HFEA Licence Committee Meeting

15 January 2015

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 3

Centre 0254 (The Agora Gynaecology and Fertility Centre) – Treatment and Storage Licence Renewal

Members of the Committee: Andy Greenfield (lay) (Chair) Debbie Barber (professional) Jane Dibblin (lay) Kate Brian (lay) Committee Secretary: Trent Fisher	Legal Adviser: Shelley Edwards, Fieldfisher Also in Attendance: Sam Hartley, Head of Governance and Licensing

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- Renewal inspection report
- Application for licence renewal
- Executive Licensing Panel minutes for the past three years:
    - Interim inspection report (02 November 2012)

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012

- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

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 and provides a full range of fertility services to self-funded patients. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

2. The centre provided 722 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2014. In relation to activity levels this is a medium-sized centre.

3. The centre is registered with the Care Quality Commission (CQC) for diagnostic and screening procedures, surgical procedures and the treatment of disease, disorder or injury. The centre was last inspected by the CQC in December 2013.

Discussion

4. The Committee noted that at the time of its renewal inspection, 30 September 2014 – 1 October 2014, recommendations relating to 2 'critical', 10 'major' and 4 'other' areas of non-compliance or poor performance were identified and several recommendations were made.

5. The Committee noted that since the inspection the PR stated that recommendations for one 'major' and two 'other' areas of non-compliance have been implemented and that the remainder of the areas of non-compliance are in the process of being implemented.

6. The Committee noted that whilst the success rates are consistent with the national average, the centre's multiple clinical pregnancy rates are unlikely to meet the current target.

7. The Committee had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

8. The Committee noted that the proposed PR holds academic qualifications and has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). She has successfully completed the HFEA PR Entry Programme.

9. The Committee noted the PR is suitable and will discharge her duty under section 17 of the HF&E Act 1990 (as amended) subject to the implementations of the recommendations of the investigation report.

10. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

11. The Committee was satisfied that the premises (including those of relevant third parties) to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report except within regard to the recommendations outstanding which relate to the premises.

12. The Committee noted the Executive's recommendation to renew the centre's Treatment and Storage licence for a period of three years without additional conditions subject to the recommendations made in the renewal inspection report being implemented within the prescribed timescales.

13. The Committee was concerned about the number and seriousness of the non-compliances, and noted the Executive's view that the PR will be considered to be suitable and to have discharged her duty under Section 17 of the Act subject to implementation of the recommendations in the report. The Committee further noted that significant improvement was required in order for the centre to reflect good practice and urged the PR to continue to address the non-compliances outlined in the report.

Decision

14. Notwithstanding the concerns the Executive and Committee had regarding the centre, the Committee agreed that it was proportionate to agree to renew the centre's licence for a period of three years without any additional conditions.

15. The Committee recommends due to the large number of non-compliances that the Executive undertakes an unannounced inspection within a year to ensure that the recommendations of the report are addressed.

Signed: Date: 29 January 2015

Andy Greenfield (Chair)

Inspection Report

Purpose of the Inspection Report
This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (LC) or 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: 30 September and 1 October 2014

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: Parvez Qureshi, Karen Conyers, Gill Walsh, Chris Hall and Tarek Hussain.

Date of Licence Committee: 15 January 2015

Centre name	The Agora Gynaecology and Fertility Centre
Centre number	0254
Licence number	L/0254/4/b
Centre address	The Agora, Ellen Street, Brighton & Hove, BN3 3LN, UK
Person Responsible	Dr Carole Gilling-Smith
Licence Holder	Dr Hossam Abdalla
Date licence issued	01/02/2011
Licence expiry date	31/01/2015
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 and provides a full range of fertility services to self-funded patients. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre provided 722 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2014. In relation to activity levels this is a medium sized centre.

Other licensed activities of the centre include storage of gametes and embryos.

The centre is registered with the Care Quality Commission (CQC) for diagnostic and screening procedures, surgical procedures and the treatment of disease, disorder or injury. The centre was last inspected by the CQC in December 2013.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period June 2013 to May 2014 show the centre's success rates are in line with national averages.

In 2013, the centre reported 170 cycles of partner insemination with 10 pregnancies. This equates to a 6% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

Between June 2013 and May 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 21%. This represents performance that is likely to be greater than the 10% multiple live birth rate target for this period (see recommendation 6).

[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 will be considered to have discharged her duty under section 17 of the HF&E Act 1990 (as amended) subject to the implementation of the recommendations made in this report;
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are considered likely to be suitable subject to the implementation of corrective actions as recommended in this report;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The LC is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two critical, 10 major and four 'other' areas of non-compliance.

Since the inspection, the PR has provided assurance that the following recommendations have been implemented:

Major areas of non compliance:

- The PR should ensure any benefit in kind is only provided in the cycle in which egg sharing donation takes place in accordance with General Direction 0001 unless there is a medical reason why they cannot be.

'Other' areas that requires improvement:

- The PR must ensure that all licensed treatment activity is reported to the Authority as required by General Direction 0005. The reporting of one treatment identified as outstanding at the time of inspection should be expedited.
- The PR should review the process by which she is assured that overseas recruited donors are only compensated in accordance with General Direction 0001.

