Executive Licensing Panel - minutes

Centre 0328 (GCRM - Belfast) – Renewal Inspection Report

Monday, 28 September 2015

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

Panel members	Juliet Tizzard (Chair) Paula Robinson David Moysen	Director of Strategy & Corporate Affairs Head of Business Planning Head of IT
Members of the Executive	Dee Knoyle	Secretary
External adviser	None	
Observers	None	

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 this is a treatment and storage centre which provides a full range of fertility services. The panel noted that in relation to activity levels this is a small centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 2013.

1.4. The panel noted that in the 12 months to 30 June 2015, the centre provided 280 cycles of treatment (excluding partner intrauterine insemination).

1.5. For IVF and ICSI, HFEA-held register data for the period April 2014 – March 2015 showed the centre's success rates were in line with national averages.

1.6. The panel noted that In 2014, the centre reported 7 cycles of partner insemination with no pregnancies. This was consistent with the national average.

1.7. Between April 2014 and March 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 18%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% maximum target.

1.8. The panel noted that at the time of the inspection on 29 and 30 July 2015, five major and six other areas of non-compliance were identified. The panel noted that the Person Responsible (PR) is committed to fully implementing all of the inspectorate's recommendations within the prescribed timescales.

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

1.10. The panel noted that the inspectorate recommends the renewal of the centre's treatment and storage licence 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.

2.2. The panel agreed it was in receipt of the appropriate documentation as required by the HFE Act 1990. 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.

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

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

2.5. The panel was disappointed with the non-compliances identified at the renewal inspection, in particular the non-compliances relating to medicines management and the quality management system. As the PR will know, taking accurate consent to legal parenthood is crucially important; therefore having appropriate procedures in place is critical for the provision of a good service for patients. The panel stressed that they expect a quick and positive response from the centre in dealing with these matters. The panel noted the deadlines set for 30 October 2015 in the renewal inspection report and asked the inspectorate to monitor the centre and report back if satisfactory progress is not made.

2.6. 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.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

12 October 2015

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: 29 and 30 July 2015

Purpose of inspection: Renewal of a licence to carry out treatment and storage

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

Inspectors: Susan Jolliffe, Karen Conyers, Shanaz Pasha, Neil McComb, Helen Crutcher.

Date of Executive Licensing Panel: 28 September 2015

Centre name	GCRM Belfast
Centre number	0328
Licence number	L/0328/1/a
Centre address	Edgewater House, Edgewater Business Park Edgewater Road. Belfast, County Antrim Northern Ireland BT3 9QJ
Person Responsible	Dr Peter McFaul
Licence Holder	Dr Ralph Roberts
Date licence issued	25 November 2013
Licence expiry date	24 November 2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

GCRM Belfast has held a treatment and storage licence with the HFEA since 2013 and provides a full range of fertility services.

The centre provided 280 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2015. In relation to activity levels this is a small centre.

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period April 2014 – March 2015 show the centre's success rates are in line with national averages.

In 2014, the centre reported 7 cycles of partner insemination with no pregnancies. This is consistent with the national average.

Multiple births[2]

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

Between April 2014 and March 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 18%: this means that the centre's multiple live birth rate is likely to be consistent with the 10% 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 six 'other' areas of non-compliance.

Since the inspection visit the PR has given a commitment to fully implementing all the following recommendations in the prescribed timescales:

Major areas of non-compliance:

- The PR should ensure compliance with medicines' management regulations.
- The PR should ensure that gametes and/or embryos are traceable from procurement to use or disposal.
- The PR should review the witnessing processes in place at the time of insemination.
- The PR should review the quality management system (QMS) to ensure that standard operating procedures (SOPs), audits and quality indicators (QIs) are in place for all activities authorised by the centre's licence and other activities carried out in the course of providing treatment services.
- The PR should ensure that CE marked medical devices are used where possible.

