Executive Licensing Panel - minutes

Centre 0077 (Regional Fertility Centre) Renewal Inspection Report

Friday, 27 January 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Paula Robinson Howard Ryan	Director of Strategy & Corporate Affairs Head of Business Planning Report Developer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that the Regional Fertility Centre is located in Belfast. The centre holds a Treatment 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 1992.

1.4. The panel noted that in the 12 months to 31 August 2016, the clinic provided 1182 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a large centre.

1.5. The panel noted that the centre's multiple birth rate, between August 2015 and July 2016, stood at 14%, and was satisfied this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.6. An inspection was carried out at the centre on 20 and 21 September 2016.

1.7. The panel noted that at the time of the inspection there were a number of areas of practice that required improvement, including three major and five 'other' areas of non-compliance.

1.8. The panel noted that since the inspection, the centre had implemented many of the recommendations, including those relating to medicines management. The centre was on track to address all the recommendations within the prescribed timetable.

1.9. The panel noted the HFEA risk tool alerts, received by the centre since the interim inspection in September 2014; these were in line with the national average.

1.10. The panel noted that the inspectorate 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.

1.11. The panel noted the inspectorate's recommendation, due to the delay in the inspection report reaching the Executive Licensing Panel, that a Special Direction to the PR under Section 24 (5A)(b) of the HF&E Act 1990 (as amended) is issued, to permit the continuation of the centre's Treatment and Storage licence from 28 February to 31 March 2017, to allow time for the administrative process of licence renewal to be completed within the usual timeframe.

2. Decision

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

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

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

2.4. The panel noted that although the non-compliances were not of a critical nature, some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

2.5. The panel endorsed the inspectorate's recommendation to renew 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.

2.6. The panel endorsed the inspectorate's recommendation to issue a Special Direction to the PR under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of the centre's Treatment and Storage licence from 28 February to 31 March 2017, to allow time for the administrative process of licence renewal to be completed within the usual timeframe.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

8 February 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: 20 and 21 September 2016

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: Shanaz Pasha (Lead), Susan Jolliffe, Louise Winstone, Cathy Hodgson, Joel McChesney.

Date of Executive Licensing Panel: 27 January 2017

Centre name	Regional Fertility Centre, Belfast
Centre number	0077
Licence number	L/0077/18/b
Centre address	Royal Maternity Hospital, Grosvenor Road, Belfast, BT12 6BB, United Kingdom
Person Responsible	Dr Peter McFaul
Licence Holder	Mr Aiden Dawson
Date licence issued	1 March 2013
Licence expiry date	28 February 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Regional Fertility Centre, Belfast has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 1182 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2016. In relation to activity levels this is a large centre.

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

The centre's licence was varied in June 2016 to reflect a change of Licence Holder.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period August 2015 to July 2016 show the centre's success rates are in line with national averages.

In 2015, the centre reported 67 cycles of partner insemination with 6 pregnancies. This represents a clinical pregnancy rate of 9%, which is in line with the national average.

Multiple births[2]

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

Between August 2015 and July 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

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

Summary for licensing decision

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

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

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

Since the inspection visit, the following recommendations have been fully implemented:

Major areas of non compliance:

- The PR should ensure that witnessing steps are recorded contemporaneously in accordance with guidance.
- The PR should ensure that the centre has a third party agreement with the gynaecology theatre

Other' areas of non-compliance

- The PR should ensure that all activities and protocols are audited against regulatory requirements and the centre's own quality indicators.
- The PR should ensure that the premises are suitable for the procedures to be performed.
- The PR should ensure that only CE marked devices are used where possible.

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non compliance:

- The PR should ensure that the procedures for the management of medicines are compliant with all regulatory requirements and guidance.

'Other' areas of non-compliance:

- The PR should ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the multiple clinical pregnancy rate indicates that the centre is likely to meet the current, no greater than 10% multiple birth rate target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (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.

