# Executive Licensing Panel - minutes

## Centre 0153 (Homerton Fertility Centre) Interim

Friday, 29 July 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Paula Robinson (Chair)<br>Joanne Anton<br>Anjeli Kara | Head of Business Planning<br>Head of Regulatory Policy<br>Regulatory Policy Manager |
| Members of the Executive | Dee Knoyle<br>Ian Brown | Secretary<br>Head of Corporate Governance |
| 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 considered the papers, which included an inspection report and licensing minutes for the last three years.

**1.2.** The panel noted that Homerton Fertility Centre, centre 0153 has held a licence with the HFEA since 1995. The centre provides a full range of fertility services.

**1.3.** The panel noted that the centre's licence is due to expire on 31 August 2018.

**1.4.** The panel noted that the inspection took place on 15 March 2016.

**1.5.** The panel noted that in the 12 months to 31 January 2016, the centre provided 945 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

**1.6.** The panel noted that for the period 1 November 2014 to 31 October 2015, HFEA-held register data for IVF and ICSI showed the centre's success rates were in line with national averages with the following exception:

- The clinical pregnancy rate following IVF treatments, involving fresh embryos using the patient's eggs, in women aged under 38 years were lower than average at a statistically significant level.

**1.7.** The panel noted that the centre's success rates have been subject to on-going monitoring by the Executive for some time. The Person Responsible (PR) has continued to monitor success rates and has regularly provided information to the Executive regarding the centre's initiatives to improve success rates. In September 2015 the centre moved to an elective frozen embryo transfer policy (as opposed to fresh embryo transfer in the same cycle of treatment) for patients who responded well to ovarian stimulation. The panel noted that the PR has provided information which demonstrates a significant improvement in clinical pregnancy rates for these patients, however as fresh embryo transfer is still indicated for some patients, the PR is urged to monitor and continue to strive to improve success rates for this group of patients.

**1.8.** The panel noted that in 2015, the centre reported 167 cycles of partner insemination with 23 pregnancies which equates to a 14% clinical pregnancy rate. This is likely to be in line with national averages.

**1.9.** Between 1 November 2014 and 31 October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 23%. This means that the centre's multiple live birth rate is likely to be statistically higher than the 10% maximum multiple live birth rate target for this period. The panel noted that the PR confirmed that the centre has reviewed its multiple birth minimisation strategy and is confident that this will help to lower the multiple pregnancy rate. The PR is encouraged to closely monitor the efficacy of the centre's revised multiple birth minimisation strategy, with the implementation of changes to treatment protocols for some patients. The PR has provided a comprehensive response with regard to the centre's high multiple clinical pregnancy rates.

**1.10.** The panel noted that at the time of the interim inspection on 15 March 2016, three major and four other areas of non-compliance were identified. The panel noted that since the inspection the PR has started to address the non-compliances and has committed to fully implementing all of the outstanding recommendations.

**1.11.** The panel noted that there was positive feedback from patients in relation to their treatment at the centre.

**1.12.** The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

## 2. Decision

**2.1.** The panel had regard to its decision tree.

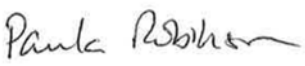
**2.2.** The panel noted the centre's low success rates in women aged under 38 years and that the centre also has a high multiple pregnancy rate. The panel noted that these areas will be monitored by the inspectorate and agreed that an update should be provided to the Executive Licensing Panel following completion of actions due to be completed by 15 September 2016.

**2.3.** The panel was satisfied that the centre was fit to have its treatment and storage licence continued.

## 3. Chair's signature

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

**Signature**



**Name**

Paula Robinson

**Date**

2 August 2016

# Interim Licensing Report

**Centre name:** Homerton Fertility Centre
**Centre number:** 0153
**Date licence issued:** 1 September 2014
**Licence expiry date:** 31 August 2018
**Additional conditions applied to this licence:** None
**Date of inspection:** 15 March 2016
**Inspectors:** Shanaz Pasha (Lead), Victoria Lamb
**Date of Executive Licensing Panel:** 29 July 2016

## 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.

Licensed centres usually receive a licence to operate 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 (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

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

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

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

## Summary for the Executive Licensing Panel

The ELP is asked to note that there are recommendations for improvement in relation to three major and four 'other' areas of non-compliance.

Since the inspection visit, the following recommendation has been implemented:

**'Major' areas of non compliance:**

- The PR should ensure that CE marked devices are used where possible.

