

# Executive Licensing Panel - minutes

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**Centre 0339 (CREATE Fertility, London St Paul's)**

## **Renewal Inspection Report**

Tuesday, 19 May 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Howard Ryan Dina Halai	Director of Strategy and Corporate Affairs Data Analyst Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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## **Declarations of interest**

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

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## **The panel had before it:**

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

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## 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 five years.
- 1.2. The panel noted that CREATE Fertility, London St Paul's has held a treatment and storage licence with the HFEA since 2014. Its licence was varied in 2015 to include embryo testing. 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, Birmingham (0348); CREATE Fertility, Manchester (0359) and CREATE Fertility, Bristol (0368). The group has a cohesive quality management system (QMS) 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 30 November 2019, the centre provided 1261 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large sized centre.
- 1.5. The panel noted that, HFEA register data, between December 2018 and November 2019, show the centre's success rates, in terms of clinical pregnancy outcomes, are in line with the national averages, with the following exception:
  - Success rates following IVF with fresh embryos in women under 38 years old are higher than average at a statistically significant level.
- 1.6. The panel noted that, in 2019, the centre reported 31 cycles of partner inseminations, with three pregnancies, and this is in line with the national average.
- 1.7. The panel noted that, between December 2018 and November 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is lower than the 10% multiple live birth rate target.
- 1.8. An inspection was carried out at the centre on the 21 and 22 January 2020.
- 1.9. The panel noted that at the time of the inspection, there was one major area of non-compliance concerning legal parenthood. There were also four 'other' non-compliances regarding the safety of premises, medicines management, imports and exports, alongside data submission. Since the inspection visit, the Person Responsible (PR) has implemented the recommendation concerning medicines management. The PR has given a commitment to fully implement the recommendations relating to legal parenthood, safety of premises, imports and exports, alongside data submission, and to provide further information or audits of practice where applicable.
- 1.10. The panel noted that, in March 2020, the PRs of the CREATE group of centres suspended fertility treatments across all their clinics in accordance with HFEA requirements and professional body guidance issued in response to the Covid-19 pandemic. In view of this, the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing all of this report's recommendations, taking into account the period of time for which treatments are suspended as a result of the pandemic.
- 1.11. The panel noted 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.
- 1.12. The panel noted that the centre is well led and provides a good level of patient support.

- 1.13.** The panel noted that the inspector will continue to monitor the centre's performance and the implementation of this report's recommendations, within satisfactory, agreed timescales, due to the earlier suspension of treatments due to the Covid-19 pandemic.
  - 1.14.** 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 agreed timescales.
  - 1.15.** 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.
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## **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 her duty under section 17 of the HFE Act 1990 (as amended).
- 2.4.** The panel particularly recognised that the success rates, following IVF with fresh embryos in women under 38 years old, are higher than average at a statistically significant level. The centre was congratulated on its low multiple live birth rate, also identified at the interim inspection.
- 2.5.** The panel noted that the centre's own patient survey was reviewed; feedback is collected on a monthly basis and many positive comments had been received. Responses from these surveys are reviewed and discussed regularly, with actions taken to address issues identified. However, the panel noted that, in the last 12 months, only 49 patients had provided feedback on their experience of the centre, through the 'Choose a Fertility Clinic' facility available on the HFEA website, giving it an average 4 star rating. The panel felt this level of feedback was low, considering the clinic's size, suggesting that the centre actively encourages patients to provide feedback through the 'Choose a Fertility Clinic' facility on the HFEA website.
- 2.6.** 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 agreed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued
- 2.7.** The panel endorsed the inspectorate's recommendation to renew the centre's ITE import certificate, in line with the centre's licence.

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### **3. Chair's signature**

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

#### **Signature**



#### **Name**

Clare Ettinghausen

#### **Date**

26 May 2020

# 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 January 2020

**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:** Sara Parlett, Sandrine Oakes, Andrew Leonard and Bernadette O'Leary (observing)

**Date of Executive Licensing Panel:** 19 May 2020

<b>Centre name</b>	CREATE Fertility, London St Paul's
<b>Centre number</b>	0339
<b>Licence number</b>	L/0339/2/b
<b>Centre address</b>	150 Cheapside, St Pauls, London, EC2V 6ET
<b>Person Responsible</b>	Professor Geeta Nargund
<b>Licence Holder</b>	Professor Stuart Campbell
<b>Date licence issued</b>	23 July 2016
<b>Licence expiry date</b>	22 July 2020
<b>Additional conditions applied to this licence</b>	None

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## Section 1: Summary report

### Brief description of the centre and its licensing history:

CREATE Fertility, London St Paul's has held a treatment and storage licence with the HFEA since 2014. Its licence was varied in 2015 to include embryo testing.

