Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
7 May 2015

Minutes – item no. 2

Centre 0076 (NURTURE) – Renewal Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Nick Jones Director of Compliance & Information Ian Peacock Analyst Programmer
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

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 the 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 the 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 the publication of Authority and committee papers

Consideration of application

1. The panel considered the papers, which included an 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 fertility services. 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 31 May 2015.

4. The panel noted that in the 12 months to 31 December 2014, the centre provided 627 cycles of treatment (excluding partner intrauterine insemination).

5. The panel noted that for IVF and ICSI, HFEA-held register data for the period October 2013 to September 2014 showed the centre's success rates were in line with national averages with the following exception:
    - success rates for IVF and ICSI in women aged 16 to 37 years were significantly above the national average.

6. The panel noted that in 2013, the centre reported 16 cycles of partner insemination with two pregnancies. This is consistent with the national average.

7. The panel noted that in 2014, the centre reported seven cycles of partner insemination with no pregnancies. Statistical analysis of the sector IUI data for 2014 has not yet been carried out.

8. Between October 2013 and September 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 18%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

9. The panel noted that at the time of the inspection on 21 and 22 January 2015, the Inspectorate identified four other areas of non-compliance. The panel noted that since the inspection the Person Responsible (PR) has fully implemented one of the recommendations and has committed to implementing the outstanding recommendations.

10. The panel noted that the Inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions.

Decision

11. 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.

12. 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).

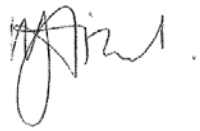
13. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

14. The panel commended the centre for having good success rates for both IVF and ICSI and achieving a good level of compliance.

15. The panel noted that the PR has committed to improve the centre's multiple births minimisation strategy and the Inspectorate will monitor the centre's multiple pregnancy rates.

16. 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.

17. The panel noted that the centre's licence is due to expire on 31 May 2015. The panel further noted that a Person Responsible has 28 days in which to accept the offer of a licence (or exercise his right to make representations against the proposed decision to grant a licence). As the existing licence will expire during this period, the panel agreed to issue Special Directions under Section 24(5A)(b) to allow for the continuation of licensed activity at the clinic. The Special Directions will come into force on 1 June 2015 and remain in force until the new licence comes into effect, or 30 June 2015, whichever is sooner.



Signed: Date: 12 May 2015
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: 21 and 22 January 2015

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, Gill Walsh and David Gibbon, Neil McComb and Zakia Ezzouyar

Date of Executive Licensing Panel: 7 May 2015

Centre name	NURTURE Fertility
Centre number	0076
Licence number	L/0076/14/b
Centre address	The East Midlands Fertility Centre Bostock's Lane Sandiacre Nottingham NG10 5QG
Person Responsible	Mr James Hopkisson
Licence Holder	Professor James Thornton
Date licence issued	01 June 2011
Licence expiry date	31 May 2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Centre 0076 NURTURE has been licenced by the HFEA since 1992 and provides a full range of fertility services. During this time the centre has been located within the Queens Medical Centre campus, Nottingham University Hospitals NHS Trust.

The Person Responsible (PR) submitted an application to the HFEA on 4 November 2014 to vary the centre's licence to reflect a change of premises and centre name to NURTURE Fertility. The application to vary the centre's licence to reflect a change of name to NURTURE Fertility and change of premises to:

The East Midlands Fertility Centre
Bostock's Lane
Sandiacre
Nottingham NG10 5QG

was considered and approved by an Executive Licensing Panel (ELP) on 27 February 2015.

It was planned that the centre's licence renewal inspection would be conducted at the new location following consideration of the application to vary the licence. A delay to building work meant that this was not possible. The licence renewal inspection was therefore conducted at the Queens Medical Centre site prior to the final preparation of this licence renewal inspection report. The centre is now fully operational at the new premises. This report reflects the findings at the time of the licence renewal inspection at Queens Medical Centre on 21 and 22 January 2015 and a site visit to the new premises on 19 February 2015.

