HFEA Executive Licensing Panel Meeting

5 September 2014

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

Minutes – Item 1

Centre 0030 – (Herts and Essex Fertility Centre) – Renewal Treatment & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Director of Strategy & Corporate Affairs David Moysen – Head of IT Rachel Hopkins – Head of Human Resources	Dee Knoyle

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:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 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)
- 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 Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment and storage centre which provides a full range of licensed treatments. The Panel noted that in relation to activity levels this is a medium-sized centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1992 and is on a four-year licence due to expire on 25 November 2014.

4. The Panel noted that in the 12 months to April 2014, the centre provided 567 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that for IVF, ICSI and FET treatments, HFEA-held register data for the period 1 March 2013 to 28 February 2014 show that the centre's success rates are in line with national averages, except for ICSI treatment in patients aged <38 years, where the success rate is significantly higher than the national average.

6. The Panel noted that in 2013, the centre reported 14 cycles of partner insemination with two pregnancies. This is in line with the national average.

7. Between 1 March 2013 and 28 February 2014, the centre's multiple clinical pregnancy rate (MPR) for all IVF, ICSI and FET cycles for all age groups was 20%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate (MLBR) target for this period.

8. The Panel noted that there was an upward trend in the MPR in 2014. Between 1 April 2013 and 31 March 2014 (ie, the most recent year's data available at the time of writing of the renewal inspection report) the MPR was 21% and represented performance that was likely to be statistically different from the 10% MLBR target.

9. The Panel noted that at the time of the inspection on 17 and 18 June 2014, the Inspectorate identified six major and three other areas of non-compliance. The Panel noted that significant improvement is required in order for the centre to reflect suitable practices and that the Inspectorate will continue to monitor the centre's performance. Failure to implement the recommendations relating to these areas of non-compliance within the prescribed timescales may result in the submission of a further report to a licensing Committee with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy. The Panel noted that the PR was committed to fully implementing all of the recommendations.

Decision

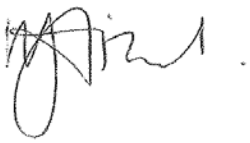
10. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

11. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and the PR has discharged their duty under section 17 of the HF&E Act 1990 (as amended).

12. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

13. The Panel endorsed the Inspectorate's recommendation to continue to monitor the centre's performance and emphasised that failure to implement the recommendations relating to the various areas of non-compliance within the prescribed timescales may result in the submission of a further report to a licensing committee, with the recommendation that appropriate regulatory action should be taken in accordance with the Authority's Compliance and Enforcement Policy.

14. The Panel endorsed the Inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions.



Signed: Date: 15 September 2014

Juliet Tizzard (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 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: 17 & 18 June 2014

Purpose of inspection: Renewal of a licence to carry out 'Treatment and Storage'.

The centre has applied to add the following activities: N/A

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: Lisa Beaumont (lead), Andrew Leonard, Janet Kirkland-MacHattie, Cathy Hodgson (audit), Barbara Lewis (audit), Pauline Barrett (observer) and Debbie Barber (observer).

Date of Executive Licensing Panel: 5 September 2014

Centre name	Herts and Essex Fertility Centre
Centre number	0030
Licence number	L/0030/16/d
Centre address	Churchgate, Bishop's College, Cheshunt, EN8 9XP, UK
Person Responsible	Mr David Ogutu
Licence Holder	Mr Michael Ah-Moye
Date licence issued	26 November 2010
Licence expiry date	25 November 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Herts and Essex Fertility Centre has held their current licence from the HFEA since November 2010. The centre has been licensed since 1992 and was formerly known as the Essex Fertility Centre and was located at Holly House Hospital. The centre provides a full range of fertility services. 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 567 cycles of treatment (excluding partner IUI) in the 12 months to April 2014. In relation to activity this is a medium sized centre.

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

An application to vary the centre's licence to change the Person Responsible (PR) from Mr Andy Glew to Mr David Ogutu was approved by an ELP in September 2013.

Pregnancy outcomes[1]

For IVF, ICSI and FET treatments, HFEA held register data for the period 1 March 2013 to 28 February 2014 show the centre's success rates are in line with national averages, except for ICSI treatment in patients aged <38 years, where the success rate is significantly greater than the national average.

In 2013, the centre reported 14 cycles of partner insemination with two pregnancies, a success rate in line with the national average.

Multiple births[2]

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

Between 1 March 2013 and 28 February 2014, the centre's multiple clinical pregnancy rate (MPR) for all IVF, ICSI and FET cycles for all age groups was 20%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate (MLBR) target for this period.

