Executive Licensing Panel - minutes

Centre 0338 (Reproductive Health Group) Renewal Inspection Report

Friday, 15 January 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) David Moysen Hannah Verdin	Director of Strategy & Corporate Affairs Head of IT Head of Regulatory Policy
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers	Anjeli Kara	Regulatory Policy 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:

- 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 completed application forms, reports and licensing minutes for the last three years.

1.2. The panel noted that this is a treatment and storage centre which provides a full range of fertility services.

1.3. The panel noted that the centre has been licensed by the HFEA since April 2014.

1.4. The panel noted that in the 12 months to 31 August 2015 the centre provided 260 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period July 2014 to June 2015 showed the centre's success rates were in line with national averages with the following exception:

- success rates following ICSI in women under 38 years old were lower than average at a statistically significant level

1.6. The panel noted that in 2014, the centre reported three cycles of partner insemination with no pregnancies. This was consistent with the national average.

1.7. Between July 2014 and June 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was less than 1%. This represented performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the renewal inspection on 14 and 15 October 2015 four major and two other areas of non-compliance were identified. The panel noted that since the inspection the PR has addressed one of the non-compliances and has committed to fully implementing the outstanding recommendations within the prescribed timescales.

1.9. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

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

1.11. The panel noted that, after the renewal inspection on 14 and 15 October 2015, the PR submitted an application to vary the centre's licence to include embryo testing. The inspectorate completed a desk based assessment for this application on 24 November 2015 and submitted a report for consideration by the Executive Licensing Panel at the same time as the centre's renewal inspection report. The panel noted that the centre plans to perform 10-20 cycles of pre-implantation genetic screening (PGS) per year. The PR has confirmed that in future, the centre may wish to offer pre-implantation genetic diagnosis (PGD) to its patients and has provided assurance that before doing so, he will provide the relevant additional evidence to the inspectorate.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate applications and fee had been submitted and that the application contained the supporting information required by General Directions 0008. Although the centre had originally applied for a treatment and storage licence and had then applied for a variation to include embryo testing, the panel considered both applications together for a treatment (including embryo testing) and storage licence.

2.2. 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 has discharged their duty under section 17 of the HFE Act 1990 (as amended).

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

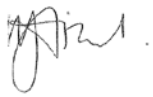
2.4. The panel noted the non-compliances and urged the PR to address them within the prescribed timescales.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence with embryo testing for a period of four years without additional conditions.

3. Chair's signature

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

Signature



Name

Juliet Tizzard

Date

25 January 2016

Inspection Report

Purpose of the Inspection Report

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

Date of inspection: 14 and 15 October 2015

Purpose of inspection: Renewal of a licence to carry out treatment 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: Susan Jolliffe, David Gibbon, Grace Lyndon, Polly Todd, Neil McComb.

Date of Executive Licensing Panel: 15 January 2016

Centre name	Reproductive Health Group
Centre number	0338
Licence number	L/0338/1/c
Centre address	Centre for reproductive health, Daresbury Park, Daresbury, Cheshire, WA4 4GE, UK
Person Responsible	Mr Luciano Nardo
Licence Holder	Mr Simon Shepherd
Date licence issued	01 April 2014
Licence expiry date	31 March 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
The Reproductive Health Group has held a treatment and storage licence with the HFEA since April 2014 and provides a full range of fertility services.

The centre provided 260 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/08/2015. In relation to activity levels this is a small centre.

An application to change the Person Responsible (PR) was agreed by the ELP on 11 July 2014. On 16 January 2015 the ELP approved an application to change the centre name from Centre for Reproductive Health to Reproductive Health Group.

Prior to the renewal inspection, the PR confirmed his wish to apply for all the activities shown on the centre's current licence.

After the renewal inspection the PR submitted an application to vary their licence to include embryo testing. The Executive has reviewed this application in a desk based assessment of documents provided by the centre. The ELP is requested to consider this application at the same time as the centre's application to renew their licence.

The PR has also submitted an application to change the Licence Holder (LH) which has been submitted to ELP for consideration at the same time as the centre's application to renew their licence.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period July 2014 - June 2015 show the centre's success rates are in line with national averages with the following exceptions:

- success rates following ICSI in women under 38 years old are lower than average at a statistically significant level

In 2014, the centre reported three cycles of partner insemination with no pregnancies. This is consistent with the national average.

Multiple births[2]

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

Between July 2014 and June 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was less than 1%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

[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 six recommendations for improvement in relation to four major and two 'other' areas of non compliance or poor practice.

The PR has implemented the following recommendation:

'Other' areas that requires improvement:

- The PR should ensure compliance with infection control regulations.

