Executive Licensing Panel - minutes

Centre 0055 (The James Cook University Hospital)

Renewal Inspection Report

Tuesday, 15 January 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Niamh Marren Helen Crutcher	Director of Strategy and Corporate Affairs Regulatory Policy Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Hannah Carpenter Richard Sydee	Senior Governance Manager Policy Officer Director of Finance and Resources

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:

- 9th 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 James Cook University Hospital has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

1.3. The panel noted that papers for the centre's renewal were originally submitted for consideration at the 11 December 2018 Executive Licensing Panel (ELP) meeting. However, at this time, the centre had not paid the required licence renewal fee. As the current licence expires on 31 January 2019, and the next meeting would not occur until 15 January 2019, the panel issued Special Directions to the centre in order to permit the continuation of the centre's treatment and storage licence from 1 February 2019 to 30 April 2019, allowing time for the required fee to be submitted, for the renewal to be considered by the ELP and for the administration process of the renewal.

1.4. The panel noted that confirmation had been received on 17 December 2018 that the centre had paid the renewal fee.

1.5. The panel noted that the current licence was renewed for a period of three years, rather than the standard four, without additional conditions in October 2015, due to the number and type of non-compliances identified at the renewal inspection. These non-compliances were all fully implemented within the prescribed timescale.

1.6. The panel noted that, in the 12 months to 30 September 2018, the centre provided 365 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a small sized centre.

1.7. The panel noted that, between 1 July 2017 and 30 June 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.8. The panel noted that, for IVF and ICSI, HFEA held register data for the period 1 July 2017 to 30 June 2018, show the centre's success rates are in line with national averages.

1.9. The panel noted that, in 2018, the centre reported 9 cycles of partner insemination with 2 pregnancies, which is in line with the national average.

1.10. An inspection was carried out at the centre on the 23 and 24 October 2018.

1.11. The panel noted that at the time of the inspection, there were five major areas of non-compliance concerning screening of donors and patients, safety and suitability of premises and facilities, the Quality Management System (QMS), equipment and materials and staff. Since the inspection visit, the Person Responsible (PR) has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

1.12. The panel noted that the inspection team recommended the renewal of the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribes 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).

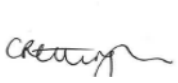
2.4. The panel recognised the PR's engagement in addressing the non-compliances identified in the renewal report. Noting the positive patient experience feedback, gained during the inspection, the panel encouraged the PR to engage patients to provide comments through the 'Choose a Fertility Clinic' mechanism, available on the HFEA website.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations in the 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

Clare Ettinghausen

Date

18 January 2019

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: 23 and 24 October 2018

Purpose of inspection: Renewal of a licence to carry out treatment and storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Dr Vicki Lamb, Dr Louise Winstone, Julie Katsaros, Polly Todd

Date of Executive Licensing Panel: 15 January 2019

Centre name	The James Cook University Hospital
Centre number	0055
Licence number	L/0055/17/b
Centre address	Department of Reproductive Medicine, Marton Road, Middlesbrough, Cleveland, TS4 3BW
Person Responsible	Mr Fayez Mustafa
Licence Holder	Mrs Mohar Goswami
Date licence issued	1 February 2016
Licence expiry date	31 January 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The James Cook University Hospital has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 365 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2018. In relation to activity levels this is a small centre.

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

The current licence was renewed for a period of three years, rather than the standard four, without additional conditions in October 2015, due to the number and type of non-compliances identified at the renewal inspection. These non-compliances were all fully implemented within the prescribed timescales. The current licence has been varied to reflect the following change:
On 1 December 2016, the Licensing Officer approved a change to recognise Mrs Mohar Goswami as the new Licence Holder.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 July 2017 – 30 June 2018 show the centre's success rates are in line with national averages.

In 2017, the centre reported nine cycles of partner insemination with two pregnancies, which is in line with the national average.

Multiple births[2]

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

Between 1 July 2017 and 30 June 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 15%. 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 his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable, with the exceptions noted in the report;
- the centre's practices are suitable, with the exceptions noted in the report;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's 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 five major areas of non-compliance which have resulted in the following recommendations.

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

Major areas of non-compliance:

- The PR should ensure that donor and patient screening and assessment practices are compliant with standard licence conditions and professional body requirements.
- The PR should ensure that there are suitable arrangements in place to ensure no unauthorised access to areas that contain patient identifying material or drugs.
- The PR should ensure that standard operating procedures (SOPs) are in place and audits performed for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence.
- The PR should ensure that all critical equipment is subject to monitoring and that corrective actions are documented.
- The PR should ensure that all staff are assessed as competent to undertake their roles.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

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

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

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

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

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are 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)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor

and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

What the centre could do better

Screening of donors (Guidance note 11)
One egg donation record was reviewed. The donor had not been screened for chlamydia and gonorrhoea prior to donating. The PR was aware that this screening had not been performed and had therefore ensured that the donor had received antibiotics to treat any potential infection. He provided evidence that treatment with antibiotics is considered to be a suitable clinical option instead of screening. The donor had also not been assessed for risk of Ebola infection (standard licence condition (SLC) T52, 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 partially 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 so that patients and staff are in safe surroundings that prevent harm.

The laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)

The centre's 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 UKAS, the national accreditation body for the UK, or another accreditation body recognised as 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 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 compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were 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 note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if 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 compliant with HFEA requirements.

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

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS 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 transport or satellite centres therefore this area was not inspected.

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

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

Process validation (Guidance note 15)

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
Access to the centre's premises is not restricted during the working day, and areas containing patient identifying material and drugs were not consistently secured when unattended, thereby enabling unauthorised access to these areas (SLC T17, see recommendation 2).

Quality management system (QMS) (Guidance note 23)
The quality manager has only been in post for a few months, and during discussions she acknowledged that there was further work to be done on the QMS to bring it up to the required standard. There were no SOPs for provision of information to patients, welfare of the child assessments, egg donor recruitment or reporting adverse incidents to the HFEA. Issues were not identified with any of these practices, except egg donor recruitment (SLC T33b, see recommendation 3).
Audits of welfare of the child assessments and egg donor recruitment had not been performed in the last two years (SLC T36, see recommendation 3).

Equipment and materials (Guidance note 26)
A fridge containing medication was not subject to temperature monitoring over the weekend and the inspection team was not assured that if any temperature deviation from the normal ranges were to occur during this period that it would be identified (SLC T24, see recommendation 4).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

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

Staff (Guidance note 2)
The centre is partially 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

Staff (Guidance note 2)
Although the PR was assured that all the staff at the centre were competent to perform their tasks, there was no evidence that the competence assessments for nursing staff were regularly reviewed (SLC T12, see recommendation 5).

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 that 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 does not perform embryo testing, therefore this area was not inspected.

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 inspectors spoke to three patients who provided feedback on their experiences. Feedback was positive, with all of the individuals providing feedback 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 perform egg or sperm sharing, therefore this area was not inspected.

Surrogacy (Guidance note 14)

The centre does not perform surrogacy, therefore this area was not inspected.

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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in 2016, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting

audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA 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 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 at the centre 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 and 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 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

Screening of patients (Guidance note 17)

Patients are not assessed for risk of Ebola infection (SLC T50d, see recommendation 1).

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22) The centre has not used embryos for training since the last inspection, therefore this area was not inspected.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping and 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 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 2016, recommendations for improvement were made in relation to one area of major non-compliance and two 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

Since the last inspection, the centre has not received any alerts relating to success rates.

Areas of practice requiring action

This 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 Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Screening of donors and patients One egg donation record was reviewed. The donor had not been screened for chlamydia and gonorrhoea prior to donating. The PR was aware that this screening had not been performed and had therefore ensured that the donor had received antibiotics to treat any potential infection. He provided evidence that treatment with antibiotics is considered to be a suitable clinical option instead of	The PR should ensure that donor screening and assessment practices are compliant with standard licence conditions and professional body requirements. The PR should audit the treatments carried out with egg donors in the centre since the last inspection in 2016 to assess the number of recipients affected by the use of donors where screening and assessment of infection risk has not been compliant.	Since the inspection our screening and assessment practices have been reviewed. The relevant SOPs and associated documentation have been updated to reflect these changes. With regard to donor screening, appropriate measures have been implemented to ensure donors are screened for chlamydia and gonorrhoea prior to donating. Documentation regarding Ebola (and Zika virus) have been incorporated into assessment processes and assessment	The inspector acknowledges the PR's response and commitment to implementing this recommendation. Summary reports of the audits and reviews of donor screening and assessment and patient assessment should be provided to the inspector by 23 January 2019. Further action required.

screening. The donor had also not been assessed for risk of Ebola infection (SLC T52).	The PR should review donor screening and assessment practices, taking into account the audit of the numbers of donors and recipients affected, and ensure measures are put in place to ensure that appropriate screening is carried out and recipients and donors are contacted about any potential risks identified in the audit. A summary report of the audit and review, including corrective actions taken, should be provided to the centre's inspector by 23 January 2019. In view of the small number of treatments provided with egg donors, the PR should audit the effectiveness of any changes introduced in this area of practice within six months. A copy of the audit should be provided to the centre's inspector by 23 July 2019.	documentation has been updated. An audit will be carried out on screening and assessment and a summary provided to the inspector by 23 January 2019.	