The centre provided 1261 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2019. In relation to activity levels this is a large centre.

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

A change of name from CREATE, St Paul's London to CREATE Fertility, London St Paul's was approved by the HFEA Licensing Officer in October 2017.

The clinic is part of the CREATE corporate group that includes four other HFEA licensed centres: CREATE Fertility, London Wimbledon (0299); CREATE Fertility, Birmingham (0348); CREATE Fertility, Manchester (0359) and CREATE Fertility, Bristol (0368). The group has a cohesive quality management system (QMS) 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.

A renewal inspection was carried out at centre 0299 on 23 January 2020. The report of that inspection is also being considered by this ELP.

### Pregnancy outcomes<sup>1</sup>

For IVF and ICSI, HFEA held register data for the period December 2018 – November 2019 show the centre's success rates are in line with national averages with the following exception:

- Success rates following IVF with fresh embryos in women under 38 years old are higher than average at a statistically significant level.

In 2019, the centre reported 31 cycles of partner insemination with three pregnancies, which is in line with the national average.

### Multiple births<sup>2</sup>

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

Between December 2018 and November 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is lower than the 10% multiple live birth rate target.

<sup>1</sup>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  $p \leq 0.002$ .

<sup>2</sup>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 one major and four 'other' areas of non compliance.

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

'Other' areas that require improvement:

- The PR should ensure that practices regarding the safe custody and access to controlled drugs (CDs) are compliant with regulatory requirements and best practice guidance.

The PR has given a commitment to fully implement the following recommendations and to provide further information or audits of practice where applicable. In view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider appropriate timescales for the implementation of the recommendations.

Major areas of non compliance:

- The PR should ensure that consent to legal parenthood in surrogacy cases, obtained and documented at the centre, is valid. The PR should also ensure that the marital status of patients having treatment is established and clearly documented.

'Other' areas that require improvement:

- The PR should ensure flammable solvents are stored appropriately in the clinic.
- The PR should ensure that evidence is obtained for the compliance of each donor sample imported with General Direction 0006, notably with respect to donor screening requirements.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframes required by General Direction 0005.

## Recommendation to the Executive Licensing Panel

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

The inspection team notes the success rates are either at, or above, the national average and their multiple clinical pregnancy 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. In March 2020 the PRs of the CREATE group of centres suspended fertility treatments across all their clinics in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this, the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing all of this report's recommendations, taking into account the period of time for which treatments are suspended as a result of the pandemic.

Centre 0339 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, notwithstanding concerns related to the lack of evidence collected by the centre to allow assessment of the compliance with HFEA requirements of screening practices at donor banks used by the centre. This is discussed in the imports and exports section of this report. 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**

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

The 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 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 broadly compliant with guidance.

#### **Prescription of intralipid ‘off label’**

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

#### **Pre-operative assessment and the surgical pathway (Guidance Note 25)**

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

#### **Multiple births (Guidance note 7; General Direction 0003)**

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

#### **Procurement of gametes and embryos (Guidance note 15)**

The centre’s procedures are compliant with HFEA requirements to:

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

#### **Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)**

The centre’s procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

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

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

### **Receipt of gametes and embryos (Guidance note 15)**

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

### **Imports and exports (Guidance note 16; General Direction 0006)**

The centre's procedures for import and export of gametes and embryos are broadly 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. The centre is 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 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)**

Two 2.5 litre bottles of flammable solvent were stored 'on the bench' in the andrology laboratory and were said to be usually stored in the consumables cupboard. This constitutes a significant fire hazard as such flammable solvents are normally stored in a dedicated solvent storage cupboard with fire retardant properties (SLC T17, Recommendation 2).

**Medicines management (Guidance Note 25)**

Access to CDs is not restricted to appropriate, designated and legally authorised personnel in that the Medical Director has access to the CD cupboard spare key and is not a named legally authorised staff member (SLC T2, Sections 3.14, 4.1.1, 4.5.2 and 4.5.4 Department of Health 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007), Recommendation 3).

It was noted that the centre informed the inspection team on day two of the inspection that the Medical Director no longer has access to the spare key.

