# Executive Licensing Panel - minutes

## Centre 0339 (CREATE, St Paul's London) Renewal Inspection Report

Monday, 6 June 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Juliet Tizzard (Chair)<br>David Moysen<br>Jessica Watkin | Director of Strategy & Corporate Affairs<br>Head of IT<br>Policy Manager |
| Members of the Executive | Dee Knoyle<br>Ian Brown | Secretary<br>Head of Corporate Governance |
| External adviser | | |
| Observers | | |

## Declarations of interest

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

## The panel had before it:

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

## 1. Consideration of application

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

**1.2.** The panel noted that CREATE, St Paul's London, centre 0339 currently holds a treatment (including embryo testing) and storage licence and provides a full range of fertility services. In relation to activity levels this is a medium-sized centre.

**1.3.** The panel noted that the centre is part of the CREATE group which also incorporates a small number of satellite clinics. The HFEA licensed centres are centrally managed with common structures and procedures. These include:

- CREATE, St Paul's London, centre 0339 - licensed since July 2014
- CREATE Fertility, Birmingham, centre 0348 – licensed since April 2016
- CREATE, centre 0299 – established centre

**1.4.** The panel noted that the approach to this renewal inspection for centre 0339 was different from the standard renewal methodology. Activities which were found to be compliant at the established and recently inspected licensed centre 0299, that are common across the group, were not reviewed in detail. Instead, local compliance with group policies and procedures were assessed by review of patient records, centre audits and observation of practice. This report therefore represents the result of a focused inspection in recognition that there has been previous detailed scrutiny of many common practices and procedures.

**1.5.** The panel noted that in the 12 months to 31 January 2016, the centre provided 758 cycles of treatment (excluding partner intrauterine insemination).

**1.6.** The panel noted that in 2015 the centre reported nine cycles of partner insemination with two pregnancies. This is likely to be consistent with the national average.

**1.7.** The panel noted that for IVF and ICSI, HFEA-held register data for the year ending October 2015 showed the centre's success rates were in line with national averages.

**1.8.** Between November 2014 and October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 7%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% maximum multiple live birth rate target.

**1.9.** The panel noted that at the time of the renewal inspection on 15 March 2016, one major and one other area of non-compliance was identified. The panel noted that similar non-compliances were noted at the renewal inspection of centre 0299 in February 2016 and recommendations were made and are being fully implemented across the group. The Person Responsible (PR) of centre 0339 and 0299 agreed that recommendations for all improvements made following the renewal inspection at centre 0299 would be implemented across all centres within the CREATE group. It was also agreed that should non-compliances continue beyond the anticipated timescale for the implementation of corrective actions, that this may result in the escalation of the categorisation of the non-compliances.

**1.10.** The panel noted that the inspectorate recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

## 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 this report being implemented within the prescribed timescales.

## 3. Chair's signature

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

### Signature

### Name

Juliet Tizzard

### Date

16 June 2016

# 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:** 15 March 2016

**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 (Lead), Susan Jolliffe, David Gibbon, Neil McComb

**Date of Executive Licensing Panel:** 6 June 2016

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| **Centre name** | CREATE, St Paul's London |
| **Centre number** | 0339 |
| **Licence number** | L/0339/1/b |
| **Centre address** | 150, Cheapside, St Pauls, London, EC2V 6ET |
| **Person Responsible** | Geeta Nargund |
| **Licence Holder** | Stuart Campbell |
| **Date licence issued** | 23 July 2014 |
| **Licence expiry date** | 22 July 2016 |
| **Additional conditions applied to this licence** | None |

# Contents

# Section 1: Summary report

**Brief description of the centre and its licensing history:**
CREATE, St Paul's London has held a treatment and storage licence with the HFEA since July 2014. This inspection represents the first on site visit to the centre since it was licensed.

The centre provides a full range of fertility services and provided 758 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2016. In relation to activity levels this is a medium sized centre

The centre's licence was varied in February 2015 by an ELP to include embryo testing.

