Executive Licensing Panel - minutes

Centre 0368 (CREATE Fertility Bristol)

Renewal Inspection Report

Wednesday, 11 March 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Anna Coundley Dan Howard	Director of Finance and Resources Policy Manager Chief Information Officer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

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

1.2. The panel noted that CREATE Fertility Bristol has held a treatment (including embryo testing) and storage licence with the HFEA since 2018 and provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos.

1.3. The panel noted that the centre is part of the CREATE corporate group that includes four other HFEA licensed centres: CREATE Fertility, London Wimbledon (0299); CREATE Fertility, London St Paul's (0339); CREATE Fertility, Birmingham (0348) and CREATE Fertility, Manchester (0359). The group has a cohesive quality management system that is effectively implemented across all centres within the group. Taking this into consideration, this inspection focussed on local compliance with group policies and procedures, as well as the compliance of the centre's premises and facilities.

1.4. The panel noted that, in the 12 months to 31 August 2019, the centre provided 224 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small sized centre.

1.5. The panel noted that, HFEA register data, between June 2018 and May 2019, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages.

1.6. The panel noted that, in 2018, the centre reported 3 cycles of partner inseminations, with no pregnancies, and this is in line with the national average.

1.7. The panel noted that, between June 2018 and May 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles, for all age groups was 0%. This represents performance that is likely to produce a multiple live birth rate significantly lower than the 10% multiple live birth rate target.

1.8. An inspection was carried out at the centre on the 12 and 13 November 2019.

1.9. The panel noted that at the time of the inspection, there were two major areas of non-compliance concerning the safety and suitability of premises and facilities, alongside medicines management. There were also two 'other' non-compliances regarding the quality management system (QMS) and obligations and reporting requirements. Since the inspection visit, the Person Responsible (PR) has implemented all the recommendations made in the report. Audits regarding medicines management and the QMS, are due, for submission to the inspectorate, by 13 May 2020. The audit surrounding obligations and reporting requirements is due for receipt on 13 August 2020.

1.10. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients. The centre is well led and provides a good level of patient support.

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

1.12. The panel noted that, 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.

1.13. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment)

Regulations 2018; these certificates are generally synchronised to the centre's HFEA licence. The inspection team recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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

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

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's ITE import certificate, in line with the centre's licence.

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

18 March 2020

Renewal 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: 12 and 13 November 2019

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: Victoria Brown, Sara Parlett, Polly Todd, Mhairi West and Debbie Jefferies (observer).

Date of Executive Licensing Panel: 11 March 2020

Centre name	CREATE Fertility Bristol
Centre number	0368
Licence number	L/0368/1/a
Centre address	1 Trinity Street, College Green, Bristol, BS1 5TE, United Kingdom
Person Responsible	Professor Geeta Nargund
Licence Holder	Mr Praful Nargund
Date licence issued	4 June 2018
Licence expiry date	3 June 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

CREATE Fertility Bristol has held a Treatment (including embryo testing) and Storage licence with the HFEA since 2018 and provides a full range of fertility services.

The centre provided 224 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2019. In relation to activity levels this is a small centre.

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

The clinic is part of the CREATE corporate group that includes four other HFEA licensed centres: CREATE Fertility, London Wimbledon (0299); CREATE Fertility, London St Paul's (0339); CREATE Fertility, Birmingham (0348) and CREATE Fertility, Manchester (0359). The group has a cohesive quality management system that is effectively implemented across all centres within the group. Taking this into consideration, this inspection has focussed on local compliance with group policies and procedures, as well as the compliance of the centre's premises and facilities.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period June 2018 to May 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported three cycles of partner insemination with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

Between June 2018 and May 2019 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 0%. This represents performance that is likely to be significantly 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 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

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

Major areas of non compliance:

- The PR should ensure compliance with medical gas storage regulations.
- The PR should ensure compliance with controlled drugs (CD) regulatory requirements and best practice guidance.

"Other" areas of non compliance:

- The PR should ensure that the quality management system (QMS) and document review processes are effective.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

The PR has implemented all these recommendations within the required timescales.

Recommendation to the Executive Licensing Panel

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

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

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided 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 centre is well led and provides a good level of patient support.

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.

Centre 0368 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

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

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are 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 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
Nothing identified at this inspection.

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 partially 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 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 UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are 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 centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

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

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

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

maintained in the specified conditions. All containers and packages are validated as fit for purpose.

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

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

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018. No imports have been made from TCS which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

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 broadly 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, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage satellite activities that 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 compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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

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

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

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
On inspection, there were a number of gas cylinders which were not appropriately secured, including empty gas cylinders awaiting collection in a main corridor and full oxygen cylinders stored in the cellar.