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

**'Major' areas of non compliance:**

- The PR should ensure compliance with medicines management regulations.
- The PR should keep the effectiveness of the centre's multiple births minimisation strategy under review, and its application and implementation to ensure that the 10% multiple live birth rate target is not exceeded.

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

- The PR should ensure that patient screening is performed within the required timescales.
- The PR should ensure that donors are compensated in line with General Direction 0001 and 0006.
- The PR should ensure that the quality management system is used continuously and effectively to improve the quality and effectiveness of the services provided.
- The PR should ensure that all records are clear and legible.

The ELP is also asked to note that the centre's success rates for IVF with fresh embryos in women under 38 years old are below the national average. The centre's success rates have been subject to on-going monitoring by the Executive for some time. The PR has continued to monitor success rates and has regularly provided information to the Executive regarding the centre's initiatives to improve success rates. In September 2015 the centre moved to an elective frozen embryo transfer policy (as opposed to fresh embryo transfer in the same cycle of treatment) for patients who responded well to ovarian stimulation.
The PR has provided information which demonstrates a significant improvement in clinical pregnancy rates for these patients, however as fresh embryo transfer is still indicated for some patients, the PR is urged to monitor and continue to strive to improve success rates for this group of patients. The ELP is also asked to note that the PR has provided a comprehensive response with regard to the centre's high multiple clinical pregnancy rates. The PR is also encouraged to closely monitor the efficacy of the centre's revised multiple birth minimisation strategy with the implementation of changes to treatment protocols for some patients. This will also be monitored by the centre's inspector.

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their experiences at the centre.

## Information about the centre

Homerton Fertility Centre is part of the Homerton University Hospital NHS Trust and is located in Hackney, east London. The centre has held a licence with the HFEA since 1995.

The centre provides a full range of fertility services.

The centre provided 945 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2016. In relation to activity levels this is a medium sized centre.

## Details of Inspection findings

## Quality of Service

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

### Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 November 2014 to 31 October 2015 show the centre's success rates are in line with national averages with the following exceptions:

- The clinical pregnancy rate following IVF treatments involving fresh embryos using the patient's eggs in women aged under 38 years are lower than average at a statistically significant level.

In 2015, the centre reported 167 cycles of partner insemination with 23 pregnancies which equates to a 14% clinical pregnancy rate. National data for this year has yet not been analysed but the centre's success rate for partner inseminations is likely to be in line with national averages.

### Multiple births[2]

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

Between 1 November 2014 and 31 October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%. This means that the centre's multiple live birth rate is likely to be statistically higher than the 10% multiple live birth rate target. The PR confirmed that the centre has reviewed its multiple birth minimisation strategy and is confident that this will help to lower the multiple pregnancy rate. See recommendation 2.

[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%.

## Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. An embryo transfer was observed during the course of the inspection. The procedure observed was witnessed using a manual witnessing system in accordance with HFEA requirements.

## Consent: To the storage of cryopreserved material

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

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

## Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out, the atmosphere in the clinic appeared calm at all times, staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

## Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following prescribed 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, consent to storage of gametes and embryos, welfare of child, medicines management and infection control.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements. See recommendation 6.

- The centre's controlled drugs audit reported 100% compliance. However, the audit report did identify one non-conformance but did not describe any corrective and preventative actions or timescales for their implementation. The scope of the audit was also considered by the inspection team to be narrow.
- The infection control audits of handwashing did not systematically record corrective and preventative actions and the dates of their implementation.

The inspection team 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 use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- the HFEA reports of adverse incidents from 2010-2012 and 2013.

Non compliance in the use of CE marked medical devices, noted in this report, show the centre has been broadly effective in ensuring compliance with guidance issued by the HFEA. See recommendation 1.

### Medicines management

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

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with guidance, as examination of entries in the controlled drugs register suggested that one ampoule of a controlled drug had been administered to at least three different patients. Alterations to errors made in the controlled drugs register are not recorded in accordance with regulations. See recommendation 3.

### 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, the inspection team 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 was reviewed in the course of the inspection: pipettes and culture media. The centre is partially compliant with HFEA requirements to use CE marked medical devices wherever possible because neither of the medical devices reviewed were CE marked. See recommendation 1.

## Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Six patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with three of the individuals providing written feedback giving compliments about the care received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- 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;
- 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 broadly compliant with HFEA requirements:

- A review of one set of patient records by the inspection team identified that the patient had undergone blood borne viral screening five months prior to egg collection. This was identified as a non compliance by a member of staff before egg collection and the proposed corrective action was to rescreen the patient at the time of embryo transfer. The patient should have been rescreened prior to egg collection, since patients undergoing fertility treatment for the first time should have been screened for blood borne viruses within the three months before treatment is provided. See recommendation 4.
- Payments to donors were reviewed at the inspection. Centre staff could not provide assurance that all sperm samples imported from outside the UK were from donors who had not received compensation in excess of that permitted under General Direction 0001. See recommendation 5.
- A review of four sets of patient records by the inspection team identified errors and corrections on patient consent forms. The consent indications seemed clear, however the amendments were not always signed and dated to indicate who had made the amendments and when. See recommendation 7.

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

Following the renewal inspection in 2014, recommendations for improvement were made in relation to two major and seven 'other' areas of non compliance.

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

## On-going monitoring of centre success rates

Since the last renewal inspection in March 2014 the centre has received 11 risk tool alerts as follows:

- Two alerts raised; in April 2016 and in November 2015 relating to multiple pregnancy rates for all treatment cycles.
- Five alerts raised; in February 2016, September 2015, January 2015, November 2014 and October 2014 relating to pregnancy rate per cycle of IVF in patients aged less than 38 years.
- One alert in February 2016 relating to pregnancy rate per cycle frozen IVF and ICSI under 40 years.
- Three alerts raised, January 2015, November 2014 and October 2014 relating to pregnancy rate per cycle of ICSI in patients aged less than 38 years.

The PR has responded to the performance alerts and there have been some improvements in success rates in the periods between the alerts. During discussions with the inspection team, the PR provided a commitment to keep success rates under review. The centre's inspector will also continue to review the centre's success rates as part of the ongoing monitoring of the centre's performance.

## Provision of information to the HFEA

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

The clinic is compliant with requirements to submit information to the HFEA.

## Legal parenthood

Where a couple to be treated with donated gametes or embryos are 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. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit did not identify any consent anomalies.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR did not respond to this correspondence.

This prompted a management review meeting on 13 November 2015, in line with the HFEA Compliance and Enforcement Policy, at which it was decided that a site visit should take place to review legal parenthood consenting practices. The centre was informed of this visit and directed to review all the records of patients who had undergone treatment with donor sperm and donated embryos created with donor sperm since 6 April 2009 when consent to legal parenthood laws changed. The audit undertaken by the centre in January 2016 identified one parenthood consent anomaly. The PR has reported to the HFEA the actions

taken to support the couple involved and to address this consenting anomaly. The Executive consider these actions to be appropriate. The centre has also reviewed and revised its legal parenthood consent procedures, undertaken staff training and provided assurance that it will continue to monitor and audit legal parenthood consent.

**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 carried out.

## 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 | Inspection team's response to the PR's statement |
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| None identified at this inspection | | | |

### ‘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 | Inspection team’s response to the PR’s statement |
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| 1. **CE marking**:<br>The following medical devices used by the centre are not CE marked: pipettes, culture media.<br><br>It is noted that the centre provided assurance that they have sourced CE marked culture media, which will be used for embryo culture from the date following the inspection.<br><br>SLC T30 | The PR should ensure that CE marked devices are used where possible.<br><br>The PR should update the centre’s inspector when responding to this report on action taken to ensure all medical devices in use are CE marked for their relevant use.<br><br>It is expected that all medical devices used by the centre should be CE marked. The PR should provide confirmation of this to the centre’s inspector by 15 September 2016. | The culture media has already been changed to a CE marked culture media.<br><br>We have ordered new pipettes from Virtolife which will be in use from June 2016.<br><br>We will also write the final report in September as directed by the HFEA. | The PR has confirmed that CE marked pipettes and culture media have been sourced and are in use.<br><br>The PR has also provided assurance that all other medical devices used by the centre are CE marked.<br><br>No further action required. |

