Executive Licensing Panel - minutes

Centre 0348 (CREATE Fertility, Birmingham)

Renewal Inspection Report

Friday, 16 February 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Helen Crutcher Anna Coundley	Head of Intelligence Risk & Business Planning Manager Information Access & Policy Manager
Members of the Executive	Bernice Ash Dan Howard Nana Gyamfi	Secretary Chief Information Officer (Observing) Licensing Information Officer (Observing)
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that CREATE Fertility, Birmingham is located in Solihull and has held a treatment (including embryo testing) and storage licence with the HFEA since 29 April 2016. The centre provides a full range of fertility services.

1.3. The panel noted that, in the 12 months to October 2017, the centre provided 216 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.4. The panel noted that HFEA held register data between July 2016 and June 2017, showed the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.5. An inspection was carried out at the centre on 21 and 22 November 2017.

1.6. The panel noted that at the time of the inspection on 21 and 22 November 2017, there was one major area of non-compliance regarding medicines management. There were also four 'other' areas of non-compliance concerning witnessing, screening, equipment and materials and record keeping. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations regarding the 'other' non-compliances and has committed, where required, to audit the effectiveness of those actions within the required timescales

1.7. The panel noted that, with regards to the major non-compliance surrounding medicines management, the PR had provided evidence that actions have been taken to implement part of the recommendation. The Executive will liaise with the PR to ensure that the recommendation is fully implemented in line with requirements.

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

1.9. The panel noted that the inspectorate will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.10. The panel noted 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 being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision trees. 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 encouraged the PR to continue use of the QMS, to best effect, to monitor and improve the effectiveness of services provided to patients.

2.4. The panel encouraged the PR to ensure that audits on medicines management, witnessing, screening and record keeping, due for receipt by 22 February 2018, are submitted within the required timescale.

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 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

Caylin Joski-Jethi

Date

21 February 2018

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 21 and 22 November 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: Janet Kirkland MacHattie, Andrew Leonard, Polly Todd, Janet Anderson-Pearce (observer).

Date of Executive Licensing Panel: 16 February 2018

Centre name	CREATE Fertility, Birmingham
Centre number	0348
Licence number	L/0348/1/b
Centre address	Ground Floor, 6270 Bishop's Court, Birmingham Business Park, Solihull, B37 7YB, United Kingdom
Person Responsible	Mr Paul Wilson
Licence Holder	Mr Praful Nargund
Date licence issued	29 April 2016
Licence expiry date	28 April 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

CREATE Fertility, Birmingham is located in Solihull and has held a licence with the HFEA since 29 April 2016. The centre provides a full range of fertility services.

The centre provided 216 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to October 2017. In relation to activity levels this is a small centre.

The Person Responsible (PR) applied for a variation of the centre's licence to add embryo testing to the centre's licensed activities. This application was approved by an ELP on 25 August 2017.

The centre is part of the CREATE group of fertility clinics.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period July 2016 – June 2017 show the centre's success rates are in line with national averages.

The centre reported three cycles of partner insemination in 2016 with no pregnancies, performance which is likely to be in line with the national average.

Multiple births[2]

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

Between July 2016 and June 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This means that the centre's multiple live birth rate is not likely to be statistically different from the 10% 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 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 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 a number of areas of practice that required improvement, including one major and four 'other' areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

'Other' areas that requires improvement:

- the PR should ensure that all laboratory activities undertaken with embryos which have been allocated for training purposes are witnessed;
- the PR should ensure with immediate effect that account is taken of the risks of exposure to/infection with Ebola virus in prospective patients, their partners and donors;
- the PR should ensure that all medical devices used are appropriately CE marked where available;
- the PR should ensure that the staff member who verifies a patient or donor's identity is documented in the patient records.

The PR has provided evidence that actions have been taken to implement part of the following recommendation. The executive will liaise with the PR to ensure that the recommendation is fully implemented in line with requirements.

Major areas of non compliance:

- the PR should ensure medicines management practices are compliant with regulatory requirements and professional body guidance.