The PR is in the progress of implementing, or has provided commitment to implement the following recommendations:

Critical areas of non compliance:

- **The PR should ensure that appropriate consent is in place for the storage of all cryopreserved gametes and embryos. This was noted to have been an issue at the last inspection.**
- **The PR should conduct an urgent review of the centre's procedures for reporting adverse events to the HFEA to identify where there are barriers to this being done consistently. The PR should ensure that all staff comply with HFEA**

incident and adverse event reporting requirements and that incidents or 'near miss' events are investigated and corrective actions are documented, implemented and periodically assessed for efficacy. Relevant incidents should be reported to the HFEA retrospectively for consideration. This was noted to have been issue at the last renewal inspection

Major areas of non compliance:

- The PR should review the regulatory requirements and process for witnessing (including the electronic witnessing reports) to ensure that all witnessing steps are appropriately documented.
- The PR should ensure that prior to the use and/or storage of donor gametes and/or embryos created with donor gametes, screening and testing requirements are complied with as follows:
    - gametes providers are screened in accordance with current relevant professional guidance;
    - screening tests are conducted by a suitably accredited laboratory, i.e. a laboratory with Clinical Pathology Accreditation (UK) Ltd (CPA) or equivalent;
    - there should be procedures in place to identify when additional screening may be required.
- The PR must ensure that diagnostic laboratory tests, including semen analysis, are conducted by a suitably accredited laboratory or that evidence of equivalence is demonstrated.
- The PR should undertake an audit of the effectiveness of the centre's multiple births minimisation strategy and determine whether there are barriers to the effective implementation of the strategy for all patients provided with licensed treatment at the centre.
- The PR should ensure that all relevant data relating to anything coming into contact with gametes and embryos is documented to ensure full traceability.
- The PR should conduct a review of the centre's quality management system (QMS) and ensure that;
    - there is an effective mechanism in place for document control which ensures that only the current version of any document is in use;
    - the centre's audit processes are robust and that staff conducting audits are competent to do so;
    - quality indicators (QIs) or objectives relevant to processes and procedures are established and that these processes are audited;
    - standard operating procedures (SOPs) are developed for all activities included on the centre's licence, and for those activities carried out in the course of providing treatment services that do not require a licence.
- The PR should ensure that all critical equipment is validated.
- The PR must ensure that all patients and donors information is kept confidential and only disclosed in circumstances permitted by law.

'Other' areas that requires improvement:

- The PR should ensure that written agreements with third parties who provide goods or services that influence the quality and safety of gametes and embryos are established.
- The PR should ensure that staff are able to demonstrate competence in all of the tasks that they perform.

Recommendation to the Licence Committee

The inspection team notes that the success rates are consistent with the national average but that the centre's multiple clinical pregnancy rates are unlikely to meet current the target. The PR should continue to use the QMS to best effect to monitor their multiple clinical pregnancy / live birth rates and to implement an effective strategy to reduce multiple birth rates to meet the current target and improve the quality of care provided to patients.

The centre had two critical, 10 major and four 'other' areas of non compliance identified at this inspection, some of which are recurring non-compliances.

At the time this report was provided to the PR for comment, the inspection team recommended the renewal of the centre's Treatment and Storage licence for a period of three years rather than the standard four subject to a commitment from the PR to fully implement the recommendations of this report within the prescribed timeframes.

The inspection team considered that the initial responses provided by the PR in responding to this report did not provide sufficient assurance that the PR would fully implement the recommendations as required. On the basis of this, the inspection team was concerned that the PR may not fulfil her duties under section 17 of the HF&E Act 1990 (as amended). In response to these concerns a management review meeting was held on 4 December 2014 in accordance with paragraph 4.6 of the HFEA's compliance and enforcement policy and concluded that there may be an on-going risk to patients and their gametes and embryos, with particular reference to witnessing procedures, the use of non validated equipment, donor selection and screening procedures and the centre's ability to demonstrate learning from adverse incidents. In accordance with paragraph 4.2 of the HFEA's compliance and enforcement policy it was agreed that informal action was warranted in the first instance if formal regulatory action was to be avoided.

To this effect the PR was invited to attend a meeting with HFEA representatives on 16 December 2014 to discuss the concerns raised by the Executive regarding the PR's apparent lack of engagement with the HFEA and insight when responding to the report. The Executive expressed concern that such lack of engagement or apparent insight may indicate that the PR is not able to fulfil her duties under section 17 of the HF&E Act 1990 (as amended).

The outcome of that meeting was that the PR agreed that the responses did not furnish the Executive with sufficient assurance that the requirements of the recommendations were fully understood and would be fully implemented. It was agreed that the PR would be given the opportunity to resubmit her response to the report in light of a number of significant changes at the centre since the time the report was reviewed.

The section 'areas of practice requiring action' at the end of this report has been updated to reflect the PR's revised responses and the Executive's review has been populated accordingly. The Executive is now assured that the PR is engaged with the HFEA and the findings of this report and that the PR has given a commitment to discharge her duty under section 17(1)(d) of the HF&E Act 1990 (as amended) in ensuring that the centre's practices are suitable.

Significant improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides. Based on all the

information provided to date, the Executive recommends the renewal of the centre's treatment and storage licence for a period of three years (rather than the standard four) without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales. An interim inspection should be conducted at the discretion of the Executive but within one year of this licence being granted. This will enable the centre's progress in implementing the recommendations to be evaluated within a shorter than usual timescale: should there be any concerns about the effectiveness of any corrective action taken this can be referred to a licensing committee. Alternatively, if the centre is able to demonstrate good progress after the interim inspection, the usual biennial inspection frequency can be resumed.

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

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 partially compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.
What the centre could do better **Witnessing (Guidance note 18)** In three of five records audited there was no appropriate record that the required witnessing step had been carried out (dish change, tube warmer clear and patient signing to confirm insemination). The disposal of unfertilised/non-viable eggs that are not used in treatment is not witnessed (SLC T71 and CoP Guidance 18.4). The insemination witness step does not record the time and the date is on a separate page which could become detached (CoP Guidance 18.8b). An audit of electronic witnessing report mismatches was reviewed and this confirmed that reasons for all mismatches identified had been noted. The audit of five records indicated that in one case a manual witness step had replaced an electronic step and this had been correctly carried out. However the electronic witnessing report did not record the step which had not been performed. These findings were discussed with the laboratory manager during inspection and the reason for this required further investigation (see recommendation 3).