CREATE, St Paul's London is part of a group that incorporates another HFEA licensed centre (CREATE, centre 0299) and a small number of satellite clinics that are all centrally managed and have common practices and procedures. An initial licence application for a third clinic (CREATE Fertility Birmingham, centre 0348) was considered by ELP on 22 April 2016. In view of the common structures and functioning of the centres within the CREATE group and that CREATE (0299) was inspected in February 2016, the approach to this inspection was different to the standard renewal methodology. Activities which were common across the group and had been found to be compliant in the course of the detailed review at centre 0299's recent renewal inspection were not reviewed in detail. Instead local compliance with group policies and procedures was assessed by review of patient records, centre audits and observation of practice.

The Person Responsible (PR) of CREATE 0299 and 0339 has agreed that recommendations for improvements made following the renewal inspection at 0299 would be implemented across all centres. It was also agreed that should continued non-compliance be observed beyond the anticipated timescale for the implementation of corrective actions that this may result in the escalation of the categorisation of the non-compliance.

This report therefore represents the result of a focused inspection in recognition that there has been previous detailed scrutiny of many common practices and procedures.

## Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending October 2015 show the centre's success rates are in line with national averages.

In 2015 the centre reported nine cycles of partner insemination with two pregnancies. National data for this year has not yet been analysed, but it is likely that this will be consistent with the national average.

### Multiple births[2]

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

Between November 2014 and October 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

## Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the 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 their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were two areas of practice that required improvement; one major and one 'other' area of non-compliance which resulted in the following recommendations:

Major areas of non-compliance:

- The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.

'Other' areas that require improvement:

- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Similar non-compliances were noted at the renewal inspection of centre 0299 in February 2016. Recommendations were made and have been implemented across the group.

## Recommendation to the ELP

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy rates meet the target.

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

## Section 2: Inspection findings

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

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

### 1. Protection of the patient and children born following treatment

#### Witnessing and assuring patient and donor identification

**What the centre does well**

**Witnessing (Guidance note 18)**
The CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and observation of practice on the day of inspection.

**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 CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

**Payments for donors (Guidance note 13; General Direction 0001)**
The CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

**Donor assisted conception (Guidance note 20)**
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The CREATE group clinics' procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

**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)**
This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection.

The centre's premises are suitable. This is important to ensure that all licensed activities

are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite/transport 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 for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

**Infection control**
This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection.

The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

**Medicines management**
It is important that the centre has procedures in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

The CREATE group clinics' procedures for management of medicines at the time of the renewal inspection of centre 0299 were broadly compliant with guidance but a recommendation for improvement was made and confirmation of its implementation has been provided.

This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection. This clinic was considered to be compliant with guidance in the implementation of these procedures.

**Pre-operative assessment and the surgical pathway**
The CREATE group has policies and procedures 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.

This area of practice is considered to be largely centre specific and local compliance was focussed on at this inspection. This clinic was considered to be locally compliant with guidance in the implementation of these procedures.

**Multiple births (Guidance note 7; General Direction 0003)**
The single biggest risk of fertility treatment is a multiple pregnancy.

The CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures.

**Procurement of gametes and embryos (Guidance note 15)**
The CREATE group clinics' 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;
- if sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of a review of the centre's records and discussions with centre staff.

**Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)**
The CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of patient records and discussions with centre staff.

**Receipt of gametes and embryos (Guidance note15)**
The CREATE group clinics' 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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of patient records and discussions with centre staff.

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

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

**Traceability (Guidance note 19)**
The CREATE group clinics' procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the clinic 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's audits of practice and discussions with centre staff.

**Quality management system (QMS) (Guidance note 23)**
The CREATE group has a QMS in place that is compliant with HFEA requirements. This clinic was considered to be compliant in the implementation of this QMS on the basis of review of the centre's records, procedures and discussions with centre staff. 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 CREATE group clinics' procedures for management of third parties were compliant with requirements at the time of the renewal inspection of centre 0299 with the exception of its third party agreement (TPA) with its diagnostic laboratory performing virology testing. A recommendation for improvement was made and evidence of its implementation has been provided.

This clinic was considered to be locally compliant in the implementation of relevant procedures on the basis of review of centre specific TPAs.

**Transport and satellite agreements (Guidance note 24; General Direction 0010)**
The CREATE group 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.

This clinic was considered to be locally compliant with the relevant HFEA requirements.

**Equipment and materials (Guidance note 26)**
The CREATE group clinics' use equipment and materials that are compliant with HFEA

requirements. All 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 CREATE group clinics' are compliant with HFEA requirements to validate critical equipment and have documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

This clinic was considered to be locally compliant with relevant HFEA requirements.

