Executive Licensing Panel - minutes

Centre 0044 (The Centre for Reproductive and Genetic Health) Renewal Inspection Report

Friday, 13 January 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Howard Ryan Trisram Dawahoo	Director of Strategy & Corporate Affairs Report Developer Digital Communications 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 The Centre for Reproductive and Genetic Health is located in London. The centre provides a full range of fertility treatment services, including embryo testing. Other licensed activities at the centre include storage of gametes and embryos. In relation to activity levels this is a large centre.

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 31 August 2016, the centre provided 1627 cycles of treatment (excluding partner intrauterine insemination).

1.5. The panel noted that the centre's success rates are generally above the national average, but the clinical multiple pregnancy rate also represents performance above the 10% multiple birth rate target.

1.6. An inspection was carried out at the centre on 25 and 26 October 2016.

1.7. The panel noted that at the time of the inspection there were a number of areas of practice that required improvement, including four major and five 'other' areas of non-compliance. The panel noted the non-compliances, particularly those relating to multiple births, medicines management, audit and record keeping, and data submission.

1.8. The panel was particularly concerned about the high multiple birth rate, though reassured by the engagement of the PR. Multiple births had previously been an issue, with the rate standing at 16% at the time of renewal in February 2013. It was noted that the rate had previously decreased, but for the year to 31 May 2016 had increased to 20%.

1.9. The panel noted there had been a good level of engagement by the PR and evidence had been provided that actions have been taken to implement all the recommendations made, and has committed to audit the effectiveness of those actions within the required timescales.

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

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel noted there has been an issue regarding multiple births at the time of the last renewal inspection and although the centre had actively engaged and addressed this, the panel expected to see an improvement in the next few months. The panel requested a progress report from the

inspectorate, so that the panel could be reassured that the centre's corrective actions are having a positive impact. This timing of this should be determined by the inspectorate, but should certainly be within the next 12 months.

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

24 January 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 October 2016

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

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

Inspectors: Andrew Leonard, Louise Winstone, Shanaz Pasha, Tarek Hussein, Chris Hall

Date of Executive Licensing Panel: 13 January 2017

Centre name	The Centre for Reproductive and Genetic Health
Centre number	0044
Licence number	L/0044/16/b
Centre address	230-232, Great Portland Street, London, W1W 5QS
Person Responsible	Mr Paul Serhal
Licence Holder	Professor Joyce Harper
Date licence issued	1 April 2013
Licence expiry date	31 March 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Centre for Reproductive and Genetic Health is located in central London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility treatment services, including embryo testing. Other licensed activities at the centre include storage of gametes and embryos.

The centre provided 1627 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2016. In relation to activity levels this is a large centre.

The centre's licence was varied on 18 July 2015 to reflect a change of premises when the centre relocated to the current address.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending 31 May 2016 show the centre's success rates are in line with national averages with the following exceptions:

- The clinical pregnancy rate following IVF in patients aged 38 years and over is above the national average at a statistically significant level;
- The clinical pregnancy rate following ICSI in patients aged less than 38 years is above the national average at a statistically significant level;
- The clinical pregnancy rate following ICSI in patients aged 38 years and over is above the national average at a statistically significant level;
- The clinical pregnancy rate following frozen embryo transfer (FET) in patients aged less than 40 years is above the national average at a statistically significant level;
- The clinical pregnancy rate following FET in patients aged 40 years and over is above the national average at a statistically significant level.

In 2015, the centre reported 142 cycles of partner insemination with 22 pregnancies which represents a pregnancy rate of 15% which is in line with the national average.

Multiple births[2]

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

For all IVF, ICSI and FET treatments performed in the year to 31 May 2016, the centre's multiple pregnancy rate (MPR) was 20%; this represents performance that is likely to produce a live multiple birth rate greater than the 10% target (recommendation 1).

[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, including four major and five 'other' areas of non-compliance.

The PR has provided evidence that actions have been taken to implement all the recommendations made, as below, and has committed to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The centre should continue to audit embryo transfer practice across the centre to ensure compliance with the centre's multiple births minimisation strategy (MBMS) and relevant HFEA CoP requirements.
- The PR should ensure that blood samples for screening tests are obtained from egg donors within a timeframe specified by the Authority.
- The PR should ensure that medicines management practices at the centre are compliant with legal requirements and professional best practice.
- The PR should ensure that electronic patient records are audited against the requirements of SLC T46 and that SOPs are always effectively audited against CoP requirements.