The centre provided 627 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2014 at the Queens Medical Centre site. In relation to activity levels this is a medium sized centre.

The new premises are designed to accommodate a maximum of 200 IUI/DI and 1500 IVF/ICSI treatment cycles per annum and to provide better patient facilities.

All existing staff and equipment have moved to the new premises. The PR has provided assurance that activity will be managed commensurate with resources and any expansion of the service will be gradual as staffing increases.

The centre's procedures and processes employed at the new location are unchanged from that observed during the licence renewal inspection. Patient information and the centre's standard operating procedures (SOPs) have been amended to reflect the relocation to new facilities where appropriate. The change of location has been communicated to all current patients and to individuals with gametes and embryos stored at the centre.

NURTURE Fertility is also registered with the Care Quality Commission (CQC).

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period October 2013 to September 2014 show the centre's success rates are in line with national averages with the following exception:

- success rates for IVF and ICSI in women aged 16 > 37 years are significantly above the national average.

In 2013, the centre reported 16 cycles of partner insemination with two pregnancies. This is consistent with the national average.

In 2014, the centre reported seven cycles of partner insemination with no pregnancies. Statistical analysis of the sector IUI data for 2014 has not yet been carried out but it is likely that this is consistent with the national average.

Multiple births[2]

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

Between October 2013 to September 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 18%. This represents performance that is unlikely to be statistically different from the 10% multiple live birth rate target for this period.

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

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of 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 four 'other' areas of non-compliance.

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

'Other' areas that require improvement:

- The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Direction 0005.

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

'Other' areas that require improvement:

- The PR should ensure that quality indicators (QIs) are established for all licensed activities and these activities are audited against compliance with the approved protocols and the regulatory requirements.
- The PR should ensure that all third-party agreements are reviewed to ensure compliance with requirements.
- The PR should review systems and processes to ensure that the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms and that completed disclosure consent forms are retained in patient records.

Recommendation to the Executive Licensing Panel

The centre has no critical or major areas of non-compliance. The centre is to be congratulated on their success rates for both IVF and ICSI in patients aged 16 to 37 years which are significantly above the national average. All other success rates are consistent with the national average.

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 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; Directions 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 will be able to receive this information.

What the centre could do better

Nothing identified at this inspection.

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 at the time of inspection were suitable. This is important to ensure that all licensed activities were being conducted in a suitable environment that was fit for purpose. The variation to the centre's licensed premises documented that the centre's new and current premises are suitable.

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 laboratories conducting tests that impact on the quality and safety of gametes and/or embryos are suitable.

The centre is compliant with HFEA requirements to processes 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 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; Directions 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; Directions 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 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; Directions 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 broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre does not currently have any satellite or transport IVF agreements.

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

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical

processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports 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

Quality management system (QMS) (Guidance note 23)
The centre has not established quality indicators (QIs) or objectives for submission of data to the HFEA. The centre has also not audited submission of data to the HFEA against compliance with the approved protocols, the regulatory requirements and QIs in the last two years (SLC T35 and T36 see recommendation 1).

Third party agreements (Guidance note 24)
Three third party agreements (TPAs) were reviewed in the course of the inspection. It was noted that in all three instances the agreements did not include:

- the identification of person(s) responsible for managing arrangements between the centre and the third party
- provision setting out how often the agreement will be reviewed and by whom
- summary of the responsibilities of the third party and agreed procedures with regard to each party's respective responsibilities,
- any specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety, and
- in the case of one TPA with a testing laboratory, description of how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.

(SLC T114 and T116 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 (PREP number T/1044/7).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships. The PR considers that there are sufficient suitably qualified and experienced staff available to conduct the current work of the centre. Assurance has been provided by the PR that an increase in activity afforded by the potential for greater capacity at the new centre will be managed in accordance with resources.

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'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);
Embryo testing and sex selection (Guidance note 10)
The centre does not undertake embryo testing.