**Process validation (Guidance note 15)**
The CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

**Simplified Culture System**
It is important that products (known as medical devices) that come into contact with gametes or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The centre has recently introduced a 'simplified culture system'; a medical device intended to generate the atmospheric and culture conditions needed to support normal fertilisation and embryo development without the need for specialised gases and equipment. The aim is to reduce the cost of IVF where possible.

This medical device is not CE marked; it has been manufactured for the centre's own use and because the centre does not intend to place the device on the market, use of this device is an option that is legally available to them.

There have been extensive discussions between the centre, the HFEA and the Medicines and Healthcare products Regulatory Agency (MHRA) regarding the introduction and use of this system because of the concern that the standard safeguards that are in place when a UK regulatory framework is followed are not available. These concerns were balanced against the HFEA's commitment to support innovation and improvement in the sector. The centre's commitment to engaging openly with the regulators throughout this period is duly noted.

The HFEA's primary consideration was the safety of patients and we did not recommend that the centre introduced this non-CE marked device, without following the UK's clinical investigation regulatory framework. However, this option of 'in house manufacturing' is technically permissible and was the centre's chosen route.

The HFEA is not in a position to provide an opinion on whether this system is safe to use, but an assessment of the system against the applicable HFEA's standard licence conditions was performed on inspection. This included a review of the information given to patients which the inspection team considered compliant with requirements to ensure

prospective patients are given sufficient information about the nature of the treatment, including consequences and risks. Staff have been trained and closely supervised by the creator of the original system. The process and equipment has been validated in compliance with HFEA requirements, although without the safeguards that come with CE marking, the inspection team is unable to form a conclusion on the suitability of this validation.

To date, the centre has performed only four treatment cycles using this system, with eggs retrieved being divided between standard culture and the simplified system and results monitored between the two groups. The numbers are too small to be able to analyse if there are any differences between the two systems yet. It is expected that the centre will continue to monitor results closely.

**Adverse incidents (Guidance note 27)**
Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

The CREATE group clinics' procedures for reporting adverse incidents are compliant with HFEA requirements. This clinic was considered to be locally compliant in the implementation of these procedures. 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**
Nothing identified at this inspection.

## Staff engaged in licensed activity
**Person Responsible (PR)**
**Staff**

**What the centre does well**

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

**Staff (Guidance note 2)**
The CREATE group 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 CREATE group clinics' procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

**Safeguarding**
The CREATE group clinics' procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection. The centre's procedures are locally compliant with safeguarding guidance.

**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)**
Centre 0339 is the only centre in the CREATE group which is licensed for embryo testing. The centre's licence was varied to include embryo testing in February 2015. At the time of inspection the centre had provided eight treatment cycles involving pre-implantation genetic screening.

SOPs, process validation and staff competence were assessed by the executive in 2015 prior to the centre being granted an embryo testing licence. These areas were not reviewed again on this inspection.

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**

This area of practice is considered to be largely centre specific and was focussed on in this inspection.

During the inspection visit the inspectors spoke to three patients who provided positive feedback on their experiences. A further five patients also provided feedback directly to the HFEA in the time since the last inspection.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

The centre's own patient satisfaction survey results were discussed on inspection. They take corrective action based on any negative trends. The results of these surveys are carefully considered and demonstrate a learning culture at the centre.

**What the centre could do better**

Nothing identified at this inspection.

### Treating patients fairly

**Counselling**
**Egg sharing arrangements**
**Surrogacy**
**Complaints**
**Confidentiality and privacy**

**What the centre does well**

**Treating patients fairly (Guidance note 29)**

The CREATE group clinics' 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 locally compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

**Counselling (Guidance note 3)**

The CREATE group clinics' 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. This

clinic was considered locally compliant in the implementation of these procedures.

**Egg sharing arrangements (Guidance note 12; General Direction 0001)**
The CREATE group clinics' 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).

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

**Surrogacy (Guidance note 14)**
The CREATE group clinics' procedures for treatment involving surrogacy were partially compliant with HFEA requirements at the time of the renewal inspection of centre 0299. A recommendation for improvement has been made in relation to establishing legal parenthood in such arrangements and this recommendation is in the process of being implemented across all clinics.

