Executive Licensing Panel - minutes

Centre 0102 (Guys Hospital) Renewal Inspection Report

Friday, 24 March 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Paula Robinson (Chair) Howard Ryan Jessica Watkin	Head of Business Planning Report Developer Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

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

1.2. The panel noted that Guys Hospital is located in London. The centre holds a Treatment (including embryo testing) and Storage licence, providing a full range of fertility treatment services.

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

1.4. The panel noted that in the 12 months to 30 November 2016, the clinic provided 3274 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a large centre.

1.5. An inspection was carried out at the centre on 10 and 11 January 2017.

1.6. The panel noted that at the time of the inspection there were five major and four 'other' areas of non-compliance that required improvement. The panel noted the non-compliances, particularly that concerning the Quality Management System and the lack of SOPs for certain activities.

1.7. The panel noted the PR had responded positively to all the recommendations made in the report.

1.8. The panel noted that the centre's multiple clinical pregnancy rate meets the 10% target. The centre's success rates were in line with the national averages, with the exception of ICSI treatment (in women over 38 and under 38) and FET treatment in women under 40 years old, which were lower than average at a statistically significant level. In 2016 the centre was asked to review its procedures for the provision of ICSI treatment. The PR responded to the request, and provided a commitment at the time of the inspection to keep these success rates under review. The panel noted that the ICSI success rates have shown improvements and were approximately in line with the national average for the last two months.

1.9. The panel noted 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.

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.

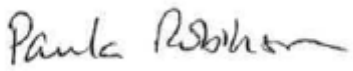
2.3. The panel was satisfied that the qualifications and character of the Person Responsible (PR) are such as is required for the supervision of licensed activities and that the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel therefore 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

Paula Robinson

Date

4 April 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: 10 and 11 January 2017

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

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

Inspectors: Vicki Lamb, Grace Lyndon and David Gibbon

Date of Executive Licensing Panel: 24 March 2017

Centre name	Guys Hospital
Centre number	0102
Licence number	L/0102/15/b
Centre address	11th Floor, Tower Wing, Guy's Hospital, London, SE1 9RT
Person Responsible	Mr Yacoub Khalaf
Licence Holder	Dr Ian Abbs
Date licence issued	01/07/2013
Licence expiry date	30/06/2017
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

Guys Hospital has held a licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 3274 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30/11/2016. In relation to activity levels this is a large centre.

On 18 September 2015 the ELP approved a variation of the licence to change the Licence Holder (LH).

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 01/09/2015 – 31/08/2016 show the centre's success rates are in line with national averages with the following exceptions:

- success rates following ICSI treatment in women under 38 years old are lower than average at a statistically significant level;
- success rates following ICSI treatment in women aged 38 years old and over are lower than average at a statistically significant level;
- success rates following FET treatment in women under 40 years old are lower than average at a statistically significant level.

In 2015, the centre reported 75 cycles of partner insemination with five pregnancies. This represents a clinical pregnancy rate of 7% which is likely to be in line with the national average.

Multiple births[2]

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

Between 01/09/2015 and 31/08/2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%: this represents performance in line with the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

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

The PR has implemented one of the recommendations:
Major areas of non-compliance:

- The PR should ensure that the suction pump is validated

The PR has given a commitment to implement all the other recommendations:
Major areas of non-compliance:

- The PR should provide an action plan with timeframes for implementation to address the infection control issues
- The PR should ensure that third party agreements are established where appropriate
- The PR should ensure that welfare of the child assessments have been reviewed by centre staff
- The PR should ensure that all licensed treatment activity is reported to the HFEA within the required timeframe

'Other' areas that require improvement:

- The PR should ensure that donors are suitably assessed and screened
- The PR should review how entries and corrections are made in the controlled drugs register to ensure compliance with Misuse of Drugs regulations
- The PR should ensure that SOPs are developed to cover all procedures and that they are up to date
- The PR should ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms

Recommendation to the Executive Licensing Panel

The centre has five major areas of concern. Some improvement is required in order for the centre to demonstrate the suitability of their practices.