This licence renewal inspection report has taken longer than normal to bring before the ELP due to: the need for communication with the PR after the inspection to clarify the compliance of the centre's activities; the inspection report undergoing a prolonged quality assurance process; and clashes between proposed licensing committee dates and recommendation completion dates. As a result, there will not be sufficient time after the ELP has considered the application, for the licensing decision to be recorded in the minutes, communicated to the PR and for the PR to have the standard 28 days to consider the licence conditions (assuming the licence is renewed as recommended), prior to the current licence expiring on 28 February 2017. Therefore the Executive recommends that the ELP issues a Special Direction to the PR under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of the centre's Treatment and Storage licence from 28 February to 31 March 2017, to allow time for the administrative process of licence renewal to be completed within the usual timeframe.

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 partially compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
An audit of six witnessing records conducted on inspection showed that in one instance, a number of manual witnessing steps undertaken were not recorded by the second witness. The PR should ensure that witnessing steps are documented contemporaneously. Standard licence condition (SLC) T71, see recommendation 1.

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 about their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment. Therefore, it is important that centres use donated gametes or embryos from identifiable donors.

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

What the centre could do better
Nothing identified at this inspection

Suitable premises and suitable practices

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

What the centre does well

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

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

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

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

to assure the quality of the services provided.

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

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

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 not have any transport or satellite arrangements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements. Most 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 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
Safety and suitability of premises and facilities (Guidance note 25)
The centre's post-procedure recovery area does not have patient call bells or emergency call bells for staff to summon help in the event of an emergency. SLC T17, see recommendation 5.

Medicines management (Guidance Note 25)
An audit of seven patient records by the inspection team showed that in two records the time the controlled drug was administered was not recorded in the patient's records. SLC T2, see recommendation 2.

Nursing staff have not received training in the management of medicines. SLC T15, see recommendation 2.

Quality management system (QMS) (Guidance note 23)
The centre has undertaken three different audits of the counselling service, however none of the audits identified whether the offer of counselling had been made or taken up prior to consent being provided. SLC T36, see recommendation 4.

The centre does not have an SOP which clearly defines the centre's procedures for obtaining consent to legal parenthood in surrogacy cases. SLC T33 (b), see recommendation 4.

The centre has not audited the centre's procedures for maintaining privacy and confidentiality within the last two years. SLC T36, see recommendation 4.

Third party agreements (Guidance note 24)
Egg collections occasionally take place in the gynaecology theatres in the main hospital, when a general anaesthetic may be required. The centre currently does not have a third party agreement with the gynaecology theatres. SLC T117, see recommendation 3.

Equipment and materials (Guidance note 26)
The 5ml tubes used during sperm preparation are not CE marked. SLC T30, see recommendation 6.

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.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent

staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
The centre does not undertake embryo testing.

2. The experience of patients

Patient feedback

What the centre does well

Twelve patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed with seven of the individuals providing written feedback to the HFEA commenting that they had compliments about their care and three of the individuals had complaints about the care that they received. The feedback provided directly to the HFEA was discussed with senior staff on inspection.

During the inspection visit the inspectors spoke to three patient couples who provided feedback on their experiences which was very positive.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)

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

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's procedures for treatment involving surrogacy are broadly compliant with HFEA requirements. It is important to protect the surrogate and any children born as a result of the treatment. However, the inspectors have some concerns regarding the clarity of roles and responsibilities for actions along the surrogacy pathway.

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
Surrogacy (Guidance note 14)
The centre occasionally facilitates treatment requiring surrogacy. One set of surrogate and intended parent's records, who are currently going through treatment, were reviewed. Whilst it was evident that the consent of the intended parents for the use of embryos to be created with their gametes in surrogacy was in place (WSG and MSG), there was no recorded consent to legal parenthood for either intended parent (SWP and SPP). The process for obtaining consent to legal parenthood, where at least one of the intended parents is genetically linked to any child born was discussed. The inspection team have concerns that the process for obtaining consent to legal parenthood in this scenario was fragmented and staff were uncertain as to who should be responsible for seeking consent to legal parenthood or when this should be sought. The inspection team considered this posed a risk that the process may not be completed effectively.