This centre was considered to be locally compliant with HFEA requirements on the basis of review of patient records. This is important to protect the surrogate and any children born as a result of the treatment.

**Complaints (Guidance note 28)**
The CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

**Confidentiality and privacy (Guidance note 30)**
The CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of observations and discussions with centre staff.

**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 CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

**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 CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

**Legal Parenthood (Guidance note 6)**

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

In October 2015, the HFEA's Chief Inspector asked all newly licensed centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided evidence of a comprehensive audit identifying no issues and evidence that their procedures for obtaining consent to parenthood are robust.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of patient notes on this inspection, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required. The centre's procedures are compliant with legal parenthood requirements.

**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**

It 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 assisted reproductive technology (ART) and those born following ART treatment.

The CREATE group clinics' procedures for accurately reporting a patient's consent to disclosure to researchers were considered broadly compliant at the time of the renewal inspection of centre 0299. Recommendations for improvement were made and are in the process of being implemented across all clinics.

This area of practice is considered to be largely centre specific and local compliance was focused on in this inspection. This clinic was considered to be partially compliant in the implementation of these procedures on the basis of review of the centre's records and data submitted to the HFEA.

**What the centre could do better**

**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**

Two discrepancies were found between 16 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. One of these discrepancies presents a risk that the HFEA may release patient identifying information, to researchers, without consent (General Direction 0005, recommendation 1).

## 3. The protection of gametes and embryos

### Respect for the special status of the embryo

**What the centre does well**

The CREATE group clinics' procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

**What the centre could do better**

Nothing identified at this inspection.

### Screening of patients
### Storage of gametes and embryos

**What the centre does well**

**Screening of patients (Guidance note 17)**

The CREATE group clinics' 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 embryos.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

**Storage of gametes and embryos (Guidance note 17)**

The CREATE group clinics' procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

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

### **Use of embryos for training staff** (Guidance note 22)

**What the centre does well**

**Use of embryos for training staff (Guidance note 22)**
The CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of discussions with centre staff.

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

## 4. Information management

### Record keeping
### Obligations and reporting requirements

What the centre does well

**Record keeping and document control (Guidance note 31)**
The CREATE group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

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

The CREATE group clinics' procedures for submitting information about licensed activities were broadly compliant at the time of the renewal inspection at centre 0299. A recommendation for improvement was made and is in the process of being implemented across all clinics.

This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection.

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)**
Twenty percent (25/126) of the IVF and thirty five percent (11/31) of the Donor Insemination (DI) treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005.

At the time of the audit there was one treatment using a donor whose information had not been provided to the HFEA. The details of this case have been supplied to the centre for correction (recommendation 2).

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

Following the initial inspection in 2014, recommendations for improvement were made in relation to one area of major non-compliance and one 'other' area of non-compliance.

The PR provided evidence that these recommendations were fully implemented before licensed activity commenced.

### On-going monitoring of centre success rates

The centre has not received any success rate risk tool alerts since it was licensed.

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

### Critical area of non-compliance

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

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| None noted. | | | |

## Major area of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| 1. **Consent to disclosure**<br>Two discrepancies were found between 16 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. One of these discrepancies presents a risk that the HFEA may release patient identifying information, to researchers, without consent.<br><br>General Direction 0005. | Discrepancies were also noted at the renewal inspection of centre 0299 in February 2016 and recommendations for improvement were made and are in the process of being implemented across all clinics.<br><br>The PR should correct the two submissions that were identified as incorrect.<br><br>The PR has committed to review the procedures for checking and submitting consent to disclosure decisions to the HFEA to ensure that consent decisions are accurately reported to the | Improvements are being implemented across all clinics.<br><br>Corrections have been sent for the discrepancies. This related to a single couple. The figure should therefore say 1 out of 16 rather than 2 out of 16.<br><br>Monthly audit's of CD's submitted to the HFEA will be held to double check that the information submitted is correct.<br><br>All patient registrations will also be checked every time a patient has a treament cycle to | The inspection team acknowledges the PR's commitment to fully implement this recommendation.<br><br>The PR has provided a copy of the CREATE group's comprehensive review which includes details of actions taken in response to the review findings.<br><br>A summary report of the audit to determine the effectiveness of this corrective action is to be submitted to the centre's inspector by 10 August 2016.<br><br>The findings of the additional |

