Executive Licensing Panel - minutes

Centre 0162 (Queens Medical Centre Fertility Unit) Renewal Inspection Report

Monday, 11 April 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Jessica Watkin Anjeli Kara	Head of Business Planning Policy Manager Regulatory Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that this is a treatment (insemination using partner/donor sperm) and storage centre. The panel noted that in relation to activity levels this is a small centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 1995.

1.4. The panel noted that in the 12 months to December 2015, the centre provided 103 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that in 2014, the centre reported 236 cycles of partner insemination with 43 pregnancies. This equated to an 18% clinical pregnancy rate which was consistent with the national average.

1.6. The panel noted that for donor insemination, HFEA-held register data for the year ending 2014, showed the centre's success rates were in line with national averages.

1.7. The panel noted that at the time of the inspection on 27 January 2016, three major and three other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to implementing all of the recommendations.

1.8. The panel noted that some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a Quality Management System (QMS) in place and the PR is encouraged to use it to best effect to monitor and improve the service provided.

1.9. The panel noted that the inspectorate recommended the renewal of the centre's treatment (insemination using partner/donor sperm) 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.

2. Decision

2.1. 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.

2.2. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge her duty under section 17 of the HFE Act 1990 (as amended).

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

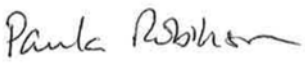
2.4. The panel noted that two of the recommendations from the earlier interim inspection had not been fully implemented and therefore had been repeated in this renewal inspection report. However, the panel also noted that the centre had lost its Quality Manager in 2014 and this may have been a contributory factor to these recommendations not being implemented. The panel noted that the centre has now appointed a new Quality Manager, and encouraged the PR to work with the Quality Manager to ensure that the recommendations were now addressed.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner/donor sperm) 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.

3. Chair's signature

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

Signature



Name

Paula Robinson

Date

20 April 2016

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: 27 January 2016

Purpose of inspection: Renewal of a licence to carry out Treatment (Insemination using partner/donor sperm) 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: Susan Jolliffe (lead), Andrew Glew.

Date of Executive Licensing Panel: 11 April 2016

Centre name	Queens Medical Centre Fertility Unit
Centre number	0162
Licence number	L/0162/14/b
Centre address	Fertility Clinic (NHS), B Floor, East Block, Queens Medical Centre, Derby Road, Nottingham, NG7 2UH, UK
Person Responsible	Dr Shilpa Deb
Licence Holder	Dr Marion Macpherson
Date licence issued	1 July 2012
Licence expiry date	30 June 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Queens Medical Centre Fertility Unit has held a Treatment (insemination using partner / donor sperm) and storage licence with the HFEA since 1995. The centre is situated within, but separate from Nottingham University Hospitals Trust.

The centre has no satellite or transport arrangements.

This current licence has been varied in March 2014 to reflect a change of Person Responsible (PR).

The centre provided 103 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to December 2015. In relation to activity levels this is a small centre.

Pregnancy outcomes[1]

In 2014, the centre reported 236 cycles of partner insemination with 43 pregnancies. This equates to an 18% clinical pregnancy rate which is consistent with the national average.

For DI, HFEA held register data for the year ending 2014 show the centre's success rates are in line with national averages.

[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 $p \leq 0.002$.

Summary for licensing decision:

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

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

The PR has provided a commitment to implement the following recommendations:

Major areas of non compliance:

- The PR should ensure that witnessing checks are performed and recorded at the time the relevant clinical or laboratory procedure takes place.
- The PR should review the quality management system (QMS) to ensure that standard operating procedures (SOPs), audits and quality indicators (QIs) are in place for all activities authorised by the centre's licence and other activities carried out in the course of providing treatment services.
- The PR should ensure that validation of all critical equipment in use is documented and that cleaning of critical equipment is recorded accordingly. The PR is asked to provide more information about the concerns regarding the dewars.

