Executive Licensing Panel - minutes

Centre 0201 (Edinburgh Assisted Conception Unit)

Renewal Inspection Report

Friday, 17 November 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anna Quinn Helen Crutcher	Director of Strategy and Corporate Affairs Scientific Policy Manager Risk and Business Planning Manager
Members of the Executive	Dee Knoyle Erin Barton	Secretary Policy Manager (Observer)
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 since the last licence renewal.

1.2. The panel noted that Edinburgh Assisted Conception Unit is also known as the Edinburgh Fertility and Reproductive Endocrinology Centre and is located at the Royal Infirmary of Edinburgh. The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing.

1.3. The panel noted that in the 12 months to 31 August 2017, the centre provided 973 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.4. The panel noted that for the year ending 31 May 2017, HFEA-held register data showed the centre's success rates, in terms of clinical pregnancy rates, were in line with national averages.

1.5. The panel noted that for the year 2016, the centre reported nine cycles of partner insemination with four pregnancies. This was consistent with the national average.

1.6. The panel noted that the centre has achieved a reduction in its multiple pregnancy rate. For the year ending 31 May 2017, HFEA-held register data showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 4%. This represents performance that is likely to be statistically lower than the 10% maximum multiple live birth rate target for this period.

1.7. The panel noted that at the time of the renewal inspection on 19 and 20 September 2017, four major and four other areas of non-compliance were identified. In particular, the panel noted the non-compliances relating to consent. The panel also noted that since the inspection three of the major areas of non-compliance have been fully implemented and the Person Responsible (PR) has committed to implementing all of the outstanding recommendations within the prescribed timescales.

1.8. The panel noted that some improvement is required for the centre to reflect suitable practices. The PR is encouraged to continue to use the Quality Management System to best effect to monitor and improve the quality of the service offered to patients.

1.9. 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. The inspectorate also recommends continued monitoring of the centre's performance and implementation of the recommendations.

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel was satisfied that the application contained the supporting information required by General Directions 0008 and the appropriate fee had been submitted.

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

2.4. 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 their duty under section 17 of the HFE Act 1990 (as amended).

2.5. 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.

2.6. The panel urged the PR to address the outstanding non-compliances within the prescribed timescales and endorsed the inspectorate's recommendation to continue to monitor the centre's performance and implementation of the recommendations, in particular those relating to consent to storage of gametes and embryos.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

27 November 2017

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: 19 and 20 September 2017

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: Karen Conyers, Janet Kirkland, Vicki Lamb and Grace Lyndon

Executive Licensing Panel: 17 November 2017

Centre name	Edinburgh Assisted Conception Unit
Centre number	0201
Licence number	L/0201/7/a
Centre address	Edinburgh Fertility & Reproductive Endocrine Centre, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh, Lothian, EH16 4SA, United Kingdom
Person Responsible	Dr K J Thong
Licence Holder	Ms Fiona Mitchell
Date licence issued	01 March 2014
Licence expiry date	28 February 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history

The Edinburgh Assisted Conception Unit is also known as the Edinburgh Fertility and Reproductive Endocrinology Centre and is located at the Royal Infirmary of Edinburgh.

The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing. Other licensed activities of the centre include storage of gametes and embryos. The current licence has not been varied.

The centre provided 973 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2017. In relation to activity levels this is a medium sized centre.

Pregnancy outcomes[1]

HFEA held register data for the year ending 31 May 2017 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2016 the centre reported nine cycles of partner insemination with four pregnancies. This is consistent with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 May 2017 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is likely to be statistically lower than 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, Statutory Licence Conditions (SLC) and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

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

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

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented:

Major areas of non-compliance:

- The PR should ensure that welfare of the child assessment is undertaken for all patients and partners.
- The PR should ensure that the consenting processes are compliant with regulatory requirements.
- The PR should ensure that effective consent to storage is in place for all gametes and embryos that are in storage.

Since the inspection visit the PR has given a commitment to implementing the following recommendations in the prescribed timescales:

Major areas of non-compliance:

- The PR should ensure that all gamete donors are screened in accordance with regulatory requirements and professional guidelines.

'Other' areas that require improvement:

- The PR should ensure that the risks of Ebola infection are considered prior to any donor or patient being treated.
- The PR should ensure that medicines management practices are compliant with the centre's standard operating procedure (SOP).
- The PR should ensure that all areas of practice are audited at least every two years.
- The PR should ensure that all adverse incidents and near misses are reported to the HFEA.

