# Executive Licensing Panel - minutes

## Centre 0254 (The Agora Gynaecology and Fertility Centre)

## Executive Update

Monday, 22 January 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Caylin Joski-Jethi (Chair)<br>Jessica Watkin<br>Helen Crutcher | Head of Intelligence<br>Policy Manager<br>Risk & Business Planning Manager |
| Members of the Executive | Bernice Ash<br>Nana Gyamfi | Secretary<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. Background

**1.1.** The Agora Gynaecology and Fertility Centre is located in Brighton and Hove and has held a treatment and storage licence with the HFEA since 2007. The centre provides a full range of fertility services to self-funded and NHS patients.

**1.2.** The panel noted that a renewal inspection was carried out at the centre on 26 and 27 September 2017. The inspection report was considered by Executive Licensing Panel at its meeting on 1 December 2017.

**1.3.** The panel noted that, at the time of inspection, there was one critical, four major and five 'other' areas of non-compliance. Since the inspection, the Person Responsible (PR) had fully implemented the 'other' areas of non-compliance concerning equipment and materials, intralipids and infection control.

**1.4.** The critical area of non-compliance related to storage dewars in the main embryology laboratory which had no low-level oxygen alarm or safety signage present on the laboratory doors. At the meeting on 1 December 2017, the panel noted that the centre had provided evidence to the inspectorate, on 29 September 2017, that the missing safety signage had been installed and the installation of an O2 monitoring system for the laboratory planned and works would be completed by 31 October 2017. However, the panel expressed concern that it did not have evidence that this critical non-compliance, relating to the safety of the premises for visitors, staff and gametes and embryos, had been fully addressed.

**1.5.** The 1 December 2017 Executive Licensing Panel decided to adjourn consideration regarding the renewal of the centre's licence until the inspectorate was able to report that the O2 monitoring system installation did in fact happen by 31 October 2017.

## 2. Consideration of application

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

**2.2.** The panel noted that the Executive had confirmed that the Person Responsible (PR) has provided evidence on 8 December 2017, confirming the O2 monitoring system was installed on 31 October 2017, and has therefore fully implemented the recommendation relating to the critical non-compliance.

**2.3.** The panel noted that the PR has also fully implemented the major recommendations concerning donor screening, the Quality Management System (QMS) and welfare of the child, within the recommended timescales.

**2.4.** The panel noted that three recommendations concerning record keeping, disclosure of information and obligations and reporting remain outstanding. The PR has committed to implementing the recommendations within the required timeframes.

**2.5.** The panel noted that the inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations being implemented within the prescribed timescales.

## 3. Decision

**3.1.** The panel welcomed the additional information from the PR, noting that rapid action had been taken to address the critical non-compliance. The panel also noted that three recommendations made in the report require further action, but these are within the prescribed timescales.

**3.2.** The panel encouraged the PR to continue to engage with the inspectorate, hoping this will result in fewer non-compliances at the time of the next inspection.

**3.3.** The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations being implemented within the prescribed timescales.

## 4. Chair's signature

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

**Signature**

**Name**

Caylin Joski-Jethi

**Date**

23 January 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:** 26 and 27 September 2017

**Purpose of inspection:** Renewal of a licence to carry out treatment 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:** Lesley Brown (lead), Louise Winstone, Polly Todd, Cathy Hodgson, Hocine Amrane.

**Date of Executive Licensing Panel:** 1 December 2017

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| **Centre name** | The Agora Gynaecology and Fertility Centre |
| **Centre number** | 0254 |
| **Licence number** | L/0254/5/a |
| **Centre address** | The Agora, Ellen Street, Brighton & Hove, BN3 3LN, United Kingdom |
| **Person Responsible** | Dr Carole Gilling-Smith |
| **Licence Holder** | Mr Hossam Abdalla |
| **Date licence issued** | 01 February 2015 |
| **Licence expiry date** | 31 January 2018 |
| **Additional conditions applied to this licence** | None |

# Contents

# Section 1: Summary report

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

The Agora Gynaecology and Fertility Centre is located in Brighton and Hove and has held a treatment and storage licence with the HFEA since 2007. The centre provides a full range of fertility services to self-funded and NHS patients.