'Other' areas that require improvement:

- The PR should ensure that consideration is given to the patient's travel and infection exposure history, prior to processing gametes for treatment or storage.
- The PR should ensure that the premises are suitable for the access, egress and storage of dewars.
- The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have three major of areas of concern.

Some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a QMS in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspection team recommends the renewal of the centre's Treatment (Insemination using partner/donor sperm) 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 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 the patient or donor to whom they relate are partially compliant with HFEA requirements.

What the centre could do better

Witnessing (Guidance note 18)
An audit of records on inspection showed that the date and time of all donor sperm processing witness points were not recorded in the donor records (recommendation 1, SLC T71 and CoP 18.8).

An audit of the records showed that the centre does not always witness placing donor gametes into storage (recommendation 1, SLC T71 and CoP 18.4(h)).

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.

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. 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 from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
Prior to the use and/or storage of donor gametes, the centre does not consider the need for additional testing that may be required depending on the donor's history and the characteristics of the gametes donated eg, RhD, Malaria, T.cruzi (recommendation 4, SLC T52(h)).

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 broadly suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The centre is compliant with HFEA requirements to process gametes 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, 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 does not conduct surgical procedures and is therefore not subject to these requirements.

Multiple births (Guidance note 7; General Direction 0003)
The centre provides insemination with partner and donor sperm only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births.

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 in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements. This is important to ensure that all gametes 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;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes (Guidance note15)
The centre has not received distributed gametes from other centres in the time since the last inspection and therefore this area of practice was not covered on this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre has not imported or exported gametes in the time since the last inspection; therefore this was not covered at this inspection.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements, with the

exception noted in recommendation 2.
These requirements are important to ensure that the centre has the ability -

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any satellite or transport arrangements in place; therefore this area of practice is not applicable to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and 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 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

Safety and suitability of premises and facilities (Guidance note 25)
The centre's liquid nitrogen tank weighing a third of a ton is moved twice a week by centre staff, from the loading bay on the ground floor level to the cryostore on B floor (two floors above ground level, and along a corridor used by the public).

Reports from the delivery company and risk assessments undertaken by the consultant

reproductive scientist and operational manager at the centre stated the distance exceeds the recommendations of the British Compressed Gas Association for the movement of heavy pressurised vessels. Alternative accommodation for storage of the dewars at ground level has been identified, and a move is anticipated in the near future. The PR is aware that the centre will need to submit a variation to premises application to the HFEA prior to this move. In the meantime staff continue to transport the gas cautiously mitigating risk where possible (recommendation 5, SLC T2, T17 and Health Technical Memorandum.02-01: Medical gas pipeline systems Part B: Operational management).

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place but this has not been used effectively to evaluate and continually improve the quality and effectiveness of the service provided in accordance with the conditions of this licence and the guidance on good practice as set out in the HFEA's CoP. The centre has not established QIs for, or audited, the following activities within the last two years; traceability, witnessing, storage of gametes (recommendation 2, SLC T35 and T36).

The centre does not have documented SOPs covering the following areas; traceability, witnessing, storage of gametes (recommendation 2, SLC T33b).

Equipment and materials (Guidance note 26)
The centre does not keep records of regular cleaning and disinfection of critical equipment (recommendation 3, SLC T26).

The centre employs a process of continual monitoring of critical equipment, with complete service records for the hood, dewars and storage tanks and temperature recordings for the fridge, and consider this is sufficient valuation. However, there is no initial formal validation document for any equipment and no system in place to ensure that new, repaired or recommissioned equipment is tested and validated before use (recommendation 3, SLC T24 and T25).

The centre has two ageing dewars used for sperm storage that staff at the centre have concerns about, sufficient to escalate these issues onto the Trust Risk Register. The Trust has agreed to fund two new dewars and identify a more suitable storage location.