What the centre could do better

2. The experience of patients

Patient feedback

What the centre does well

The Inspectors did not have an opportunity to speak to any patients during this inspection. Three patients have however provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with one 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 limited 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.

The PR provided assurance that once the centre has moved to their new premises, they will be conducting regular patient surveys to gather feedback about the care and service provided at the new centre.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF& E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements, any benefits in kind are made in accordance with Direction 0001. This is important to ensure that:

- care is taken when selecting egg sharer's 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 and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Nothing identified at this inspection.

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

What the centre does well

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

Legal Parenthood (Guidance note 6)
The partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born in order to become the legal parent. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. On this inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that actions had been taken in response to the audit findings.

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
The centre's procedures for taking consent to disclosure to researchers are broadly 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

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
In order to determine the accuracy of the information provided to the HFEA register, a sample of patient and partner consent to disclosure records held by the centre was compared to the consent decision recorded by the centre on the HFEA register.

In one of 16 patient / partner records reviewed the consent decision recorded on the HFEA register did not accurately represent the consent decision recorded in the primary record held by the centre. In two further instances a consent decision was recorded on the HFEA register but the original consent forms were not in the patient / partner record at the centre (Chair's Letter CH(10)05, guidance supplementary to Chair's Letter CH(10)05 and Direction 0007 see recommendation 3).

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.
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 ; Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements. A sample audit of treatment data conducted on inspection by the HFEA register team showed that all IVF treatments had bee reported to the HFEA with the time specified by Direction 0005.

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

Obligations and reporting requirements (Guidance note 32 ; Direction 0005)
In order to determine the timeliness of reported treatment information to the HFEA, on inspection, a sample audit of treatment records held at the centre were compared with information provided to the HFEA register, of the sample, 8% (1/12) of the donor insemination treatments conducted had been reported outside the time required by Direction 0005.

In four records reviewed, the cause of infertility submitted by the centre to the HFEA register was different from that recorded in the patient / partner registration forms held at by the centre (SLC T9(e) and T41and Direction 0005, see recommendation 4).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2012, recommendations for improvement were made in relation to two 'other' areas of non-compliance.

The PR provided information and evidence that one of the recommendations was fully implemented within the prescribed timescale.

The following recommendation has now been implemented but was not completed within the required timescales:

- The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification and take corrective action where appropriate. Action could include the introduction of a check step to confirm that critical work areas are cleared in between egg collection cases.

On-going monitoring of centre success rates

The centre received three HFEA risk based alerts relating to multiple pregnancy rates in February and August 2014 and March 2015. During discussions at the time of the inspection, the PR provided assurance that he will continue to keep the centre's multiple pregnancy rates under review and has initiated a further revision of the centre's multiple birth minimisation strategy. In consideration that the PR gave a commitment to implement changes to the multiple births minimisation strategy then a further recommendation is not considered proportionate at this time. The efficacy of any further revision to the strategy will be monitored closely by the centre's inspector.

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
None			

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
1. Quality Management system The centre has not established QIs for submission of data to the HFEA. The centre has not audited submission of data to the HFEA against compliance with the approved protocols, the regulatory requirements and QIs in the last two years. Two non-compliances noted in this report relate to this area of practice. SLC T33(b) and T36.	The PR should ensure that QIs are established for the submission of data to the HFEA and they should be provided to the centre's inspector by 22 April 2015. The PR should ensure that the submission of data to the HFEA is audited against compliance with the centre's own QI's and regulatory requirements by 22 July 2015 and a copy of the audit summary should be provided to the centre's inspector by 22 August 2015.	QI's have now been generated for data submission in line with HFEA requirements, see attached. The centre has performed an audit of data submission to the HFEA in line with HFEA data submission requirements. (performed 5/1/15, report attached). Moderate levels of compliance were noted in some areas and root cause analysis has been performed to investigate this. Re-audit scheduled for 1/7/15. Report to be sent to HFEA by 22/8/15.	The Executive acknowledges the PR's response and actions with regard to this recommendation. The PR has provided a copy of the quality indicators and an audit of the submission of data to the HFEA and detail of corrective actions implemented. The audit scheduled for submission to the HFEA in August 2015 is awaited. Further action is required.
2. Third party agreements Three third party agreements (TPAs) were reviewed in the	The PR should ensure that all third-party agreements are reviewed to ensure compliance	Quality Manager to begin the process of reviewing all 3rd Party agreements. Summary report to	The Executive acknowledges the PR's response and actions

