Executive Licensing Panel - minutes

Centre 0365 (IVF London)

Renewal Inspection Report

Tuesday, 2 June 2020

HFEA Teleconference Meeting

Panel members	Richard Sydee (Chair) Howard Ryan Helen Crutcher	Director of Finance and Resources Data Analyst Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that IVF London is located in Elstree and has held a treatment (including embryo testing) and storage licence with the HFEA since 2018. The centre provides a full range of fertility treatments.

1.3. The panel noted that, in the 12 months to 30 November 2019, the centre provided 41 cycles of treatment (excluding partner intrauterine inseminations). In relation to activity this a small sized centre.

1.4. The panel noted that, for IVF and ICSI, HFEA held register data, for the period between November 2018 and 31 October 2019, show the centre's success rates are in line with national averages.

1.5. The panel noted that, in 2019, the centre did not provide any cycles of partner insemination treatment.

1.6. The panel noted that, HFEA register data, between 1 November 2018 and 31 October 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This represents performance that is not likely to be statistically lower than the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on the 11 and 12 February 2020.

1.8. The panel noted that at the time of the inspection, there was one major area of non-compliance concerning medicines management. There was also one 'other' non-compliance relating to suitable premises. Since the inspection, the Person Responsible (PR) has fully implemented both of the recommendations made in the report.

1.9. The panel noted that the centre is well led and provides a good level of patient support.

1.10. The panel noted that the inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions.

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 congratulated the centre on actively promoting the completion of the 'Choose a Fertility Clinic' rating system, available on the HFEA website, for patients to provide feedback on their experience at the centre; in the last 12 months, seventeen patients had provided feedback through this mechanism, a significant proportion given the low volume of treatment cycles, giving the clinic an average five star rating.

2.5. The panel particularly noted that, with regards to the non-compliance concerning medicines management, several issues were identified at the inspection, and was pleased and encouraged to see the PR's level of response in addressing these so swiftly.

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

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

8 June 2020

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high-quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 11 and 12 February 2020.

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

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

Inspectors: Nicola Lawrence (lead), Sara Parlett and Sandrine Oakes.

Date of Executive Licensing Panel: 5 May 2020

Centre name	IVF London
Centre number	0365
Licence number	L/0365/1/a
Centre address	Caspian House, The Waterfront, Elstree, Borehamwood, WD6 3BS, United Kingdom
Person Responsible	Mr Alpesh Doshi
Licence Holder	Dr Hetal Doshi
Date licence issued	17 September 2018
Licence expiry date	16 September 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

IVF London is located in Elstree and has held a Treatment (including embryo testing) and Storage licence with the HFEA since 2018. The centre provides a full range of fertility treatments.

IVF London was granted a two-year initial licence which is usual for a new centre.

The centre provided 41 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2019. In relation to activity levels this is a small centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 November 2018 – 31 October 2019 show the centre's success rates are in line with national averages.

In 2019 the centre did not provide any cycles of partner insemination treatment.

Multiple births[2]

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

Between 1 November 2018 – 31 October 2019 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. 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) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged 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 the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were two areas of practice that required improvement, including one major and one 'other' area of non-compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non-compliance:

- The PR should ensure that entries into the controlled drug register and patient records relating to controlled drugs are compliant with regulatory and best practice requirements.

'Other' areas that requires improvement:

- The PR should ensure that all medical gases are stored safely and kept secure at all times.

Recommendation to the Executive Licensing Panel

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

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

Both of the recommendations have been implemented prior to the inspection report being considered by the Executive Licensing Panel.

The centre is well led and provides a good level of patient support.

The inspection team recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions.

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)
This centre does not recruit donors, therefore requirements related to its procedures were not relevant at this inspection. The centre indicated in their licence renewal application that they intend to recruit donors in the future. It was agreed that, prior to this activity commencing, the PR will ensure that appropriate processes and documentation are in place and staff will have been assessed as competent to undertake this activity.

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 broadly suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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

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

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

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

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

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

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

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

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

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

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

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

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

Third party agreements (Guidance note 24)
The centre's third party agreements, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
This centre does not have transport and satellite arrangements, therefore requirements related to its procedures were not relevant at this inspection.

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

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre has not had any adverse incidents to date but will report all adverse incidents (including serious adverse events and reactions) to the HFEA and investigate all adverse incidents that 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

Safety and suitability of premises and facilities (Guidance note 25)
In the medical gas cylinder storage room, several unused and one used oxygen cylinders were not adequately secured.

Immediately following the inspection, the PR provided evidence that a suitable storage trolley had been purchased and the cylinders are now secured.

SLC T17; section 8.29 Department of Health (DH) Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006).

See recommendation 2.

Medicines management (Guidance Note 25)
On inspection, several issues were identified relating to the controlled drug (CD) register:

- Entries made in respect of each class of drugs are not adequately recorded in clear separate parts of the register (Section 19(b) Misuse of Drugs (safe Custody) Regulations (2001)).
- Several entries did not record the unit and/or time of the drug administered and/or disposed (section 1.7.4 NICE Guideline [NG46] 'Controlled drugs: safe use and management' (2016); page 7 The Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Controlled Drugs in Perioperative Care' (2019)).
- Entries related to CD received from external pharmacies are not written in words and do not record the requisition number (sections 4.7.2.1 and 4.7.2.2 DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007)).