**Imports and exports (Guidance note 16; General Direction 0006)**

The centre does not fully review screening test results for all donor sperm imported to the centre. HIV, Hepatitis B and Hepatitis C results are reviewed, but not other screening tests or the quarantine period that has been applied. The centre instead relies on the third party agreements with the donor banks to ensure compliant testing in these areas.

The inspection team considers that a more active review of screening test results for each donor sample received should be performed and documented as part of the centre's process for release of imported donor sperm for use in treatment.

General Directions 0006, SLC T52 and T53.

## Recommendation 4.

### ▶ Staff engaged in licensed activity

Person Responsible (PR)

Leadership

Staff

#### What the centre does well

##### Person Responsible (Guidance note 1)

The PR has complied with HFEA requirements.

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

##### 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.
<b>What the centre could do better</b> Nothing identified at this inspection.

<p><b>▶ Embryo testing</b>  Preimplantation genetic screening  Embryo testing and sex selection</p>
<p><b>What the centre does well</b></p> <p><b>Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)</b>  The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• no information derived from tests conducted has been used to select embryos of a particular sex for social reasons</li> <li>• 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.</li> </ul> <p>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.</p>
<p><b>What the centre could do better</b>  Nothing identified at this inspection.</p>

## 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 forty nine patients have provided feedback in the last 12 months, giving an average 4 star rating to the clinic. For a large clinic, this suggests that CaFC patient feedback may not be actively sought for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR has committed to promoting the use of this facility and this will be followed up at the next inspection.

Patient feedback from CaFC included both positive and negative comments. However, no trends/themes were apparent in the negative feedback.

The website also gives the ability for patients to comment on the cost of treatment. Although the majority of patients confirmed that they had paid what they expected, six patients stated 'it was way above the estimate'. This was discussed with centre staff in detail and the inspection team reviewed the centre's approach to providing personalised costed treatment plans and the information presented on the centre's website. The inspection team considered the centre's presentation of costs was clear, transparent and compliant with CoP guidance.

The centre's own most recent patient survey responses were also reviewed. Feedback is collected on a monthly basis and was positive. Survey responses are reviewed and discussed regularly by centre staff and actions are taken to address any issues identified.

During the inspection the inspectors spoke to one patient couple who provided very positive feedback on their experiences.

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 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's procedures for treatment involving surrogacy are partially 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**

## **Surrogacy (Guidance note 14)**

Refer to the legal parenthood section of this report and recommendation 2.

### **Information**

#### **What the centre does well**

##### **Information (Guidance note 4)**

The centre's procedures for providing information to patients and/or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

#### **What the centre could do better**

Nothing identified at this inspection.

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

#### **What the centre does well**

##### **Consent (Guidance note 5;6)**

The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

##### **Legal parenthood (Guidance note 6)**

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

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in November 2018, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Six 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 partially 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****Legal parenthood (Guidance note 6)**

In one record reviewed on inspection the intended parent, in a surrogacy arrangement, had completed a SPP (*your consent to being the legal parent in surrogacy*) consent form. However, the surrogate was married and therefore her husband would have been the legal parent of any child born as a result of the surrogate's treatment and not the intended parent.

In addition, the intended parent had completed a PBR (*your consent to being registered as the legal parent in the event of your death*) consent form. This form is not for use in surrogacy arrangements.

It is noted that this treatment was unfortunately unsuccessful and therefore there was no negative impact on the patients and this represents a 'near miss'.

The inspection team was concerned that this indicates a lack of understanding of legal parenthood in surrogacy cases by centre staff.

Human Fertilisation and Embryology Act 2008 (as amended).

Reviewing five sets of notes where patients had treatment with donor sperm, the following was noted:

- in two patients' records, the question asked to patients was 'are you married to your partner or someone else?'. This requires two separate responses to be given, whereas only one was recorded.
- in two patients' records, the marital status was not recorded by the clinician at initial consultation. On further review, the marital status was recorded on the patients' registration forms as 'married'. However, this is not enough to establish if they are married to the partner with whom they were seeking treatment or someone else.

A woman who is still married or in a civil partnership may wish to be treated with a new partner. If she wishes her new partner to be registered as the legal parent of any child born from this treatment, then evidence to show that her husband/wife/civil partner does not consent to the treatment must be obtained in order for the woman's new partner to be the legal parent of any child born as a result of the treatment (CoP 6.24 and 6.28).

The inspection team acknowledges that the centre modified its practices on the second day of the inspection. However, following the changes, one additional marital status option added to the drop-down menu on the centre's electronic progress note was 'cohabit'. This is not a marital status. Furthermore, the centre is encouraged to consider recording the marital status of patients coming for treatment on their own. The inspection

team was concerned that recording an incorrect marital status may lead staff to guide patients to complete inappropriate consent forms.