DH (2006) Medical Gases; Health Technical Memorandum 02-01 sections 8.29; 8.31; 8.36.

See recommendation 1.

Medicines management (Guidance Note 25)
On inspection, the CD register was reviewed and the following was found:

- In an audit of seven patient records, three records showed there were discrepancies in the recorded amount of CD given to the patient, between the CD register and the patient's notes.
- In another record the amount of CD recorded as being given to the patient in the CD register, was not recorded in the patient's records.
- The carry-over of drugs from one page to another was not signed or recorded in all cases.
- In some entries the time of administration was recorded in the space where the amount of drug given should be recorded.

Department of Health (DH) (2007) 'Safer management of Controlled Drugs: a guide to good practice in secondary care (England) section 4.7.1.3; Misuse of Drugs Regulations 2001 (regulation 19); The Controlled Drugs (Supervision of Management and Use) Regulations 2013.

See recommendation 2.

Quality management system (QMS) (Guidance note 23)
Clinic staff were not aware of updates that had been made to several standard operating procedures (SOPs) used by the entire CREATE group, e.g the SOPs for the transport and distribution of embryos and gametes and for donor screening.

The SOP for surrogacy has not been updated to reflect the new changes to parental order application nor does it reference the recent DH professional practice guidance 'Care in Surrogacy' and 'The Surrogacy Pathway'.

SLC T32 and T33b; DH (2018) 'Care in Surrogacy - Guidance for the care of surrogates and intended parents in surrogate births in England and Wales'; DH (2018) 'The Surrogacy Pathway: Surrogacy and the legal process for intended parents and surrogates in England and Wales'.

See recommendation 3.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
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.

Leadership
The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

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

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

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only three patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

No patients were available to speak to inspectors during this visit however the centre's own most recent patient survey responses were reviewed. Feedback is sought by the clinic at several points in the patient pathway and response rates were reasonable. The feedback received was largely positive. All positive and negative feedback received is discussed at team meetings and acted upon if required.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
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.

Patient support (Guidance note 3)

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

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 sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing 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's procedures for treatment involving surrogacy are compliant with HFEA requirements, with the exception noted in the QMS section of this report and recommendation 3. 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 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.

While the focus on legal parenthood consenting has been in place since February 2014, this centre only opened in 2018. The centre's proposed legal parenthood consenting practices were considered compliant at the time of licensing in 2018.

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

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

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

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre does not currently use embryos for training staff therefore requirements related to the use of embryos in training were not relevant at this inspection.

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

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

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
Between 1 September 2018 and 31 August 2019, 65% (69/106) of the IVF and 50% (3/6) of the DI reported treatments reviewed post inspection, were reported to the HFEA outside the period required by General Direction 0005.

General Direction 0005, SLCT41.

See recommendation 4.

Section 3: Monitoring of the centre's performance

Following the initial inspection in 2018, recommendations for improvement were made in relation to three areas of major non compliance.

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

On-going monitoring of centre success rates

Since the centre was granted its treatment and storage licence in 2018 the centre has not received any alerts from the HFEA with regards to the success rates of treatments and the success rates are currently in line with national averages.

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 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.

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. Safety and suitability of premises and facilities On inspection, there were a number of gas cylinders which were not appropriately secured, including empty gas cylinders awaiting collection in a main corridor and full oxygen cylinders stored in the cellar. DH (2006) Medical Gases; Health Technical Memorandum 02-01 sections 8.29; 8.31; 8.36.	The PR should ensure compliance with medical gas storage regulations. The PR should inform the centre's inspector of the actions taken to implement this recommendation when responding to this report. It is expected that compliant storage arrangements for medical gas cylinders are in place by 13 February 2020.	We have already addressed this by ordering additional gas cylinder cage. It will be fixed within 2 weeks. In the meantime, the gas cylinders are chained to ensure that they are secured. There will be no empty cylinders kept outside of "gas cylinder area" when they are awaiting collection. We will ensure that we are fully compliant. However, I consider the grading for this non-compliance to be disproportationately high.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The executive notes the PR's comments regarding the grading of the non-compliance. This non-compliance was graded as a major because the unsafe storage of gas cylinders poses an indirect risk to the safety of staff, patients and anyone else using the corridor in which the gas cylinders were stored. The PR has provided the