The inspection team notes the success rates for ICSI and FET are below the national average and their multiple clinical pregnancy rates meet the target. The PR should ensure that the quality management system (QMS) is used to best effect to monitor and improve the quality of the service offered to patients.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

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 broadly 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)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to

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

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

What the centre could do better

Screening of donors (Guidance note 11)
Centre staff could not provide evidence, or explanations, that donors are screened for HTLV or other conditions depending on their travel and exposure history (SLC T52g and h) (see recommendation 6).

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 process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by 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 partially 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 broadly compliant with guidance.

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

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

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

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

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

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

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and

that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance 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 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 broadly 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 partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does conduct transport IVF. 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 partially 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. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Infection control (Guidance Note 25)
Some of the privacy curtains should have been changed in May 2016, some linen was being stored on the floor in the recovery area and the floor in the cryoroom was cracked. These issues present a potential infection risk (SLC T2) (see recommendation 1).

Medicines management (Guidance Note 25)
The centre does not record alterations in the controlled drugs register in accordance with regulations. There was an error in the controlled drugs register that was crossed out and a new entry overwritten, rather than written as an explanatory foot note with a record of the date the error was corrected (SLC T2, SLC T47 and Misuse of Drugs Regulations 2001, schedule 20 (c)) (see recommendation 7).

Quality management system (QMS) (Guidance note 23)
Not all activities are covered by standard operating procedures (SOPs), including, but not necessarily limited to, medicines management and the management of a clinical emergency. Some SOPs had not been reviewed by the review dates stated on the SOP SLC T33b and SLC T34) (see recommendation 8).

Third party agreements (Guidance note 24)
There is no third party agreement with the theatres where surgical sperm retrievals and egg collections are performed under general anaesthetic. Whilst it is recognised that these treatments do not occur frequently, nevertheless they are not performed on the premises covered by an HFEA licence (SLC T111) (see recommendation 2).

Equipment and materials (Guidance note 26)
The suction pump used during egg collection has not been validated (SLC T24) (see recommendation 3).

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 partially 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

Welfare of the child (Guidance note 8)
In two cases a welfare of the child form had been completed by the patients and their partners but there was no evidence that it had been reviewed by centre staff prior to treatment being provided. In two additional cases a welfare of the child form had been completed and reviewed by centre staff prior to treatment which resulted in a live birth, however when returning for further treatment, there was no evidence of welfare of the child having been reassessed (SLC T56) (see recommendation 4).

Embryo testing
Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

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

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

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

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

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit the inspectors spoke to three patients who provided feedback on their experiences. A further four patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with three 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 sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

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

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

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not perform egg sharing.

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 / 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.

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 one couple was affected by legal parenthood consent anomalies. This case was concluded in May 2016 following a declaration of parenthood being made by the Family Division of the High Court.

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.

Inspectors visited the centre in August 2016, the focus of which was learning from legal parenthood consent anomalies. As part of that visit, the inspection team reviewed 30 patient records where consent to legal parenthood may be required. No anomalies which could pose a challenge to effective consent to legal parenthood were identified.

To provide further assurance of the effectiveness of the centre's procedures, on this inspection eight sets of patient records, where treatment with donor sperm had recently been provided, were reviewed. In two instances 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 both cases.

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)
It 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.