The centre provided 926 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2017. In relation to activity levels this is a medium centre.

The centre was last inspected for an unannounced interim inspection on 21 January 2016. At this inspection two 'other' areas of non-compliance were identified in relation to the responsible use of websites and the use of non-CE marked 5ml tubes, both of which were corrected by the time the report went to ELP. The findings of this inspection were a marked improvement on the findings of the licence renewal inspection in October 2014 and the centre was commended on their engagement with the HFEA in achieving a good level of compliance since the licence renewal inspection.

The report of the October 2014 licence renewal inspection was considered by Licence Committee (LC) rather than an ELP as there were a significant number and range of non-compliances identified running to two critical and 10 major areas of non-compliance. The LC endorsed the executive's recommendation to grant a licence for three years (with no additional conditions) rather than the usual four and also required the executive to conduct an unannounced inspection within one year of the licence coming in to force (ie the January 2016 inspection).

There has been no application to vary this licence since it was granted in February 2015.

The centre is also registered with the Care Quality Commission (CQC). The last CQC inspection was in December 2013, all standards inspected against were met on that occasion.

### Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 May 2016 – 31 April 2017 show the centre's success rates are in line with national averages.

In 2016, the centre reported 68 cycles of partner insemination with eight pregnancies. This represents a clinical pregnancy rate of 12%, which is in line with the national average.

### Multiple births[2]

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

Between 1 May 2016 and 31 April 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. 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 Person Responsible (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 her 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 one critical, four major and five 'other' areas of non compliance.

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

**'Other' areas of non compliance:**

- The PR should ensure appropriately CE marked medical devices are used where available.
- The PR should ensure that clinical waste is disposed of correctly.
- The PR should ensure that information about reproductive immunology treatments follows the guidance provided by the MHRA on the 'off-label' use of medicines.

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

**Critical area of non compliance:**

- **The PR should ensure premises are safe for visitors, staff and gametes and embryos.**

**Major areas of non compliance:**

- The PR should ensure donor screening is compliant with HFEA and professional body guidelines.
- The PR should ensure the quality management system is effective.
- The PR should ensure that a woman must not be provided with treatment services unless account has been taken of the welfare of the child.
- The PR should ensure that proper records are maintained.

**'Other' areas of non compliance:**

- The PR should ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

## Recommendation to Executive Licensing Panel

The centre has four major of areas of concern and one critical area of concern. Their success rates are within the national average and their multiple clinical pregnancy /live birth rates meet or are below the target; a significant improvement from a multiple clinical pregnancy rate of 21% in 2014.

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a quality management system (QMS) and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The inspection team recommends the renewal of the centre's treatment and storage 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 partially 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**

**Screening of donors (Guidance note 11)**

Out of four donor records selected for a screening audit, one donor record showed blood samples had been taken outside of the required timescales. With initial screening being performed in January 2016 and egg collection taking place in March 2016, with no re-screening.

There is no evidence to confirm that consideration is made to the requirements for Ebola and Zika virus screening or additional screening as per the patient's ethnicity. In some records there is a tick box that asks about a patient's recent travel but nothing further to indicate discussions for additional screening. During discussions, a staff member could not provide assurance that she was aware of the latest guidance on Ebola and Zika virus screening (SLC T52, SLC T53, Clinic Focus September 2017, EUTCD 2006, Professional Body Guidelines 2008). See recommendation 2.

## 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 partially suitable. It 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 not compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality, with the exception noted under safety and suitability of premises and facilities.

**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 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 broadly 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 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 process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is not compliant with guidance.

