Executive Licensing Panel - minutes

Centre 0119 (Birmingham Women's Hospital) Renewal Inspection Report

Friday, 9 September 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) David Moysen Jessica Watkin	Head of Business Planning Head of IT 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 the Assisted Conception Unit at Birmingham Women's Hospital provides a full range of fertility services including embryo testing. In relation to activity levels this is a large centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 1992.

1.4. The panel noted that in the 12 months to 31 March 2016, the centre provided 1208 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period January 2015 to December 2015 showed the centre's success rates were in line with national averages with the following exception:

- success rates following ICSI treatment involving fresh embryos in patients aged 38 years and over were above average

1.6. The panel noted that in 2015, the centre reported 60 cycles of partner insemination with five pregnancies. This represents a clinical pregnancy rate of 8%, which is in line with the national average.

1.7. Between January 2015 and December 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 14%. This represented performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the renewal inspection on 21 and 22 June 2016, six major and four other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has started to address the non-compliances and has committed to fully implementing all of the outstanding recommendations within the prescribed timescales. The panel noted that the inspectorate will continue to monitor the centre's performance and implementation of these recommendations.

1.9. The panel noted that significant improvement is required in order for the centre to demonstrate the suitability of their practices.

1.10. The panel noted that the PR is encouraged to continue to use the Quality Management System to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

1.11. The panel noted that the inspectorate recommends the renewal of the centre's treatment (including embryo testing) 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 noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. 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 his duty under section 17 of the HFE Act 1990 (as amended).

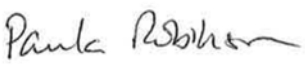
2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

2.5. The panel noted that there are recommendations with timescales for implementation set shortly after this Executive Licensing Panel meeting and agreed that the inspectorate should provide the panel with an update, at the next available meeting, confirming whether the outstanding recommendations were 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

16 September 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: 21 and 22 June 2016

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) 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: Shanaz Pasha (lead), Susan Jolliffe, Lesley Brown, Sharon Fensome-Rimmer (observer), Neil McComb and Joel McChesney

Date of Executive Licensing Panel: 9 September 2016

Centre name	Assisted Conception Unit, Birmingham Women's Hospital
Centre number	0119
Licence number	L/0119/16/b
Centre address	Assisted Conception Unit, Birmingham Women's Hospital, Edgbaston, Birmingham, B15 2TG.
Person Responsible	Dr Sue Avery
Licence Holder	Mr Neil Savage
Date licence issued	1 December 2012
Licence expiry date	30 November 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Assisted Conception Unit at Birmingham Women's Hospital has been licensed by the HFEA since 1992 and currently holds a Treatment (including embryo testing) and Storage licence. The centre provides a full range of fertility services.

The centre provided 1208 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2016. In relation to activity levels this is a large centre.

Other licensed activities at the centre included storage of gametes and embryos and embryo testing.

The centre's current licence was varied in June 2015 to reflect a change of Licence Holder.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period January 2015 to December 2015 show the centre's success rates are in line with national averages with the following exception:

- success rates following ICSI treatment involving fresh embryos in patients aged 38 years and over are above average

In 2015, the centre reported 60 cycles of partner insemination with 5 pregnancies. This represents a clinical pregnancy rate of 8%, which is in line with the national average.

Multiple births[2]

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

Between January 2015 and December 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

[2]The HFEA use a conversion factor of 1.27 to convert the 10% 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 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 six major and four 'other' areas of non-compliance.

Since the inspection visit the PR has fully implemented the following recommendation:

Major area of non compliance:

- The PR should ensure that donors are screened in accordance with standard licence conditions and professional body guidelines.

The PR has given a commitment to fully implement the remaining recommendations in the prescribed timescales:

Major areas of non compliance:

- The PR should ensure that all imports and exports of gametes and embryos comply with the requirements of General Direction 0006.
- The PR should ensure it is possible to identify and locate gametes and embryos, and critical equipment used to process them, during any step from procurement to use in treatment or disposal.
- The PR should ensure that the centre's quality management system (QMS), notably the audits performed and the standard operating procedures (SOPs), is reviewed so that it can effectively guide, monitor and improve the services provided.
- The PR should ensure that all critical equipment is validated and that only CE marked medical devices are used.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframes required by General Direction 0005.

'Other' areas that require improvement:

- The PR should commission a risk assessment of the ventilation in the cryostore.
- The PR should ensure that practices are suitable for the prevention and control of infection.
- The PR should ensure that procedures for the management of medicines are compliant with all relevant regulatory requirements and guidance.

- The PR should ensure that the centre has a third party agreement with the main hospital theatres.

Recommendation to the Executive Licensing Panel

The centre has more than five major of areas of concern but no critical areas of concern.