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 broadly compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

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

What the centre could do better

Screening of donors (Guidance note 11)
Donors of gametes and embryos are not consistently screened in accordance with current professional body guidance. Egg donor / sharer records were compliant with requirements but sperm donor records were not. There was no evidence of screening for cystic fibrosis and karyotype in two sperm donor records reviewed (SLC T52(a) In cases where testing is initiated by the centre, blood testing is conducted by a suitably accredited laboratory. However, where diagnostic testing / screening are initiated outside of the centre by the patient's / donor's General Practitioner or other organisation, the PR could not confirm whether these tests had been conducted in a suitably accredited laboratory(SLC T53a(see recommendation 4).

Payments for donors (Guidance note 13; General Direction 0001)
The PR could not provide assurance that donors recruited by overseas sperm banks are only compensated in accordance with General Direction 0001 (see recommendation 13).

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation

Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

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

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure 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.

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 partially compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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

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

Multiple births (Guidance note 7; General Direction 0003)

The centre's procedures are 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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

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

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

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

or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is 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 broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has no satellite or transport arrangements in operation.

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

The centre is partially 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 partially compliant with HFEA requirements. The centre reports some incidents (including serious adverse events and reactions) to the HFEA. The centre has investigated 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

Laboratory accreditation (Guidance note 25)
The centre is carrying out diagnostic semen analysis but does not have CPA (or equivalent) accreditation. Evidence of equivalence was reviewed and was considered satisfactory with the exception of the process validation which requires review against professional (WHO) guidelines for diagnostic semen analysis. CPA accreditation or demonstration of equivalence for diagnostic semen analysis remains outstanding since the most recent interim and last renewal inspection (SLC T21) (see recommendation 5).

Multiple births (Guidance note 7; General Direction 0003)
The centre is unlikely to meet the current multiple birth rate target (General Direction 0003) (see recommendation 6**)**

Imports and exports (Guidance note 16; General Direction 0006)

The PR was unable to provide assurance that overseas donors were only compensated in accordance with General Direction 0001 (see recommendation 13).

Traceability (Guidance note 19)
Traceability systems to record all consumables coming into contact with gametes or embryos were not robust. Traceability documentation was incomplete and inaccurate and it was not possible to clearly identify which consumables had been used for patients in several examples (e.g. culture media, labware). Equipment traceability was not complete as it did not include recording of which centrifuge was used during treatment. Non-compliances relating to the traceability of gametes and embryos were noted at the last inspection (SLC T99) (see recommendation 7).

Quality management system (QMS) (Guidance note 23)
The submission of data to the HFEA has not been audited against compliance with approved protocols, the regulatory requirements and quality indicators (SLC T35 and SLC T36). The storage audit and known donor screening audit which were performed have not been documented with clear findings and corrective actions (SLC T36). The SOPs for traceability, semen analysis, import/export of gametes and embryos, transport conditions, recall management, legal parenthood, welfare of the child and witnessing have not been reviewed against professional guidance, current practice and regulatory requirements (SLC T33b). There are no SOPs in place for donor recruitment, assessment and screening (of sperm donors) and submission of data to the HFEA (SLC T33) (see recommendation 8).

Third party agreements (Guidance note 24)
The centre's renewal application stated that the centre has a third party agreement with an overseas sperm bank but no evidence of an agreement was available on inspection for any overseas sperm banks. Also there are no third party agreements in place with couriers used by the centre. A complete list of all third-party agreements is not maintained by the centre (SLC T111 and T115) (see recommendation 15).

Equipment and materials (Guidance note 26)
Not all critical equipment has been validated (e.g. some dewars, dry shipper, centrifuge, refrigerator, Gilson pipettes, suction pump for egg collection, tube warmers, emergency transport incubator, warming ovens). The corrective actions following out of range alerts identified during daily/weekly monitoring of equipment was not clearly documented (SLC T24). Validation of critical equipment was identified as a non-compliance at the centre's last renewal inspection (see recommendation 9). Although some products which are not CE marked have been identified and replacements sourced, there has not been a formal review of the CE mark status of all medical devices in use and such a review would be of benefit (SLC T30).

Adverse incidents (Guidance note 27)
During the time since the last inspection in the centre has reported four incidents to the HFEA.

A review of the centre's own incident reporting database (commenced early 2013) against incidents reported to the HFEA since the time of the last inspection showed that circa 20 incidents considered by the inspection team to warrant reporting to the HFEA have not been reported. A review of these incidents showed recurring incidents relating to the same or similar areas of practice such as breach of patient confidentiality, failures in

donor screening, consent and laboratory practice incidents. The centre's own analysis of these incidents commonly cited similar factors namely staff not adhering to SOPs, inexperienced staff working without senior supervision and lack of staff training. Further discussion with staff and review of the database showed that the centre's own internal review showed that 54% (7 of 13) incidents reported in 2014 to date were attributed to non adherence to the centre's SOPs. It appears that, although a potential cause may have been documented on the centre's data base, in reality there has been little meaningful investigation, follow up or learning sufficient to prevent the recurrence of similar incidents. The non reporting of so many incidents was discussed with the PR during the inspection. The PR was in some instances unaware that the incident had not been reported and in other instances felt that the incidents had been managed in house and did not require reporting. It is noted that failure to report all relevant incidents was cited as a non-compliance at the centre's last renewal inspection. This area of practice would not have been assessed during the centre's most recent, interim inspection in 2012 (SLC T118, General Direction 0011) (see recommendation 2).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
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 (T/1109/7).

Staff (Guidance note 2)
The centre is partially compliant with HFEA staffing requirements.

The centre has 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

Staff (Guidance note 2
Relevant staff were not able to provide evidence of competence to take consent to use of gametes / embryos in training or research (SLC T12 and T15a) (see recommendation 14).

Comment [A1]: They don't carry out research or consent for research do they? Remove and just leave training?

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

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

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); and Embryo testing and sex selection (Guidance note 10)
The centre does not perform embryo testing and therefore this area of practice is not applicable to this inspection.