In the meantime; the PR has assured the inspection team that increased physical monitoring of the ageing tanks will be implemented as a short term measure until a new location is identified, where the new tanks can be sited (recommendation 3, SLC T17).

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/1262/81).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

What the centre could do better
Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account 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
The centre does not create embryos or perform embryo testing and therefore this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

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

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)

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

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)

The centre does not undertake egg and sperm sharing arrangements and therefore this area of practice is not applicable to this inspection.

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

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

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

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent; Legal Parenthood 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)
When a couple to be treated with donated gametes are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided evidence that their audit was comprehensive and that their current procedures for obtaining consent to parenthood are robust.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of patient notes, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required. The centre's procedures are compliant with legal parenthood consent requirements.

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 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
Two discrepancies were found between 21 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. Therefore the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent (recommendation 6, CH(10)05 and Gen Dir 0005 5).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre does not create embryos therefore this area of practice is not applicable to this inspection.

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 broadly 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.

Storage of gametes and embryos (Guidance note 17)
The centre's procedure for storing gametes is compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers. The storage of gametes 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.

What the centre could do better

Screening of patients (Guidance note 17)
Prior to the processing of patient gametes, intended for use in treatment or storage, the centre does not consider the need for additional testing that may be required depending on the patient's travel and exposure history eg, RhD, Malaria, CMV,and T.cruzi (recommendation 4, (SLC T50(d)).

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 does not use embryos for training staff therefore this area of practice is not applicable to this inspection.

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 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 centre provided an annual return for IUI treatments undertaken in 2014 within the required timeframe (General Direction 0005).

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better
Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

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

The PR provided evidence that some of these recommendations were fully implemented.

The following recommendations have not been implemented:

The centre has not established QIs or quality objectives relevant to following procedure: Traceability (see recommendation 2).

The centre has not audited some of the procedures against compliance with the approved protocols, the regulatory requirements and QIs in the last two years (see recommendation 2).

No time of witnessing is recorded. In addition, records of witnessing steps are not retained in the patient's records. (see recommendation 1).

On-going monitoring of centre success rates

In the last year, the centre did not receive any performance alerts related to their treatment outcomes for donor insemination.

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, General Direction 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. Witnessing The centre does not record the date and time that witnessing takes place in the donor's record. SLC T71 and CoP 18.8. **This was a non-compliance at the last inspection.** The centre does not always witness placing donor gametes into storage. SLC T71 and CoP 18.4(h)).	The PR should ensure that witnessing checks are appropriately performed and recorded at the time the relevant clinical or laboratory procedure takes place. The PR should conduct a full review of the centre's witnessing procedures (for patients and donors, including why the changes required following the last inspection were not implemented, and provide a summary report by 27 April 2016. Within three months of implementing changes, the centre should carry out an audit of witnessing to ensure	Witnessing checks are now appropriately performed and recorded at the time the lab procedure takes place. The following forms have been updated accordingly and are now in use: 'and.form.08' (Storage Report), 'and form.10' (Removal checklist), 'and.form.11' (Donor transport), 'and.form.16' (Donor freeze report), 'and.form.36' (Transfer frozen IN). The following SOPs have also been updated and are in use: 'and.sop.12' (Sperm Preparation), 'and.sop.17' (In-out dewar movement),	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that a summary report of the findings of the review will be submitted by 27 July 2016. Further action is required.

	that the proposed corrective actions have been effective in ensuring compliance. A copy of the audit report should be supplied to the centre's inspector by 27 July 2016.	'fert.sop14' (Witnessing) A full review has been conducted into the centre's witnessing procedures. Dated witnessing has been in place for many years and without incident. However, following the last interim inspection in 2014 'and.form.17' (IUI Sperm Preparation) was improved to included witnessing checks recording the time of the relevant procedure. This action was approved by the HFEA inspection team at the time. An audit of witnessing process will take place within three months of implementing the current changes to ensure that the proposed corrective actions have been effective in ensuring compliance.	
2. Quality management system (QMS) There is no SOP to direct the following procedures; • witnessing • traceability • storage of gametes.	The PR should review the barriers to learning in this area, which has been a non-compliance in the last two reports; a copy of the review and action plan should be provided by 27 April 2016.	Following the interim 2014 HFEA inspection, the witnessing SOP was updated. All witness points were dated, but not all time-points were included. This is now in place for all procedures and will be audited within 3 months.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that a summary report of the findings