Recommendation to the Executive Licensing Panel

The inspection team commends the centre on achieving a low multiple pregnancy rate and, in so doing, reducing the single biggest risk of infertility treatment. The inspection team also notes that the centre's success rates are consistent with the national average.

Recommendations are however made in response to four major of areas of concern.

Some improvement is required for the centre to reflect suitable practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided.

The inspection team considers that there is sufficient information available to recommend renewal of the centre's licence and has referred to the HFEA Guidelines for Licensing regarding the length of licence. In overall consideration of all information to hand, the inspection team considers that it is appropriate to recommend 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.

The centre's inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required 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)
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. The centre's procedures for screening donors are partially compliant with HFEA requirements.

Payments for donors (Guidance note 13; General Direction 0001)
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. 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.

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)
Egg donors are not screened for syphilis at the time of donation (recommendation 1, SLC T52b and T53b), although they are screened for syphilis as part of the donor recruitment process. The PR assured the inspection team that syphilis testing will be repeated at the time of donation with immediate effect.

The centre does not consider the risks of Ebola virus infection in potential donors prior to donation (recommendation 5, SLC T52h). The PR assured the inspection team that such a risk assessment will be carried out for all potential donors with immediate effect.

The centre's SOP for screening egg donors does not describe the requirement to screen egg donors at the time of donation, or the screening tests required (recommendation 1 SLC T33b). The inspection team noted that although the SOP was not sufficiently detailed, appropriate donor screening had been carried out in practice, with the exceptions noted above.

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 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 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 to be accredited by Clinical Pathology Accreditation (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 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'
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 single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

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 and 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 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 establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. The centre has a QMS that is broadly compliant with HFEA requirements.

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 and satellite arrangements therefore this area of practice is not relevant to this inspection.

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

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

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

Adverse incidents (Guidance note 27)
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. The centre's procedures for reporting adverse incidents are broadly 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.

What the centre could do better

Medicines management (Guidance Note 25)
During an audit of the controlled drugs register, the inspection team noted that the administration and disposal of controlled drugs was not being consistently documented in accordance with the centre's medicines management SOP (recommendation 6, SLC T33b).

Monthly audits of medicines management by the Trust pharmacy department had noted similar findings. However, there was no evidence that these findings had been highlighted as not compliant with the centre's own SOP, or that corrective actions had been identified or implemented (recommendation 6, SLC T36). This was notably different to other audits of practice carried out by the centre.

Quality management system (QMS) (Guidance note 23)
The centre has not audited the following practices within the last two years; the provision of information, donor recruitment, assessment and screening, and confidentiality and privacy (recommendation 7, SLC T36).

Adverse incidents (Guidance note 27)
The centre had not reported one adverse incident relating to a breach of confidentiality to the HFEA (recommendation 8, SLC T118). This was discussed with the relevant staff and it was clear that a thorough review and investigation had been undertaken and consideration given to reporting the adverse incident to the HFEA, as occurs for any adverse incident at the centre. However, the PR and other centre staff considered the incident did not need to be reported; the inspection team considered otherwise.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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)
Staff involved in donor recruitment, assessment and screening could not provide documented evidence of the assessment of their competence in this area of practice (recommendation 1, SLC T15a).

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 partially 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

Welfare of the child (Guidance note 8)
In one of five medical records reviewed on inspection, a welfare of the child assessment had been completed twice for the patient but there was no record of an assessment having been completed for the partner (recommendation 2, SLC T56). The inspection team noted that this couple did not have a successful cycle.

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 and opportunities to discuss the implications of their treatment, and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

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, no patients were available to speak with the inspectors about their experiences at the centre. Eleven patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with seven of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

Centre staff provided their most recent patient satisfaction survey which had been conducted during a two-week period in May 2017. A total of 38 responses had been received. During the same time period, an additional 20 surveys on the accessibility of the centre's patient information video were also received. In all areas reviewed, 77 to 100% of patients rated a variety of aspects of the service as either good or excellent. These findings were discussed during the centre's annual management review meeting and shared with staff.

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 or sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not carry out treatment involving egg or sperm sharing therefore this area of practice is not relevant to this inspection.

Surrogacy (Guidance note 14)
The centre does not carry out treatment involving surrogacy therefore this area of practice is not relevant to this inspection.

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH (11)02)
The centre's procedures for providing information to patients and/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

Legal parenthood
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 partially 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 one couple was affected by legal parenthood consent anomalies. At the previous inspection in September 2015, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. The PR confirmed that this couple had sought a declaration of legal parenthood which has been granted by a court and legal costs have been covered by the centre.