What the centre could do better

Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit we spoke to five patients who provided feedback on their experiences. A further 19 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with ten of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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

- 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 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 partially 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 the exception of breaches of confidentiality noted under adverse incidents) 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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
Although this is not documented in the centre's patient information the quality manager described that in the event the patient does not have sufficient eggs to share, she may elect to donate all the eggs collected and return for another cycle (see recommendation 10).

Confidentiality and privacy (Guidance note 30)
Four breaches of confidentiality were noted on centre's own data base (SLC T43) (see recommendation 11).

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and / or donors are partially 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
The centre does not have written patient information for use of embryos or gametes in training or research (see recommendation 12).

Comment [A2]: As above

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 broadly compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

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

What the centre could do better

Consent (Guidance note 5;6)
Staff were not able to provide documented evidence of the assessment of their competence to take consent to use of gametes / embryos in training or research SLC T15a (see recommendation 14).

3. The protection of gametes and embryos

Respect for the special status of the embryo
What the centre does well The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities. • licensed activities only take place on licensed premises; • only permitted embryos are used in the provision of treatment services; • embryos are not selected for use in treatment for social reasons; • embryos are not created by embryo splitting; • embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and • embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.
What the centre could do better Nothing identified at this inspection.

Screening of patients Storage of gametes and embryos
What the centre does well **Screening of patients (Guidance note 17)** The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. **Storage of gametes and embryos (Guidance note 17)** The centre's procedures for storing gametes and embryos are partially 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 **Storage of gametes and embryos (Guidance note 17)** The centre did not have effective consent in place for storage of :

embryos from four couples (including one couple who had submitted a withdrawal of consent in June 2014 but whose embryo(s) had not yet been discarded); one sperm sample where a copy of the centre's own signed agreement to freezing was in place but was contradicted by an HFEA MGI consent form in the records (dated after both the centre's agreement and sperm storage date) which indicated 'No' to storage. Storage of sperm beyond the consented storage period was an issue at the interim inspection in 2012. The PR gave assurance that the centre's bring forward system would be reviewed and made more robust (see recommendation 1).

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 partially 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

Use of embryos for training staff
The centre does not have an SOP or written patient information for use of embryos in training.

The absence of suitable information could mean that consent to the use of embryos in training was not informed (SLC T95 and T97) (see recommendations 12).

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

What the centre could do better

Record keeping and document control (Guidance note 31)
No version control was evident on documents printed from the centre's data base (SLC T34) (see recommendation 8).

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
All 115 IVF treatments in the audit sample had been reported to the HFEA, but the reporting of one DI treatment in the audit sample of 136 was outstanding at the time of inspection.

77% of IVF and 63% of DI treatments in the audit sample were reported within the 10 working day period required by Direction 0005.

A small number of minor errors in submitted data were identified on inspection. These have been communicated to the centre for correction (SLC T9(e) / T41 and General Direction 0005) (see recommendation 16).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2012, recommendations for improvement were made in relation to one area of critical non-compliance, five areas of major non-compliance and no other areas of non-compliance.

The PR provided information and evidence that some of the recommendations were fully implemented within the prescribed timescales. However, despite assurances provided by the PR at the time of the last interim inspection, at this inspection recommendations for improvement were found not to have been implemented or not effectively implemented as described in the body of this report.

On-going monitoring of centre success rates

In 2014, the centre received one HFEA Risk Based Assessment Tool (RBAT) alert relating to their success rates for ICSI for patients under 38 years of age.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, 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. Storage of gametes and embryos The centre did not have effective consent in place for storage of : embryos from four couples (including one couple who had submitted a withdrawal of consent in June 2014 but whose embryo(s) had not yet been discarded); one sperm sample where a copy of the centre's own signed agreement to freezing was in place but was contradicted by an HFEA MGI consent form in the records (dated after both the centre's agreement and sperm storage date) which indicated 'No' to storage. Storage of sperm beyond the consented storage period was an issue	The PR should ensure that appropriate consent is in place for the storage of all cryopreserved gametes and embryos. The PR should update the centre's inspector on immediate actions to be taken relating to the samples identified as being stored without consent. The PR should review the bring forward procedures	We confirm that all samples from our audit were found to have valid consent for initial storage. The audit considered all embryos/sperm stored since the clinic opened in 2006 3 cases of embryos stored beyond consent: i) Not contactable - to be discarded on 2nd January 2015 when two embryologists are available for witnessing ii) New consents sent &	The Executive acknowledges the PR's response to this recommendation and actions since the inspection. The PR is reminded that information regarding the fate of one set of embryos and a sperm sample noted to be out of consent remains outstanding. The PR

at the interim inspection in 2012. The PR gave assurance that the centre's bring forward system would be reviewed and made more robust	and implement a robust system for identifying the imminent expiry of consent to storage. An action plan should be submitted to the centre's inspector by the time the PR responds to this report detailing the actions to be taken to implement a robust bring forward system and a timescale for the implementation of any required actions. The PR should conduct an audit of information held in the centre's database against written consents to ensure accuracy of the electronic record and review processes for recording and logging storage six months after the implementation of any actions to ensure that any changes are effective and a summary of this audit be provided to the centre's inspector by 1 May 2015.	returned. iii) New consents sent & returned We will be fully compliant on 2nd january 2015 following disposal of above Recommended actions: Full audit of cryostored material to ensure: i) adequate consent ii) adequate infection screen iii) verification of material. Bring-Forward-System: The current and predecessor bring-forward systems appear to have been insufficent. Possible reasons of failure of previous systems: i) spreadsheet inaccuracy ii) staff changes iii) reliance on spreadsheet rather than the database.	should provide and update regarding these samples by 1 February 2015. The PR should provide a summary of the changes made to the 'bring forward' system in practice and the results of the stored material audit by 1 May 2015. Further action is required.