'Other' areas that requires improvement:

- The PR should ensure that proper records are kept.
- The PR should ensure that the screening of patients and partners is performed in a compliant manner.
- The PR should ensure that traceability data is recorded regarding which centrifuge is used to process sperm for use in treatment.
- The PR should ensure third party agreements (TPAs) with providers of laboratory testing services are updated as required and the performance and compliance of the provider of sperm procurement services are audited.
- The PR should ensure that all licensed treatment activity and disclosure consent information is accurately reported to the Authority within the required timeframes.

Recommendation to the ELP

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

The inspection team notes that the centre's success rates are generally above the national average, but the clinical multiple pregnancy rate also represents performance above the 10% live multiple birth rate target. The PR is encouraged to continue to use the Quality Management System (QMS) to monitor and improve the multiple live birth rate.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to use the QMS to best effect to monitor and improve the compliance and quality of the service provided.

The inspector will continue to monitor the centre's performance to ensure effective implementation of the recommendations in this report.

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 partially compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

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

siblings) from the HFEA or the clinic where they received treatment. Therefore it is important that centres use donated gametes or embryos from identifiable donors.

The centre's 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

Screening of donors (Guidance note 11)
Blood samples taken from egg donors for screening purposes are not consistently obtained within a timeframe specified by the Authority nor is an appropriate timeframe for taking such blood samples stated in the egg donor recruitment SOP (SLC T53; recommendation 2).

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 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 processes 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 broadly 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 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 centre's procedures for providing this therapy are broadly compliant with professional body and HFEA guidance. The process for administering and monitoring patients during intralipid infusion was considered to be suitable however one non compliance related to the keeping of records regarding such treatment is discussed below in 'Record Keeping'.

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 MBMS 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 centre is partially compliant with the HFEA requirement to meet the 10% multiple live birth rate target. 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 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 their characteristics and biological functions;
- shipped in a container that is designed for the transport of biological materials and that maintains their safety and quality;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- transported in a secure container/package which ensures that they 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 partially 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 broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage transport and satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by transport and 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. Nearly all 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 staff.

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA and has investigated 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

Multiple births (Guidance note 7; General Direction 0003)
The MPR for the year to 31 May 2016 (20%) is significantly above the performance required to meet the 10% multiple birth rate target (SLC T2).

Five HFEA risk tool alerts related to the high MPR have been issued to the centre in the last year. On each occasion the centre has responded appropriately and provided evidence of this to the HFEA. The initial actions taken – audits, staff training and improving patient information - have had limited effect. The centre's latest actions, taken in August 2016, were to introduce elective single embryo transfer (eSET) criteria for patients having FET and to modify eSET criteria for patients having blastocyst transfers. Comparative data regarding the MPR in woman who have eSET and in those who do not, was also added to patient information and the embryo transfer consent form. These

actions are likely to have more impact on the MPR, in the opinion of the inspection team, and their efficacy is being monitored (recommendation 1).

Laboratory accreditation (Guidance note 25)
In some cases, blood samples for screening of individuals providing gametes for use in their treatment together with their partner, were tested by laboratories which had not been confirmed as holding suitable accreditation, for example by CPA (UK) Ltd or another body accrediting to an equivalent standard (SLC T50a; recommendation 6).

Medicines management (Guidance Note 25)
Three areas of non compliance or poor practice were observed in the medicines management practices at the centre (SLC T2; recommendation 3):

- Single use ampoules of midazolam are used for more than one patient, contrary to their single use specification (Royal College of Anaesthetists 'Controlled drugs in perioperative care' 2006). This carries significant risk (NPSA NHS Signal 1316: Multiple use of single use injectable medicines).
- The time of administration of controlled drugs (fentanyl and remifentanil) is not consistently recorded in the patient records or the controlled drugs register (Department of Health: Safer Management of Controlled Drugs (2006); NICE Guideline: Controlled drugs: safe use and management (2016)).
- Nurses routinely dispense 'top up' medicines to patients but there is no SOP to direct this process (SLC T33b). This duty is an extension to the nurse's role and should only be performed where there is a SOP to guide safe practice and when suitable training has been provided (NMC Standards for Medicines Management 2015).