SLC T 33 (b). The centre has not established QIs and has not audited the following areas; • witnessing • traceability • storage of gametes. SLC T35 and T36. **These were identified as areas for improvement at the time of the last two inspections.**	The PR should ensure the development of documented SOPs for these procedures. Copies of the SOPs should be provided to the centre's inspector by 27 April 2016. The PR should ensure the establishment of QIs and audits for all activities. Documentation demonstrating the establishment of the QIs and copies of the outstanding audits should be provided to the centre's inspector by 27 July 2016.	There are SOPs to direct witnessing, traceability and storage of gametes (e.g. 'fert.sop.14' Witnessing, 'and.sop.12 'Sperm preparation, 'fert.sop.12' Management of materials, 'and.sop.15' Cryopreservation & storage). These have been in place for many year. However, as requested these SOPs will be reviewed and forwarded to the HFEA. Barriers to learning have been reviewed in the last 12 months, and were primarily due to loss of our Quality Manager in 2014. We now have a new Quality Manager. The Quality Indicators that are already in place will be reviewed and added to accordingly. These will then be audited to demonstrate compliance. Non-conformities are continuously monitored to ensure ongoing compliance in these areas.	of the review will be submitted by 27 July 2016. Further action is required.
3. Equipment and materials		Whilst cleaning and	Assurance has been received

(Guidance note 26) The centre does not keep records of regular cleaning and disinfection of critical equipment and the premises. SLC T26.	The PR should ensure that the cleaning and disinfection of all critical equipment and premises is recorded accordingly. Confirmation from the PR should be forwarded to the centre's inspector by 27 April 2016.	disinfection of all critical equipment already takes place, this has not been adequately recorded. New forms are now in place to reflect this and the SOP ('and.sop.21' Good lab practice) has been updated to ensure robust records are kept. This area will be audited within the next 3 months.	that a record of cleaning and disinfection is now in place, and an audit will be provided by 27 July 2016. Further action is required.
Validation of the hood, dewars storage tanks and fridge has not been documented. There is no system in place to ensure that new, repaired or recommissioned equipment is tested and validated before initial use. SLC T24.	The PR should ensure that validation of all critical equipment is documented; and should develop a process for testing and revalidation of any new or repaired equipment. The PR should provide a list of all critical equipment including the date of validation or the planned date by which validation is expected to be completed (27 July 2016 at the latest).	The validation policy has been updated to include process validation and validation of equipment. Validation records have been improved for all critical equipment. The existing SOP for testing and revalidating new or repaired equipment ('and.sop.24' Equipment) will be reviewed. We have divided our existing equipment list to highlight all critical equipment. This includes details on the dates of validation.	The PR has updated the validation policy; and is reminded that a list of all critical equipment including the date, or planned date of validation is required by 27 July 2016. Further action is required.
The centre has two ageing dewars used for sperm storage; the centre has	The PR should escalate her concerns about both the ageing dewars and lack of	The current sperm storage capacity situation is under review by the Directorate	It is expected that relocation will be fast tracked to ensure the move takes place by

escalated their concerns about the reliability and need for replacement onto the Trust risk register, the Trust has agreed to fund two new dewars. These have not been purchased. SLC T17	capacity for sperm storage to ensure that these are addressed in a safe and timely manner.	Management Team. A long term solution has been proposed, for which details will be provided in due course. Short-term mitigation includes the use of increased physical monitoring at weekends. To ease capacity issues, further small dewars will be purchased and introduced to the cryostore by summer 2016 unless relocation can be fast-tracked.	October 2016 or sooner if the increased physical monitoring identifies any concerns that may compromise the storage of gametes. The PR should provide the centre's inspector with an update on progress with meeting this recommendation by 27 May 2016 or earlier if there is any material change.