The inspection team notes that the centre's success rates are consistent with the national average and their multiple clinical pregnancy / live birth rates meet or are below the target.

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS in place. The PR is encouraged to continue to use the QMS to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance and the implementation of the report's recommendations.

The inspection team recommends the renewal of the centre's Treatment (including embryo testing) 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 partially compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are 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 ensure the donor conceived will be able to receive all required information.

What the centre could do better
Egg donors are not systematically screened for viral and infectious diseases within the timeframe specified by the Authority. The centre's SOP for egg donation describes the screening to be undertaken but does not refer to the appropriate timeframe (SLC T53b; see recommendation 1).

Suitable premises and suitable practices

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

What the centre does well

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

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

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 (Guidance note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management (Guidance note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Prescription of intralipid 'off label'
The centre does not prescribe intralipid therefore this area of practice was not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

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

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

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

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

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

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

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

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite links.

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

The centre is partially compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports some 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)
During the inspection the low level oxygen alarm in the cryostore sounded frequently. The cryostore has basic ventilation and extraction cannot be boosted when the alarm sounds (SLC T2; see recommendation 7).

The centre's SOP describing the actions to be taken if the low level oxygen alarm is triggered does not include actions to take if the alarm does not stop (SLC T33b; see recommendation 4).

Infection control
The laboratories appeared clean and well maintained, however records of laboratory and equipment cleaning are not documented (SLC T26; see recommendation 8).

On inspection, four sharps bins were filled beyond the indicated full mark on the container. When notified of this by the inspection team, the PR ensured these containers were replaced immediately (SLC T2; see recommendation 8).

Medicines management
Examination of six sets of patient records highlighted that the time of administration of a controlled drug was not recorded in two patient records. The centre's SOP states that the time of administration of a controlled drug should be recorded. A review of the controlled drugs register identified that on a number of occasions the time of administration of a controlled drug was not recorded in the controlled drugs register (The Misuse of Drugs Regulations, 2001, schedule 19; see recommendation 9).

Imports and exports (Guidance note 16; General Direction 0006)
The centre was unable to provide evidence that recent imports of gametes and embryos met the requirements of General Direction 0006 (see recommendation 2).

Traceability (Guidance note 19)
The centre does not label egg collection tubes. This was a non-compliance in the previous report. It is acknowledged that centre staff ensure that the critical work areas are clean and clear before preparing for the next patient, however the centre could not provide assurance that the completion of this procedure is documented and/or confirmed as completed by a second member of staff (SLC T101; see recommendation 3).

The centre does not record critical equipment (e.g. centrifuges, flow hoods and tube warmers) used during the processing of gametes and embryos (SLC T99; see recommendation 3).

Quality management system (QMS) (Guidance note 23)
The centre has not conducted audits of donor screening and use of embryos in training and the centre's audits generally do not include vertical process audits of practice against SOPs (SLC T36; see recommendation 4).

The centre's audit reports (e.g. infection control) do not consistently record the corrective and preventative actions identified in response to audit findings and the dates of their implementation (SLC T36; see recommendation 4).

The centre does not have written SOPs for a number of activities (e.g. import and export of gametes and embryos; withdrawal of consent; use of embryos in training; equipment failure) and some SOPs need updating (e.g. responding to the low oxygen monitor alarm), as noted elsewhere in this report (SLC T33; see recommendation 4).

Third party agreements (Guidance note 24)
Occasionally patients with complex medical histories undergo egg collection in the main hospital operating theatres rather than in the centre's procedure room. The centre does not have a written third party agreement with the main hospital theatres (SLC T111; see recommendation 10).

Equipment and materials (Guidance note 26)
The dry shipper used to transport gametes and embryos has not been validated (SLC T24; see recommendation 5.

The following medical devices used by the centre are not CE marked: 14ml round bottom tubes; 5ml tubes; 50x90ml petri dishes; 15ml conical tubes; serological pipettes (SLC T30; see recommendation 6).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological sciences 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.

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.

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

Safeguarding (Guidance note 25)
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's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

2. The experience of patients

Patient feedback

What the centre does well

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

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)

The 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's procedures for egg and/or sperm sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg and/or sperm providers donating for benefits in kind;
- egg and/or sperm providers are fully assessed and medically suitable; and

- the benefit offered is the most suitable for the egg or sperm 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; Chair's Letter 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)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the

partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

On this inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and a prior offer of counselling was seen to be in place prior to treatment in all cases.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted because:

- 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 partially compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better The centre does not maintain a log of embryos used in training and therefore cannot audit the procedures by which embryos are used in training or provide documented evidence that all embryos used in training have been used in appropriate training activities (SLC T36, SLC T93; see recommendation 4).