Traceability (Guidance note 19)
No record is kept for traceability purposes of the centrifuge used to process sperm for use in treatment (SLC T99; recommendation 7).

QMS (Guidance note 23)
The centre's audits are generally of a good standard however some SOPs contain regulatory requirements and other information which has been superseded, suggesting the audit of SOPs against the regulatory requirements is not always effective (SLCs T36; recommendation 4).

The centre has not audited the quality of the records kept on the electronic records system against the requirements of SLC T46 (SLC T36; recommendation 4). It is important that this audit is performed since some required data was not present in all patient records reviewed on inspection and the centre must have reassurance regarding the quality of their electronic records before stopping the collection of paper based records.

The portfolio of information for patients has been recently audited for completeness and is compliant, however whether this information is consistently and successfully delivered to patients has not been audited in the last two years (SLC T36).

Third party agreements (Guidance Note 24)
Some TPAs with providers of laboratory testing services do not discuss the procedures for maintaining traceability during the submission of samples and the transmission of results back to the centre (SLC T114; recommendation 8).

The suitability of a provider of sperm procurement services and their compliance with the terms of their TPA, have not been reviewed in the last two years (SLCs T36 and T112; 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 serious 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 the inspectors spoke to three patients who provided feedback on their experiences. A further 14 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was fairly positive, with seven of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received. Some complaints were also received in the written feedback regarding non-clinical activities. These were discussed with the PR during the inspection and he advised that the centre's own feedback monitoring had led to corrective actions already being taken to address these matters.

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;
- has committed and caring staff appreciated by the patients.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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.

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)
The centre does not undertake these activities therefore these requirements were irrelevant at this inspection.

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. 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 no couples were affected by legal parenthood consent anomalies. At the inspection on 17 October 2014, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

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 reviewed four 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 seen to be in place before treatment in all cases. The centre's most recent quarterly audit of legal parenthood consents in all relevant cases treated in the quarter was also reviewed and provided good evidence of compliant practice.

In summary, the inspection team considers the processes used to obtain consent to legal parenthood 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 broadly compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases patient identifying information, to researchers, with the consent of the patient. 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)
Two discrepancies were found between 20 completed patient/partner/donor disclosure consents in patient records and the consent decision submitted by the centre to the register. In these instances, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent. In addition, no disclosure consent was found for one patient's partner (General Directions 0005 and 0007, recommendation 9)

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 broadly 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

Screening of patients (Guidance note 17)

In some cases, blood samples for screening of individuals providing gametes for use in their treatment together with their partner, were not obtained within three months of the gametes first being provided (SLC T51b; recommendation 6)

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 broadly 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 HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings. The centre's procedures for submitting information about licensed activities to the Authority are broadly compliant with HFEA requirements.

The HFEA register audit team found no evidence of systemic problems with the accuracy of the centre's submission of data to the register. A small number of errors were noted and the centre has been advised of them so that the register forms can be corrected.

What the centre could do better

Record keeping and document control (Guidance note 31)
Some electronic patient records did not include:

- by whom the patient/donor was reliably identified (SLC T46b);
- a record of the information provided (SLC T46c);
- a record of the offer of counselling and the patients response to it (SLC T46c);
- medical history of sufficient detail (SLC T46d);
- the rationale for the prescription of drugs off-licence (e.g. intralipid), if so prescribed (Clinic Focus, July 2015).

It is not clear in the electronic donor records if an assessment has been made of the need for additional screening tests on the basis of the donor's recent travel and medical history (SLC T52h). Centre staff assured the inspection team that the assessment is made but is not recorded if further tests are not required.

For one transport of sperm under General Direction 0006, the centre could not provide documentary evidence of the centre overseas being licensed or accredited by a Competent Authority (General Direction 0006). The inspection team consider it likely that the overseas centre is so licensed or accredited but the centre staff could only provide evidence of certification of the QMS.

See recommendation 5.