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 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, with the exception noted below in the 'Consent' section.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born as a result of it. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA, so that the HFEA holds an accurate record of patients' consent and only releases patient identifying information to researchers with a patient's consent.

The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

What the centre could do better

Consent (Guidance note 5;6)
During an audit of records, it was noted that some consent forms had been completed prior to the patient's first consultation appointment at the centre. The inspection team was concerned that the patient may not have received all relevant information and an offer of counselling prior to providing their consent (recommendation 3, HF&E Act 1990 (as amended), Schedule 3, 1(a), 1(b)). In one case, an email accompanying the forms was noted to state that the forms 'must' be completed prior to the appointment.

This finding was discussed with the PR who explained that the centre's practice is to send out a general information pack and several forms (such as welfare of the child, consent to disclosure and consent to treatment) to the patients so that they have time to read the documents prior to their consultation. Information regarding treatment options and the implications of each consent are then discussed with patients at their first consultation and an offer of counselling is made. The PR confirmed that if a patient has completed the forms prior to the appointment, the consent would be reviewed during the consultation (after the provision of information and offer of counselling), and the clinician or nurse would check that the patient did not want to revise their consent as a result. The inspection team was assured that this is the case, but considered that patients should not be instructed to complete consent forms prior to their first consultation when all relevant information and an offer of counselling would be discussed.

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 the 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 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. It is important to ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, it is important that the centre only stores gametes and embryos in accordance with the consent of the gamete providers.

The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements.

What the centre could do better

Screening of patients (Guidance note 17)

The centre does not consider the risks of Ebola virus infection in patients prior to treatment (recommendation 5, SLC T50d). The PR assured the inspection team that this risk will be considered in each case with immediate effect.

Storage of gametes and embryos (Guidance note 17)
On the day of the inspection the centre did not have effective consent for the storage of cryopreserved embryos for one couple (recommendation 4, HF&E Act 1990 (as amended) Schedule 3, 8(2)). The inspection team noted that the bring forward system had been used and the centre had contacted the couple prior to the expiry of the consent. However, the couple had not responded and the centre had failed to follow this up.

Use of embryos for training staff (Guidance note 22)

What the centre does well

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

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information about licensed activities to the Authority are compliant with HFEA requirements.

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 September 2015, recommendations for improvement were made in relation to one critical, four major and two 'other' areas of non-compliance or poor practice.

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 in September 2015 the centre has not received any HFEA risk tool alerts related to their success rates.

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

Critical area of non-compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None 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
Screening of donors 1. The centre does not screen egg donors for syphilis at the time of donation. The centre's SOP for screening egg donors does not describe the requirement to screen egg donors at the time of donation, or the screening tests required. Staff involved in donor recruitment, assessment and screening could not provide documented evidence of the assessment of their competence in this area of	The PR should ensure that egg donors are screened in accordance with regulatory requirements and professional guidelines. The PR should provide the centre's inspector with the revised egg donor screening SOP and evidence of staff training regarding the changes in practice, when responding to this report. The PR should ensure that the competence of relevant staff to undertake donor recruitment, assessment and screening, is assessed and documented.	Oocyte donors are seen at a doctor's clinic for assessment and a detail medical history is taken. All screening tests for the donors including syphilis serology are arranged at this appointment. Although the protocol for the Selection and Screening of Oocyte donors [CP-EFR-R-OD&Sel] did not describe the screening tests for oocyte donors, the Centre has a checklist of tests which complies with HFEA requirements [CR-EFR-R-chEdon], see attached.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided all the requested information and evidence of staff training regarding the changes in practice. The executive notes the initial findings of the audit of treatments carried out with egg donors or embryos created with donated eggs, since the last renewal inspection in 2013. The findings of the full