Patients are not assessed for risk of Ebola infection (SLC T50d).	The PR should ensure that patient assessment practices are compliant with standard licence conditions. The PR should review patient assessment practices and ensure measures are put in place to ensure that appropriate assessment and screening is carried out. A summary report of the audit and review, including corrective actions taken, should be provided to the centre's inspector by 23 January 2019. The PR should audit the effectiveness of any changes introduced in this area of practice within three months. A copy of the audit should be provided to the centre's inspector by 23 April 2019.		
2. Safety and suitability of premises and facilities Access to the centre's premises is not restricted during the working day, and areas containing	The PR should ensure that there are suitable arrangements in place to ensure no unauthorised access to areas that contain	Since the inspection a full review of the access points to the department has taken place. A works order has been placed for a swipe pad and bell to be installed at the front	The inspector is pleased to hear that work has already started to implement this recommendation and the inspector looks forward to receiving confirmation that all

patient identifying material and drugs were not consistently secured when unattended, thereby enabling unauthorised access to these areas (SLC T17).	patient identifying material or drugs. The PR should review the current arrangements for access. A summary report of this review, including corrective actions taken, should be provided to the centre's inspector when responding to this report. It is expected that actions taken to ensure there is no unauthorised access will be in place by 23 February 2019.	entrance to the department so that patients and visitors need to be received by a member of staff before entering the department. In the meantime, arrangements have been made for staff to be 'on duty' to receive patients. Locks have been procured to ensure medications are kept in locked cupboards/cold storage. Confirmation and a further update about security will be provided to the inspector by 23 February 2019	actions have been completed by 23 February 2019. Further action required.
3. QMS There were no SOPs for provision of information to patients, welfare of the child assessments, egg donor recruitment or reporting adverse incidents to the HFEA. Issues were not identified with any of these practices, except egg donor recruitment (SLC T33b).	The PR should ensure that SOPs are in place for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence. The PR should provide evidence that SOPs have been created for these activities by 23 January 2019.	Since the inspection, a full action plan and review of the QMS, audit and SOPs has been carried out with a deadline of 31 December 2018 for completion. Specific SOPs and audits mentioned during the inspection and in the report have been completed as follows: Welfare of the Child Donor Screening Equipment and Materials Egg Donor Recruitment	The inspector acknowledges the PR's response and commitment to implementing this recommendation. The inspector will request copies of the SOPs for provision of information to patients, welfare of the child assessments, egg donor recruitment or reporting adverse incidents to the HFEA by 23 January 2019.

Audits of welfare of the child assessments and egg donor recruitment had not been performed in the last two years (SLC 36).	The PR should ensure that activities and processes authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are audited at least every two years. The PR should provide summary reports of the audits performed for these activities by 23 February 2019.	Reporting Adverse Incidents. Summary reports of the audits will be provided to the Inspector by 23 February 2019.	Summary reports of the audits should be provided to the inspector by 23 February 2019. Further action required.
4. Equipment and materials A fridge containing medication was not subject to temperature monitoring over the weekend and the inspection team was not assured that if any temperature deviation from the normal ranges were to occur during this period that it would be identified (SLC T24).	The PR should ensure that all critical equipment is subject to monitoring and that corrective actions are documented. The PR should inform the centre's inspector of actions taken when responding to this report. Within three months of the implementation of corrective actions, the centre should carry out an audit of the temperature monitoring to ensure that the corrective actions implemented have been effective in ensuring compliance. A summary report	Since the inspection a review of critical equipment temperature monitoring has taken place and new equipment procured so that more robust temperature readings are taken over weekends. An audit will be carried out on the temperature control and a summary report of the audit will be provided to the Inspector by 23 April 2019.	The inspector is satisfied that suitable corrective action has been taken. A summary report of the audit should be provided to the inspector by 23 April 2019. Further action required.

	of the findings of the audit should be provided to the centre's inspector by 23 April 2019.		
5. Staff There was no evidence that the competence assessments for nursing staff were regularly reviewed (SLC T12).	The PR should ensure that all staff are assessed as competent to undertake their roles. The PR should provide the centre's inspector with details of nurse competency assessments when they have been completed. It is expected that these will have been completed by 23 February 2019.	Since the inspection, competency documentation has been reviewed and updated. Specifically, there is now a full competency and induction pack in place for nursing staff. Existing staff have undertaken competency review and a competency timetable has been established to ensure regular review of documentation. The nursing competency assessments will be provided to the Inspector by 23 February 2019.	The inspector acknowledges the PR's response and commitment to implementing this recommendation. Details of nurse competency assessments should be provided to the inspector by 23 February 2019. Further action required.

Other areas of practice that requires improvement

Other areas of practice that require improvement are 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.

An ‘other’ area of non-compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Responses from the Person Responsible to this inspection report