**Pre-operative assessment and the surgical pathway (Guidance Note 25)**
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 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 note 15)**
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 partially 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 compliant with HFEA requirements.

**Transport and satellite agreements (Guidance note 24; General Direction 0010)**
The centre does not have transport and satellite treatment links therefore this area of practice is not applicable to this inspection.

**Equipment and materials (Guidance note 26)**
The centre uses equipment and materials that are broadly compliant with HFEA requirements. Most 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 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)**
The cryostore room is very small and cramped and the functionality of the extraction fan was unclear. The centre's own risk assessment dated 1 September 2017 makes the following recommendations 'Consider placing a toughened glass window in the store room door to identify whether anyone on the floor' and 'Consider whether it is possible for extraction system to be fitted in the dewar store room'. No timescale for action was provided.
Two large dewars have been sited in the main embryology laboratory, with no low level oxygen monitoring, and no safety signage on laboratory doors.
A diesel generator is housed on the ground level of the building, adjacent to the nitrogen storage room. A strong smell of diesel fumes was present in the nitrogen storage room on

inspection. Assurance was provided by the building estates management that the generator had been risk assessed and necessary ventilation was present. However, the centre had not considered the risk of volatile organic compounds (VOCs) to embryos and gametes, no VOC monitoring had been performed (SLC T17, SLC T23, SLC T24). See recommendation 1.

**Infection control (Guidance Note 25)**
On inspection, the clinical waste bins were found to be overflowing, with a number of bags on top of the waste bin. (SLC T17, The Health and Social Care Act 2008 'Code of Practice on the prevention and control of infections and related guidance'). See recommendation 7.

**Prescription of intralipid 'off label'**
The patient information regarding reproductive immunology therapies did not make clear that these therapies are prescribed 'off-label' and what that means for the patient (SLC T58). See recommendation 8.

**Quality management system (QMS) (Guidance note 23)**
On inspection, the following issues were noted:

- **Standard Operating Procedures (SOPs)**

The following SOPs are beyond their review date, last reviewed in 2014; Adverse incidents, confidentiality and privacy, record keeping.
The counselling policy has not been reviewed for three years and does not describe current service provision (SLC T32, SLC T33).

- **Audit**

The centre has not audited the following procedures; Donor recruitment, assessment and screening, submission of data to the HFEA.
A review of a recent traceability audit identified a mismatch between the results presented in the audit report and the raw data.
The latest Welfare of the Child audit listed findings that did not appear to relate to the audit, eg. 'Trial ET catheter is no longer used; galipot is filled when indicated by clinician and Q tips are used. Instruments are disposed of into an instrument bin'. The audit did not identify a timeframe for implementation of corrective actions, but did state date for re-audit (September 2017) (SLC T32, SLC T36).

- **Quality Indicators**

The centre has not developed a quality indicator for submission of data to the HFEA.
There is a mismatch between the laboratory key performance indicators (KPIs) documented in the quality management master document, and the KPIs recorded in the laboratory monitoring record.
The centre audits the performance of the laboratory, but does not audit the performance of individual practitioners (SLC T32, SLC T35).

- **Staff competencies**

Laboratory staff take consent for oncology sperm storage. Assurance of receiving relevant training was provided during the inspection, but no documented evidence was available to demonstrate the training provided (SLC T32, SLC T15).See recommendation 3.

**Equipment and materials (Guidance note 26)**
During a review of laboratory media and consumables one item of plasticware: sperm collection pots, were found to not be appropriately CE marked (SLC T30). 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 partially compliant with HFEA requirements.

**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**
**Welfare of the child (Guidance note 8)**
In one patient record, reviewed by the inspection team, the welfare of the child assessment had not been completed by the staff member (SLC T56). See recommendation 4.