practice. SLCs T52b, T53b, T33b and T15a.	Evidence of this should be provided to the centre's inspector by 20 December 2017. The PR should audit the treatments carried out with egg donors or embryos created with donated eggs, since the last renewal inspection in 2013, to assess the number of recipients affected by the use of non-compliantly screened donors. The PR should assess the risks to the recipients and provide a summary of the findings of the review, including corrective actions with timescales for implementation, to the centre's inspector by 20 December 2017. In view of the small number of treatments provided with egg donors, the PR should audit the effectiveness of changes introduced in this area of practice within six months. A copy of the audit should be provided to the centre's inspector by 20 March 2018.	Syphilis serology is now added to be rechecked at the time of donation (see item 2 on check list). The following protocols were reviewed and updated to reflect the recommendations made by the HFEA with regards to syphilis screening; Oocyte Donation and Selection of donors [CP-EFR-R-OD&Sel], Oocyte Donors: Initial Consultation with Doctor [CP-EFR-R-DrOD] and Oocyte Donation (Nursing) [CP-EFR-R-ODnrs]. The Egg Donation/Recipient Programme Checklist [CF-EFR-R-T-chEdon] was also updated to reflect the additional screening requirements during stimulation. A new nursing competency document will be created to evidence their competency to carry out donor recruitment, assessment and screening. This competency assessment will be conducted every year in line with all other nursing	audit due by 20 December 2017 are awaited. Evidence of the competency assessments due by 20 December 2017, and audit of practice due by 20 March 2018 are awaited. **Further action is required**.

		competencies. As evidence, staff will be assessed a month after signing the appropriate protocol to determine competence. An example will be sent to the HFEA by the 20/12/2017. An audit will be conducted which will look at patients treated with donor eggs and embryos since November 2013. This will assess patients treated using donor eggs where the donor had not been screened for syphilis at time of donation. Initial investigations indicate that over this period, there were 15 oocyte donors and 14 recipients and all had syphilis serology tests carried out at the first clinic appointment and all were negative. One donor did not have any oocytes for donation. Five recipients who conceived from oocyte donation were tested negative for syphilis at their antenatal appointment. These initial investigations indicate that the risk to oocyte recipients is	

		likely to be very low, but a full audit and further investigations will be carried out to confirm this and a report will be provided by the 20.12.17 For embryo donation, the Centre only offers treatment using supernumerary embryos donated by couples for treatment. These embryos have been frozen and syphilis serology was carried out on the donors before donation. There is no risk of syphilis infection in this group so they will be excluded from the audit. An audit of patient files will be carried out to determine if the new screening process has been adhered to and a report will be submitted to the HFEA by the 20.03.2018	
Welfare of the child 2. In one of five medical records reviewed, a welfare of the child assessment had been completed twice for the patient but there was no record of an assessment having been completed for the partner.	The PR should ensure that welfare of the child assessment is undertaken for all patients and partners. The PR should review the case identified and consider whether any actions need to	For the initial finding, as identified at the time of inspection, there are no actions required at this time as there was no conception from the treatment cycle. The couple are not intending to have any further treatment so	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The executive notes the PR's assurances in relation to the

SLC T56.	be taken specifically with regard to this couple. The review should also consider why this error was not identified prior to treatment. A summary of the findings of the review including corrective actions, with timescales for implementation, should be provided to the centre's inspector with the response to this report.	no further action will be taken. The PR has completed a DATIX incident form and reported this to the HFEA. Following this unexpected finding, an audit of 100 sets of case notes was carried out by the Quality Manager to determine if the finding identified by the HFEA was a one off incident or part of a previously unidentified trend (audit report attached). The audit was completed on the 18.10.17 and revealed that the finding identified by the HFEA was unlikely to represent a trend as no similar errors identified. Based on the findings from this audit it is recommended that auditing of this area is carried out every year as outlined in the current audit schedule and no immediate follow up is required.	case identified and the findings of the audit of 100 records. The PR has also provided information as to why this error had not been identified, and the corrective actions to be taken to prevent any recurrence. **No further action is required**.
Consent 3. During an audit of records, it was noted that some consent forms had been completed prior to the	The PR should ensure that the consenting processes are compliant with regulatory requirements.	Consent forms are sent to patients in advance of their appointment at the Centre to allow them the opportunity to	The executive acknowledges the PR's response and his commitment to fully implementing this

patient's first consultation appointment at the centre. The inspection team were concerned that the patient may not have received all relevant information and an offer of counselling prior to providing their consent. HF&E Act 1990 (as amended), Schedule 3, 1(a), 1(b).	The PR should review the centre's processes to minimise risks associated with patients completing consent before attending a consultation. A summary of the findings of the review including corrective actions, with timescales for implementation, should be provided to the centre's inspector with the response to this report.	read and understand the content without the pressure of reading and completing them during the medical consultation. The consents to disclosure (CD), WT/MT and the welfare of the child assessments or relevant consents, depending on treatment, are all sent out in a pack. Patients were previously informed in the New Patient Appointment Letter [CF-EFR-R-L-NPAppt] (new version attached) to complete the consent forms. The process of issuing patients with these consent forms in advance has not changed. However, the aforementioned letter has now been updated to state, "Enclosed with this letter are a number of information sheets and HFEA consent forms. Please fill in the consent forms if you feel comfortable doing so, but DO NOT sign and date the declaration at the back of each form until you have attended the Doctor Screening Appointment. Please bring all consent forms with you to your	recommendation. The PR has provided the findings of the review and actions taken to minimise risks associated with patients completing consent before attending a consultation. The centre will audit effectiveness of the actions implemented. **No further action is required**.