The inspection team note however an upward trend in the MPR in 2014. Between 1 April 2013 and 31 March 2014 (i.e. the most recent year's data available at the time of writing of this report) the MPR is 21% and represented performance that is likely to be statistically different from the 10% MLBR target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% MLBR target to a MPR target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with Section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under Section 17 of the HF&E Act 1990 (as amended);
- the premises are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including six major and three 'other' areas of non-compliance.

The PR has provided a response confirming his commitment to implement all the recommendations, these being:

Major areas of non compliance:

- The PR should ensure that the storage dewars are validated.
- The PR should ensure that wherever possible only CE marked consumables are used.
- The PR is required to review the storage arrangements for the medical gas cylinders to ensure the safety of the premises.
- The PR should review the effectiveness of the centre's multiple birth minimisation strategy, in light of the increasing MPR in 2014, which now represents performance likely to be significantly different from the MLBR target of 10%.
- The PR should ensure that all licensed treatment activity is reported to the Authority, and within the timeframe required by General Direction 0005.
- The PR should ensure that patients are provided with information (in writing or verbally) regarding the perceived risk of children conceived through ICSI having inherited genetic, epigenetic and/or chromosomal abnormalities.

'Other' areas that requires improvement:

- The PR should ensure that sperm donors are screened in accordance with current professional guidance, to include a physical examination for genital warts and herpes.
- The PR should ensure that quality indicators are established for counselling.
- The PR should ensure that an audit is undertaken for the provision of information.

Recommendation to the Executive Licensing Panel

The inspection team notes that the centre has no critical areas of concern but does have six major of areas of concern.

The inspection team also notes that the centre's success rates are consistent with or, as in the case of ICSI in patients <38 years old, greater than, the national averages but that the MLBR target is unlikely to be met. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve the clinical pregnancy/live birth rates and to review and implement an effective strategy to reduce the MLBR to meet the target, so as to improve the quality of the service offered to patients.

Significant improvement is required in order for the centre to reflect suitable practices. The inspector will continue to monitor the centre's performance. Failure to implement the recommendations relating to these areas of non-compliance within the prescribed timescales may result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

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

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are broadly compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-

conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment. Therefore it is important that centres use donated gametes or embryos from identifiable donors.

The centre's procedures are compliant with HFEA requirements to ensure the donor conceived and their parents will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
A physical exam for herpes and genital warts is not carried out for sperm donors prior to donation. This is non compliant with CoP Guidance 11.21 and SLC T52 a.
See recommendation 7.

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 generally 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 premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are 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 single biggest risk of fertility treatment is a multiple pregnancy.

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, however the centre is only partially compliant with assessing the effectiveness of the strategy through regular audits and evaluation.

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.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- The container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and have enough information supplied with them to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

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

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

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

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

The centre is 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 compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Multiple Births (Guidance note 7; General Direction 0003)
The inspection team note an upward trend in the MPR in 2014. Between 1 April 2013 and 31 March 2014 (i.e. the most recent year's data available at the time of writing this report) the MPR is 21% and represented performance that is likely to be statistically different from the 10% MLBR target (General Direction 0003 (b)). See recommendation 4.

Safety and suitability of premises and facilities (Guidance note 25)
The storage premises for gas cylinders were considered potentially hazardous given the size of the storage cupboards within a closed corridor, the number of cylinders (some stored horizontally), the relative lack of ventilation in the area, the cylinder contents (carbon dioxide and oxygen) and the absence of any gas monitoring in the area. Health and safety guidance advises that such cylinders should be stored in a well ventilated area (SLC T17). See recommendation 3.

Quality management system (QMS) (Guidance note 23)
The centre has not established quality indicators or objectives relevant to counselling (SLC T35). See recommendation 8.

The centre has not undertaken an audit of the provision of information within the last two years (SLC T 36). See recommendation 9.

Equipment and materials (Guidance note 26)
The storage dewars have not been validated (SLC T24). See recommendation 1.

The protein supplement used in culture media used by the centre is not CE marked (SLC T30). 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 complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1250/81).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements related to staffing arrangements.

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 inspection team noted good practice: two members of staff have successfully completed an apprenticeship in health and social care and are now qualified health care assistants.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account 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 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

The centre does not undertake these activities therefore this area of practice was not inspected.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit, the inspectors spoke to two couples who provided feedback on their experiences. A further 38 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive; the majority of the individuals providing written feedback to the HFEA complimented the centre about the care that they received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly
Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) and 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 inspection team were not able to see the counsellor on the day of inspection, however they are satisfied that the counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors prior to them providing their consent to licensed activities and/or legal parenthood.

