Executive Licensing Panel - minutes

Centre 0348 (CREATE Fertility, Birmingham) Initial Inspection Report

Friday, 22 April 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Anna Rajakumar Trisram Dawahoo	Head of Business Planning Scientific Policy Manager Digital Communications Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary 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. Background

1.1. CREATE Fertility, Birmingham is located at:

Ground Floor, 6270 Bishops Court
Birmingham Business Park
Solihull Parkway
Birmingham B37 7YB

1.2. The centre is part of the CREATE group of fertility centres.

1.3. The proposed Person Responsible (PR) has applied for a treatment and storage licence. An initial licence application was received by the HFEA in December 2015. The centre plans to provide a full range of fertility services to NHS and private patients in Birmingham and the Midlands area.

1.4. The centre currently operates as a satellite to the CREATE Centre for Reproduction and Advanced Technology (centre 0299) and CREATE St Pauls, London (centre 0339).

1.5. A full desk based assessment was performed followed by an inspection visit on 22 March 2016.

2. Consideration of application

2.1. The panel considered the papers which included an application form, inspection report, CV of the proposed Person Responsible (PR) and Licence Holder (LH) and licensing minutes for the past three years.

2.2. The panel noted the report of the inspection carried out on 22 March 2016.

2.3. The panel noted that the proposed PR, Mr Paul Wilson, holds academic qualifications in the field of medicine. The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HFE Act 1990 (as amended) section 16(2)(c)(i) and (ii) (including acting in the capacity of PR). The proposed PR has successfully completed the HFEA PR Entry Programme.

2.4. The panel noted the suitability of the proposed (LH), Mr Praful Nargund.

2.5. The panel noted the suitability of the premises for the conduct of licensed activities.

2.6. The panel noted that at the time of the inspection on 22 March 2016 one major and two other areas of non-compliance were identified. The panel noted that since the inspection the PR has fully implemented all of the recommendations to address these non-compliances.

2.7. The panel noted that the inspectorate considered that there is sufficient information available to recommend:

- the appointment of the proposed Licence Holder;
- the appointment of the proposed Person Responsible;
- the grant of a treatment and storage licence for a period of two years subject to the implementation of the recommendations in this report.

3. Decision

3.1. The panel referred to its decision tree.

3.2. The panel was satisfied that the appropriate application form was submitted. A treatment and storage application form was submitted which also included embryo testing, however the panel noted that the inspectorate has clarified with the PR that the centre requires a treatment and storage licence without embryo testing.

3.3. The panel noted that the inspectorate had received the supporting information required by General Directions 0008 and was satisfied that the fee had been paid.

3.4. The panel was satisfied that the proposed PR, Mr Paul Wilson will discharge his duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Mr Wilson as the Person Responsible when the new licence comes into effect, in accordance with section 18A of the HFE Act 1990 (as amended).

3.5. The panel was satisfied with the suitability of the proposed LH, Praful Nargund. The panel agreed to appoint Mr Nargund as the Licence Holder when the new licence comes into effect.

3.6. The panel was satisfied that the premises to be licensed (and those of relevant third parties) are suitable for the conduct of licensed activities based on evidence provided within the report.

3.7. The panel was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

3.8. The panel referred to 'guidance on periods for which new or renewed licences can be granted' which states that an initial treatment/storage/non-medical fertility services licence would normally be granted for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence.

3.9. The panel agreed to grant the licence for treatment and storage for a period of two years with no additional conditions.

4. Chair's signature

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

Signature

Name

Paula Robinson

Date

29 April 2016

Inspection Report

Purpose of the Inspection Report

This is a report of an assessment and inspection, carried out to determine whether an application for a new licence will meet essential requirements. The 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: 22 March 2016

Purpose of inspection: Issue of a licence to carry out treatment and storage.

Inspection details: The report covers the findings from a desk-based assessment of submitted documentation, an inspection visit and communications received from the centre.