		Appointment where we will be happy to answer any questions prior to you signing the declaration on each of the forms." Given the time pressures surrounding an appointment, it was agreed that patients should still be provided with these documents in advance so that they are familiar with the forms, able to ask questions regarding the content and provide informed consent on the day of appointment. The centre will review the process of obtaining consent after 3 months to determine if the new wording mentioned above is working more effectively.	
Storage of gametes and embryos 4. On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved embryos for one couple.	The PR should ensure that effective consent to storage is in place for all gametes and embryos that are in storage. The PR should develop an action plan to resolve this case	In this case, the embryos of X had been identified on the 25th July 2016 by the bring forward system as expiring within the next year. All the procedures outlined in the final year review protocol had been followed	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided the

HF&E Act 1990 (as amended), Schedule 3, 8(2).	and advise the centre's inspector of this when responding to this report. The PR should aim to resolve this issue by 20 December 2017. The PR should conduct a review to identify why the bring forward system has not been fully effective in ensuring that this case was followed up. A summary of the findings of the review should be provided to the centre's inspector by 20 December 2017. The PR is reminded of guidance issued by the HFEA in CH (03)03 in relation to the timely disposal of cryopreserved material where there is consent to do so, and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	correctly: the patient had been sent letters in July and November 2016 but no reply was received. Attempts were then made to contact the couple by phone in May, June and July 2017 and an attempt at email contact was made at the end of July. A final attempt to phone the couple was carried out on 2nd August 2017. When all avenues had been exhausted and the couple were considered lost to contact, the embryos were scheduled for discard. A "Decision to thaw and allow stored embryos to perish" form was completed and placed in the notes. This form outlines all the attempts made to contact a couple and the form/notes is then reviewed by the HFEA PR (or the Consultant embryologist in his absence) and the Embryologist who has managed the review procedures. Although the embryos had been scheduled for discard and the paperwork prepared, the final sign off for discard had not been carried	findings of the review into this case, the actions taken to resolve the issue, and the further investigations planned. **No further action is required**.

		out and we will need to conduct a more detailed investigation to find out why this final step in the process had not happened in a timely manner and identify corrective action(s) to make this part of the procedure more robust. In this particular case, given that all the processes of the final review had been carried out, the procedure was reviewed by the PR and the agreement to dispose signed off on 25/09/2017. The embryos were subsequently allowed to perish. The embryology spread sheet of material in storage and the database of sperm in storage were then each interrogated and there were no further samples identified in storage without active consent to store.	

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
Screening of patients and donors 5. The centre does not consider the risks of Ebola virus infection in donors or patients prior to donation or treatment. SLCs T50d and T52h. The inspection team accepts that the frequency of Ebola infection is low, hence have graded this as an 'other' non-compliance.	The PR should ensure that the risks of Ebola infection are considered prior to any donor or patient being treated. The PR should review the centre's processes for considering and assessing the risks of infection with Ebola virus based on a patient or donor's travel history. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector with the PR's response to this report. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A	Patients are asked whether they have medical illness before starting treatment as part of the checklist. The medical team ensures that a patient/couple does not have significant illness before commencing treatment. A section has been added to the IVF Doctor's Appointment protocol [CP-EFR-R-DrAppt] focusing on patients who have travelled to an area with an active Ebola outbreak (already covered in donor protocols and treatment forms). An audit will be conducted within 3 months to record the effectiveness of these changes. A report will be submitted to the HFEA by the	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided all the requested information in relation to this area of practice. The audit of practice due by 20 December 2017 is awaited. **Further action is required**.