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

One donor insemination (DI) treatment of the 69 DI treatments audited, had not been reported to the Authority. This was because it was incorrectly recorded on the centre's database as having involved insemination with partner rather than donor sperm. Furthermore, 28 of 132 IVF treatments audited and four of 69 DI treatments had been reported to the HFEA outside of the required timeframe (General Direction 0005; SLC T41; recommendation 9).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, recommendations for improvement were made in relation to three major and one 'other' area of non compliance or poor practice.

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

On-going monitoring of centre success rates

In the last year, the centre has not been sent any HFEA risk tool alerts related to success rates but has however been sent five risk tool alerts related to the centre's high multiple clinical pregnancy rate. The PR's responses to these alerts are described in the section 'Multiple Births'.

Areas of practice requiring action

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None 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. Multiple births The centre is unlikely to meet the current multiple birth rate target (SLC T2). The MPR for the most recent year is 20% and is significantly above the performance required to meet the target.	The inspection team notes the actions taken by the centre since August 2016 in response to the high multiple pregnancy rate and that the efficacy of these actions will not yet be reflected in HFEA register data. Given this, the inspection team make no recommendations at this point except that the centre should continue to closely monitor and audit embryo transfer practice across the centre to ensure compliance with the centre's MBMS and relevant HFEA CoP requirements.	We will undertake the recommended audit(s) relating to the minimization strategy and the information sheet has been amended as requested.	The inspection team notes the PR's response and evidence which indicates that the centre continues to work to reduce its multiple pregnancy rate. The centre's inspector will continue to monitor the success of the centre's actions via the on-going monitoring system. Further actions are required.
2. Donor selection and screening Blood samples from egg donors are not obtained within a timeframe	The PR should review the centre's procedures to ensure that egg donors are screened within the timeframe specified by the Authority and that this	The egg donor recruitment SOP has been updated as requested.	The inspection team notes the PR's response and evidence which indicates that this recommendation has been implemented.

specified by the Authority nor is an appropriate timeframe for taking such blood samples stated in the egg donor recruitment SOP (SLC T53).	timeframe is clearly stated in the donor recruitment SOP. The PR should advise the centre's inspector of the actions taken to implement this recommendation by 26 January 2017. Within three months of the implementation of changes, the centre should audit whether the actions have been effective. A summary report of the findings of the audit should be provided to the centre's inspector by 26 April 2017.	The action(s) requested have been implemented and blood samples are to be taken at the time of egg collection. Recommendation(s) implemented	The centre's egg donor recruitment SOP now requires donor screening during the selection process and then again just prior to egg collection. The inspection team await the report of the audit of egg donor screening, due on 26 April 2017, to confirm the changes made have been effective. Further actions are required
3. Medicines management Three 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. When responding to this report, the PR should provide confirmation that the practice of using single use ampoules for multiple patients has ceased and that the time of administration of a controlled drug is now consistently documented in the patient record and the controlled drugs register. As part of the review of medicines management practices, the PR should	We have implemented the requested changes regarding ampoule usage. The time of administration of controlled drugs has always been documented contemporaneously as standard practice on the patient anaesthetic record. However, we have now amended our procotol to include simultaneous recording of the time of administration of the	The inspection team notes the PR's response which indicates that elements of this recommendation have been implemented already and the remainder is in progress. The centre's inspector has also been verbally advised that the review of medicines management practices has been completed. The inspection team await the report of the audit of the centre's adherence to the documented medicines

	consider the practice of dispensing 'top up' medicines to patients, to ensure that staff are trained to dispense medicines and that legal requirements for medicines labelling and the provision of appropriate drug information are met. In so doing, the PR should seek the advice of a registered pharmacist to review practice and assist in the formulation of an appropriate dispensing SOP and to provide any further training necessary. The PR should provide a summary of the review, details of any resulting actions, and a copy of the SOP to the centre's inspector by 26 January 2016. 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 April 2017.	controlled drugs in the CD register. Recommendation(s) implemented. Medication despensing only occurs in exceptional circumstances when needed stat and not stocked by a pharnacy / chemist nor can be fulfilled by our home medication provider. Additional training will be arranged for the nurses. A Pharmacist is being arranged to review practices and SOP.	management procedure, due on 26 April 2017, to confirm the changes made have been effective. Further actions are required
4. The QMS (audits) Some SOPs contain regulatory requirements and other information which has been superseded, suggesting the audit of SOPs against	The PR should ensure that: • the SOPs are audited against CoP requirements; • the electronic patient records are audited against the requirements of SLC T46;	The relevant SOPs will be reviewed against the HFEA CoP over the next 6 months starting Jan 2017. The auditing of the electronic records against T46 and	The inspector notes the PR's response and commitment to implement this recommendation. The inspection team consider it proportionate that the audits needed are added to