## Embryo testing

| Preimplantation genetic screening<br>Embryo testing and sex selection |
| --- |
| **What the centre does well**<br><br>**Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)**<br>The centre does not perform embryo testing, therefore this area of practice is not applicable to this inspection. |
| **What the centre could do better**<br>Nothing identified at this inspection. |

## 2. The experience of patients

### Patient feedback

**What the centre does well**

During the inspection the inspectors were unable to speak to any patients to provide feedback on their experiences. The centre's most recent patient survey responses were reviewed. Feedback was positive with 31 of the individuals providing written feedback, mostly giving compliments about the care that they received. There were also several negative comments regarding contacting the centre and these were discussed with the quality manager. She advised the inspectors that actions have already been taken to address this matter. The inspection team urges the centre to continue to monitor patient feedback to ensure the actions taken are effective.

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 sharing arrangements (Guidance note 12; General Direction 0001)**

The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind;
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

**Surrogacy (Guidance note 14)**
The centre does not provide treatment involving surrogacy therefore this area of practice is not applicable to this inspection.

**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; 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 has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the interim inspection in January 2016, 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. 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)**
The HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born following ART treatment. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient.

Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA.

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

**What the centre could do better**
**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**
Two discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. In both incidents the patients had not provided consent to disclosure, however data submitted to the register was recorded as the patients had provided consent to disclosure. Therefore the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent (CH(10)05 and General Direction 0005 5) See recommendation 9.

## 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
### 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, with the exceptions noted under donor screening. 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 partially 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 HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements.

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

**What the centre could do better**
**Record keeping and document control (Guidance note 31)**
An audit of patient records performed by the inspection team identified;

- In three of five records reviewed the marital status could not be determined.
- In all five records reviewed the 'Doctor's checklist' which identified what procedures and consents had been completed, were either blank or had not been completed fully.
- In one of five records the offer of counselling had not been documented (the centre have since confirmed that the patient attended counselling).

(SLC T46 and SLC T47). See recommendation 5.

**Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)**
The centre has not provided an annual return for partner IUI treatments undertaken in 2016.

Two percent (3/126) of IVF and 3% (6/199) of the DI treatments reviewed at inspection had not been reported to the HFEA.

Twenty eight percent (34/123) of the IVF and 33% (64/193) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005.

Some data quality issues identified have been notified to the centre for correction.

These findings indicate that the centre's procedures for submitting information about licensed activities to the Authority are partially compliant with HFEA requirements (General Direction 0005, SLC T4, SLC T41). See recommendation 10.

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

Following the interim inspection in 2016, recommendations for improvement were made in relation to two 'other' areas of non compliance.

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

## Areas of practice requiring action

This section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, 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.

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| **1. Safety and Suitability of Premises**<br>Storage dewars are sited in the main embryology laboratory which has no low level oxygen alarm. There is no safety signage present on the laboratory doors. | The PR was asked to immediately order and install safety signage and arrange an $O_2$ monitoring system for the laboratory. The PR confirmed by email that the work has been commissioned and will be installed by the end of October 2017. | The Safety signage has been installed on the Lab door. Quantum are installing the low level oxygen alarms on Tuesday 31st October 2017. | The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation.<br><br>The Executive will work with the PR to vary the licence to include the proposed cryostore room. |
| A recent risk assessment of the cryostore recommended actions to be taken. | The PR should confirm that all work has been completed when responding to this report. | All actions on the current risk assessment completed. | The PR has committed to provide the requested risk assessment. |
| | The PR should provide a report of their response to | The outcome of the risk assessment demonstrated the | Further action required. |

