Executive Licensing Panel - minutes

Centre 0035 (Oxford Fertility)

Renewal Inspection Report

Friday, 14 July 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anjeli Kara Jessica Watkin	Director of Strategy & Corporate Affairs Regulatory Policy Manager Policy Manager
Members of the Executive	Bernice Ash	Secretary
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 Oxford Fertility holds a Treatment (including embryo testing) and Storage licence and provides a full range of licensed activities.

1.3. The panel noted that the centre has been licensed by the HFEA since 1992.

1.4. The panel noted that, in the 12 months to February 2017, the centre provided 2,321 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.5. The panel noted that HFEA held register data for the period March 2016 to February 2017 showed that the centre's IVF and ICSI success rates are in line with national averages, with the exception of IVF in women under 38 years old where success rates are higher than average at a statistically significant level. The panel noted that annual IUI data for 2015 and 2016 had not been submitted by the centre.

1.6. The panel noted that between March 2016 and February 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on 25 and 26 April 2017.

1.8. The panel noted that at the time of the inspection there were three major and six 'other' areas of practice which required improvement. The panel noted that, since the inspection, the Person Responsible (PR) has fully implemented the 'other' non-compliances recommendations concerning safety of premises, traceability, process validation and information control.

1.9. The panel noted that the PR has provided a commitment to implementing the major areas of non-compliance regarding medicines management, CE marking and data submission; disclosure of information, alongside the outstanding 'other' non-compliances concerning satellite arrangements and storage.

1.10. The panel noted that some improvement is required for the centre to demonstrate the suitability of their practices and the PR has been encouraged to use their Quality Management System (QMS) to monitor and improve the success rates and the service provided to patients.

1.11. 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 the 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 noted the non-compliances, expressing particular concern regarding data submission to the HFEA, observing it had been upgraded to a major non-compliance, as it had been a recurring issue. The panel urged the PR to engage with this issue seriously.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions subject to the recommendations 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

25 July 2017

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: 25 and 26 April 2017

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Sara Parlett, Grace Lyndon, Lesley Brown, Cathy Hodgson

Date of Executive Licensing Panel: 14 July 2017

Centre name	Oxford Fertility
Centre number	0035
Licence number	L/0035/13/d
Centre address	Institute of Reproductive Sciences, Oxford Business Park North, Oxford, Oxfordshire, OX4 2HW
Person Responsible	Mr Tim Child
Licence Holder	Ms Anne Francis
Date licence issued	1 October 2013
Licence expiry date	30 September 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Oxford Fertility has held a licence with the HFEA since 1992 and provides a full range of licensed treatments.

The centre provided 2,321 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to February 2017. In relation to activity levels this is a large centre.

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

The current licence has been varied three times since it was issued. A change of centre name from Oxford Fertility Unit to Oxford Fertility was approved by an ELP in December 2015. A change of Licence Holder was approved by an ELP in January 2016 and a further change of Licence Holder was approved by the Licencing Officer in March 2017.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period March 2016 – February 2017 show the centre's success rates are in line with national averages with the following exception:

- IVF in women under 38 years old are higher than average at a statistically significant level.

Annual IUI data for 2015 and 2016 has not been submitted by the centre (recommendation 3).

Multiple births[2]

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

Between March 2016 and February 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from 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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of 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 a number of areas of practice that required improvement, comprising three major and six 'other' areas of non compliance.

Since the inspection, the PR has fully implemented the following recommendations:

Other' areas that requires improvement:

- The PR should ensure clinical waste and gas cylinders are stored safely and securely at all times.
- The PR should ensure that seating in clinical areas is 'wipe clean'.
- The PR should ensure that which centrifuge is used to process sperm for use in treatment is traceable.
- The PR should ensure that further validation of the use of Spermobil is performed, as directed in the centre's original validation document.

The PR has given a commitment to fully implement the remaining recommendations:

Major areas of non compliance:

- The PR should ensure that medicine management practices are compliant with regulatory requirements and best practice guidance.
- The PR should ensure that CE marked medical devices are used where available.
- The PR should ensure that all licensed treatment activity and disclosure consent information is accurately reported to the Authority within the required timeframes.