Egg sharing arrangements (Guidance note 12; General Directions 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

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

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients 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 provide the following information to patients in writing or verbally: the risk of children conceived through ICSI having inherited genetic, epigenetic or chromosomal abnormalities (CoP Guidance 21.1b). This puts the centre at risk of failing to provide proper information about treatment to patients giving consent, as required by the HF&E Act 1990 (as amended), Schedule 3 S.3 (1b). See recommendation 6.

The centre may also wish to include within their written information that ICSI may reduce the number of eggs available for treatment, to further improve the quality of the consent process, as this information is important and is currently provided only verbally.

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before their involvement in 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

Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

The renewal application form records that the centre proposes to start to use embryos for training staff in embryo and blastocyst biopsy. These practices are also expressly authorised by the Authority as practices for which embryos may be used in training.

What the centre could do better

Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The centre's procedures for submitting information about licensed activities to the Authority are partially 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.

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

What the centre could do better
The audit team noted that 39% (46/118) of the IVF and 14% (1/7) of the DI treatments reviewed at inspection had not been reported at all to the HFEA, which is non-compliant with General Direction 0005. See recommendation 5.

Section 3: Monitoring of the centre's performance

Following the interim inspection in June 2012, recommendations for improvement were made in relation to one area of critical non-compliance, three areas of major non-compliance and nine 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

In the last 12 months, the centre has been sent one risk tool alert related to the clinical MPR in April 2014. The centre should be aware that late reporting can trigger a retrospective reset of CUSUM plots. Where this occurs this can mean an alert is not received despite there being performance trends that are a cause of concern. The centre is advised to review CUSUM plots regularly, particularly if there has been late reporting or even when an alert has not been received. See recommendation 4.

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
None			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The storage dewars (critical equipment) have not been validated. (SLC T24)	The PR should validate each of the storage dewars and copies of the validation documents should be provided to the centre's inspector by 18 September 2014.	Each of the storage dewars will be validated and a copies of the validation documents provided to the inspector by 18 September 2014.	The PR has committed to implement this recommendation by 18 September 2014. This will be reviewed by the Executive through the on-going monitoring system.
2. The protein supplement used in culture media is not CE marked. (SLC T30)	We would not recommend the implementation of precipitous changes that might impact on the quality of treatment provided to patients; however it is a requirement that all materials coming into contact with gametes and embryos are CE marked. In consideration of this, the PR should consider the CE marked options available to replace this protein supplement and should also confirm whether the supplier can/is	We will be contacting the supplier to confirm if CE mark application has been considered. If not, will recommend this as per HFEA recommendation. A response as well as options and plans will be provided to the HFEA by 18 September 2014.	The PR has committed to implement this recommendation by 18 September 2014. This will be reviewed by the Executive through the on-going monitoring system.

	in the process of obtaining a CE mark for this product. The PR should advise the HFEA of the options available and the centre's plans to become fully compliant with SLC T30 by 17 June 2015. The options and plan should be provided to the HFEA by 18 September 2014. The PR should also assess the risks of continuing to use non CE marked product in their culture medium: a summary of the assessment and any action taken to mitigate any risks should also be provided to the centre's inspector by 18 September 2014.		
3. The storage facilities for gas cylinders were considered potentially hazardous given the size of the storage cupboards within a closed corridor, the number of cylinders (some horizontally stacked), the relative lack of ventilation in the area, the cylinder contents (carbon dioxide and oxygen) and the absence of any gas monitoring in the area.	The PR should undertake a review of the centre's compliance with the relevant Health Technical Memorandum, which is available on the HFEA website.* A summary report of the review and any action identified as required should be submitted to the centre's inspector by 31 August 2014. *Medical Gases Health Technical Memorandum 02-01: Medical gas pipeline systems Part B: Operational	A health and safety assessment of the clinic, including the storage facilities for gas cylinders was done by an external health and safety consultant in March 2014. They had no concerns about the available storage facilities. A report will be forwarded to the inspector.	The lead inspector acknowledges the PR's response and will await submission of the health and safety report. This will be followed up through the on-going monitoring system.