course of the inspection. It was noted that in all three instances the agreements did not include: • the identification of person(s) responsible for managing arrangement between the centre and the third party • provision setting out how often the agreement will be reviewed and by whom • summary of the responsibilities of the third party and agreed procedures with regard to each party's respective responsibilities, • any specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety, and • in the case of one TPA with a testing laboratory, description of how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct	with standard licence condition requirements. A summary report of the findings of the review including a list of all third party agreements included in the review planned corrective actions and the timescale for their implementation should be provided to the centre's Inspector by 22 July 2015.	be sent to the HFEA by the Quality Manager by22/7/15	with regard to this recommendation. The summary report scheduled for submission to the HFEA in July 2015 is awaited. Further action is required.

sample SLC T114 and T116			
3. Disclosure of information, held on the HFEA Register, for use in research A discrepancy was found between one of 16 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. In two further instances a disclosure consent form on the patient file was not observed. One of these cases refers to an imported donor in which the Register records that consent to disclosure for contact research has been given. The centre has been provided with the references required for correction. CoP Guidance Note 5, Chair's Letter CH(10)05, Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007	The PR should ensure that that where errors have been identified by the HFEA register team these are corrected by 22 April 2015. The PR should review systems and processes to identify why errors have arisen in the reporting of patient and partner disclosure consent information supplied to the Authority. The PR should provide a summary of the review and of any corrective actions identified as a result and the timescale for their implementation by 22 July 2015. Three months after the implementation of any changes to procedure, the PR should conduct an audit to ensure the efficacy of the changes, and a summary should be provided	53481 has been amended. USCJM3009 - awaiting copy of CD from donor bank. X8588, awaiting notes to arrive from off site facility to investigate the issue. Root cause analysis performed covering all of HFEA data submission issues and summary report attached. Audit of CD submission to be schedulued for September 2015 and results of the audit to be sent to the HFEA by 22/10/15.	The Executive acknowledges the PR's response and actions with regard to this recommendation and the corrections required regarding consent to disclose decisions recorded. The PR should inform the centre's inspector when this is complete. The PR should inform the centre's inspector when this is complete. A clear and comprehensive root cause analysis had been provided which also gives detail of the corrective actions taken. The audit scheduled for submission to the HFEA in October 2015 is awaited.

	to the centre's inspector by 22 October 2015.		Further action is required.
4. Obligations and reporting requirements 8% (1/12) of the donor insemination treatments reviewed had been reported outside the time required by Direction 0005. In four records reviewed, the cause of infertility submitted by the centre to the HFEA register was seen to be different from that recorded in the patient / partner registration forms held at by the centre. SLC T9(e) and T41and Direction 0005	The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Direction 0005. The systems and processes used for licensed treatment data submission should be reviewed to enable the reasons for poor quality submissions to be identified and addressed. The PR should provide detail of this review, actions identified in response to the findings and the timescale for their implementation by 22 April 2015. In consultation with the HFEA register team where discrepancies were noted, the PR should ensure corrections are made and confirm this has been done when responding to this report.	Corrections have now been done. See attached root cause analysis of HFEA data submission.	The Executive acknowledges the PR's response and actions with regard to this recommendation. A clear and comprehensive root cause analysis had been provided which also gives detail of corrective actions taken. No further action is required.

Reponses from the Person Responsible to this inspection report