'Other' areas that requires improvement:

- The PR should ensure that written agreements with satellite centres are submitted to the HFEA prior to starting a new satellite service and that the agreements comply with the requirements of General Directions.
- The PR should ensure that storage consent is not restricted to tie in with payment.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the centre's success rates are at or above the national average and their multiple clinical pregnancy rates meet the target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a robust quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

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

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

▶ **Witnessing and assuring patient and donor identification**
What the centre does well **Witnessing (Guidance note 18)** The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.
What the centre could do better Nothing identified at this inspection.

▶ **Donor selection criteria and laboratory tests** Screening of donors prior to procuring, processing gametes and embryos Payments for donors Donor assisted conception
What the centre does well **Screening of donors (Guidance note 11)** The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos. **Payments for donors (Guidance note 13; General Direction 0001)** The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused. **Donor assisted conception (Guidance note 20)** It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes

and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

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

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis

and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been

transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

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

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

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

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

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

Traceability (Guidance note 19)
The centre's procedures are broadly compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

Satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements, with an exception detailed below. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose, with exceptions detailed below, and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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

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

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

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
On the day of inspection, clinical waste bags were being stored in an unlocked yellow bin in the outdoor waste store. The clinical waste was potentially accessible by the public (SLC T17).

In the outdoor medical gas storage area, 26 cylinders were unsecured. Free standing cylinders pose a risk of toppling (SLC T17 and Health & Safety at Work Act 1974, Health Technical Memorandum (HTM) 02 (8.29)).

Recommendation 4.

Medicines management (Guidance Note 25)

There are several observations relating to the management of medicines (SLC T2; recommendation 1):

- the centre's controlled drugs accountable officer (CDAO) has recently left the centre and the new CDAO has not been registered with the Care Quality Commission (CQC) (Controlled Drugs (Supervision of management and use Regulations, 2013);
- the disposal of the portion of each ampoule of controlled drugs dispensed but not administered is not witnessed or recorded (The Misuse of Drugs Regulations 2001, Section 27). Shortly after the inspection, evidence was provided that this non compliance has been resolved;
- prior to administering intra venous (IV) paracetamol, IV Hartmann's solution and codeine to patients, the staff member observed did not formally check the patient's identity, drug dose, strength or expiry date or confirm these checks with a second person (NMC standards for medicines management 2010, standard 2);
- IV paracetamol was administered to a recovering patient in significantly less time than the 15 minutes dictated by British National Formulary (BNF) guidance.
- the temperature of the medicines fridge is not monitored (SLC T24).

Infection control (Guidance Note 25)
The seating in some clinical areas, including the embryo transfer room, are covered with permeable fabric and are therefore not 'wipe clean' (Health Building Note (HBN)00-09: Infection control in the built environment (3.113); recommendation 5).

Traceability (Guidance note 19)
A record of which centrifuge is used to process sperm for treatment is not kept and is therefore not traceable (SLC T99; recommendation 6).

Satellite agreements (Guidance note 24; General Direction 0010)
The centre has satellite arrangements with four clinics. These arrangements were disclosed on the centre's renewal application form, but the agreements had not been submitted to the HFEA before the services started as required by General Direction 0010. These were provided on the second day of inspection. Two of the satellite agreements do not include all requirements of General Direction 0010 (recommendation 7).

Equipment and materials (Guidance note 26)
There are four observations relating to CE marking:

- the centre uses an appropriately CE marked egg collection flush media during egg collection, however this CE mark is invalidated due to supplementation of the media with a prescription only medicine (Heparin Sodium), and is therefore used 'off-label'.
- when performing in vitro maturation of oocytes, the centre uses an appropriately CE marked media, however this CE mark is invalidated due to supplementation with a prescription only medicine (menotrophoin) and is therefore used 'off label'.
- Spermobil, an in vitro diagnostic device used to activate immotile or poorly motile sperm, is being used 'off-label' as a medical device.

The use of materials 'off-label' and any associated risks is not discussed with patients.

- the following consumables used in the laboratory are not CE marked: 5 ml round bottom tubes and serological pipettes.

SLC T30 and T31; recommendation 2.

Process validation (Guidance note 15)
The centre performed an initial process validation of the Spermobil procedure in February 2015, based on published studies. The validation document identified a need to perform a further retrospective evaluation of clinical results once in use at the centre, however this validation step remains outstanding (SLC T72). The validation also failed to identify that Spermobil is CE marked as an in vitro diagnostic device only (for further detail see the 'equipment and materials' section of this report) (recommendation 8).