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| A generator sited within the building, emits a strong smell of diesel.<br><br>SLC T17, T24. | their own cryostore risk assessment, along with planned actions and a timescale for work to be carried out to the centre's inspector by 26 December 2017.<br><br>The PR should risk assess the diesel generator, focusing on any risk of VOCs being released into the embryology laboratory.<br><br>A copy of this risk assessment along with any proposed corrective actions should be provided to the centre's inspector by 26 December 2017. | need to fully asses our cryostorage facilities long term. A room within the Agora premises has been idenitifed as meeting the required criteria to house all cruyostorage dewars. This room has an outside wall. A window will be installed, positive pressure ventillation/extraction will be installed and low level oxygen monitoring and liquied nitrogen monitorin for each Dewar will be installed. Time scales for completion of works on the new cryostore room are January 2018.<br><br>The Diesel generator has been risk assessmed and is fit for purpose (risk assessment to follow). VOC meter will be used to monitor any fumes being released into the embryology Lab. | |

### 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 |
|---|---|---|---|
| **2. Donor Screening**<br>On inspection the following issues were noted:<br>• In one record the donor had not been re-screened prior to donation.<br>• The check lists for blood tests seen in the records do not prompt for Zika/Ebola or any additional testing as per the patient's ethnicity and there was nothing to evidence in the records that account had been taken of these screening requirements.<br>• A staff member could not provide assurance | The PR should ensure that donors are screened at the time of donation in line with professional body guidance and CoP requirements.<br><br>The PR should review the centre's donor screening practices to ensure they are compliant with this recommendation.<br><br>A summary report of this review should be provided to the centre's inspector by 26 December 2017.<br><br>Three months after the review the PR should audit donor records to ensure that corrective actions | The record identified during the inspection was from an egg donor. The inspectors accepted during the inspection that there is no specific requiement for NAT screening egg donors. However we do feel it is best practice and have implented NAT screening of all egg donors 5 days before egg collection to ensure we have the results back on day of egg collection. This has been routine practice at the Agora since May 2017. Sperm donors are all routinely screened as per HFEA Code of Practice using NAT testing. The Agora is therefore compliant with CoP requirements.An audit will be | The Executive acknowledges the PR's response and her summary of screening practices, however, the PR is reminded that although there is no specific requirement for NAT testing of egg donors, all donors must be screened for HIV 1 and 2, HCV, HBV and syphilis at the time of donation (EUTD/2006/17/EC, Clinic Focus March 2013).<br><br>The PR has committed to provide the requested audits.<br><br>Further action required. |

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| that she was aware of the latest guidance on Ebola and Zika virus screening<br><br>SLC T52, EUTCD 2006, professional body guidelines 2008. | implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 26 March 2018. | done in November to ensure compliance.<br><br>All documentaiton has been amended to clarify questions that should be routinely asked to exclude patients at risk of having been exposed to Zika/Ebola. Clear instruction to all staff members has been given to ensure they are alerted to the need for additional screening. Audit of Zika/Ebola screening will be done in March 2018. | |
| **3. Quality Management System**<br>On inspection the following issues, as detailed in the body of this report, were noted:<br>• The centre does not have SOPs to direct all activities, and several SOPs were beyond their review date.<br>• The centre has not established quality indicators for all activities. | The PR should review the QMS to ensure it is effective and provides assurance of compliance of the range of activities carried out in the course of providing treatment services, against regulatory requirements, the centre's SOPs and quality indicators.<br><br>The PR should provide a summary report of the review and an action plan for the timescales for implementation, | At the time of inspection prority had been given to updating/reviewing all SOPs with changes required. Those identified as having not been reviewed at the time of inspection did not need updating but will all be reviewed by December 2017.<br><br>No quality indicator for consent identified and this has been addressed, For all other | The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation.<br><br>Further action required. |