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| 2. **Multiple Pregnancy Rate**<br>Between 1 November 2014 to 31 October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 23%. If there is no change to the centre's multiple pregnancy rate our analysis suggests that the 10% multiple live birth target is likely to be exceeded.<br><br>CoP 7.1 and SLC T2 | The PR should keep the effectiveness of the centre's multiple births minimisation strategy under review, and its application and implementation to ensure that the 10% multiple live birth rate target is not exceeded.<br><br>The PR should provide the centre's inspector with an update on progress in reducing the multiple clinical pregnancy rates by 15 June and again by 15 September 2016. | The multiple pregnancy rates have risen and these have gone hand in hand with the rise in pregnancy rate. With freezing of embryos for young patients , our pregnancy rates have doubled and the twins rates have also increased .The rise of pregnancy rate has been dramatic with the freeze all policy<br><br>We noticed that 52% of our twins came from day 3 embryo transfer. We are planning to extend culture to lower day 3 transfers and aim to replace only 1 blastocyst or freeze 1 blastocyst.. We are using Time lapse technology to cuture the day 3 embryos and increase our freezing to blastocyst stage. This is likely to decrease the day 3 transfers of 2 embryos and tranfer of 1 blastocyst. We aim to rebview this change in 6 months | The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.<br><br>The PR has undertaken a review of the centre's multiple pregnancy rate and provided a report to the executive outlining changes to the centre's single embryo transfer policy.<br><br>Further action is required. |
| 3. **Medicines management**: Review of the controlled drugs register suggested that in one instance an ampoule of a controlled drug had been used | The PR should review medicines management practices to ensure they comply with all relevant regulations. A report of this | We have asked the threates to write a report with the corrective actions.<br>The report will inlcude the corrective measures which will | The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. |

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| for at least three different patients. This is contrary to professional guidelines.<br><br>The Controlled Drugs (Supervision of Management and Use) Regulations 2013 and SLC T2.<br><br>Review of the controlled drugs register showed that the centre does not record alterations in line with the regulations; changes should be corrected in a margin note or footnote and specify the date a correction is made and by whom.<br><br>Misuse of Drugs Regulations 2001, schedule 20 (c) and SLC T2. | review, with corrective actions and timescales for implementation where necessary, should be provided to the centre's inspector by 15 June 2016.<br><br>Within three months of the implementation of corrective actions, the centre should carry out an audit of medicines management procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit detailing the corrective actions with evidence supporting their implementation should be supplied to the centre's inspector by 15 September 2016.<br><br>The PR should also undertake a review to identify the factors that have led to this non-compliance. A summary report of the review including corrective actions and the timescale for their implementation should be provided to the centre's | be implemented and time scales required. We will send this report to the HFEA by the 16th of June.<br><br>We will also work with the theatres to complete an audit after the corrective actions have been implented. We will send this completed audit to the HFEA by 16th September.<br><br>We are waiting for the theatres to complete their investigations and will send our review to the HFEA. | The PR has provided a report of the review of medicines management carried out by the relevant Trust theatres. Corrective and preventative actions have been implemented.<br><br>Further action is required. |

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| | inspector by 15 June 2016. | | |

### ‘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 | Inspection team’s response to the PR’s statement |
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| 4. **Screening of patients**:<br>In one set of patient records reviewed by the inspection team, the patient’s viral screening had been undertaken five months prior to egg collection. This non-conformance had been identified by a staff member; however the plan of action was to re-screen the patient at embryos transfer and not before treatment was commenced<br><br>SLC T51b | The PR should review records of patients who have had gametes or embryos placed in storage in the last three months to determine whether screening has been performed within the required timescales.<br><br>A summary report of the review along with corrective actions and a timescale for the implementation of those actions should be provided to the inspector by 15 June 2016.<br><br>Three months after the review the PR should audit screening of patients to assess whether the corrective actions have had the desired effect. A summary report of the audit should be provided to the inspector by 15 September 2016. | We plan to review the records of patients who had frozen gametes and embryos in the past 3 months and audit it aganst the standard protocol.<br><br>We will plan corrective measures once the review is complete. I will forward the review and the corrective measures recommended. We will send this report by the 16th of June. We will also plan a workshop on our corrective measures in May 2016.<br><br>A reaudit will be conducted after the corrective measures have been implemented and the findings will be submitted to the HFEA by the 16th of September. | The Executive acknowledges the PR’s response and his commitment to fully implementing this recommendation.<br><br>The PR has provided a report outlining the review of all patient records who have had gametes or embryos placed in storage from 1 January 2016 – 31 March 2016. Corrective and preventative actions have been implemented, including revision of the screening of patients SOP.<br><br>Further action is required. |