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of 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 centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

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

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

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

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

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

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit, no patients were available to speak with the inspectors about their experiences at the centre. However, the centre's most recent patient survey responses were reviewed. The feedback from 182 patients was generally very positive.

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

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

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

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

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

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

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

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy 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 procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

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

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

Information

What the centre does well

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

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

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

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

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

necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all 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 sent the report of the audit to the HFEA within the required timeframe. The audit showed that 10 couples were affected by legal parenthood consent anomalies.

At the centre's interim inspection in 2015, the inspection team reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings: all affected patients were contacted by the centre and offered support and advice. One couple decided to pursue a legal declaration of legal parenthood, the costs of which were paid by the centre. In December 2016, the case was heard in the Family Division of the High Court by Sir James Munby and a declaration of legal parenthood was made.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team discussed learning from the court case and reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was in place before treatment in all cases.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

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

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Seven discrepancies were found between 38 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. In two of these cases, the patients had not consented to non-contact research but the data submitted by the centre to the HFEA indicated that the patients had. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent (General Direction 0010; recommendation 3).

3. The protection of gametes and embryos

Respect for the special status of the embryo

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

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

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

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are broadly compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Storage of gametes and embryos (Guidance note 17)
When patients are eligible to store gametes or embryos for more than 10 years, the extended storage period is linked to payment when patients have a poor credit history with the centre. It is important that patients are free to choose how long to consent to store for, within what is permitted by regulations, and that their decision is not fettered to payment (CoP Guidance 5.7; recommendation 9).

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

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

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

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
One percent (1/123) of the IVF and five percent (2/44) of the DI treatments reviewed at inspection had not been reported to the HFEA (General Direction 0005).

Two percent (3/123) of the IVF and 26% (11/44) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005.

The centre has not submitted data for IUI treatments for 2015 or 2016. This appears to be due to confusion with the electronic submission process rather than an oversight by centre staff (General Direction 0005).

Recommendation 3.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, recommendations for improvement were made in relation to three major and one 'other' areas of non compliance.

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

Areas of practice requiring action

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

Critical area of non compliance

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

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

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. **Medicines management** A number of concerns related to medicines management practices at the centre were noted, as detailed within the report. SLC T2.	The PR should review the centre's procedures to ensure that medicines management practices are compliant with legal requirements and professional best practice. It is noted that the centre has already implemented corrective action to ensure the disposal of controlled drugs dispensed but not administered is recorded. The PR should provide a summary of the review, including details of any resulting corrective actions should be provided to the centre's inspector by 26 July 2017.	Medicines Management procedures have been updated and we will conduct a full audit against the revised protocol and submit the findings / actions to the HFEA within the required timescale of 26.07.17. The recording of disposal was implemented immediately following the inspection and compliance will be measured as part of this review. A further audit has been scheduled after 3 months and a report will be provided to the inspector by 26th October 2017.	The executive notes the PR's response and engagement in implementing the recommendation. **Further action is required.**

	Three months after the implementation of corrective actions, an audit of the centre's adherence to their documented medicines management procedures should be performed and a report of the audit provided to the centre's inspector by 26 October 2017.		
2. **CE marking** The centre uses an appropriately CE marked egg collection flush media during egg collection, however this CE mark is invalidated due to supplementation of the media with a prescription only medicine (Heparin Sodium) 'off-label'. When performing in vitro maturation of oocytes, the centre uses an appropriately CE marked media, however this is invalidated due to supplementation with a prescription only medicine (menotrophoin)	The PR should ensure that CE marked medical devices are used where available. Where CE marked medical devices are being supplemented with 'off-label' prescription only medicines and where in vitro diagnostic devices are used 'off-label' as a medical device and there are no suitable alternatives available, the PR should conduct a full risk assessment, seeking expert advice from the MHRA (as exceptional approval may be required: see https://www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device). A copy of this risk assessment,	- We are still assessing the impact as the media is not the same composition as non-heparinised, which has implications for use and storage and potentially the egg environment. We will respond further by 26.07.17. IVM - this review is also in progress and we will report further by 26.07.17 For the above we will review the MHRA risk assessment / advice in respect of the above and feedback by 26.07.17 Spermobil patient information has been updated to fully inform patients of the CE status and	The executive notes the PR's response and engagement in implementing the recommendation. We note that the centre is assessing the supplementation of the flush and oocyte maturation media and we would not recommend precipitous changes that might impact on the quality of treatment. The PR is reminded that a risk assessment and expert advice from the MHRA is also required for use of Spermobil in treatment. The centre's patient information now clearly states that Spermobil is CE marked for diagnostic use only, but that

