audit reports do not always include corrective and preventative actions, or the timeframes for their implementation. The inspection team is concerned that this failing may lead to centre staff not effectively addressing non compliances and non conformances in their activities.<br>• The clinic’s processes for implementing learning are not consistently effective | The PR should ensure that the QMS is robust generally and, notably, in the areas of concern identified in the report.<br><br>The actions taken to implement this recommendation, including those to address the specific areas of concern identified in this report, should be forwarded, with appropriate evidence, to the centre’s inspector by 28 February 2018. | 1) Audit Plan and Summary sheet has been redesigned to include details of non-conformities found and correctiveactions required together with a timeframe (copy attached)<br><br>2) The internal staff training session on conducting an audit will be repeated with a focus on documentation and feeding back to line manager to agree corrective actions and timelines for implementation.<br><br>3) As the corrective actions from the patient paperwork audit were fedback verbally to the Laboratory Director who | The Executive acknowledges the PR’s commitment to addressing this non-compliance.<br><br>No further action is required. |

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| because guidance issued by the HFEA has not been implemented in some cases, as noted in the main body of the report.<br><br>SLCs T32 and T36 | | has since moved on from IVI and have not be recorded in sufficient detail, the clinic will repeat the audit and submit to HFEA the worksheets, and summary by 28th February | |

### ‘Other’ areas of practice that requires improvement

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

| Area of practice and reference | Action required and timescale for action | PR Response | Executive review |
|---|---|---|---|
| **2) Equipment and materials**<br>Documentation supporting ‘validation or specific certification’ was not present for two non-CE marked medical devices.<br><br>SLC T28 | The PR should ensure that documentation supporting ‘validation or specific certification’ is present for all medical devices.<br><br>The actions taken to implement this recommendation, with appropriate supporting evidence, should be communicated to the centre’s inspector by 28 February 2018. | Validation documents attached | The Executive acknowledges the PR’s commitment to addressing this non-compliance.<br><br>No further action is required |
| **3) Traceability**<br>Egg collection tubes are not labelled with appropriate patient identifiers or an electronic tag. This practice has been risk assessed and appropriate risk control measures to mitigate any risks have been implemented, however the risk assessment has not been documented nor is the completion of a key risk | The PR should ensure either that egg collections tubes are appropriately labelled, or that a risk assessment of the current practice of not labelling the tubes is documented and that checks are made and documented in patient records that risk control measures are implemented in each case. | Risk assessment has been completed covering non labeling of EC tubes- (attached)<br>Laboratory record sheets will be amended to include a double witnessing step to confirm all tubes have been processed and isolator cleaned between patients<br><br>2) We will perform an audit to check that the isolators are been | The Executive acknowledges the PR’s commitment to addressing this non-compliance.<br><br>We look forward to receiving an audit summary report in May 2018. |

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| control measure – the clean up and physical checks of all critical work areas between egg collections – documented in patient records when completed.<br><br>SLC T101 | The actions taken to implement this recommendation, with appropriate supporting evidence, should be communicated to the centre's inspector by 28 February 2018.<br><br>A report of an audit to verify whether the actions taken have been effective, should be sent to the centre's inspector by 28 May 2018. | cleared and cleaned between cases and it is double witnessed | |
| **4) Screening**<br>Centre staff make no consideration of possible past or present Ebola virus exposure or infection when assessing patients, their partners and donors.<br><br>The likelihood of past or present Ebola exposure or infection is considered extremely unlikely, hence this non compliance being listed as an 'other'.<br><br>SLC T50d and T52h | The PR should ensure with immediate effect that patients, their partners and donors are assessed for possible past or present Ebola virus exposure or infection. The PR should ensure that patient information is available regarding the risks associated with the exposure to this virus.<br><br>The PR should consider, with expert advice if necessary, if there is any risk to patients and donors resulting from the past failure to perform Ebola assessment. If risk is present, appropriate risk control measures should be implemented. | 1) Amended New patient questionnaire to include Ebola exposure<br><br>2) Amended virology screening consent to include Zika and Ebola exposure - attached<br><br>3) Two new patient information sheets regarding Ebola and Zika virus wriiten for use with IVI treatment booklet.<br><br>4) Following SOPs amended to require staff to record possible exposure to the viruses and discuss implications for treatment.<br>Med SOP 1.1 - Medical Consultation | The Executive acknowledges the PR's commitment to addressing this non-compliance.<br><br>We look forward to receiving an audit summary report in February 2018. |

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| | The PR should inform the centre's inspector of the actions taken to implement this recommendation when responding to this report.<br><br>Three months after implementing corrective actions, the PR should audit their effectiveness. A summary report of this audit should be provided to the centre's inspector by 28 February 2018. | Med SOP 1.15 - Follow up Consultation<br>Med SOP 1.16 - Compensated Egg Sharing<br><br>Nurse SOP 2.1 - Consent Consultation<br>Nurse 2.2 Consent Form Completion<br>Nurse SOP 2.8 - Returning for Treatment after 2years or a Baby<br>Nurse SOP4.2 - IUI Consent Consultation<br>Nurse SOP 6.1 - Egg Sharing<br>Nurse SOP 6.2 Alturistic Oocyte Donation Recruitment<br>Nurse SOP 6.3 - Oocyte Recipient Recruitment<br>Nurse SOP 6.8 - Criteris for Egg Donors<br>Nurse SOP 6.9 - Surrogacy Host<br>Nurse SOP 6.10 - Surrogacy Commissioning Couple Coordination | |

| Additional information from the Person Responsible |
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