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The centre's procedures for submitting information about licensed activities to the Authority are partially compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register. Two percent of the IVF treatments reviewed at inspection had not been reported to the HFEA and 58% (75/127) of the IVF and 100% (65/65) of the DI treatments reviewed had been reported outside the period required by General Direction 0005 (General Direction 0005, SLC T41; see recommendation 6).

It is acknowledged that the centre reported having a number of IT issues that affected data submission to the HFEA which were out of the centre's control.

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 one 'other' area of non-compliance.

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

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 identified			

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
Donor Screening 1. Egg donors are not systematically screened for viral and infectious diseases within the timeframe specified by the Authority, nor does the SOP for egg donation describe the correct timeframe. SLC T53b	The PR should ensure egg donors are screened within the timeframe specified by the Authority. The SOP for screening of egg donors should be revised to include the timeframe. This recommendation should be immediately implemented and the centre's inspector advised of the actions taken when the PR responds to this report. Copies of the updated SOP and confirmation of relevant staff training should be provided to the centre's Inspector by 22 September 2016.	Revised SOP was submitted to the Centre's Inspector on 30.06.2016, together with a revised egg donor pathway. SOP was revised in collaboration with the Senior Nurses who are responsible for egg donor screening and all have been familiarised/trained according to the revised SOP.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The PR has provided a copy of the updated SOP as requested. No further action is required.

Imports and Exports 2. The centre has imported gametes and embryos in the last 12 months but was unable to provide documented evidence that these imports met the requirements of General Direction 0006. General Direction 0006	The PR should ensure that all imports and exports of gametes and embryos comply with the requirements of General Direction 0006. The PR should conduct a review against the requirements of General Direction 0006 of all gametes and embryos imported or exported by the centre since the last inspection. A summary of the report should be sent to the centre's inspector by 22 September 2016.	Review will be completed and submtted by 22nd of September	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. Further action is required
Traceability 3. The centre does not label egg collection tubes. This was a non-compliance in the previous inspection report. SLC T101 The centre does not record critical equipment used in the processing of gametes and embryos (e.g. centrifuges, flow hoods and tube warmers).	The PR should immediately ensure that egg collection tubes are labelled or that the practice of not labelling the tubes is risk assessed; any risk control measures deemed necessary must be implemented. The action taken to implement this recommendation should be included in the PRs response to this inspection report. If performed, the risk assessment should also be included.	A risk assessment was carried out following the previous inspection and procedures and paperwork agreed, such that no further action was required. The inspection identified that there was no record of worksurfaces being cleared. Laboratory forms including sign off had been agreed following the last inspection, but recent mailmerge set up to populate the lab records reverted to a previous version of the lab form. The version with the sign off and witness	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The PR has provided a copy of the updated laboratory forms. Further action is required.

SLC T99	The PR should review procedures to ensure that all critical equipment used in the processing of gametes and embryos is fully traceable. The action taken to implement this recommendation should be included in the PRs response to this inspection report. The PR should conduct an audit three months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 22 December 2016.	box for clearing the bench has now been reinstated, and a further copy submitted to our centre's current inspector. Paperwork for recording which equipment was used for each case was submitted to the Centre's inspector for approval on 27/06/2016 Audit findings will be submitted by 22 December 2016	
QMS 4. The centre's audit programme needs to be reviewed because: i. the centre has not conducted audits of donor screening and use of embryos in training; ii. the centre's audits generally do not include vertical process audits of practice against SOPs;	The PR should review the centre's audit programme to ensure that it is compliant in the range of audits performed, the methodology used and the documentation of corrective and preventative actions and their implementation. The PR should provide the centre's inspector with a copy of the review and an action	A review of the audit issues raised has been submitted with this response.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The PR has provided copies the SOPs requested. Further action is required.

iii. The centre's audit reports (e.g. infection control) do not consistently record the corrective and preventative actions identified in response to audit findings and the dates of their implementation. SLC T36. The centre does not have written SOPs for a number of activities (e.g. import and export of gametes and embryos; withdrawal of consent; use of embryos in training; equipment failure) and some SOPs need updating (e.g. responding to the low oxygen monitor alarm). SLC T33b.	plan for the implementation of this recommendation by 22 September 2016. The PR should provide copies of the audits and SOPs identified in this report as non compliant by 22 September 2016	SOP for import was sent to the Centre's inspector on 30/06/2016 Withdrawal of consent is covered by a number of relevant SOPs - there is specific SOP for withdrawal of consent for storage, and for withdrawal of consent by donors. Withdrawal of consent to treatment is covered by a general SOP and others specific to treatment groups - this have been suplied to the Centre's inspector alongside this response. The SOPs for the use of gametes and embryos in training and for dealing with equipment failure have been submitted alongside this response. SOP covering responding to the low-oxygen monitor was submitted to the Centre's inspector on 27/06/2016	