The PR has given a commitment to fully implement the following recommendations in the prescribed timescales:

Major areas of non compliance:

- The PR should ensure that the centre's procedures for accurate patient record keeping are compliant with all relevant regulatory requirements and guidance.
- The PR should review the quality management system (QMS) to ensure that standard operating procedures (SOPs) are in place for all activities authorised by the centre's licence and other activities carried out in the course of providing treatment services.
- The PR should ensure that personnel are available in sufficient number and are qualified and competent for the tasks they perform.
- The PR should review the post procedure care to ensure patients are recovered safely.

'Other' areas that requires improvement:

- The PR should ensure compliance with medicines management regulations.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have four major of areas of concern and two 'others'.

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

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

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

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

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/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 of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic

siblings) from the HFEA or the clinic where they received treatment.

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

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

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
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 to ensure patients and staff are in safe surroundings that prevent harm.

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by Clinical Pathology Accreditation (UK) Ltd or another body accrediting to an equivalent

standard. This is important to assure the quality of the services provided.

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

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are partially 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; Directions 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;
- transported in a container/package which is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and

has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

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

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 in place 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 compliant with HFEA requirements.

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

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of 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 also 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. The centre investigates all adverse incidents. 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

Infection control
A sharps box in the clinical room was overfull; it was filled above the designated 'full line' marked on the container for safety purposes to protect staff from a potential sharps injury. (SLC T2; CoP Guidance 25.20(a) recommendation 5)

There was no identified infection control lead: The previous post holder had recently left and is yet to be replaced. (SLC T2)(CoP Guidance 25.20(c)) (recommendation 5)

Medicines management
The centre does not record alterations in the controlled drugs register in line with the regulations: Changes should be corrected by a margin note or footnote to specify the date a correction is made. (Misuse of Drugs Regulations 2002, schedule 20 (c)) (SLC T2) (recommendation 6).

Surgical pathway
The centre uses conscious sedation for the majority of egg collection cases. Patients are transferred from theatre post-procedure to recover in one of eight single rooms that are side by side. Room eight is adjacent to the recovery nurses' area and is currently used for storage, while room one is furthest away. All these recovery rooms have solid doors and if these doors are closed and patients are alone, the patients are only observed by staff when entering the room to complete scheduled blood pressure, pulse and temperature observations. The inspection team was concerned because in between observations, the patients are not visible or audible to staff and if they develop a medical problem and are in distress, staff will not observe this which could delay assistance being provided.

It was noted that the beds in the eight recovery rooms had solid fixed headboards. The inspection team was concerned that this was not suitable if a patient required resuscitation, where access to the airway is required from behind the patient

(SLC T2) (CoP guidance 25.28) (recommendation 4)

Quality management system (QMS) (Guidance note 23)
The centre does not have SOPs directing the processes for;

- counselling
- confidentiality and privacy
- medicines management
- record keeping including when to scan and shred documents, processing requests for access to records, and preventing amendments to electronic records. (See recommendation 1)
- donor recruitment, assessment and screening

(SLC T33(b)) (recommendation 2).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1247/81).

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements. The centre has 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

Staff (Guidance note 2)
The individual responsible for the clinical embryology laboratory is an experienced embryologist who has worked overseas and been employed at the centre since it opened in March 2014, but who is not registered with the HCPC. (SLC T14) (CoP guidance 2.19 (c)) (recommendation 3).

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 the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided, are compliant with HFEA requirements.

Safeguarding
The centre's 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 does not perform embryo testing therefore this area of practice is not applicable to this inspection. However following the inspection the PR submitted an application to vary their licence to include embryo testing. This was reviewed in a desk based assessment, which is documented in a separate report.
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 21 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 14 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg [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) and ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

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

Counselling (Guidance note 3)

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)

The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and

- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre does not provide treatment involving surrogacy.

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; CH(11)02)
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 and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's 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). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities:

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

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

Record keeping and document control (Guidance note 31)
The patient records reviewed on inspection had a number of inaccuracies and some records were not fully completed. Some current records (2015) also contained old versions of HFEA consent forms (from 2010 for example). The record numbers and details were reported to the PR on the day of inspection. Examples of inaccuracies noted by the inspection team included: the date of birth written instead of the date of signing on the consent form page declaration; five consent forms with no patient identifier or centre number; two post procedure clinical records with no date to identify when they were written. The centre uses electronic records and consent and clinical records are scanned and placed into the information management system. It is therefore important to ensure the patient identifier is correct on each sheet in case they get separated or scanned into the incorrect folder, and to ensure when they are printed off that they can be matched correctly.(SLC T38) (recommendation 1)

Section 3: Monitoring of the centre's performance

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

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 July 2015, the centre received one risk based assessment tool (RBAT) alert regarding the provision of ICSI in patients <38 years. Following the alert the centre undertook a review investigating the possible causes of the reduction in success rates. This identified a possible explanation, and corrective action was implemented.