Inspectors: Louise Winstone, Andrew Leonard and Grace Lyndon

Date of Executive Licensing Panel: 22 April 2016

Centre name	CREATE Fertility, Birmingham
Centre number	0348
Centre address	CREATE Fertility, Birmingham, Ground Floor, 6270 Bishops Court, Birmingham Business Park, Solihull Parkway, Birmingham, B37 7YB
Proposed Person Responsible	Paul Wilson
Proposed Licence Holder	Praful Nargund

Contents

Section 1: Summary report

Brief description of the centre:
CREATE Fertility, Birmingham will operate as part of the CREATE group of fertility centres and will treat NHS and private patients in Birmingham and the Midlands area. The proposed Person Responsible (PR) has applied for a treatment and storage licence. The centre proposes to provide a full range of fertility services.

The centre currently operates as a satellite to the CREATE Centre for Reproduction and Advanced Technology (centre 0299) and CREATE St Pauls, London (centre 0339).

An initial licence application was received by the HFEA in December 2015. A full desk based assessment was performed followed by an inspection visit on 22 March 2016.

Centre's anticipated activity levels:

Type of treatment	Maximum number of proposed treatment cycles
In vitro fertilisation (IVF)	1500
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination (IUI)	500

Other licensable activities	✓ or Not Applicable (N/A)
Storage of gametes	✓
Storage of embryos	✓
Embryo testing	N/A*

* It should be noted that the application form includes embryo testing as a proposed licensed activity but the PR before and during the inspection stated that embryo testing was not to be included in the licence application at this time.

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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- subject to the PR implementing the recommendations made in this report, it is considered likely that the PR will discharge his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are considered suitable subject to the implementation of recommendations in this report;
- the centre's practices are considered suitable subject to the implementation of recommendations in this report;
- the application contains the supporting information required by General Direction 0008, in application for 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 was one major and two 'other' areas of non compliance.

Since the inspection visit, recommendations to address all these non compliances have been fully implemented, these being:

Major area of non compliance:

- The PR should develop a competence assessment framework for the clinical staff.

'Other' areas that require improvement:

- The PR should identify measures to mitigate the risk of nurses' not having line of sight observation of some of the beds in the recovery area.
- The PR should ensure that bacteriological assessment of relevant areas is performed to ensure their suitability.

Recommendation to the Executive Licensing Panel

The inspection team considers that there is sufficient information available to recommend:

- the appointment of the proposed Licence Holder;
- the appointment of the proposed Person Responsible;
- the grant of a treatment and storage licence for a period of two years subject to the implementation of the recommendations in this report.

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 proposed 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 will ensure 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 proposed 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/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's proposed 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)
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 centre's proposed procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this 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
Transport 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)
It is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre's proposed procedures 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 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 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 UKAS or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre's proposed systems to manage and monitor the prevention and control of infection are broadly compliant with guidance.

Medicines management
The centre's proposed arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines are compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre's proposed procedures are broadly 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 procedure.

Multiple births (Guidance note 7; General Direction 0003)
The centre's proposed 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 proposed 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, to keep 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 proposed 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;
- in a container/package that is secure and ensures that the gametes or embryos are maintained in the specified conditions.

Receipt of gametes and embryos (Guidance note 15)
The centre's proposed 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.

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

Traceability (Guidance note 19)
The centre's proposed 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,
- 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 in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre will not participate in transport services but the proposed procedures for operating satellite arrangements are compliant with HFEA requirements.

Equipment and materials (Guidance note 26)
The centre will use equipment and materials that are compliant with HFEA requirements. All of the equipment and materials to be used in licensed activity are designated for the purpose and will be 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 proposed 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 proposed procedures for reporting adverse incidents are compliant with

HFEA requirements. The centre will report all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has processes in place to investigate all adverse incidents that may occur. 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

Pre-operative assessment and the surgical pathway
Patients will recover post procedure in a recovery area in one of four curtained bays. The nurses' station has no line of sight observation of two of these bays. It was not clear that patients within them will be observed and monitored at all times during recovery. The inspection team were concerned that patients within these bays could develop a medical problem and be in distress, but the nursing staff may not be aware of this, delaying the provision of support and assistance (SLC T17; recommendation 2).

Infection control
The clinical areas have not yet been tested for microbiological cleanliness. The PR advised that a further deep clean was planned after which microbiological testing will be performed, prior to commencing licensed activities (SLC T17; recommendation 3). The inspection team consider this arrangement will ensure compliance when it is completed.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The proposed PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1288/82).