'Other' areas that require improvement:

- The PR should ensure that information provided to patients when considering whether to consent to the use of their embryos in training includes all the HFEA requirements.
- The PR should ensure that the time at which witnessing steps are carried out is documented.
- The PR should ensure that all records are clear, legible and have document control procedures to record the history of the documents.
- The PR should ensure that all information is kept confidential and only disclosed in circumstances permitted by law.
- The PR should ensure the safe storage of medical gases.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have five major of areas of concern. The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy rate is likely to meet the target.

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

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

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better

The centre uses an electronic witnessing system, but does not carry out additional manual witnessing steps at insemination (Code of Practice Guidance Note 18 (18.28) (SLC T 71) (recommendation 5).

The placing of gametes and/or embryos into storage is witnessed but the time of this witness step is not recorded (Code of Practice Guidance Note 18 (18.8.) (SLC T71) (recommendation 7).

Donor selection criteria and laboratory tests

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

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection

during treatment, processing and storage of gametes and/or embryos.

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

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

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

What the centre could do better

Nothing identified at this inspection.

Suitable premises and suitable practices

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

What the centre does well

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

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation 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
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

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

Pre-operative assessment and the surgical pathway
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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

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

Traceability (Guidance note 19)
The centre's procedures are partially 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,
- identify the donor and recipient of particular gametes or embryos,
- to identify any person who has carried out any activity in relation to particular gametes or embryos, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

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

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite agreements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements.

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 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
The centre had eight full gas cylinders that were stored in a room on the ground floor. Medical gas cylinders should be kept in a purpose built cylinder store that allows the cylinders to be kept safe, accessible and well ventilated. A risk assessment was performed in 2012, however this does not address whether the chosen location for storage meets current regulatory requirements regarding ventilation, accessibility and safety (SLC T17) (recommendation 10).

Medicines management
The centre does not record alterations in the controlled drugs register in line with the regulations; changes should be corrected by a margin note or footnote to specify the date a correction is made. (Misuse of Drugs Regulations (Northern Ireland) 2002, schedule 20 (c) and SLC T2) (recommendation 1).

Review of the controlled drugs register showed that on two separate occasions, a single drug ampoule (midazolam) had been used for two separate patients; this is contrary to professional guidelines (SLC T2) (recommendation 1).

Traceability
The records for one patients indicated that an embryo had been used for training purposes but no records of this were found in the training logs. Subsequent to the inspection, the centre staff confirmed that the embryo had not been used for training but that it had been discarded after assessment prior to use. Therefore the records did not provide accurate information to ensure that all gametes and embryos are traceable from procurement to use or disposal (SLC T99) (recommendation 2).

Quality management system (QMS)
The centre does not have an SOP for;

- counselling
- legal parenthood
- lone workers
- handling or investigating actions to be taken if a product is recalled.

(SLC T33) (recommendation 3).

Corrective actions resulting from audits are not always documented and in most cases there is no record of the implementation of these corrective actions (SLC T36) (recommendation 3).

The centre has not established QIs for the following activities;

- Counselling
- Legal parenthood
- (SLC T35) (recommendation 3).

Equipment and materials
The following medical devices in use are not CE marked: tubes used for egg collection, tubes used for sperm preparation and serological pipettes (SLC T30) (recommendation 4).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1228/81).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements. The centre has suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

What the centre could do better

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

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

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

The centre does not perform embryo testing therefore this area of practice is not applicable to this inspection.

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 5 patients who provided feedback on their experiences. A further 6 patients provided feedback directly to the HFEA in the time since the last inspection, and the centre provided their patient feedback and satisfaction surveys for the last year. Feedback was very positive, the patients rated the service highly for good communication, being friendly and professional and having a clean environment. There were no negative comments.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) 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 broadly compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent (recommendation 3).

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg and/or sperm sharing arrangements are compliant with

HFEA requirements. This is important to ensure that:

- care is taken when selecting egg and/or sperm providers donating for benefits in kind
- egg and/or sperm providers are fully assessed and medically suitable.