In addition, the following issues were identified relating to anaesthetic records:

- In one record, the amount of CD administered did not reconcile with the amount recorded in the CD register. On discussion with the anaesthetist, it was clarified that the amount was the same, but it had been diluted with another drug and the latter volume had been recorded in the patient's anaesthetic chart.
- In one record, the unit of drug administered was illegible.
- In one record, the CD name was illegible, and the time of administration was not recorded
  (Chapter 7 The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Good practice, a guide for departments of anaesthesia, critical care and pain management' (2006)).

SLC T2.

See recommendation 1.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

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

The PR has academic qualifications in the field of 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.

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

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

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.
The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

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

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

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

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Seventeen patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff at the clinic.

The centre actively promotes the completion of the CaFC patient rating system to its patients but does not currently collect their own patient feedback. The PR explained this is to prevent patients becoming overwhelmed with requests for completing questionnaires. CaFC ratings are reviewed regularly by the PR. Promotion of CaFC is important, but the PR has agreed to consider other ways of collecting patient feedback in the future.

During the inspection the inspectors spoke to three patients who also provided positive feedback on their experiences.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Patient support (Guidance note 3)
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

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

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

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
This centre does not offer egg and/or sperm sharing arrangements, therefore requirements related to its procedures were not relevant at this inspection.

Surrogacy (Guidance note 14)
This centre does not offer surrogacy treatments, therefore requirements related to its procedures were not relevant at this inspection.

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

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

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

What the centre does well

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

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

The centre's proposed legal parenthood consenting practices were considered compliant at the time of licensing in 2018 and at its interim inspection in July 2019.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Four sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements. This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

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

Storage of gametes and embryos (Guidance note 17)

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

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)

The centre’s procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

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

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2019, recommendations for improvement were made in relation to one area of major non-compliance.

The PR provided information and evidence that the recommendation was fully implemented within the prescribed timescale.

On-going monitoring of centre success rates

Since the last interim inspection in July 2019, the centre has received no risk tool alerts regarding treatment success rates.

Areas of practice requiring action

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

Critical areas of non-compliance

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

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None			

Major areas of non-compliance

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

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

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Medicines Management There were several issues noted on inspection relating to medicines management. These are described in the body of the report. SLC T2. Sections 19(a, 19 (b), 27 (3) Misuse of Drugs (safe Custody) Regulations (2001)). Section 1.7.4 NICE Guideline [NG46] 'Controlled drugs: safe use and management' (2016).	The PR should ensure that entries into the controlled drug register and patient records relating to controlled drugs are compliant with regulatory and best practice requirements. The PR should review the centre's SOP for the administration and record of CD information to ensure that it is compliant with regulatory requirements. That done, the PR should ensure that all relevant staff, including medical staff, are made aware of the SOP and their obligations to adhere to it.	New CD registers, as recommended by the inspectors, deemed to be 'compliant', have been received and are in use at the clinic. The new CD registers capture the amount of CD supplied, the amount administered and the amount discarded. We now use 2 CD registers: One captures all Schedule 2 drugs and the other one captures all Schedule 3 drugs in line with the inspectors recommendations to ensure	The executive acknowledges the PR's review of processes and action taken in implementing this recommendation. No further action required beyond submission of the audit due by 12 May 2020.

Page 7 The Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Controlled Drugs in Perioperative Care' (2019)). Sections 4.7.2.1 and 4.7.2.2 DH 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007). Chapter 7 The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Good practice, a guide for departments of anaesthesia, critical care and pain management' (2006).	The PR should provide details of how this has been achieved when responding to this report. The PR should ensure that the area of non-compliance identified here is incorporated into the centre's audit criteria for controlled drugs records. Three months after the date of this review the PR should conduct an audit of controlled drug register entries and related patient records to ensure corrective actions implemented have been effective. A summary of the audit should be provided to the centre's inspector by 12 May 2020.	that entries are made in respect of each class of drugs are adequately recorded in clear separate parts of the register Medicines management SOP has been amended to include the above. The anaesthetic patient chart has been reviewed by our lead Anaesthetist. The area of non-compliance identified here has been incorporated into the centre's audit criteria for controlled drugs records. An additional parameter that will be audited going forward is the Anaesthetic chart compared to the details logged in the CD registers to ensure complete accuracy and reflection of information on both sides. We shall provide a summary of the audit by the 12th May 2020.	

Other areas of practice that require improvement

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

An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
2. Premises In the medical gas cylinder storage room, several unused and one used oxygen cylinders were not adequately secured. Immediately following the inspection, the PR provided evidence that a suitable storage trolley had been purchased and the cylinders were now secured. SLC T17. Section 8.29 DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006).	The PR should ensure that all medical gases are stored safely and kept secure at all times. The inspection team acknowledges that the PR acted promptly on the findings by the end of the inspection. The PR has provided evidence that all gas cylinders are now adequately secured.	A multi cylinder trolley has now in use and all unchained cylinders have been secured and photographic evidence sent to the inspector.	The executive acknowledges the PR's response, review of processes and action taken in implementing this recommendation. No further action required.

Reponses from the Person Responsible to this inspection report