		The patient management system “ACU” has a function enabling it to perform the “bring forward” role. The ACU function has ability to consider: 3 months, 6 months & 12 months ahead. The cryostorage audits will facilitate the use of the ACU “bring forward system” and verify the data before we “go live” live with the system Feb 2015. The current system and ACU software will be run in parallel to ensure that no errors or ommissions occur. The system will then be overseen by the Lab Manager, on a monthly basis. We will submit all audit findings prior to the recommended date of May 2015	
2. Adverse incidents A review of the centre’s own incident reporting database (commenced early	The PR should conduct an urgent review of the centre’s procedures for reporting	We accept that our incident reporting to the HFEA has been inconsistant. All incidents	The Executive acknowledges the PR’s response to this

2013) against incidents reported to the HFEA since the time of the last inspection showed that circa 20 incidents considered by the inspection team to warrant reporting to the HFEA have not been reported. A review of these incidents showed recurring incidents relating to the same or similar areas of practice such as breach of patient confidentiality, failures in donor screening, consent and laboratory practice incidents. The centre's own analysis of these incidents commonly cited similar factors namely staff not adhering to SOP's, inexperienced staff working without senior supervision and lack of staff training. Further discussion with staff and review of the database showed that the centres own internal review showed that 54% (7 of 13) incidents reported in 2014 to date where attributed to non adherence to the centre's SOPs. It appears that, although a potential cause may have been documented on the centre's data base, in reality there has been little meaningful investigation, follow up or learning sufficient to prevent the recurrence of similar incidents. The non reporting of so many incidents was discussed with the PR during the inspection. The PR was in some	adverse events to the HFEA to identify where there are barriers to this being done consistently. The PR should ensure that all staff comply with HFEA incident and adverse event reporting requirements and that incidents or 'near miss' events are investigated and corrective actions are documented, implemented and periodically assessed for efficacy. Relevant incidents should be reported to the HFEA retrospectively for consideration. This has been escalated to a critical non-compliance in accordance with the HFEA compliance assessment framework due to the recurrence of this non-compliance and the volume and nature of incidents found not to have been reported to the HFEA.	have been recorded on our in-house non-confomities Action plan: We will ensure all incidents are investigated and reported appropriately to the HFEA with full root cause analysis and corrective and preventative action We will look to avoid incidents relating to patient treatment/storage/screening by implementing the following: - pre-cycle meeting with Embryologist/ Nurse +/- Clinician to determine compliance of forthcoming / planned cycle (eg consents / screening / treatment modality / etc) - Review of all Medical, Nursing and Lab SOP`s with implementation of staff training - Review and annual assessment of clinical competencies -Team training : HFEA are to provide support in terms of Incident Reporting & Grading. We have been in contact with Paula Nolan to arrange this.	recommendation and commitment to full implementation of this recommendation. The Executive will continue to support the PR in achieving this. The PR has now reported all incidents identified on inspection to the HFEA and where required these have been followed up. The centre's own incident and non-conformance data base will be audited against that reported to the HFEA at the next inspection. Further action is required.

instances unaware that the incident has not been reported and in other instances felt that the incidents has been managed in house and did not required reporting. It is noted that failure to report all relevant incidents was cited as a non-compliance at the centre's last renewal inspection. This area of practice would not have been assessed during the centre's most recent, interim inspection in 2012 SLC T118, General Direction 0011		The imprtance of condifidentiality will be addressed with all staff with particular emphasis for the administrative team	

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
3. Witnessing In three of five records audited there was no appropriate record that the required witnessing step had been carried out (dish change, tube clear and patient signing to confirm insemination). The disposal of unfertilised/non-viable eggs that are not used in treatment is not witnessed. The insemination witness step does not record the time, and the date is on a separate page which could become detached. An audit of electronic witnessing report mismatches was reviewed and this confirmed that reasons for all mismatches	The PR should review the regulatory requirements and process for witnessing (including the electronic witnessing reports) to ensure that all witnessing steps are appropriately documented. The outcome of that review and any actions resulting should be reported to the centre's inspector when responding to this report. The PR should conduct an audit of witnessing practice and documentation (including electronic	We have reviewed the regulatory requirements and process for witnessing. Our actions are to include: - IUI form updated to include date & time on same page. - Sperm form: time added to the date section when the sample is released from the lab for insemination. - Audit of Witnessing : to ensure the Matcher process map is reflected in lab practice (due for submission by 1st May 2015)	The Executive acknowledges the PR's response and actions regarding the implementation this recommendation. The outcome of the scheduled witnessing audit should be provided by 1 May 2015. Further action is required.

identified had been noted, The audit of five records indicated that in one case a manual witness step had replaced an electronic step and this had been correctly carried out. However the electronic witnessing report did not record the step which had not been performed, These findings were discussed with the laboratory manager during inspection and the reason for this required further investigation SLC T71) and CoP Guidance 18.4 and 18.8b	witnessing reports) six months after the implementation of any actions to ensure that any changes are effective and a summary of this audit be provided to the centre's inspector by 1 May 2015.	We have liaised with the Matcher Team and have separated the IVF & ICSI procedure pathways to ensure accuracy of electronic witnessing. The witnessing pathway reflects the actual procedural pathway. - All critical steps (IVF & ICSI insem, ET & donor sperm samples) all have additional "manual" witnessing – as these steps are considered "critical". - Non / abnormal fert disposal step: the lab form will contain a relevant section similar to "disposal of embryos" section. - "Matcher" competency (with special reference "new" members of Team) to be created.	
4. Screening of donors Donors of gametes and embryos are not consistently screened in accordance with current professional body	The PR should ensure that prior to the use and/or storage of donor gametes and/or embryos created with donor gametes, screening and testing requirements are	We will ensure only CPA accredited labs are used to perform tests. We have a list of all the local CPA accredited labs to ensure	The Executive acknowledges the PR's response and actions regarding the implementation of this recommendation.