Staff (Guidance note 2)
The centre's processes for ensuring suitably qualified and competent staff, in sufficient number, are present to carry out the licensed activities, are partially compliant with HFEA requirements. 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. The centre's staff are registered in accordance with the appropriate professional and/or statutory bodies.

What the centre could do better

Staff (Guidance note 2)
The centre is developing a competence framework to use during the recruitment,

induction and on-going assessment of nursing and clinical staff, but this is not yet in place (SLC T12 and T15a; recommendation 1). The inspection team have no concern regarding the competence of the centre staff already recruited but consider that a competence framework will assist the development of the staffing resources.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's proposed procedures for taking 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.

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
This section is not relevant as the centre will not be performing preimplantation genetic screening, embryo testing or sex selection when it commences activities.

The PR advised on inspection that embryo testing may be undertaken in the future, hence it being included in the application form, but that he does not wish to apply for this activity at the present time. Thus he wishes to withdraw embryo testing activities from the current application.

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

2. The experience of patients

Treating patients fairly
Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's proposed 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 proposed procedures appeared compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's proposed 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 proposed 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;
- the benefit offered is the most suitable for the egg provider and recipients.

Surrogacy (Guidance note 14)
The centre's proposed procedures for surrogacy arrangements are 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 proposed 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 feedback and complaints as an opportunity to learn and improve services.

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

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

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's proposed 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 and 6)
The centre's proposed 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.

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

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

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's proposed 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 will only take place on licensed premises;
- only permitted embryos will be used in the provision of treatment services;
- embryos will not be selected for use in treatment for social reasons;
- embryos will not be created by embryo splitting;
- embryos will only be created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman;
- embryos will only be 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
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's proposed 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 proposed 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 will only store 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 (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's proposed 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
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's proposed 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 proposed procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

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

Areas of practice requiring action

This section sets out matters which the inspection team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

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. **Staffing** The centre does not have a competence framework to use during the recruitment, induction and on-going assessment of nursing and clinical staff (SLC T12 and T15a).	The PR should develop a competence framework to use during the recruitment, induction and on-going assessment of nursing and clinical staff. A copy of the framework should be provided to the centre's inspector when the PR responds to this report.	CREATE Fertility will use its established global competency framework which was submitted and evaluated during CREATE's other clinics inspections. On the day of inspection clinical and nursing competency documentation was available. The inspector was provided with template forms for perusal. Individual competency forms are completed during recruitment, induction period and signed off by their supervisor/assessor. Ongoing assesment of competence is performed through the internal audit mechanism and continual review of KPI's. The	The PR has submitted a competence framework to be used during the recruitment, induction and on-going assessment of nursing and clinical staff. No further action is required.

		documentation supporting the the competency framework is attached.	

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. **Pre-operative assessment and the surgical pathway** The nurses' station has no line of sight observation of two of the bays in the recovery area. The inspection team were concerned that patients within those bays could develop a medical problem and be in distress, but the nursing staff may not be aware of this delaying the provision of support and assistance (SLC T17).	Since the inspection the PR has provided a risk assessment of the recovery bay and the practices to be used to ensure suitable monitoring of patients during recovery. It includes risk control measures to be used given the lack of line of sight observation of the two recovery bays. No further actions are required.	No further action required	No further action is required.
3. **Infection control** The clinical areas have not yet been tested for microbiological cleanliness (SLC T17).	The PR advised that a further deep clean was planned after which microbiological testing will be performed, prior to commencing licensed activities. The PR should provide the	A deep clean has been completed and samples have been taken for microbiological examination. The results are due week beginning 4th April and will be forwarded to the inspector.	The Executive acknowledges the PR's response and awaits the microbiological results. Further action is required. 05 April 2016: The PR has provided the microbiological

	centre's inspector with a copy of the summary of the microbiological testing prior to commencing licensed activity and, if possible, before the inspection report is considered by a licensing committee.		testing results. No further action is required.

Reponses from the Person Responsible to this inspection report
The Person Responsible and the staff at Create Fertility Birmingham are grateful to the inspection team for their time and advice during the inspection. It was a very productive and constructive inspection for our new centre. We thank them immensely. We look forward to providing a successful,safe and invidualised IVF service to women and couples in the Midlands and beyond.