Recommendation 1.

### 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'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 compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

##### **Obligations and reporting requirements (Guidance note 32; General Direction 0005)**

The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found some evidence of problems with the timeliness 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)**

Twelve per cent (16/131) of the IVF and 28% (14/50) of the DI treatments in the sample of treatments reviewed post inspection, were not reported to the HFEA within the 10 working day period required.

General Direction 0005, SLC T41. Recommendation 5.

## Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, no recommendations for improvement were made.

### **On-going monitoring of centre success rates**

The centre has not received any success rate risk tool alerts since the last inspection.

## 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 areas 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 areas 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
<p><b>1. Legal parenthood</b> In one record reviewed on inspection, the intended parent, in a surrogacy arrangement, had completed a SPP (<i>your consent to being the legal parent in surrogacy</i>) consent form. However, the surrogate was married and therefore her husband would have been the legal parent of any child born as a result of the surrogate’s treatment.</p> <p>In addition, the intended parent had completed a PBR (<i>your consent to being registered as the legal parent in the event of</i></p>	<p>The PR should ensure that consent to legal parenthood in surrogacy cases, obtained and documented at the centre, is valid.</p> <p>The PR should perform an audit of all cases involving surrogacy in the last two years to provide assurance that the correct consent forms were completed. A summary of these findings should be provided to the centre’s inspector by 1 July 2020.</p> <p>The PR should review the centre’s procedures for</p>	<p>The SOP has been updated to reflect findings. Staff will have further re-training to ensure their knowledge is up to date. A competency assessment will be performed on relevant staff We will re audit all Surrogacy cases within last 2 years. We will send a summary of this audit before 1st July 2020 or as the situation regarding the COVID-19 pandemic allows.</p> <p>We have updated our SOP and all relevant checklists to correctly establish the marital status of all patients, as</p>	<p>The executive acknowledges the PR’s response and commitment to implementing this recommendation.</p> <p>The centre’s inspector will continue to liaise with the PR to consider an appropriate timescale for submitting the reviews and audits of practice and providing staff training, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic.</p> <p><b>Further action is required.</b></p>

<p><i>your death</i>) consent form. This form is not for use in surrogacy arrangements.</p> <p>It is noted that this treatment was unfortunately unsuccessful and therefore there was no negative impact on the patients and this represents a 'near miss'.</p> <p>The inspection team was concerned that this indicates a lack of understanding of legal parenthood in surrogacy cases by centre staff.</p> <p>Human Fertilisation and Embryology Act 2008 (as amended).</p> <p>Reviewing five sets of notes where patients had treatment with donor sperm, it was noted that the marital status of the patients was not always clear.</p> <p>CoP 6.24 and 6.28.</p>	<p>establishing legal parenthood in surrogacy arrangements. A summary of the findings of the review, including corrective actions and the timescales for implementation should be provided to the centre's inspector by 1 July 2020.</p> <p>The PR should ensure that the marital status of patients having treatment is established and clearly documented.</p> <p>The PR should review the centre's procedures for documenting marital status and a summary of the findings of the review, including corrective actions and the timescales for implementation,</p>	<p>advised at the time of inspection. We have implemented a robust system of checking marital status in IDEAS for all patients. We will re - audit within 3-6 months or as the situation regarding the COVID-19 pandemic allows.</p>	
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	<p>should be provided to the centre's inspector by 1 July 2020.</p> <p>The PR should audit the effectiveness of changes introduced in these areas of practice. In view of the current suspension of treatment services due to the COVID-19 pandemic, the centre's inspector will liaise with the PR to consider an appropriate timescale for submitting this audit.</p>		
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▶ **Other areas of practice that require improvement**

'Other' areas of practice that require improvement are any areas of practice which cannot be classified as either a critical or major area of non compliance, but which indicate 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.