Health and safety guidance advises that such cylinders should be stored in a well ventilated area. (SLC T17)	management: http://www.uk.airliquide.com/file/otherelement/pj/htm%2002-01%20medical%20gases%20part%20b%20-%20operational%20management89661.pdf		
4. The inspection team note an upward trend in the clinical MPR in 2014. Between 1 April 2013 and 31 March 2014 (i.e. the most recent year's data available at the time of writing of this report) the MPR is 21% and represented performance that is likely to be statistically different from the 10% MLBR target. (General Direction 0003 (b) and SLC T2)	The PR is required to review the effectiveness of the audit and evaluation of the multiple birth minimisation strategy, given that the MPR has been increasing in 2014 and now represents performance significantly different from the MLBR target. The PR is required to provide a summary of the review, identifying any actions to be taken, to the HFEA by 18 September 2014.	The clinic is continually reviewing the multiple birth policy to minimise our multiple pregnancy rates. Outcome of the latest review as well as recommendations will be provided to the inspector by 18 September 2014.	The PR has committed to implement this recommendation by 18 September 2014. This will be reviewed by the Executive through the on-going monitoring system.
5. 39% (46/118) of the IVF and 14% (1/7) of the DI treatments reviewed at inspection had not been reported at all to the HFEA, which is non-compliant with General Direction 0005.	The PR must ensure that all licensed treatment activity is reported to the Authority, and within the timeframe required by Direction 0005. The PR should undertake an audit	Data submission issues including technical difficulties with EDI have now been ironed out and all the data has been submitted. Cathy Hodgson, HFEA Register Information Team	The Executive acknowledges the action taken by the centre to address the data submission issues, in particular working with the HFEA Registry Team. The

	of data submission to the HFEA to ensure that the factors leading to late or non submission are identified; the results of the audit should be documented and any corrective actions identified and implemented. A summary of the audit should be submitted to the centre's inspector by 18 September 2014. An audit should be conducted three months after implementing any changes, to confirm that any changes made to systems and processes are having the desired effect. A report of this audit should be provided to the HFEA by 18 January 2015.	Leader will be visiting the clinic in the week commencing 11/08/2014 to provide further training and assistance to minimise data submission difficulties in future.	PR has committed to implement this recommendation. This will be reviewed by the Executive through the on-going monitoring system.
6. The centre does not provide the following information to patients in written documentation or verbally: the risk of children conceived through ICSI having inherited genetic, epigenetic or chromosomal abnormalities (CoP Guidance 21.1b). This puts the centre at risk of failing to provide proper	The PR should ensure the information provided to patients concerning ICSI satisfies the requirements of CoP Guidance 21.1b. The PR should provide the centre's inspector with a summary report of changes made to patient information or evidence of how the relevant information will be provided verbally, by 18 September 2014.	Patient information provided at initial consultation and in the ICSI consent forms has been ammended to include the potential risks of genetic and epigenetic or chromosomal abnormalities following ICSI treatmment. The copies will be provided to the inspector by 18 September 2014.	The Executive acknowledges the action taken by the centre to implement this recommendation, and will await submission of a copy of the amended patient information by 18 September 2014.

information about treatment to patients giving consent, as required by the HF&E Act 1990 (as amended), Schedule 3 S.3 (1b).			

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
7. The PR should ensure that sperm donors are screened in accordance with current professional guidance, to include a physical examination for genital warts and herpes. (CoP Guidance Note 11.21).	The PR is required to ensure that all donors are screened in accordance with current professional guidance. Evidence of this action should be provided to the centre's inspector by 18 September 2014.	The donor screening SOP has been ammended to include physical examination for genital infectious lesions (genital warts and herpes). Copy of the ammended SOP to be provided to the inspector by 18 September 2014.	The Executive acknowledges the action taken by the centre to implement this recommendation, and will await submission of a copy of the amended SOP by 18 September 2014.
8. The centre has not established quality indicators or objectives relevant to counselling. (SLC T35)	The PR should ensure the establishment of quality indicators or objectives for these procedures. Documentation demonstrating the establishment of the quality indicators or objectives should be provided to the centre's inspector by 18 September 2014.	Quality indicators for counselling to be set up and documentation to be forwarded to the inspector by 18th September 2014	The PR has committed to implement this recommendation by 18 September 2014. This will be reviewed by the Executive through the on-going monitoring system.
9. The centre has not undertaken an audit of the provision of information within the last two years.	The PR is required to ensure that an audit of the provision of information is undertaken, the results are documented and	An audit of the provision of information will be conducted in 2014 and outcome as well as recommendations	The PR has committed to implement this recommendation by 18 September 2014. This will be

(SLC T36)	any corrective actions identified are implemented. A summary of this audit should be submitted to the centre's inspector by 18 December 2014.	forwarded to the HFEA by 18 September 2014.	reviewed by the Executive through the on-going monitoring system.

Reponses from the Person Responsible to this inspection report
This inspection was very positive with useful feedback that we have taken on board. We are in the process of making all the necessary changes in our practice / documentation in order to further improve our practice as per the inspector's recommendations.