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| • There is a mismatch between laboratory KPIs documented in the QMS and those documented in the laboratory paperwork.<br>• Laboratory KPIs are not audited per practitioner.<br>• Audits were not available for all activities.<br>• Audit reports contained inaccurate information, and did not record a timescale for corrective actions.<br>• Evidence of training provided for taking the consent to store sperm from oncology patients has not been documented.<br><br>SLC T15, T32, T33, T35, T36. | to the centre's inspector by 26 December 2017.<br><br>The PR should address the non-compliances within the QMS identified in this report and provide a summary report to the centre's inspector detailing the actions taken by 26 December 2017. The centre's inspector will then request a sample of documents to review including audits, SOPs and quality indicators to ensure they are compliant with regulatory requirements. | activites as per SAQ KPIs have been set.<br><br>The Clinic has appointed in August 2017 a Head of Embryology (George Koustas) with extensive Quality Management experience to address all the non-compliances identified in the report and will ensure Laboratory KPIs and audit reports are addressed. SInce the instalation of Meditex it will be easier to audit each practioner against the KPIs. Consent has been added to the Lab competencies. Competencies will be completed on all lab staff by the end of November. The Welfare of the Child audit that contained inaccurate information was an administrative error. However a repeat audit is due in December.<br>A summary report of all acitons taken re the QMS will be provided to the centre's inspector by 26th December 2017. | |

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| **4. Welfare of the child**<br>In one patient record, reviewed by the inspection team, the welfare of the child assessment had not been completed by the staff member.<br><br>SLC T56. | The PR should ensure that a woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.<br><br>The PR should review the centre's practices and procedures for conducting WOC assessments and provide a summary report of this review, including corrective actions taken and timescales for implementing corrective actions, to the centre's inspector when responding to this report.<br><br>The PR should ensure that a further welfare of the child audit is completed and a summary report of this audit submitted to the centre's inspector by 26 December 2017. | This is due to be re-audited in December. The PR will review the centre's practices but on this occasion the omission was down to human error and the process which should have been followed was incomplete. There were two sets of notes in this same-sex couple and the WOC assessment had been completed on both partners but only contained in one set of notes. This has been addressed. Each individual pateint will have their own WOC assessment record on Meditex (system allows patient and partner records to be linked). | The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation.<br><br>Further action required. |

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| **5. Record Keeping**<br>An audit of patient records performed by the inspection team identified;<br><br>• In 3 of 5 records reviewed the marital status could not be determined,<br>• In all five records reviewed the checklists which identified what procedures and consents had been completed, were either blank or had not been completed fully.<br>• In 1 of 5 records the offer of counselling had not been document.<br><br>SLC T46 and T47. | The PR should ensure that proper records are maintained.<br><br>The PR should review the centre's processes and procedures for completion of patient records. A summary report, including corrective actions and timescales for implementation should be provided to the centre's inspector by 26 December 2017.<br><br>Three months after this review, the PR should conduct an audit of the patient records to ensure compliance with this recommendation. A summary report of this audit should be provided to the centre's inspector by 26 March 2018. | Registration form is being updated to include marital status and confirmation of marriage to each other. We are asking patients to provide a form of marriage certificate as part of this confirmaiton process at registration.<br><br>Moving to Meditex the centre is developing the equivalent checklists that can be completed during consultaitons and other processes direclty on the patients electorinic record. This includes the offer of counselling. An audit will be performed in March 2018. | The Executive acknowledges the PR's response and her summary of corrective actions.<br><br>The PR has committed to provide the requested audit.<br><br>Further action required. |

## 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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| **6. Equipment and Materials**<br>The following medical device used by the centre is not appropriately CE marked; sperm collection pots.<br><br>SLC T30. | The PR should ensure appropriately CE marked medical devices are used where available.<br><br>We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this the PR should identify suitable CE marked alternatives by 26 December 2017 and provide confirmation, along with a timeline of introduction to the centre's inspector.<br><br>The PR should aim to be fully compliant no later than 26 March 2018. | All products are now CE marked (only sperm pots were not CE marked at the time of inspeciton but these are now CE marked). | The Executive acknowledges the PR's response and assurance of compliance.<br><br>No further action required. |
| **7. Infection Control**<br>On inspection, the clinical waste bins were found to be overflowing, with a | The PR should ensure that clinical waste is disposed of correctly to limit the risk in infection or injury to personnel. | As explained on the day of inspection, the company who collects the clinical waste had lost their key and therefore | The Executive acknowledges the PR's response and assurance of compliance. |