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
4. **Screening of patients and donors** Prior to the use and/or storage of patients / donor gametes, the centre does not consider the need for additional testing that may be required. SLC T52(h) T50(d)	The PR should review the screening SOP for patients and donors, to include consideration of exposure and travel history. A copy of the revised SOP and action plan to inform staff of changes should be sent to the centre inspector by 27 April 2016.	The relevant SOPs ('and.sop.19' Donors, 'fert.sop.11' Screening) have been updated to include consideration of exposure and travel history.	The executive acknowledges the PR's response. The action plan and revised SOP's are required by 27 April 2016. Further action required.
5. Safety and suitability of premises and facilities The centre's liquid nitrogen tank is stored at a distance that exceeds the recommendations of the British Compressed Gas Association for the movement of heavy pressurised vessels.	The PR should ensure that the liquid nitrogen is stored in suitable premises, with safe access and egress. The centre has identified a more suitable location and plan to move in the near future. An action plan and timeline for works should be	The NUH Trust is aware of the situation and a process for moving to new suitable premises is underway. An action plan and timeline will be provided. In the interim, vigilance has been heightened to negate risk to the present storage vessels (as described above).	The executive acknowledges the PR's response. The PR should provide the centre's inspector with a copy of the action plan and timeline by 27 May 2016 or provide an update earlier if there is any material change to the proposed plan.

SLC T2 and SLC T17. Health Technical Memorandum.02-01: Medical gas pipeline systems Part B: Operational management	made known in the response to this report, and an update given when the relocation has taken place. It is expected that the move will have taken place by 27 July 2016.		Further action is required.
6. Disclosure of information, held on the HFEA Register, for use in research In two of the 21 patient consent to disclosure forms reviewed, the patients had not consented to contact research but the data submitted by the centre to the HFEA indicated that the patients had. General Direction 0007. It is noted that contact research would not be initiated by the HFEA and it would be expected that if the clinic was asked to initiate contact research, consent forms would be reviewed before patients are contacted.	The PR has corrected the two submissions that were identified as incorrect. The PR should review the procedures for checking and submitting consent to disclosure decisions to the HFEA to ensure that consent to disclosure decisions made by patients are accurately reported to the HFEA. A summary of the findings and any corrective actions identified should be submitted to the centre's inspector by 27 July 2016. It is also recommended that the clinic undertakes a further sample audit of the records of 100 patients who have been reported as having given	The procedures for checking and submitting consent to disclosure decisions to the HFEA ('fert.sop.17' Consenting Procedures) has been reviewed and updated. Following communication with the HFEA Information Compliance and Audit Manager on 14.03.16, 100 patients were identified who have been reported as having given consent to non-contact disclosure of their information to researcher on the HFEA register. Previous audits have shown a high rate of compliance. However, a fresh audit is now underway to confirm whether the observation made at the inspection was a one-off.	The executive acknowledges the PR's response and her commitment to implementing this recommendation. A copy of the review summary and audit findings is required by 27 July 2016. Further action is required.

	consent to non-contact disclosure of their information to researchers on the HFEA register. The purpose of this audit is to identify whether the observation made on inspection represents a systemic failure of the recording of this consent in cases where there is a risk that information could be disclosed if the consent is not reported accurately. The PR should advise the HFEA of the findings of this audit by 27 July 2016. On completion of the audit it is recommended that the PR should liaise with the HFEA's register team to consider the most proportionate way to implement corrective actions to mitigate any risks identified by the audit.		

Reponses from the Person Responsible to this inspection report
Actions are underway as requested to address all issues raised at the inspection to ensure time-lines are met.