Recommendation to the Executive Licensing Panel:

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

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

Some improvement is required in order for the centre to demonstrate the suitability of their practices. 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 (including embryo testing) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better
Witnessing was not documented during vitrification of an embryo during training or at the dispatch to the testing laboratory of trophectoderm samples from embryos biopsied for training purposes. In addition, the removal and thawing of embryos consented to training activities from the 'training' dewar were not witnessed. The witnessing activities not undertaken or recorded were associated with training activities only, and thus could not impact on embryos to be used in treatment (SLC T71; recommendation 2).

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are broadly compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes 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
The centre team does not assess donors for possible exposure to/infection with Ebola virus (SLC T52(h); recommendation 3).

Suitable premises and suitable practices

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 premises of the centre's satellite facilities and 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 to be accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are 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 partially 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 / 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 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 transport agreements and satellite activities are restricted to other centres within the CREATE group. Systems to manage these satellite activities are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA

requirements. The majority 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

Medicines management (Guidance Note 25)

- in one patient record there was a discrepancy between the amount of drug given to the patient and that recorded in the controlled drugs register;
- there was no documented evidence of the witnessing of the carry-over of the amount of controlled drugs in stock from one page to another in the controlled drugs register;
- in four out of five patient records seen on inspection, the unit of measure of the controlled drug administered to the patient had not been recorded.

(DH 2007 'Safer Management of Controlled Drugs: a guide to good practice in secondary care (England) Section 4.7.1.3; Controlled Drugs in Peri-operative Care 2006; recommendation 1).

Equipment and materials (Guidance note 26)
The sample pots used to collect sperm samples are CE marked but not at the appropriate level, i.e. as a class II medical device (SLC T30; 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 biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised

by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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

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

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account 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)
A variation of the centre's licence to add embryo testing to the licensed activities performed at the centre was approved by an ELP on 25 August 2017. At the time of the inspection, the centre team had not completed any treatment cycles involving embryo testing.

The centre's embryo testing procedures were discussed on inspection and this, in addition to the information provided for the variation of the licence, indicated that the centre is compliant with HFEA requirements related to embryo testing. 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 embryo is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information and every opportunity 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

There were no patients available to discuss their experiences at the centre with the inspection team and no patients have provided feedback directly to the HFEA since the centre opened. The lead inspector therefore discussed the centre's process for obtaining feedback from patients and how this is shared with the centre team and any issues addressed. A patient feedback folder was also reviewed in addition to an audit of patient feedback gathered for October 2017.

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 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 counsellor was unavailable at the time of the inspection however she had previously met with a HFEA inspector at another CREATE centre and she is appropriately accredited. The lead inspector reviewed audits of the provision of counselling and this was also discussed with members of the centre's team. It was considered that the centre's procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind;
- egg providers are fully assessed and medically suitable; and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre team had, at the time of the inspection, not performed any treatments involving surrogacy arrangements. Procedures for such treatments were discussed with the centre team and were considered to be compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

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

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

Information

What the centre does well

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

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

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

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements.

This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

The centre commenced activities in April 2016 and was therefore not in operation in February 2014 when the HFEA asked all centres to audit their practices in this area.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed the centre's most recent audit of legal parenthood consents in addition to reviewing three sets of patient records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. The audit was considered to be suitably robust and recorded no non conformances and evidence of appropriately completed parenthood consenting processes were seen to be present in each patient record. The PR also assured the inspection team that the centre's normal practice was to offer counselling to all patients receiving donor gametes and to document this offer of counselling in the patient records. The inspection team therefore considers the process used to obtain consent to legal parenthood to be 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

The centre team does not assess patients and partners for possible exposure to/infection with Ebola virus (SLC T50(d); recommendation 3).

Use of embryos for training staff

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)** The centre's procedures for keeping records are broadly 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.
What the centre could do better The centre does not document in the patient record by whom the patient/donor has been reliably identified (SLC T46(b); recommendation 5).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to one 'other' area of non compliance.