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| | HFEA. A summary of the findings and any corrective actions identified are to be submitted to the centre's inspector by 10 May 2016.<br><br>Three months after the implementation of corrective action, the PR should ensure that an audit specific to each centre is performed to ensure that these corrective actions have been effective. This audit should be submitted by 10 August 2016.<br><br>It is also recommended that the clinic undertakes a further sample audit of the records of 100 patients who have been reported as having given consent to non-contact disclosure of their information to researchers on the HFEA register. The purpose of this audit is to identify whether the observation made on inspection represents a systemic failure of the recording of this consent in cases where there is a risk that | check if there has been a Variation of Consent.<br><br>A summary of the findings and corrective actions were submitted to the HFEA before the deadline of 10th May.<br><br>An audit will be held three months after the implementation of corrective actions and will be submitted to the HFEA by 10th August 2016.<br><br>A further audit of 100 patients who have been reported as having given consent to non-contact disclosure of their information to researchers will be conducted as recommended by the HFEA and the findings will be submitted by 15 September 2016. | sample audit is to be submitted to the HFEA by 15 September 2016. |

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| | information could be disclosed if the consent is not reported accurately.<br><br>The PR should advise the HFEA of the findings of this audit by 15 September 2016.<br><br>On completion of the audit it is recommended that the PR should liaise with the HFEA's register team to consider the most proportionate way to implement corrective actions to mitigate any risks identified by the audit. | | |

## Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| **2. Data submission**<br>Twenty percent (25/126) of the IVF and thirty five percent (11/31) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005.<br><br>At the time of the audit there was one treatment using a missing donor. The details of this case have been supplied to the centre. | Discrepancies were also noted at the renewal inspection of centre 0299 in February 2016 and recommendations for improvement were made and are in the process of being implemented across all clinics.<br><br>The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.<br><br>The PR has committed to reviewing the procedures used to submit licensed treatment data and address the reasons for delayed submissions. A summary of the findings and any corrective actions identified are to be submitted to the centre's inspector by 10 May 2016. | An additional EDI administrator is currently being recruited to help with the submission of data to the HFEA so that all treatments will be reported within the correct timeframe. This administrator will be in post by June 2016.<br><br>A full review was conducted and a report has been submitted to the HFEA.<br><br>Initially there was a technical delay with the implementation of the IDEAS based portal that is used to submit data to the HFEA. The HFEA were informed of this at that time and all delayed submisions were completed as soon as the technical problem was resolved. | The PR has provided a copy of the CREATE group's summary of the review of procedures for data submission, including the corrective action implemented.<br><br>A summary report of the audit to determine the effectiveness of this corrective action is to be submitted to the centre's inspector by 10 August 2016.<br><br>The executive will liaise with the centre regarding the one potentially unregistered donor. |

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| | Three months after the implementation of corrective actions, the PR should ensure that an audit specific to each centre is performed to ensure that these corrective actions have been effective. This audit should be submitted by 10 August 2016. | We still frequently experience technical issues with data submission through IDEAS portal and are addressing this with technical advisors.<br><br>The Centre was not made aware of the details of the 1 unregistered donor. At the time of running your report it is possible that there was an error relating to treatment with a donor.<br><br>It is therefore, a possibility that an error was made when the T form was submitted e.g. Donor 12345 could have been inputted as Donor 1234. This does not mean that the donor was not registered, but merely that there was possibly a typing error.<br>A further review and audit will be undertaken after three months. | |

| Reponses from the Person Responsible to this inspection report |
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| I thank the inspection team on behalf of CREATE St Paul's staff for their time and valuable advice.We are also grateful to our patients who provided the feedback and co-operated fully on the day of inspection.We consider an external inspection as an opportunity for exchanging thoughts, experiences and for learning. We pride ourselves in providing a high quality, low drug, low risk , lower cost, and less invasive IVF treatments. Increasing safety, quality and accessibility in IVF is our commitment. We are proud that we have not had a single woman admitted to hospital with OHSS and our multiple pregnancy rate remains to be low. We provide an expert, individualised Natural and Milder stimulation IVF treatments.We are also a NHS provider for East of England CCGs. We thank our inspector and the senior HFEA team for their advice and guidance in facilitating the introduction of innovative "Simplified Culture System (SCS)" to reduce the cost of IVF treatment. |