'off label'. Spermobil, an in vitro diagnostic device, is being used 'off-label' as a medical device. The use of materials 'off-label' and their associated risks are not discussed with patients The following consumables used in the laboratory are not CE marked: 5 ml round bottom tubes and serological pipettes. SLC T30 and T31.	including the advice provided by the MHRA should be provided to the centre's inspector by 26 July 2017. Patient information should be reviewed and amended to reflect the use of 'off-label' medical devices and prescription only medicines and should include information on any possible risks associated with the 'off-label' use. A copy of the amended patient information should be provided to the centre's inspector by 26 July 2017. The PR should ensure that CE marked 5ml tubes and serological pipettes are in use by 26 October 2017 and confirmation of this provided to the centre's inspector.	risks.(copy attached) We are still sourcing CE marked 5ml tubes and will report further on our progress by 26.10.17 We can confirm that we have moved to using CE marked pipettes already.	it has been used in several clinics throughout the world with no known adverse effects. However it then states that '…it is approved for use in fertility treatment by the HFEA if the patient has been informed of the CE marking status and has given their prior consent.' The executive acknowledges that the HFEA's Scientific and Clinical Advances Advisory Committee considered the use of this type of reagent in 2012 when considering whether gamete activation should be an approved process. The process was approved however no reagents were specified, indeed the HFEA is not in a position to 'approve' the use of any specific reagents. The PR should revise the patient information further to ensure its accuracy. **Further action is required.**
3. **Data submission; Disclosure of information** One percent (1/123) of	The PR should review procedures and take appropriate corrective actions to ensure: • that all licensed treatment	Data submission procedure are being monitored to assess improvement or identify issues.	The executive notes the PR's response and engagement in implementing the recommendation.

the IVF and five percent (2/44) of the DI treatments reviewed at inspection had not been reported to the HFEA (General Direction 0005). Two percent (3/123) of the IVF and 26% (11/44) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. Seven discrepancies were found between 38 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. In two of these, the patients had not consented to non contact research but the data submitted by the centre to the HFEA indicated that the patients had. This failing leads to a risk that the	activity is reported to the Authority within the timeframe required by General Direction 0005. • disclosure consent information supplied to the Authority accurately reflects that recorded on disclosure consent forms. • the correction of the seven disclosure consent submissions identified as being incorrect. These recommendations should be implemented by 26 July 2017 and the centre's inspector informed of the results of the review and the actions taken. An audit should subsequently be performed to ensure the actions taken are effective. A report of this audit should be provided to the centre's inspector by 26 October 2017. The PR should ensure that the IUI data for treatments in 2015 and 2016 is submitted to the HFEA by the time of responding to this report.	We will ensure all licensed treatment activity is reported within the required timescales and disclosure consent is accurate. The incorrect submissions identified (seven) have been corrected. We will further review the all data and feedback to the inspector all findings / actions by 26.07.17 and re-audit and report back by 26.10.17. IUI data for 2015 and 2016 have been submitted again. We will undertake the non-contact disclosure to researchers to ensure consent is being recorded correctly and feedback the results of the audit to the HFEA and registry team as requested.	IUI data has been submitted. The centre reported 16 cycles of IUI in 2015 with one pregnancy and seven cycles of IUI in 2016 with no pregnancies. This performance is in line with the national average. **Further action is required**