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Thirty-eight patient records were audited. Ten discrepancies were found between completed patient/partner disclosure consents in patient notes and the related consent data submitted for inclusion on the register. In all the cases noted the patients had consented to disclosure of information but the consent decision reported to the HFEA was that they had not consented. Whilst this does not pose a risk of inadvertent disclosure of information to researchers by the HFEA, this does not represent the consent providers' wishes (CH(10)05 and General Direction 0005) (see 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 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 compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

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

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

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
15% (19/132) of the IVF and 44% (32/72) of the donor insemination (DI) treatments reviewed on inspection had been reported to the HFEA outside the period required by General Direction 0005. The centre also has high error rates that are frequently not corrected within the expected time frame (General Direction 0005 and SLC T41) (see recommendation 5).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, recommendations for improvement were made in relation to three areas of major 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 2016, the centre was asked to review procedures for the provision of ICSI treatment in patients aged 38 and over in April and November, and ICSI treatment in patients aged under 38 in August, September and November. The PR responded to the request and during discussions at the time of the inspection, and provided a commitment to keep success rates in this group of patients under review. Success rates for both these groups of patients have shown improvements and have been approximately in line with the national average for the last two months.

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

Critical area of non-compliance

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

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

Major area of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. **Infection control** Some of the privacy curtains should have been changed in May 2016, some linen was being stored on the floor in the recovery area and the floor in the cryoroom was cracked. These issues present a potential infection risk. SLC T2	When responding to this report, the PR should provide an action plan with timeframes for implementation to address observations described in this report.	This issue has been addressed and the designated member of staff that is responsible for infection control has committed to devising an alert system to ensure a timely change of curtains. Following the HFEA inspection, the Matron has created a cleaning schedule with a checklist for all clinical rooms with immediate effect. In addition there is a nominated team member responsible for cleaning and tidying up the clinical rooms using the checklists. The detailed checklist is inclusive of all the cleaning activities such as checking expiry date of the disposable curtains as	The inspector is satisfied that the PR has taken appropriate action to address this issue. The inspector will follow up with the PR to ensure the repair to the cryoroom floor is resolved within a reasonable timescale.

		well as ensuring that linen is not stored on the floor. Before the HFEA inspection the crack in the floor in the cryoroom had been identified by the embryology team and the floor had been inspected by the estates department who had sealed it off with tape and were awaiting estimates for the repair. The job has now been approved and a PO has been raised. We are now awaiting a confirmed repair date.	
2. Third party agreements There is no third party agreement with the theatres where surgical sperm retrievals and egg collections are performed under general anaesthetic. SLC T111	The PR should ensure that third party agreements are established with these theatres. Copies of these agreements should be forwarded to the centre's inspector by 11 July 2017.	The third party agreement is being authorised and will be provided by the set date.	The inspector is confident the third party agreements will be forwarded by the required date.
3. Equipment and materials The suction pump used during egg collections has not been validated. SLC T24	The PR should ensure that the suction pump is validated by 11 April 2017 and should inform the centre's inspector when this has been completed.	The suction pump has now been validated and the confirmation is attached.	The PR has provided evidence that this issue has been resolved.
4. Welfare of the child In two cases the welfare of	The PR should ensure that welfare of the child	The gap has been highlighted to the team and the welfare of	This is a suitable response and the inspector awaits

the child form had been completed by the patients but there was no evidence that it had been reviewed by centre staff. In two additional cases a welfare of the child form had been completed and reviewed by centre staff, but the couple had subsequently had a child and the welfare of the child form had not been redone. SLC T56	assessments have been reviewed by centre staff, and repeated where appropriate, before treatment is provided. A summary of actions taken, along with any amended documents, should be forwarded to the centre's inspector by 11 April 2017. Three months after the implementation of changes welfare of the child assessments should be audited to determine whether the actions taken have been effective. A summary of the audit should be forwarded to the centre's inspector by 11 August 2017.	the child assessment will be audited with the findings and corrections shared by the set date. A further audit will be performed three months later and the findings will be reported.	submission of the documents by the required dates.
5. Obligations and reporting requirements (Guidance note 32; General Direction 0005) 15% (19/132) of the IVF and 44% (32/72) of the donor insemination (DI) treatments reviewed on inspection had been reported to the HFEA outside the period required by General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframe required by General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for high error rates. A summary of the findings of the review, any	I am fully committed to addressing this important issue which was largely contributed to by our current database. We are in the process of procuring a comprehensive data management system that is expected to address these issues. We are regularly auditing data submission for completion accuracy. The suggested review is being	This is a suitable response and the inspector awaits submission of the documents by the required dates.