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| number of bags on top of the waste bin.<br><br>SLC T17, The Health and Social Care Act 2008 'Code of Practice on the prevention and control of infections and related guidance'. | The PR should review the centre's arrangements for clinical waste collection to ensure that clinical waste is collected in a timely manner.<br><br>The PR should inform the centre's inspector of the actions taken to ensure compliance with this recommendation when responding to this report. | had not collected all waste that day. They have since been issued with new keys and continue to collect waste twice a week. Clinical Waste room has been cleared of paint cans and cardboard. This will be continually assessed and audited. | No further action required. |
| **8. Intralipids**<br>The patient information regarding reproductive immunology therapies did not make clear that these therapies are prescribed 'off-label' and what that means for the patient.<br><br>SLC T58. | The PR should ensure that information about reproductive immunology treatments follows the guidance provided by the MHRA on the 'off-label' use of medicines.<br><br>Copies of the revised information should be submitted to the centre's inspector by 26 December 2017. | Written Patient Information regarding immunological therapies was provided to the inspection team at the end of the inspection and this contains the fact that all therapies are off label. I believe therefore this comment may not be correct. The written information will be sent with this report. | The Executive acknowledges the PR's response.<br><br>The PR made further revisions to the patient information and consent forms following the inspection. The revised documents satisfied the executive<br><br>No further action required. |
| **9. Disclosure of information held on the HFEA Register for use in research**<br>Two discrepancies were found between completed | The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately | The procedures have been reviewed and since the implementaiton of Meditex it is unlikely that discrepancies will occur. An audit will be conducted in 6 months. | The Executive acknowledges the PR's response and her summary of corrective actions.<br><br>The PR has committed to provide the requested audit. |

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| patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register.<br><br>CH(10)05 and General Direction 0005 5. | reflects that given and recorded on disclosure consent forms. The PR should also correct the submissions that have been identified as being incorrect. These recommendations should be implemented by the time this inspection report is returned and the inspector informed of the results of the review and actions taken.<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 the centre's inspector by 26 April 2018. | | The PR is working with the HFEA to correct the submissions that have been identified as being incorrect.<br><br>Further action required. |
| **10. Obligations and reporting requirements.**<br>The centre has not provided an annual return for partner IUI treatments undertaken in 2016.<br><br>Two percent (3/126) of IVF and 3% (6/199) of the DI treatments reviewed at | The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.<br><br>The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for | The Annual return has been provided and The Head of Embryology is restructuring the way data is submitted to ensure timely submission of all data. This will be audited in 6 months time. We are aware of late submission of treatment forms but since implementation of Meditex this | The Executive acknowledges the PR's response and her summary of corrective actions.<br><br>The Executive acknowledges receipt of the annual return for partner IUI treatments. |

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| inspection had not been reported to the HFEA<br><br>28% (34/123) of the IVF and 33% (64/193) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005.<br><br>Some data quality issues identified have been notified to the centre for correction.<br><br>General Direction 0005, SLC T4, SLC T41 | missing and delayed submissions. This recommendation should be implemented by the time the inspection report is returned and the inspector informed of the results of the review and actions taken.<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 the centres inspector by 26 April 2018. | has already staretd to improve. This will be audited in 6 months time.<br><br>We have taken on board the data qaulity issues identified which in part have been due to the switch over from ACUsys to Meditex and the need for manual reporting. An audit will be conducted within 6 months. | The PR is working with the HFEA to correct missing and delayed submissions.<br><br>The PR has committed to provide the requested audit.<br><br>Further action required. |

| Responses from the Person Responsible to this inspection report |
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| We would like to thank the inspeciton team for their useful feedback and positive comments. We will ensure we provide our inspector with all the appropriate information within the required time frames. |