During discussions at the time of the inspection, the PR provided a commitment to keep success rates in this group of patients under review.

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

Critical area of non compliance

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

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

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Record keeping The patient records reviewed on inspection had a number of inaccuracies and some were not fully completed. SLC T38.	The PR should ensure that the centre's procedures for accurate patient record keeping are compliant with all relevant regulatory requirements and guidance. The PR should perform a review to identify the causes of the poor record keeping issues noted on inspection. A summary report of the findings of the review, including corrective actions and the timescale for implementation of the corrective actions, should be submitted to the centre's inspector by 15 January 2016. Three months after the implementation of corrective actions, the centre should	The Record keeping and Information management policy has been reviewed, and the document will be submitted to the centre's inspector by the proposed deadline. Since the inspection, two additional SOPs relevant to this area of practice have been produced and introduced at the centre. These include: a) the scanning of documents in to the patients notes, and b) the shredding of confidential documents. An initial review of the existing record making and record keeping pathways has been carried out by senior clinical team post-inspection. It was	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

	perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 15 April 2016.	noted that some clinical record keeping relevant to the post-procedure period had to be improved. The existing clinical notes template has therefore been amended and already introduced in routine clinical practice. The patient identifier appears on each sheet of the notes. The consultant anaesthetist's signature line appears at the bottom of all the relevant pages. Some issues with inaccurate record keeping had been identified. The nursing staff has been informed of the importance of attention to detail when completing the consent forms with the patient(s) and when entering data on to the electronic system Ideas. An additional step has been implemented which entails double checking the clinical records, including the signed consent forms and the virology screening results prior to the patient starting treatment. A weekly baseline meeting at which the notes are reviewed and the forthcoming	

		cycle details discussed has been scheduled every Thursday morning. A member of the nursing team is in charge of checking the consents for completeness and accuracy and the test results in advance of each meeting. It is thought that this approach will help to pick up any inaccuracies prior to the commencement of treatment.	
2. Quality management system (QMS) The centre does not have an SOP for; • counselling • confidentiality and privacy • medicines management • record keeping • donor recruitment, assessment and screening. SLC T33 (b)	The PR should ensure the development of documented SOPs for these procedures. Copies of the SOPs should be provided to the centre's inspector by 15 January 2016.	Within the centre there are available and up to date SOPs for all the procedures in relation to the following: -Counselling -Confidentiality and Privacy -Medicines management -Record keeping -Donor recruitment, assessment and screening With regard to the Medicines management, in addition to the existing Medicines management policy, the Controlled Drugs Administration Note has been introduced and made available to the relevant members of the team to ensure they always	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

		remember to record what supplied, administered and dispensed (SAD). The staff within the centre and within each relevant department are familiar with the relevant SOPs. All documents will be submitted to the inspector by the deadline. These activities are already part of the centre's audit plan. The team will continue to audit them, disseminate the findings and ensure that the corrective actions are implemented. Audits on Counselling, Confidentiality and privacy, Record keeping, Donor recruitment had already been carried prior to the inspection, and the team at the centre was aware of some weaknesses. Findings had been disseminated through the centre's newsletter 'Lessons Learned' and the corrective actions implemented. A plan for re-audit is in place.	

3. Staff The individual responsible for the clinical embryology laboratory is not registered with the HCPC. SLC T14; CoP guidance 2.19c	The PR should review the skill mix in the laboratory, and inform the inspector when responding to this report, how the centre will ensure the individual responsible for the clinical embryology laboratory is registered with the HCPC (or other equivalent body). By 15 April 2016 it is expected that the individual responsible for the clinical embryology laboratory should be registered with the HCPC. The PR should provide the Executive on this date with an update on progress to registration and then with monthly updates thereafter until registration has been achieved.	BS applied to HCPC in February 2014 through the international route as he was coming from overseas. On 30th May he was advised that as his degree(s) were from UK Universities, application would have to be via the domestic route. However, the degrees obtained were not on the list of University courses approved by the HCPC for Clinical Scientists as they pre-dated any such requirement. He was advised to apply for a course run by the Association of Clinical Scientists which would be full time over 3 years, or to apply for STP Embryology position. Further advice suggested that the most appropriate route was through a new 'Equivalence' Certificate administered through the Academy for Healthcare Science (AHS). As it was a new programme, only expressions of interest were being taken in June 2014. In February 2015 the application process opened via an online submission of evidence. He was led to believe that the	The Executive acknowledges the PR's response and appreciates that progress is being made to fully implementing the recommendation in the agreed time. Further action is required.