The centre also has high error rates that are frequently not corrected within the expected time frame. General Direction 0005 and SLC T41	corrective actions and timescales for implementation should be provided to the centre's inspector by 11 April 2017. The PR should conduct an audit six months after implementing any corrective actions to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 11 November 2017.	implemented and the findings of which will reported by the date. The audit after 6 months will be reported by the date given.	

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
6. Screening of donors Centre staff could not provide evidence, or explanations, that donors are screened for HTLV or other conditions depending on their travel and exposure history. SLC T52g and h	The PR should ensure that donors are suitably assessed and screened. A summary of actions taken should be forwarded to the centre's inspector by 11 April 2017. Six months after the implementation of changes an audit of screening should be undertaken to determine whether the actions taken have been effective. A summary of the audit should be forwarded to the centre's inspector by 11 November 2017.	The history sheet is being updated to reflect travel history as suggested and will be reported by the given date An audit will be implemented 6 months after the implementation and findings will be reported by the given date.	This is a suitable response and the inspector awaits submission of the documents by the required dates.
7. Medicines management The centre does not record alterations in the controlled drugs register in accordance with regulations. There was an error in the controlled drugs register that was crossed out and a new entry	The PR should review how entries and corrections are made in the controlled drugs register to ensure compliance with Misuse of Drugs regulations. A summary of the findings of this review, any corrective actions and timescales for implementation	The theatre staff have been made aware of completing the record considering the required regulations and the summary of the findings will be reported within the given time.	This is a suitable response and the inspector awaits submission of the documents by the required date.

overwritten, rather than written as an explanatory foot note with a record of the date the error was corrected. SLC T2, SLC T47 and Misuse of Drugs Regulations 2001, schedule 20 (c)	should be provided to the centre's inspector by 11 April 2017.		
8. Quality management system Not all activities are covered by standard operating procedures (SOPs), including, but not necessarily limited to, medicines management and the management of a clinical emergency. SLC T33b Some SOPs had not been reviewed by the review dates stated on the SOP. SLC T34	The PR should ensure that SOPs are developed to cover those procedures described in this report, and any other procedures that are not covered by SOPs. Copies of these SOPs should be forwarded to the centre's inspector by 11 April 2017. The centre's existing SOPs should be reviewed to ensure that they are up to date and suitably reflect current practice. The PR should confirm this has been done, along with what action has been taken, by 11 April 2017.	The medicine management SOP is being drafted according to Trust policy (enclosed) and a copy will be forwarded by the given date. Please note that the pharmacy audit CD regularly and no non conformities have been found. This is currently being looked into and the actions that have been taken will be forwarded by the given date.	The inspector is confident the documents will be forwarded by the required date.
9. Disclosure of information, held on the	The PR should review procedures and take	This will be reviewed and the findings and all necessary	The inspector is confident the documents will be forwarded

HFEA Register, for use in research (General Direction 0005) Thirty-eight sets of notes were checked and 10 discrepancies were found between completed patient/partner disclosure consents in patient notes and the related consent data submitted for inclusion on the register. In all the cases noted the patients had consented to disclosure of information, but the it was reported to the HFEA that they had not consented. CH(10)05 and General Direction 0005	appropriate corrective actions to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms. The PR should also correct the submissions that have been identified as being incorrect. Confirmation of the corrections and a summary of the findings of the review, any corrective actions and timescales for implementation should be provided to the centre's inspector by 11 April 2017. The PR should conduct an audit six months after implementing any corrective actions to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 11 November 2017.	details as suggested will be reported by the given date. An audit after 6 months of implementation will be reported by the given date.	by the required dates.

Reponses from the Person Responsible to this inspection report
In addition to the response above, we are committed to continue to be compliant with HFEA regulations and all areas highlighted by the in sectors will be addressed by the set date