The PR provided information and evidence that this recommendation was fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

In 2017 the centre did not receive any alerts from the HFEA risk based assessment tool to review procedures for the provision of treatments.

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.

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 partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Medicines management The following non compliances were observed: • in one patient record there was a discrepancy between the amount of drug given to the patient and that recorded in the controlled drugs register; • there was no documented evidence of the witnessing of the carry-over of the amount of controlled drugs in stock from one page to another in the controlled drugs register; • in four out of five patient records seen on	The PR should ensure medicines management practices are compliant with regulatory requirements and professional body guidance. The PR should inform the centre's inspector of the actions taken to address these non-compliances when responding to this report. The PR should conduct an audit of the documentation in the controlled drug register three months after the implementation of corrective actions to see that they have	The drug in question is not part of the controlled drugs register, we store it in the controlled drugs cupboard for logistical safety reasons. Therefore I believe the discrepancy found should be noted as 'other areas of practice that requires improvement'. Following the inspection the findings and actions required were discussed with the lead anaesthetist and diseminated to his team. .The CD book used in our clinic is a legitimate scheduled 2 register that has an allocated	The inspector acknowledges the PR's response and actions taken towards compliance with this recommendation. The classification of a major non-compliance is not related solely to the discrepancy between the patient's record and the controlled drug register but encompasses the other observations related to medicines management documented in the inspection report. The inspector does however maintain that a discrepancy in

inspection, the unit of measure of the controlled drug administered to the patient had not been recorded. DH 2007 'Safer Management of Controlled Drugs: a guide to good practice in secondary care (England) Section 4.7.1.3 Controlled Drugs in Peri-operative Care 2006.	been effective. A summary report of this audit should be provided to the centre's inspector by 22 February 2018.	index page at the front of the book specifically for documenting the drug and page numbers.This was correctly updated when the drugs were transferred to another page. There is no indicted area at the bottom of each page for this purpose, therefore staff followed the format as per register instructions. Whilst we acknowlege the Safer management of controlled drugs guide 2007 (section 4.7.1.3) , a decade later new CD books have been introduced with an alternative index to provide a comprehensive audit trail . All CD drugs are checked daily both pre and post theatre . . We have implemented a daily audit tool that is completed by the anaesthetic team to ensure all documentation is completed and is correct. With regard to drug administration and units, the CD book is cross checked against the patient records prior to the anaesthetist and patients leaving the clinic. This	the documentation of the amount of drug administered to a patient could have serious consequences. The inspector acknowledges the PR's explanation regarding the design of the CD register, however good medicines management practice requires that the carry-over of stock is documented **and witnessed** to ensure safe management and custody of controlled drugs. The executive expects that the PR will ensure that procedures are implemented to ensure compliance with guidance. Further action required. Audit to be received by 22 February 2018.

		audit is signed off and dated at the end of the clinical list. A quarterly report will be undertaken to audit the daily checks and confirm ongoing compliance. The 3 monthaudit will be completed & submitted by 22nd February.	

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.

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
2. Witnessing Witnessing was not documented at several points during the use of embryos in training. The witnessing activities not undertaken or recorded could not impact on embryos to be used in patient treatment, hence this non compliance being graded as an 'other' non compliance. The inspection team are concerned because the failure to witnessing during training activities may undermine good and compliant witnessing practice during treatment. SLC T71.	The PR should ensure that all laboratory activities undertaken with embryos allocated for training purposes are witnessed. The PR should ensure that staff are aware of this and that it is documented in the relevant SOP. The PR should, after a period of three months, perform an audit of the witnessing during the use of embryos in training. A summary report of the results of this audit should be provided to the centre's inspector by 22 February 2018.	I can confirm that the embryos used for training were witnessed when they were removed from the treatment cycle and placed in a separate dedicated training dewar which does not contain patient embryos for treatment. In our post inspection feedback meeting the lab team have agreed to perform witness steps with 'training' material as they would with treatment cycles. Witness sheets for 'training' have been implemented. The audit will be completed and summary submitted within the requested time frame.	The inspector acknowledges the PR's response and actions taken towards compliance with this recommendation. Audit to be received by 22 February 2018.
3. Screening The centre team does not assess patients and donors for	The PR should ensure with immediate effect that patients, partners and donors are	Prior to the inspection, Ebola was included in our infection control SOP as one of	The inspector acknowledges the PR's response and actions taken towards compliance with