<b>Area of practice and reference</b>	<b>Action required and timescale for action</b>	<b>PR response</b>	<b>Executive review</b>
<p><b>2. Safety of premises</b> Two 2.5 litre bottles of flammable solvent were stored 'on the bench' in the andrology laboratory and were said to be usually stored in the consumables cupboard. This constitutes a significant fire hazard as such flammable solvents are normally stored in a dedicated solvent storage cupboard with fire retardant properties.</p> <p>SLC T17.</p>	<p>The PR should ensure flammable solvents are stored appropriately in the clinic.</p> <p>The PR should inform the executive of the steps taken to address this non compliance when responding to this report.</p>	<p>We will acquire a solvent storage cupboard as soon as is practically possible, considering the closure of the clinic due to the COVID-19 pandemic.</p>	<p>The executive acknowledges the PR's response and commitment to implementing this recommendation. We note that this recommendation can't be implemented immediately, due to the current situation.</p> <p><b>Further action required.</b></p>
<p><b>3. Medicines management</b> Access to CDs is not restricted to appropriate, designated and legally authorised personnel in that the Medical Director has access to the CD cupboard spare key and is not a named legally authorised staff</p>	<p>The PR should ensure that practices regarding the safe custody and access to CDs are compliant with regulatory requirements and best practice guidance.</p> <p>It was noted that the centre</p>	<p>The relevant SOP has been updated to reflect that the Medical Director does not have access to the CD cupboard and spare keys.</p>	<p><b>No further action is required.</b></p>

<p>member.</p> <p>SLC T2, Sections 3.14, 4.1.1, 4.5.2 and 4.5.4 Department of Health 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007).</p>	<p>informed the inspection team on day two of the inspection that the Medical Director no longer has access to the spare key.</p>		
<p><b>4. Imports and exports</b> The centre does not fully review screening test results for all donor sperm imported to the centre. HIV, Hepatitis B and Hepatitis C results are reviewed, but not other required screening tests or the quarantine period that has been applied. The centre instead relies on the third party agreements with the donor banks to ensure compliant testing in these areas.</p> <p>The inspection team considers that a more active review of screening tests needs to be performed and documented for each donor sample received, as part of the centre's process for release of imported donor sperm for use in treatment.</p> <p>General Directions 0006, SLC</p>	<p>The PR should ensure that evidence is obtained for the compliance of imports with General Direction 0006, notably with respect to the screening of each sperm donor.</p> <p>The PR should review the centre's procedures and a summary of the findings of the review, including corrective actions and the timescales for implementation, should be provided to the centre's inspector by 1 July 2020.</p> <p>The PR should audit the effectiveness of changes introduced in these areas of practice. In view of the current suspension of treatment services due to the COVID-19 pandemic, the centre's inspector will liaise with the PR</p>	<p>We have reviewed our practice with regards to the import of semen donors and no longer rely on the TPA, but actively check donor screening before samples are imported to the clinic. This comprises requiring donor banks to release the original screening documents instead of relying on a declaration from the bank itself. We have updated our donor checklists to reflect this requirement and ensure screening of all samples is thorough. We will audit our processes within the timescale indicated to determine correct implementation.</p>	<p>The executives notes the immediate actions that have been taken by the PR to address the findings of the inspection team.</p> <p>The centre's inspector will liaise with the PR to consider an appropriate timescale for submitting the audit of practice, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic.</p> <p><b>Further action is required.</b></p>

T52 and T53.	to consider an appropriate timescale for submitting this audit.		
<p><b>5. Data submission</b>  Twelve per cent (16/131) of the IVF and 28% (14/50) of the DI treatments in the sample of treatments reviewed post inspection were not reported to the HFEA within the 10 working day period required.</p> <p>General Direction 0005 and SLC T41.</p>	<p>The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframes required by General Direction 0005.</p> <p>The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for delayed submissions. This recommendation should be implemented by 1 July 2020.</p> <p>The PR should audit the effectiveness of changes introduced in these areas of practice. In view of the current suspension of treatment services due to the COVID-19 pandemic, the centre's inspector will liaise with the PR to consider an appropriate timescale for submitting this audit.</p>	<p>Additional staff members have been trained in submission of data to the authority as from January 2020. We will reaudit the submissions within a suitable timescale in view of the COVID-19 pandemic.</p>	<p>The executives notes the immediate actions that have been taken by the PR to address the findings of the inspection team.</p> <p>The centre's inspector will liaise with the PR to consider an appropriate timescale for submitting the audit of practice, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic.</p> <p><b>Further action is required.</b></p>

### Reponses from the Person Responsible to this inspection report

I would like to thank our Lead inspector and the entire inspection team for their time and guidance during the inspection. We found it to be a supportive and collaborative process. I thank our staff and patients who helped and cooperated during the inspection. We are proud of our Natural and Mild IVF clinical protocols which have helped us to consistently protect patient safety and reduce complications such as OHSS while maintaining excellent success rates. We are also proud of our low multiple pregnancy and birth rates.