The centre has a generic surrogacy SOP but this did not provide clear directions for legal parenthood consent requirements. SLC T33(b), see recommendation 4.

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. The couple was informed of the anomalies and the implications thereof. The centre subsequently provided support to the couple in the manner expected by the Authority in that they were advised to seek legal advice and financial support in doing so was offered. The couple's response at that point was that they intended to proceed with adoption. However the couple has not responded to numerous communications from the centre or their legal team in providing confirmation that this is complete or to provide an update. The inspection team acknowledges the centre's attempts to contact the couple.

On this inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

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

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

In summary, the inspection team considers the processes used to obtain consent to legal

parenthood at the centre appear to be compliant with HFEA requirements.

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

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients' identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better
Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
A sample of 34 patient and partner consent to disclosure records were reviewed on inspection to determine whether the disclosure consent recorded in the couple's files is accurately reflected on the HFEA register. Eight discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent information submitted by the centre for inclusion on the register. In each instance the consent recorded in the patient / partner record gave consent to disclosure however the decision recorded on the HFEA register stated that consent was not given. Whilst this does not pose a risk that the HFEA could inadvertently disclose information to researchers without consent, it does not accurately reflect the consent provider's wishes. CH(10)05 and General Direction 0005, see recommendation 7.

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
Storage of gametes and embryos (Guidance note 17)
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 broadly 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)
As part of this inspection, the register team reviewed a sample of patient treatment records.

9% (1/11) of the DI treatments reviewed at inspection had not been reported to the HFEA and 80% (8/10) had been reported outside the period required by General Direction 0005 with an average delay of 125 days. General Direction 0005 and SLC T41, see recommendation 8.

Section 3: Monitoring of the centre's performance

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

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

On-going monitoring of centre success rates

Since the interim inspection in September 2014, the centre has received the following HFEA risk tool alerts

- four alerts relating to pregnancy rate per cycle of IVF in patients aged 38 years or under;
- two alerts relating to pregnancy rate per cycle of ICSI in patients aged 38 years or under and;
- one alert relating to frozen IVF and ICSI (FET) in patients aged 40 or under.

The PR responded appropriately to the alerts in all instances and provided evidence of actions taken for improvement. It should be noted that the centre has received only one alert which related to pregnancy rates for IVF in patients aged 38 years and under in the last year. The centre's current success rates are in line with the national average.

The PR has committed to continue to monitor the centre's success rates for this group of patients.

Areas of practice requiring action

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

Critical area of non compliance

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

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

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Witnessing An audit of six witnessing records conducted on inspection showed that in one instance, a number of manual witnessing steps undertaken were not recorded by the second witness. SLC T71	The PR should ensure that witnessing events are recorded contemporaneously. This recommendation should be implemented immediately and the centre's inspector advised of the actions taken when the PR responds to this report. Within three months of having implemented any corrective actions, the centre should audit witnessing practices to ensure compliance. A summary report of the audit should be sent to the centre's inspector by 20 December 2016.	Witnessing SOPs will be reviewed, supplemented by additional training/competancy as required. The requested audit will be submitted.	The PR has provided confirmation that witnessing SOPs have been reviewed and additional training has been provided. A witnessing audit has been submitted which shows 100% compliance. No further action is required.

2. Medicines Management An audit of seven patient records by the inspection team identified that in two records the time that the controlled drug was administered was not recorded in the patient records. SLC T2 Nursing staff have not received training in the management of medicines. SLC T15	The PR should ensure that the procedures for the management of medicines are compliant with all regulatory requirements and guidance. The PR should ensure that the time of the administration of controlled drugs is recorded in the patient's record. The PR should conduct a review of the centre's medicines management procedures and this should include staff training requirements. A summary of the review should be sent to the centre's inspector by 20 December 2016. Within three months of having implemented any corrective actions, the centre should audit the recording of controlled drug administration in patient records to ensure actions taken are effective. A summary report of the audit should be sent to the centre's inspector by 20 March 2017.	The relevant SOP to be reviewed and action taken to ensure all required staff complete training. A review will be submitted by the 20/12/16. The requested audit to be completed and submitted.	The Executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has submitted the required evidence by 20 December 2016. The Executive awaits the report of the audit by 20 March 2017. Further action is required.