HFEA may release patient identifying information, to researchers, without consent. The centre has not submitted data for IUI treatments for 2015 or 2016. General Direction 0005. **Data reporting was an issue at the previous two inspections and as a result has been upgraded to a major non-compliance.**	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 information could be disclosed if the consent is not reported accurately. The PR should advise the HFEA of the findings of this audit by 26 October 2017. 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
4. **Safety of premises** Clinical waste bags were being stored in an unlocked yellow bin in the outdoor waste store. Clinical waste was potentially accessible by the public. In the outdoor gas storage area, 26 cylinders were unsecured. Free standing cylinders pose a risk to toppling. SLC T17 and Health & Safety at Work Act 1974, Health Technical Memorandum (HTM) 02 (8.29).	The PR should ensure clinical waste and gas cylinders are stored safely and securely at all times. Evidence confirming the implementation of this recommendation should be submitted to the centre's inspector by 26 July 2017.	Clinical waste bins auto lock on closure but should be checked on each closure that the lock is operated correctly. Random checks have been in force and in addition a daily two-week sample check taken in June. On one occasion one bin was found unlocked and reported / rectified immediately. This check and sampling will continue to be repeated. Outdoor gas storage - Completed - see attached photo of individual restraints for gas cylinders.	The executive notes the PR's response and details of actions taken. No further action is required.
5. **Infection control** The seating in some clinical areas, including the embryo transfer room, did not have 'wipe clean' surfaces.	The PR should ensure seating in clinical areas is 'wipe clean'. The PR should provide confirmation of compliance with this recommendation to the centre's inspector by 26	new seating complying with infection control standards have been procured and we await delivery of the new seating for ET / Scan rooms.	The executive notes the PR's response. No further action is required.

Health and building note 00-09:Infection control in the built environment 2013	July 2017.		
6. **Traceability** No record is kept for traceability purposes of the centrifuge used to process sperm for use in treatment. SLC T99.	The PR should ensure that traceability records are maintained for the centrifuge. The PR should provide confirmation that this information is being recorded to the centre's inspector by 26 July 2017.	Completed - we can confirm that the centrifuge used is now recorded for all patients post-inspection. We will further check compliance with an audit by 26.07.17	The executive notes the PR's response. No further action is required**.**
7. **Satellite arrangements** The centre has satellite arrangements with four clinics. These arrangements were disclosed on the centre's renewal application form, but the agreements had not been submitted to the HFEA before the services started as required by General Direction 0010. These were provided on the second day of inspection. Two of the satellite agreements not include all requirements of General Direction 0010 agreements are not submitted to the HFEA prior to the satellite	The PR should ensure that prior to starting any new satellite service, the written agreement together with related patient information with the satellite centre is submitted to the HFEA. The PR should ensure that these written agreements comply with the requirements of General Direction 0010. The PR should review the agreements already in place and provide copies of the revised agreements to the centre's inspector by 26	The existing agreements are under review against the General Direction 0010 and revised copies will be forwarded as required within the specified timeframe.	The executive notes the PR's response and commitment to implementing the recommendation. **Further action is required.**

arrangement commencing. Two of three satellite agreements submitted after the inspection do not include all requirements of General Direction 0010.	October 2017.		
8. **Process validation** The centre performed an initial process validation of the Spermobil procedure in February 2015, based on published studies. The validation document identified a need to perform a further retrospective evaluation of clinical results once used at the centre, however this validation step remains outstanding. The validation failed to identify that Spermobil is CE marked as an in vitro diagnostic device only (for further detail see the 'equipment and materials' section of this report). SLC T72.	A further validation of the process for use of Spermobil should be performed, to include retrospective analysis of the centre's own data and with special consideration to the safety of using an IVD 'off –label'. A copy should be provided to the centre's inspector by 26 July 2017.	Validation for Spermobil has been undertaken with the clinic data. See attached document.	The PR has submitted a new process validation document for Spermobil. This includes a retrospective evaluation of clinical results at the centre and its CE mark status. No further action is required.
9. **Storage** When patients are eligible to store gametes or embryos for	The PR should ensure that people giving consent to storage of their gametes or	The procedure is under review to ensure standard and extended storage	The executive notes the PR's response and commitment to implementing the

more than 10 years, the extended storage period is linked to payment when patients have a poor credit history with the centre. CoP Guidance 5.7.	embryos are always free to choose how long to store for, within what is permitted by regulations. Contractual agreements covering payment should be separate to consent. The PR should provide a copy of the updated procedure to the centre's inspector by 26 July 2017.	requirements are clear for patients. We will submit a copy of the updated procedures by 26.07.17	recommendation. **Further action is required.**

Reponses from the Person Responsible to this inspection report
Thankyou to the HFEA for a fair and balanced inspection and report. We are happy to have again achieved an overall very positive report. We have taken on-board the comments and have responded with timescales for action.