possible exposure to/infection with Ebola virus. The likelihood of past or present Ebola exposure or infection is considered extremely unlikely, hence this non compliance being graded as 'other'. SLCs T50(d) and T52(h)	assessed for possible past or present exposure to/infection from Ebola virus. The PR should also ensure that patient information is available regarding the risks associated with exposure to this virus. The PR should consider, with expert advice if necessary, if there is any risk to patients/donors, resulting from the failure to perform an assessment of past or present Ebola virus exposure or infection in patients and donors to date. If risk is present, appropriate risk control measures should be implemented. The PR should inform the centre's inspector of the actions taken to address this non-compliance when responding to this report. Three months after the implementation of corrective actions the PR should audit patient and donor screening practice to ensure these actions have been effective. A	the 'Notifications of infectious diseases'. Post Inspection; Our SOP's & Checklists were updated to reflect practice of assessing the possible exposure to Ebola virus. Clin SOP 25 B. Egg Donor assessment and screening. CNCL 5. EGG DONOR CHECKLIST v2. CDB 09. Registration form & Genetic & Medical History Questionnaire. CDB 01. Checklist for sperm donors. CN CL 01 Pre-Treatment Check List. We also updated our Information Poster in the waiting area & consultation rooms. Prior to the inspection we routinely assessed for the zika virus which includes Africa. We have not had any patient/donor that has been to an affected area, therefore I do not believe there is sufficient risk to our patients and donors to require any further control measures. An audit will be submitted	this recommendation. The inspector accepts the PR's assurances that they have not treated any patients or donors who have visited an affected area. Audit to be received by 22 February 2018.

	summary report of this audit should be provided to the centre's inspector by 22 February 2018.	within the required time frame.	
4. Equipment and materials The sample pots used to collect sperm samples are CE marked but not at the appropriate level, i.e. as a class II medical device. SLC T30.	The PR should use medical devices which are CE marked at an appropriate level, if they are available. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this the PR should inform the centre's inspector of the actions he intends to take to address this non-compliance when responding to the inspection report.	We were using CE marked sperm sample pots - as soon as it was brought to our attention they were not at the appropriate level the CREATE group ordered the appropriate level of CE marked products. The current sample pots will be used for semen analysis not in a treatment cycle. Note (I believe there is only 1 product on the market that is appropriately CE marked, so if there is an issue with supply we may have to use our old CE marked pots - which have been validated for use).	The inspector acknowledges the PR's response and actions taken towards compliance with this recommendation. No further action.
5. Record keeping The centre does not document in the patient record by whom the patient/donor has been reliably identified. SLC T46.	The PR should ensure that the staff member who verifies a patient's identity is documented in the patient's records. The PR should inform the centre's inspector of the actions taken to address this	Post Inspection Feedback meeting with our Administration team it was agreed that whoever takes the photo ID will photcopy it then this copy is signed and dated by the member of the team who has authorised that the ID is correct.	The inspector acknowledges the PR's response and actions taken towards compliance with this recommendation. Audit to be received by 22 February 2018.

	non-compliance when responding to this report. Three months after corrective actions have been implemented, the PR should perform a records audit to ensure these actions have been effective. A summary report of this audit should be provided to the centre's inspector by 22 February 2018.	An audit will be undertaken within the required time frame.	

Reponses from the Person Responsible to this inspection report
The PR and staff of Create Fertility Birmingham are grateful to the inspection team for their time and thorough inspection. We always appreciate the guidance from the inspection team and the HFEA in general for their support. We are committed to delivering the most cost-effective and the best care to our patients. Create Fertility takes pride in reducing complications, preventing OHSS and providing less invasive and successful treatment options to women and couples .