Equipment and Materials 5. The dry shipper has not been validated. SLC T24 The following medical devices used by the centre are not CE marked: 14ml round bottom tubes, 5ml tubes, 50x90ml petri dishes, 15ml conical tubes, serological pipettes. This is despite HFEA guidance provided in 2013 on expectations with respect to the use of CE marked medical devices SLC T30.	The PR should ensure that all critical equipment is validated. The PR should conduct a review of the validation status of all critical equipment. A summary report of the review should be provided to the centre's inspector by 22 September 2016. The PR should conduct a review of all medical devices in use at the centre to identify where products are not CE marked and take action to source alternatives. The PR should provide the centre's inspector with a copy of the review by 22 September 2016, including a list of all medical devices indicating their CE mark status and, where they are not CE marked, the proposed actions to source alternatives with timescales for implementation. All corrective actions should be implemented by 22 December 2016.	The Dry Shipper has been validated.The outcome of the validation review will be submitted by September 22nd. The review will be submitted by 22nd September	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. Further action is required.
Obligations and reporting requirements. 6. The HFEA register audit team found evidence of	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframes required by	The SOP for completion of Data forms has been revised to ensure that the forms are passed to the data entry clerks	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation.

problems with the timeliness and accuracy of the centre's submission of data to the Register, as discussed in the body of the report. SLC T41; General Direction 0005.	General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for delayed submissions. This recommendation should be implemented by the 22 September 2016 and the inspector informed of the results of the review and actions taken. The PR should conduct an audit three months after implementing any corrective actions, to confirm their effectiveness. A summary of the audit should be provided to the centre's inspector by 22 December 2016.	immediately the form has been triggered (ie. Intention to treat, immediately the cycle has been initiated, and treatment for on the day of embryo transfer/cycle completion). A copy of the revised SOP has been submitted to the Centre's Inspector The Audit results will be submitted by 22 December.	The PR has provided a copy of the updated SOP as requested. Further action is required.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Premises and facilities 7. The cryostore has basic ventilation but is unable to boost the extraction when the low level oxygen alarm sounds. SLC T17	The PR should commission a risk assessment of the ventilation in the cryostore. A summary report should be sent to the centre's inspector by 22 September 2016.	A ventilation engineer has conducted a survey of the ventilation in the cryoroom and is preparing a report. A risk assessment is being carried out in collaboration with the Trust Risk Manager. Outcomes of both witll be submitted by September 22nd.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. Further action is required.
Infection Control 8. The centre does not document the cleaning and deep cleaning of the laboratory and equipment. It was noted on the day of the inspection that four sharps bins were filled beyond the fill line. SLC T2	The PR should ensure that records of the cleaning of the laboratory and equipment are maintained. The PR should provide confirmation that this recommendation has been implemented when responding to the report. The PR should ensure that staffs are informed that they should only fill sharps bins to the fill line. The next infection control audit should include a review this matter to ensure that staff are acting on this information so that sharps bins	Cleaning records are now being maintained. All staff have been informed of the need to change sharps bins when or before they rerach the fill line. Laminated notices have been put in place where appropriate. The infection control audit will be provided by December 22.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. Further action is required.

	are filled only to the appropriate fill level. A report of this audit should be provided to the centre's inspector by 22 December 2016.		
Medicines Management 9. A review of the centre's controlled drugs register and patient records identified that the time of administration of controlled drugs is not routinely recorded. Misuse of Drugs Regulations, 2001, schedule 19	The PR should ensure that the time of administration of controlled drugs is recorded in the patient records and the controlled drugs register. The PR should conduct a review of administration of controlled drugs record keeping. A summary of the review should be sent to the centre's inspector by 22 September 2016. Within three months of having implemented any corrective actions, the centre should audit controlled drug administration practices to ensure compliance. A summary report of the audit should be sent to the centre's inspector by 22 December 2016.	A review of the recording of controlled drugs is being conducted and the outcome will be submitted by September 22. The Audit outcome will be submitted by December 22.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. Further action is required.

Third party agreements 10. The centre does not have a written third party agreement with the main hospital theatres in which egg collections are occasionally performed. SLC T111	The PR should ensure that an appropriate third party agreement is developed and formalised with the main hospital operating theatres. The centre's inspector should be provided with a copy of the formalised third party agreement by 22 September 2016	The agreement is currently awaiting signature and will be submitted by September 22nd.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. Further action is required.

Reponses from the Person Responsible to this inspection report