guidance. Egg donor / sharer records werecompliant with requirements but sperm donor records were not. There was no evidence of screening for cystic fibrosis and karyotype in two sperm donor records reviewed. In cases where testing is initiated by the centre, blood testing is conducted by a suitably accredited laboratory. However, where diagnostic testing / screening is initiated outside of the centre by the patient's / donor's General Practitioner or other organisation, the PR could not confirm whether these tests had been conducted in a suitably accredited laboratory SLC T52a, g and h	complied with as follows: o gametes providers are screened in accordance with current relevant professional guidance; o screening tests are conducted by a suitably accredited laboratory, i.e. Clinical Pathology Accreditation (UK) Ltd (CPA) or an equivalent accrediting body; o there should are procedures in place to identify when additional screening may be required. The PR should review the regulatory requirements and process for screening donors. A summary of this review and detail of any actions implemented as a result of this review should be provided to the centre's inspector by 1 January 2015. The PR should inform the	tests performed can be verified as being from an accredited lab. Our routine provider is HCA laboratories which are CPA Accrediated. In terms of the requirements to screen donors we accept that our approach has been inconsistant. We have discussed with the inspecting HFEA Officer, our actions regarding CF screening and donor gametes. The frozen sperm samples, without CF screening will not be used and will be discarded once the patient has been notified. In Jan / Feb 2015 ee will be performing an audit of all cryostored material - this will include the donor material to determine it meets the HFEA requirements. To avoid future non-compliance we will impliment a pre-donation/screening meeting with	The Executive considers the PR's actions with regard to the known donor samples which had not been screened for CF and karyotyping to be satisfactory. The PR is to inform the centre's inspector when this action is completed. The PR is asked to provide a copy of the centre's donor screening SOP by 1 March 2015. The PR should provide detail of the outcome of the scheduled donor screening audit by revised date of 1 April 2015. Further action is required.

	centre's inspector of the actions taken regarding the lack of cystic fibrosis and karyotype screening for these particular donors when responding to this report. The PR should perform an audit of a representative sample of donor records and provide a summary of the audit to the centre's inspector by 1 January 2015. Three months after the implementation of corrective actions, the centre should perform an audit of a random representative sample of donor records to ensure that these corrective actions are effective. This audit should be provided to the centre's inspector by 1 April 2015.	Embryologist/ Nurse +/- Clinician to determine freeze dates and screening required for compliance before sample production and this will be re-verified at pre-cycle meeting to determine the samples are suitable to be used in treatment.	
5. Laboratory accreditation The centre is carrying out diagnostic semen analysis but does not have CPA (or equivalent) accreditation.	The PR must ensure that diagnostic laboratory tests, including semen analysis, are conducted by a suitably accredited laboratory or that	We will ensure only CPA accredited labs are used to perform tests. We have a list of all the local	The Executive acknowledges the PR's response and commitment to implement this recommendation. The PR is asked to provide a copy of the

Evidence for equivalence was reviewed and was considered satisfactory with the exception of the process validation which requires review against professional (WHO) guidelines for diagnostic semen analysis. CPA accreditation or demonstration of equivalence for diagnostic semen analysis remains outstanding since the most recent interim and last renewal inspection. SLC T21	evidence of equivalence can be demonstrated. The PR should submit an updated process validation for diagnostic semen analysis when responding to this report if the centre wishes to demonstrate that they have status equivalent to that conferred by CPA accreditation.	CPA accredited labs to ensure tests performed can be verified as being from an accredited lab. We accept that andrology services require their own accreditation and any result provided regarding semen analysis will be for assessment purposes only and non-diagnositic. Our routine provider is HCA laboratories which are CPA Accrediated. Semen Analysis Validation: We have reviewed our semen analysis validation process and have completed a Validation of the process. our Semen Analysis SOP is compliant with WHO 2010 edition (the "progression" recording relates the how the ACU programme accepts data). The SOP is to be reviewed. Participation in NEQAS & very low failed fert rates with IVF also validate the process .	diagnostic semen analysis SOP and process validation by 1 March 2015. Further action is required.

6. Multiple births The centre is unlikely to meet the current multiple birth rate target General Direction 0003	The PR should undertake an audit of the effectiveness of the centre's multiple births minimisation strategy and determine whether there are barriers to the effective implementation of the strategy for all patients provided with licensed treatment at the centre. A summary report of the audit findings including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 1 January 2015.	We have a continuous review approach to the development of our Multiple Birth Minimisation Strategy. Action plan: - Patient education: much stronger guidance - Ongoing / rolling audit of sET vs dET. - Monthly audit - Monthly discussion at Management Meetings with action plans - Individual Practitioner eSET compliance audit – quarterly reports. - Modifying current policy to ensure <38 yrs old are sET on 1st & 2nd attempt, dependant on embryo quality. Awaiting 4th quarter results - for submission to HFEA.	The Executive acknowledges the PR's response and commitment to the implementation of this recommendation. The PR should provide a copy of the centre's own audit of results and practice relating to eSET for the 4th quarter. The Executive will continue to monitor the centre's multiple clinical pregnancy rates. Further action is required.
7. Traceability Traceability systems in place to monitor usage of consumables and reagents are not robust. Equipment traceability was not complete as it did not include recording of which centrifuge	The PR should ensure that all relevant data relating to anything coming into contact with gametes and embryos is documented to ensure full traceability;	Traceability : we record relevant data regarding consumables and can confirm the consumables are CE marked. In addition to this, we have	The Executive acknowledges the PR's response and actions regarding the implementation of this recommendation. A copy of correspondence with the software company

was used during treatment (SLC T99)	The PR should review practices with regard to traceability processes and practices currently in use. A summary review and update on the implementation of any resulting actions should be provided to the centre's inspector by 1 December 2014. Six months after the implementation of any actions the PR should undertake an audit to ensure that actions taken are effective. A summary of the audit and any actions resulting from it should be provided to the centre's inspector by 1 June 2015.	completed the following actions: - "Matcher" has been updated with consumables & Mediaware and is now compliant. - We can now print a patient report, similar to the "Matcher Witnessing Report" - which will list and identify the QC for the consumables used in a patients treatment cycle. - Media batches are also recorded directly (additionally) on the lab sheets. As regards to identifying either centrifuge: the two centrifuges will now be allotted different roles in terms of sample preparation. #1 : for the initial centrifugation of the sample & density gradient stage. i#2: for the wash stage. This approach will simplify the tractability process and will make rpm & time adjustments unnecessary. A traceability audit will be	regarding changes to the traceability function has also been provided. The PR should provide a summary of the traceability audit by 1 June 2015.