	summary report of the findings of the audit should be provided to the centre's inspector by 20 December 2017.	20.12.17.	
Medicines management 6. During an audit of the controlled drugs register, the inspection team noted that the administration and disposal of controlled drugs was not being consistently documented in accordance with the centre's medicines management SOP. Monthly audits of medicines management by the Trust pharmacy department had noted similar findings. However, there was no evidence that these findings had been highlighted as not compliant with the centre's own SOP, or that corrective actions had been identified or implemented. SLCs T33b and T36.	The PR should ensure that medicines management practices are compliant with the centre's SOP. The PR should review the centre's processes for the documentation of the supply, administration and disposal of controlled drugs, to ensure that practices are compliant with the centre's SOP, regulatory requirements and professional guidelines. The review should also include the process for auditing medicines management, to ensure that it includes an assessment of compliance with the SOP, and that audit findings are clearly documented and reviewed, and lead to the implementation of appropriate corrective actions. A summary report of the findings of these reviews including corrective actions, with timescales for	During the inspection it was identified that one of the anaesthetists completed the controlled drug book in a manner which is not in keeping with the NHS Lothian policy. The book is completed accurately. However, this particular anaesthetist prefers to write "nil" in the sections relating to discard when the full amount is used. The NHS Lothian Trust protocol for this is to leave the discard section blank if nothing is discarded. After discussion with the Lead Pharmacist in the controlled drug governance team, it was confirmed that the policy was not to fill in the discard box if there was nothing to discard. However, it was advised that it would still be acceptable to fill in the discard box providing it is unambiguous ie. writing Nil or 0.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided the findings of the review in relation to this area of practice. The competency assessments due by 20 March 2018 and audit due by 20 June 2018 are awaited. **Further action is required**.

	implementation, should be provided to the centre's inspector by 20 December 2017. Following the review, the PR should ensure that all relevant staff receive training in the management of medicines, and that competence assessments are undertaken that generally, and in this area of practice, include adherence to the centre's SOPs. Confirmation of this should be provided to the centre's inspector by 20 March 2018. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 20 June 2018.	As the above method for recording the disposal of controlled has been deemed acceptable by the NHS Lothian Controlled Drugs Governance Team, the PR feels that it is not possible to have corrective actions for tis aspect of the HFEA finding. The Protocol for the management of controlled drugs [CP-EFR-R-CtrlDrugProt] within EFREC has been updated to include a section which states that it is acceptable to populate the discard field if there is nothing to discard as long as it is unambiguous ie. writing Nil or 0. The Quality manager has contacted the Pharmacy which issues and audits controlled drugs within the centre. It was agreed that the Controlled Drugs protocol [CP-EFR-R-CtrlDrugProt] has been updated to reflect the agreed responsibilities between EFREC and Pharmacy. - EFREC takes full	

		responsibility for the controlled drugs once accepted into the department. - Pharmacy will conduct a quarterly audit which will be reported to the Senior Charge Nurse and Quality Manager within EFREC. - All findings will be reported via the NHS Lothian DATIX system and assigned to EFREC for investigation - All findings will include the patient initials and infertility number so that they are identifiable by EFREC but no other area. - EFREC will supply details of any corrective actions to Pharmacy regarding any findings they identify.	
QMS 7. The centre has not audited the following practices within the last two years: the provision of information; donor recruitment, assessment and screening; and confidentiality and privacy SLC T36.	The PR should ensure that all areas of practice are audited at least every two years The centre should audit the areas of practice noted in the report and provide a summary report of the findings to the centre's inspector by 20 December 2017.	The audits for the recruitment, assessment and screening of sperm, oocyte and egg donors have been carried out (reports attached). The findings identified within these audits will be addressed within the next 3 months. The audit for the provision of	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided the requested audits of donor recruitment, assessment and screening.

		information and confidentiality and privacy will be carried out and a report submitted prior to the 20.12.17	The remaining audits due by 20 December 2017 are awaited. **Further action is required**.
Adverse incidents 8. The centre had not reported one adverse incident relating to a breach of confidentiality to the HFEA. SLC T118. This non-compliance has been graded as 'other' because the inspection team accepts that incident reporting and investigation at the centre is thorough and generally compliant. In this case staff considered the incident did not need to be reported; the inspection team considered otherwise.	The PR should ensure that all adverse incidents and near misses are reported to the HFEA. The PR should review all adverse incidents in the centre's incident register since the time of the last inspection in 2015 and report retrospectively to the HFEA any which fulfil the criteria of adverse incidents or near misses. This recommendation should be implemented by 20 December 2017.	The PR and Quality Manager will review all incidents reported on DATIX from November 2015 and for potentially unidentified HFEA reportable incidents. A report will be submitted to the HFEA by the 20.12.17.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The review due by 20 December 2017 is awaited. **Further action is required**.

Reponses from the Person Responsible to this inspection report