the regulatory requirements is not always as effective as is necessary and/or that regulatory change is not consistently and effectively processed by the QMS (SLCs T36 and T32). The centre has not audited the quality of the records kept on the electronic records system against the requirements of SLC T46 (SLC T36). The delivery of information to patients has not been audited in the last two years (SLC T36).	• the actual provision of information to patients is audited. The PR should advise the centre's inspector of the actions taken to implement this recommendation by 26 January 2017.	actual provision of information has been implemented and added to the audit schedule for this two year audit cycle which started in 2016. Recommendation(s) implemented	the audit schedule for 2016/17, notwithstanding that the audit of compliance of medical record keeping will be audited by 26 April 2017, to confirm the implementation of recommendation 5. Further actions are required

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
5. Record keeping Some electronic patient records did not include: • by whom, the patient/ donor has been reliably identified (SLC T46b); • a record of the information provided (SLC T46c) • a record of the offer of counselling and the patients response to it (SLC T46c); • medical history of sufficient detail (SLC T46d); • The rationale for prescription of drugs off licence in patients to whom they are prescribed (Clinic Focus, July 2015); It is not clear in the electronic donor records if	The PR should ensure that proper records are kept. The PR should provide details of the actions taken to implement this recommendation to the centre's inspector by 26 January 2017. Within three months of the implementation of changes, the centre should audit whether the actions have been successful. A summary report of the findings of the audit should be provided to the centre's inspector by 26 April 2017.	Checklists to confirm the identity, information provided, offer of counselling and screening due to travel exposure and medical reasons already exist as reviewed during the inspection. These checklists have been fully implemented and updated where necessary to improve useability. Recommendation(s) implemented CRGH operates a paperless system for all patient record. A paperless system is based on using standardized / generic electronic forms, fields and tabs. Therefore, some of the fields/questions will not be relevant to all patients and can be perceived as "short on content". In addition, the design of the database requires information to be recorded in a number of different sections which can give the impression that the data is short on content, inconsistent and difficult to navigate.	The inspection team notes the PR's response, which indicate that this recommendation has been considered and actions taken to implement it. The inspection team notes also that the shortness of detail in specific patient records was in areas considered relevant. The inspection team acknowledges the PR's comments concerning the organisation of the patient record into multiple sections and the recording of the rationale for intralipid treatment in the medical history section and treatment plan, but

an assessment is made of the need for additional screening tests on the basis of the donor's recent travel and medical history (SLC T52h). For one transport of sperm under General Direction 0006, the centre could not provide documentary evidence that the centre overseas was accredited by a Competent Authority (General Direction 0006).		The medical record contains the required information split into multiple sections. For instance, the full management detailed plan including the drug regime, investigations etc is documented and signed off under the "treatment cycle section" and will not be visible on the medical history. However as good practice we have revised the electronic template of the medical history to remove all fields that are not relevant to our patients. As a further "sophistication" we are to introduce validation rules for the required fields on the electronic forms. Each patient has clear documentation when intralipids is recommended by the doctor. On consultation the doctor writes in medical history when intralipids are recommended and this also goes in the intended treatment plan. The patients medical history is thorough and documented showing the reasons for the recommendation. On inspection this was discussed and several examples were looked at. The nurse showed a clear and quick association for the reasons that the patient had been recommend intralipids although the inspector felt the association could have been documented clearer i.e. written in	not in the medical/treatment record section. The inspection team await the report of the audit of the completeness of the patient records kept by the centre, due on 26 April 2017, to confirm the changes made have been effective. Further actions are required