		process was 100% completed by the end of April 2015. However, requests for more information were made in June 2015 and that was completed in September 2015. Despite regular e-mails and a recent phone call, the requirements and timetable of the next stage of the process have not been made clear. It is understood that a portfolio of evidence is required, and this has largely been completed by end of quarter one of 2016, but how long it would take to the AHS to review its contents are unknown. It is only after the end of this process that the equivalence certificate can be awarded and the application to the HCPC be made.	
4. Surgical pathway. The nursing staff cannot easily observe or communicate with patients recovering post procedure in single rooms with solid doors. When the doors are closed the nurse cannot see or hear the patients and	The PR should complete a risk assessment of the post procedure recovery area, including the type and frequency of nursing observation and the type of bed used, to ensure patients are recovered safely	The post-surgery pathway has been reviewed by the senior clinical team at the centre. The return-to-room (i.e., recovery records) section has been introduced in the anaesthetic chart. This document is completed by the consultant	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

would not hear inside the room without entering. If the patients develop a medical problem and are in distress, staff will not observe this, which could delay assistance being provided. The beds in the recovery rooms had fixed headboards, which would make resuscitation difficult if access to the airway was required. SLC T2; CoP guidance 25.28	The PR should inform the inspector of their findings and actions to ensure the beds and post procedure area is fit for purpose. A copy of the findings should be submitted to the inspector by 15 January 2016.	anaesthetist whilst the patient is recovered in theatre post-surgery. The consultant anaesthetist decides when the patient is fully recovered (based on ABC and AVPV assessment) and at that stage instructs the theatre and nursing team to transfer the patient back to the room. The patient, who at this stage is conscious, is observed by the nursing on the ward. The standard post-surgery observation protocol is followed. A risk assessment of the recovery procedure and area will be performed and the findings submitted to the centre's inspector by the proposed deadline.	

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.Infection control There was no identified infection control lead in post at the time of inspection. SLC T2; CoP guidance 25.20c. The centre had a sharps box in the clinical room that was filled above the designated 'full line'. SLC T2; CoP guidance 25.20(a).	The PR should ensure that a person is identified as the infection control lead for the centre by 15 January 2016. The PR should ensure that sharps boxes are not filled above the safe level. A review of infection control practices and summary of findings should be sent to the lead inspector by 15 January 2016.	Fertility specialist nurse, LB, has agreed to take up the post of infection control lead for the Reproductive Health Group with immediate effect. She will be linked with the relevant regional infection control network and will be enrolled in regular training updates. In order to ensure that the sharps bins are used as per guidance and replaced safely whenever appropriate, a dedicated policy has been created, some documents have been updated and a number of measures have be implemented, as follows: -sharps bins SOP -sharps waste weekly check list -health and safety monthly check list -pathway for the management	The Executive acknowledges the PR's responses. No further action is required.

		of sharp injuries and accidents involving blood and bodily fluids -segregation poster sharp waste We start the independent weekly checks of the sharps bins this week (w/c 7 December 2015). The exercise is going to be carried out randomly by a non-clinical member of the RHG team and in the first instance will continue for 4 consecutive weeks and then until compliance is noted for a full month. The monthly Health & Safety checks are carried out by the nurse manager or the lead fertility nurse, and the audit sheets presented and discussed at the quarterly Health & Safety meetings.	
6. Medicines management Review of the controlled drugs register showed that the centre does not record alterations in line with the regulations; i.e. changes should be corrected by a margin note or footnote to specify the date a correction is	The PR should review practices and ensure compliance with medicines management regulations. Within six months, the centre should carry out an audit of medicines management	Measures have been put in to place to ensure that the practice falls in line with the regulations. The ODP and the anaesthetists have been informed of the importance of recording the alterations as well as correcting the changes	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

made. Misuse of Drugs Regulations 2002, schedule 20 (c); SLC T2.	procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit detailing the corrective actions with evidence supporting their implementation should be supplied to the centre's inspector by 15 April 2016.	by a margin note or footnote to specify the date the correction is made and by whom. The centre will carry out an audit of the medicines management procedures and the summary report will be submitted to the centre's inspector by the deadline.	

Reponses from the Person Responsible to this inspection report

The inspection carried out on 14th and 15th October 2015 for the purpose of renewal of the licence to carry out treatment and storage at the centre 0338 was a positive, constructive and interesting experience for all the team. As PR of the centre, I appreciated the fair input of the inspectors in reviewing the areas of practice as well as their advice and comments that are all summarised in the submitted 'Inspection Report'. Post-inspection I was pleased to notice that some of the areas that required improvement had already been identified by the team working at the centre and that measures had already been implemented to ensure compliance and safety of practice.