			centre's inspector with evidence that arrangements have been implemented to ensure that medical gas cylinders are stored safely. No further action required
2. Medicines management On inspection a number of issues were noted regarding practices relating to controlled drugs – see main body of report for details. DH (2007) 'Safer management of Controlled Drugs: a guide to good practice in secondary care (England) section 4.7.1.3. Misuse of Drugs Regulations 2001 (regulation 19). The Controlled Drugs (Supervision of Management and Use) Regulations 2013.	The PR should ensure compliance with controlled drugs regulatory requirements and best practice guidance. The PR should review medicines management practice and procedure, including, but not exclusively, the issues identified at this inspection and provide a summary report of this review including corrective actions taken and timeframes for implementation to the centre's inspector by 13 February 2020. Three months after the implementation of corrective actions the PR should audit practice and procedure involving controlled drugs to ensure compliance has been achieved and maintained.	A full audit of all CD's administered since the centre opened has already taken place.The Lead Nurse, PR and Lead Anaesthatist have had a meeting to discuss this report, and have implemented weekly audits to ensure compliance. Our audits since the inspection have shown 100% compliance. We will send the summary report as requested.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The PR has provided a review of medicines management practices and procedures at the centre and has implemented corrective action to address this non-compliance. An audit of practice and procedure involving controlled drugs has been provided to the centre's inspector, in which no issues were identified. No further actions are required beyond completion of the audit of practice to check compliance, due 13 May 2020.

	A summary report of this audit should be provided to the centre's inspector by 13 May 2020. The inspection team note that on the day of inspection, following the findings relating to controlled drugs, the lead anaesthetist spoke to inspectors, acknowledging the findings of the inspection. He committed to completing a full audit of the controlled drugs register and addressing areas of practice that have fallen short of required standards. The anaesthetist and the PR provided assurance to the inspection team that this area of practice will be addressed and improved, going forward.		

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
3. QMS Clinic staff were not aware of updates that had been made to several SOPs used by the entire CREATE group. The SOP for surrogacy has not been updated to reflect the new changes to parental order application nor does it reference the recent DH professional practice guidance 'Care in Surrogacy' and 'The Surrogacy Pathway'. SLC T32 and T33b. DH (2018) 'Care in Surrogacy - Guidance for the care of surrogates and intended parents in surrogate births in England and Wales', and DH (2018) 'The Surrogacy	The PR should ensure that the QMS is used effectively to improve the quality and effectiveness of the services provided. The PR should carry out a review of the QMS including a review of the processes for dissemination of information throughout the CREATE group and processes for incorporating guidance from the HFEA and DH into clinic practice. The PR should provide a summary report of this review, including corrective actions taken to address this non compliance, to the centre's inspector by 13 February 2020.	The QMS is centralised and there is a group Lead and team to manage this effectively. Since the inspection, we have carried out a review of the processes for dissemination of information for all clinics. We will send you a summary report as requested. At the time of our inspection, the Surrogacy SOP was being reviewed by the document owner.This has been completed. A summary report would be sent as requested.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The PR has provided a review of the QMS at the centre and within the CREATE group. No further actions are required beyond completion of the audit of practice to check compliance, due 13 May 2020.

Pathway: Surrogacy and the legal process for intended parents and surrogates in England and Wales'.	Three months after the implementation of corrective actions, the PR should audit practice to ensure that the actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 13 May 2020.		
4. Obligations and reporting requirements Between 1 September 2018 and 31 August 2019, 65% (69/106) of the IVF and 50% (3/6) of the reported DI treatments reviewed post inspection, were reported to the HFEA outside the period required by General Direction 0005. General Direction 0005. SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for delayed submissions. The PR should provide a summary report of this review, including corrective actions taken to address this non compliance, to the centre's inspector by 13 February 2020. The PR should conduct an	The EDI portal was not working until May 2019, and therefore no submissions could be made before then electronically. Since May, the Laboratory has been sending all reports within the required timeframe. A summary of the audit will be sent as requested.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The PR has reviewed the procedures use to submit data, and has identified the reason for the delayed submissions as being that the EDI system was not installed until May 2019. Thus the inspection team accept that the centre may not be wholly responsible for this non compliance. No further actions are required beyond completion of the audit of practice to check compliance, due 13 August 2020.

	audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 13 August 2020.		

Reponses from the Person Responsible to this inspection report
I would like to thank our Lead inspector and her team for their time and guidance. I thank all the inspectors and our staff for their attention and collaboration to make the inspection a constructive and positive experience. My only criticism is that we were never informed by the HFEA about policies for "group" inspections, in particular about upgrading " of any non-compliances within the group . I therefore find it to be unfair to upgrade the non-compliance to the next level when it does not pose any harm to the patient, gametes or embryos. At Create fertility, we take great pride in providing less drug-intensive, safer and cost-effective treatments to women and couples. We have an excellent track record in prevention of OHSS and reducing multiple birth rates whilst achieving good success rates. Our patient satisfaction rates are high and we provide services to both NHS and self-funded patients. We thank our Lead inspector for her ongoing guidance and support.