		exactly the same line in the medical records. The Clinic focus July 2015 does not state the documentation must be so closely associated and simply states ' record the reasons for prescribing this medicine in the patients records'.	
6. Patient screening and laboratory accreditation In some cases, blood samples for screening of individuals providing gametes for use in their treatment together with their partner, were: • not obtained within three months of the gametes first being provided (SLC T51b) • tested by laboratories which had not been confirmed as holding suitable accreditation, for example by CPA (UK) Ltd or another body accrediting to an equivalent standard (SLC T50a).	The PR should ensure that for patients and partners providing gametes for their own use, all screening tests are carried out by laboratories which are appropriately accredited and are performed on blood samples obtained within three months of the gametes first being provided. The PR should provide details of the actions taken to implement this recommendation to the centre's inspector by 26 January 2017. Within three months of the implementation of change, the centre should conduct an audit of patient and partner screening to confirm that the actions taken are effective. A summary report of the findings of the audit should be provided to the centre's inspector by 26 April 2017.	We have amended our patient information to inform patients of the appropriate accrediated laboratory requirement for tests to be accepted by CRGH. If The laboratory is not appropriately accrediated the results will not be accepted. The patient will have the option to repeat the tests at CRGH or at an appropriately accrediate lab of their choice. Recommendation(s) implemented If screening test results provided by referred patients are not within 3 months of first treatment date they will be repeated. For patients having screening tests at CRGH they will be performed once treatment is confirmed. The timing of the screening tests has been reiniterated to staff. Recommendation(s) implemented	The inspection team notes the PR's response which indicates that this recommendation has been implemented. The inspection team await the report of the audit of patient screening tests, due on 26 April 2017, to confirm the changes made have been effective. Further actions are required

7. 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 all equipment (notably the centrifuge used to process sperm for use in treatment) and materials which may influence the quality and safety of gametes and embryos are traceable. When responding to this report, the PR should provide confirmation that this information is being recorded to ensure traceability. 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 April 2017.	The lab record for sperm preparation has been amended to include centrifuge traceability. A copy of the form has been provided to the HFEA. Recommendation(s) implemented	The inspection team notes the PR's response and evidence which indicates that this recommendation has been implemented. The inspection team await the report of the audit, due on 26 April 2017, to confirm the changes made have been effective. Further actions are required
8. Third party agreements Some TPAs with providers of laboratory testing services do not include protocols for maintaining traceability during the submission of samples and the transmission of results back to the centre (SLC T114).	The PR should ensure TPAs with providers of laboratory testing services are updated as required and the performance and compliance of the provider of sperm procurement services are audited. A report of the actions taken to implement these recommendations should be	The template TPA has been amended to cover traceability protocol regarding samples and results. The new TPA has been sent to the relevant parties. Recommendation(s) implemented	The inspection team notes the PR's response and evidence which indicates that the first part of this recommendation has been implemented. The centre's inspector is liaising with the PR regarding the centre's plans to assess the

The suitability of a provider of sperm procurement services and their compliance with the terms of their TPA with the centre, have not been reviewed in the last two years (SLCs T112 and T36).	provided to the centre's inspector by 26 January 2017.		suitability of the provider of sperm procurement services. Further actions are required.
9. Obligations and reporting requirements; Disclosure of information One DI treatment had not been reported to the Authority because it was incorrectly recorded as having involved insemination with partner, rather than donor, sperm. Furthermore, 28 of 132 IVF treatments and four of 69 DI treatments had been reported to the HFEA outside of the required timeframe (General Direction 0005; SLC T41). Two discrepancies were found between 20 completed	The PR should review procedures and take appropriate corrective actions to ensure: • all licensed treatment 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 two disclosure consent submissions identified as being incorrect. These recommendations should be implemented by 26 January 2017 and the centre's inspector informed of the results of the review and the actions taken.	The procedure for submitting forms to the HFEA has been reviewed and weekly audits of EDI implemented ensure forms are submitted in a timely fashion. The two CD forms mentioned have been corrected as requested.	The inspection team notes the PR's response and evidence which indicates that this recommendation has been implemented. The inspection team await the report of the audit of data submission to the HFEA, due on 26 April 2017, to confirm the changes made have been effective. Further actions are required

patient/partner/donor disclosure consents in patient records and the consent decision submitted by the centre to the register (General Directions 0005 and 0007).	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 April 2017.		

Response from the Person Responsible to this inspection report