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| 5. **Payments to donors**:<br>Centre staff could not confirm that all imported sperm donors had been reimbursed in line with General Direction 0001.<br><br>SLC T69, General Directions 0001 and 0006. | The PR should ensure that confirmation that donors are compensated in line with General Direction 0001 is received before donor sperm is imported under General Direction 0006. The PR should provide confirmation of how this will be achieved when responding to this report.<br><br>The PR should review all donor sperm imported since the last inspection to determine whether any sperm donors were compensated in excess of the amounts specified in General Direction 0001. A summary report of the review along with corrective actions and a timescale for the implementation of those actions should be provided to the inspector by 15 June 2016.<br><br>Six months after the review the PR should audit the compensation provided to imported sperm donors to assess whether the corrective actions have had the desired effect. A summary report of the | We procure donor sperm from sperm banks in the UK and abroad. We do not recruit donors.<br><br>We have asked the foreign sperm banks to confirm in writing about the compensation given to sperm donors in their clinics.<br><br>Our third party agreement will indicate the compensation clinics give to donors . We will send you these reports by June 2015.<br><br>We will also ask the sperm banks to audit on compensation for 10 cases which we randomly pick to confirm that the change in protocols have been followed. | The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.<br><br>The PR has obtained confirmation from the sperm banks that the donors of all sperm samples imported since the last inspection, were reimbursed in line with General Direction 0001.<br><br>Further action is required. |

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| | audit should be provided to the inspector by 15 December 2016. | | |
| 6. **QMS**:<br>The scope of the controlled drugs audit was very narrow. Audit reports do not consistently and systematically document the corrective actions identified and the dates of implementation.<br><br>SLC T32 and SLC T36 | The PR should review the scope of audits to ensure that they meet compliance with regulatory requirements and approved protocols. The PR should also review the centre's processes for documenting the corrective actions identified by audits and the dates of their implementation. A summary of the findings of the review, including corrective actions and the timescale for their implementation, should be provided to the centre's inspector by 15 June 2016. | We will under take a review of the drugs audit to ensure that it meets the regulatory requirements.<br><br>We will review the audit process for the drug audit and include it in our QMS review. This will also be included in our annual audit schedule for 2016. | The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. However, the supporting evidence provided by the PR, still lacks depth and detail. This does not constitute a failure to implement this recommendation. The centre's inspector will work closely with the PR and Quality Manager to provide guidance in refining their audit processes.<br><br>Further action is required. |
| 7. **Patient records**:<br>A review of four sets of patient records at the inspection identified errors and corrections on patient consent forms. The consent indications seemed clear, however the amendments were not always signed and | The PR should ensure that all records are clear and legible, and that amendments to records are signed and dated. The centre's records management SOP should be reviewed to ensure it documents compliant records | We will make changes to our consent amendment policy. We will plan to conduct a workshop to highlight the amendment policy and discuss the implemenation of the new protocol. We will send the documents with the corrective | The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation.<br><br>The PR has confirmed that the centre has made changes to the |

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| dated to indicate who had made the amendments and when.<br><br>SLC T47 | management practices, including an amendments policy.<br><br>The centre's inspector should be advised by 15 June 2016 of the actions taken to implement these recommendations. Within three months of the recommendations being implemented, the centre should undertake an audit of consent forms to ensure that the corrective actions have been effective. A summary report of the findings of the audit should be sent to the centre's inspector by 15 September 2016. | actions planned in June 2016. We will also plan an audit which will be completed by September 2016 . | patient records protocol and discussed this at a staff meeting.<br><br>Further action is required. |

| Additional information from the Person Responsible |
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| Our fresh IVF/ICSI sucecss rates currently are in line with the national averages from the regular KPIs. Our centre now freezes almost 50% - 60% of all our treatment cycles with significantly high success rates which have been sent in the earlier report. Our fresh cycles are mainly of a few normal responder and the large majority of poor responders. The over responders which account for at least 45% of our patients . In addtion some of the normal responders also go into the freeze all category. Thus almost 70 % of patients under 38 will have the embryos frozen without a fresh embryo transfer. Thus our fresh cycle results are mainly consist of the poor responders who have a lower result. We offer a 40% to 46% Clinical pregnancy rate for the frozen cycle.The fresh transfers will continue to be lower since they are offerred to poor respoders. We aim to review our treatment for normal responders , which is being studied by a nation wide study and will move to a freeze all if the results are better with the frozen group. We are not yet certain how to treat the poor responders since freezing does not improve the success rate . .<br><br>Note: The outcome data provided by the PR in response to this report has not yet been verified by the HFEA. |