		conducted and reported upon by June 2014 CE marking : We are now fully compliant	
8. Quality management system No version control was evident on documents printed from the centre's data base. The submission of data to the HFEA has not been audited against compliance with approved protocols, the regulatory requirements and quality indicators. The physical tank storage audit and known donor screening audits which were performed had not been documented in an audit report format with clear findings and corrective actions. The SOPs for traceability, semen analysis, import/export, transport conditions, recall management, legal parenthood, welfare of the child and witnessing have not been reviewed against professional	The PR should conduct a review of the centre's quality management system (QMS) and ensure that; ° there is an effective mechanism in place for document control which ensures that only the current version of any document is in use; o the centre's audit processes are robust and that staff conducting audits are competent to do so. o QIs or objectives relevant to processes and procedures are established and that these processes are audited; o SOPs are developed for all activities included on	The Q-pulse QMS system has proven an effective tool for document control. The non-compliances were not related to version control of documents but to implementation and staff training. This is being addressed and continually improving as part of our QMS In terms of version control, Q-pulse holds the current version of documents and staff print directly from Q-pulse. Photocopying documents is not permitted We have re-introduced version control sections to documents. In terms of audit , many areas of practice have been audited and by staff qualified to do so. The areas of non-compliance had not been auditted but once all SOPs and processes have been updated they will all be auditted	The Executive acknowledges the PR's response to this recommendation regarding document and version control. The Executive acknowledges the PR's response and actions regarding the other requirements of this recommendation. The PR should provide detail of the audits required as described throughout this report. The recommendation stands that the PR should provide the centre's inspector with a schedule with anticipated timescales for completion of these actions required by the revised date of 1 March 2015 and provide a copy of the outstanding audit reports by 1 June 2015. Further action is required.

guidance, current practice and regulatory requirements and non-compliances related to traceability, witnessing and validation of semen analysis are noted in this report. There are no SOPs in place for donor recruitment, assessment and screening (of sperm donors) and submission of data to the HFEA. SLC T33, T34, T35 and T36	the centre's licence, and for those activities carried out in the course of providing treatment services that do not require a licence. The PR should provide the centre's inspector with a schedule with the anticipated timescale for completion of these actions when responding to this report. The PR should provide a copy of the final audit reports to the centre inspector by 1 June 2015.	in 2015 Jan / Feb 2015 cryostorage audits will be performed and the results of the audit shared with the HFEA. All SOP`s are "living" documents and are subject to update as practice developes.  The SOP`s are in the process of review to ensure they reflect practice.	
9. Equipment and materials Not all critical equipment has been validated (e.g. some dewars, dry shipper, centrifuge, refrigerator, Gilson pipettes, suction pump for egg collection, tube warmers, emergency transport incubator, warming ovens). The corrective actions following out of range alerts identified during daily/weekly monitoring of equipment was not clearly documented.	The PR should ensure that all critical equipment is validated. The PR to submit an action plan listing all critical equipment, the date of validation and/or the expected date by which validation will be achieved when responding to this report.	The process of equipment re-validation has commenced. HFEA will be kept appraised of progress. In terms of daily monitoring, this is always performed but we accept HFEA`s recommendation regarding its documentation - we have modified the Monitoring record sheet accordingly.	The Executive acknowledges the PR's response to this recommendation. A list of consumables, including their CE marking status has been provided. The PR has provided a list of critical equipment to be validated and a schedule by which this will be achieved.

Validation of critical equipment was identified as a non-compliance and the centre's last renewal inspection. Although some products which are not CE marked have been identified and replacements sourced, there had not been a formal review of the CE mark status all medical devices in use and such a review would be of benefit SLC T24 and SLC T30	The PR should ensure that all validations are completed by 1 April 2015. On completion of the validations the centre's inspector will ask for a sample of validation documents to be submitted for review. The PR should conduct a review of all medical devices currently in use to identify where products may not be CE marked. The PR should provide the centre's inspector with a list of all relevant devices (this includes disposables, equipment, and culture medium) indicating the CE mark status of these products. Where devices are in place that are not CE marked then the PR should indicate what action will be taken and the timescale for the actions by 1 January 2015. It is expected that all medical devices should be CE approved by 1 April 2015.	In terms of CE marking, whilst all of our consumables are tested using the industry "gold standard", Mouse Embryo Assay (MEA), we have ensured that all of our consumables are CE marked.	Progress with this will be monitored. All equipment identified as requiring validation must have this in place by 1 April 2015. A representative sample of validation documentation will be requested by the Executive when this is complete. Further action is required.