3. Third Party Agreements Egg collections occasionally take place in the gynaecology theatres in the main hospital. The centre currently does not have a formal third party agreement with the gynaecology theatres. SLC T117	The PR should ensure that an appropriate third party agreement is developed and formalised with the gynaecology theatres. The centre's inspector should be provided with a copy of the third party agreement by 20 December 2016.	This is currently being developed .	The Executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has provided a copy of the TPA. No further action is required.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. QMS The centre has undertaken three different audits of the counselling service, however none of these were broad enough in scope to examine and document whether the offer of counselling was made prior to obtaining consent. SLC T36 The centre does not have an SOP which clearly defines the centre's procedures for obtaining legal parenthood consents in surrogacy cases. SLC T33 (b) The centre has not conducted an audit of confidentiality and privacy in the last two years. SLC T36	The PR should ensure that all activities and protocols are audited against regulatory requirements and the centre's own quality indicators. The PR should send copies of the requested audits and SOP to the centre's inspector by 20 December 2016.	An annual audit is conducted which include confirming that counselling was offerred to all patients prior to obtaining consent to treatment. This offer of counselling is usually 4-6 months before the consents are completed. I will forward a copy of the last audit which demonstrated 100% complance. The requested SOP and audit will be completed.	The Executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has submitted copies of the requested audits and SOP. No further action is required.

5. Premises and facilities The centre's post-procedure recovery area does not have patient call bells or emergency call bells for staff to summon help in the event of an emergency. SLC T17	The PR should ensure that the premises are suitable for the procedures to be performed. The PR should review how patients and staff may summon help if required and assess any risk of not having patient call bells in this area. A summary report and action plan should be sent to the centre's inspector by 20 December 2016.	Call buttons are to be installed where required. Report to follow.	The Executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has provided confirmation of installation of call bells in the recovery area and blood room. No further action is required.
6. Equipment and materials The 5ml tubes used during sperm prep are not CE marked. SLC T30 It is noted that the HFEA's assessment framework recommends classification as a major non compliance but in consideration of the plastic ware involved this has been classified as an 'other' non compliance.	The PR should ensure that only CE marked devices are used where possible. The PR should confirm the actions taken to source CE marked tubes when responding to the report. It is expected that suitable CE marked tubes will be in place by 20 December 2017.	CE marked tubes have been identified and are ordered.	The Executive acknowledges the PR's response and his commitment to fully implement this recommendation. No further action is required.

7. Disclosure of information held on the HFEA Register, for use in research. Eight discrepancies were found between 34 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. It is noted that the centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected. CH(10)05 and General Direction 0005	The PR should review procedures for the submission of consent to disclosure decision provided to the HFEA register to ensure that the decision recorded on the register accurately reflects the consent decision given and recorded on disclosure consent forms. The PR should ensure that the consents identified as being incorrect are corrected and provide confirmation that this has been done when responding to this report. 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 20 March 2017.	The submissions have been corrected. Our processes are under review and a report will be submitted. Requested audit to be done.	The Executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has provided confirmation of the correction of the consent data. The Executive await the audit report by 20 March 2017.

8. Obligations and reporting requirements 9% (1/11) of the DI treatments reviewed at inspection had not been reported to the HFEA and 80% (8/10) had been reported outside the period required by General Direction 0005 with an average delay of 125 days. General Direction 0005 SLC T41	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should undertake an urgent review of the process for submitting donor treatment data to identify why there have been significant delays. The PR should provide the centre's inspector with the preliminary findings of this review and proposed actions when responding to this report 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 20 March 2017.	The review has been conducted and will be submitted with this report. Audit to be done.	The Executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has provided evidence of the review undertaken and the corrective actions implemented. The executive awaits the report of the audit by 20 March 2017. Further action is required.

Reponses from the Person Responsible to this inspection report