10. Egg sharing arrangements Although this is not documented in the centre's patient information the quality manager described that in the event the patient does not have sufficient eggs to share, she may elect to donate all and return for another cycle General Direction 0001	The PR should ensure any benefit in kind may only be provided within the cycle in which donation takes place in accordance with General Direction 0001, unless there is a medical reason why this cannot be. The PR should review the patient information to ensure it accurately reflects General Direction 0001 and also review processes and practices such that where there is a medical reason why benefit in kind cannot be provided in the cycle in which donation takes place, this is clearly recorded in the patient's records. A summary of the review and corrective actions taken should be provided to the centre's inspector by 1 January 2015.	Our egg sharing information is updated. We feel the discussion regarding compensation during the same cycle of treatment should be discussed face to face with the patient and recorded in the notes and this is reflected in the revised SOP and consent form. We do not believe this should be within the written patient information on egg sharing. There is currently no mention of financial or treatment benefits and how they are calculated within this information sheet.	The Executive notes the PR's assurance that where there is a medical reason why benefit in kind cannot be provided in the cycle in which donation takes place, this will be recorded in the patient's records No further action is required.
11. Confidentiality and privacy Four breaches of confidentiality were noted on the centre's own data base	The PR must ensure that all patients and donors information is kept confidential and only disclosed in circumstances	We strive to protect patient confidentiality . We are grateful that HFEA have offered support in terms of	The Executive acknowledges the PR's response to this recommendation. The recommendation remains

SLC T43	permitted by law. The PR should review the centre's procedures for ensuring all information is kept confidential. A summary of this review should be provided to the centre's inspector when responding to this report. The PR should conduct an audit of confidentiality six months after the implementation of any actions to ensure that any changes are effective and a summary of this audit be provided to the centre's inspector by 1 May 2015.	Team training in terms of "Incident Reporting & Grading" . This will be invaluable in terms of highlighting the requirement of data protection. The PR will meet with the Team to discuss and highlight the importance of data protection. The PR will then audit confidentiality six months later to establish the effectiveness of the actions. Further actions, as required.	that the PR should provide a summary of the findings of the review of the centre's processes for maintaining confidentiality by the revised date of 1 March 2015. The PR should provide a summary of the audit and any actions resulting from it to the centre's inspector by 1 May 2015.
12. Use of embryos for training staff The centre does not have an SOP or written patient information for use of embryos in training or research The absence of suitable information could mean that consent to the use of embryos in training was not informed	The PR should develop an SOP and written patient information relating to the use of embryos in staff training. Copies should be provided to the centre's inspector by 1 January 2015. No embryos should be used in training until the information has been submitted to the HFEA	We have created a written information sheet for the use of embryos in training and research. To be completed: SOP to be written regarding the use of embryos in staff training An audit of the implementation of this SOP to take place in	The Executive notes the PR's response and commitment to implement this recommendation. A draft copy of the proposed patient information regarding donation for use in training or research has been provided and appears to be suitable. A copy of the SOP should be provided to the centre's

SLC T95 and T97	and approved as compliant with requirements. Six months after the implementation of this SOP the PR should audit the implementation of the SOP to ensure that actions taken are effective. A summary of the audit and any actions resulting from it should be provided to the centre's inspector by 1 July 2015.	June 2015	inspector by the revised date of 1 March 2015. The PR is to provide a summary of the audit and any actions resulting from it to the centre's inspector by 1 July 2015. Further action is 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
13. Payments for donors The PR could not provide assurance that overseas recruited donors are only compensated in accordance with General Direction 0001	The PR should review the process by which she is assured that overseas recruited donors are only compensated in accordance with General Direction 0001 A summary of this review and actions implemented to ensure that compliance with General Direction 0001 can be demonstrated should be provided to the centre's inspector by 1 January 2015.	We have statements from donor sperm suppliers – confirming compliance with General Direction 0001	The Executive acknowledges the PR's response and proposed actions to implement this recommendation.
14. Staff Staff were not able to provide evidence of competence to take consent to use of gametes / embryos in training or research SLC T12 and SLC T15a	The PR should ensure that staff are able to demonstrate competence in all of the tasks that they perform. The PR is to provide the centre's inspector with an action plan, as to how this is to be achieved including timescales for the assessment of competence when	With the implementation of our new patient information alongside staff training and audit we will be fully compliant and provide results of our latest audit by end of February	The Executive acknowledges the PR's response to this recommendation. The PR is to inform the centre's inspector when training on the new SOP has been provided to relevant staff. This should be

	responding to this report.		provided by 1 March 2015. Further action is required.
15. Third party agreements The centre's renewal application stated third party agreement with an overseas sperm bank but no evidence was made available on inspection for any overseas sperm banks. Also there are no third party agreements in place with couriers used by the centre. A complete list of all third-party agreements is not maintained by the centre SLC T111 and T115	The PR should ensure that written agreements with third parties who provide goods or services that influence the quality and safety of gametes and embryos are established. A list of all third party agreements should be provided to the to the centre's inspector by 1 January 2015. A sample of agreements will then be requested for review.	We have approached our overseas suppliers and our regular Courier to re-request TPAs. Overseas supplier #!: has a TPA signed. Overseas supplier #2: has produced a HFEA document saying a TPA is not required - HFEA please advise. We are endeavouring to engage them in a TPA. Overseas supplier #3 : currently negotiating a TPA.	The Executive acknowledges that the requirements for TPAs with overseas sperm providers have been the point for some discussion and that a formal TPA may not be required. A list of all third party agreements remains outstanding and should be provided by 1 February 2015.
16. Obligations and reporting requirements All 115 IVF treatments in the audit sample were found to have been reported to the HFEA, but the reporting of one DI treatment in the audit sample of 136 was outstanding at the time of inspection. 77% of IVF and 63% of DI treatments in the audit sample	The PR must ensure that all licenced treatment activity is reported to the Authority as required by General Direction 0005. The reporting of one treatment identified as outstanding at the time of inspection should be expedited by the time the PR responds to this report.	The lab staff have organised their rota/workload to ensure they are now reporting cycles within 10 working days.	The Executive acknowledges the PR's response and will monitor the commitment to implement this recommendation. The outstanding treatment has been reported to the HFEA. No further action is

were reported within the 10 working day period required by Direction 0005. A small number of minor errors in submitted data were identified on inspection. These have been communicated to the centre for correction SLC T9(e) / T41 and General Direction 0005).			required.

Reponses from the Person Responsible to this inspection report
I accept a number of areas in practice require urgent attention but I am confident that following recent Laboratory restructuring and the Action plan set out in our respponses we are able to address all areas of non-compliance effectively and within the time scales set out in this report.