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

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are broadly 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

Confidentiality and privacy
An external company provides the centre with ongoing IT support for their electronic medical records systems. However, the inspection team was not assured that the centre had reviewed or considered how they protect access to electronic patient records or mitigate the risks of inadvertent access to patient identifying information by this third party (SLC T43) (recommendation 9).

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and/or donors are broadly 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

Information for patients regarding donation of embryos for use in training does not include information that they can vary or withdraw consent until the embryos are used in training, and whether any information will be fed back to them (SLCT97c and d) (recommendation 6).

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)
The partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born in order to become the legal parent. 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. During the inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that no corrective actions were needed.

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 and those born following treatment.

What the centre could do better.

Disclosure of information held on the HFEA Register, for use in research.
It was noted that of 28 records reviewed during the inspection, there were two discrepancies between completed patient/partner consent to disclosure to researchers in the patient's records and that recorded on the HFEA register. The inspection team noted that the discrepancy identified was not one that carried a risk of inadvertent disclosure to researchers against the patient's wishes.

(General Direction 0007, Guidance Note 5: Consent to treatment, storage, donation and disclosure of information, and Chair's Letter CH(10)05 and guidance supplementary to Chair's Letter CH(10)05) (recommendation 11)

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

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

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better

Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

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

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

What the centre could do better

Record keeping and document control
Three SOPs reviewed at inspection (SOP reference Lab 17, 24 and 96) did not record the last review date on the document. (SLC T34) (recommendation 8).

The theatre documentation included a prescription for drugs to be administered during the surgical procedure. Review of the documentation showed that a 'tick' is used to indicate where the drug has been prescribed and/or administered. The inspection team considered that the meaning of a tick can be misinterpreted and that the notation was unclear and contrary to professional guidelines (SLC T2) (recommendation 8).

Section 3: Monitoring of the centre's performance

Following the initial inspection in 2013, a recommendation for improvement was made in relation to 1 area of major non-compliance.

The PR provided information and evidence that this recommendation was fully implemented.

On-going monitoring of centre success rates

In the last 12 months, the centre did not receive any performance related alerts.

Areas of practice requiring action

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

Critical area of non compliance

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

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

Major area of non compliance

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

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

Area of practice and Reference	Action required and timescale for action	PR Response	Executive Review
1. Medicines management Review of the controlled drugs register showed that the centre does not record alterations in line with the regulations; changes should be corrected by a margin note or footnote to specify the date a correction is made. Misuse of Drugs Regulations (Northern Ireland) 2002, schedule 20 (c) and SLC T2. Review of the controlled drugs register showed that on two separate occasions, a single drug ampoule (midazolam) had been used for two separate patients; this is contrary to professional	The PR should ensure compliance with medicines management regulations. The PR should undertake a review to identify the factors that have led to this non-compliance. A summary report of the review including corrective actions and the timescale for their implementation should be provided to the centre's inspector by 30 October 2015. Within three months, the centre should carry out an audit of medicines management procedures to ensure that the corrective actions have been effective in	A review is being undertaken and a summary report will be forwarded as requested. Following implementation of any corrective actions an audit of compliance will take place. A summary report will be forwarded as requested	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

guidelines. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 and SLC T2.	ensuring compliance. A summary report of the audit detailing the corrective actions with evidence supporting their implementation should be supplied to the centre's inspector by 30 October 2015.		
2. Traceability The records for one patients indicated that an embryo had been used for training purposes but no records of this were found in the training logs. Subsequent to the inspection, the centre staff confirmed that the embryo had not been used for training but that it had been discarded. SLC T99.	The PR should ensure that gametes and/or embryos are traceable from procurement to use or disposal. The PR should ensure that practices and procedures are reviewed to allow for full traceability. Evidence of this should be submitted to the centre's inspector by 30 October 2015.	A review of our practices and procedures is underway to ensure full traceability of all gametes and embryos. Evidence to be forwarded as requested.	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.
3. Quality management system (QMS) There is no SOP to direct the following procedures; • counselling • taking consent to legal parenthood • lone working • actions to be taken if a product is recalled.	The PR should ensure the development of documented SOPs for these procedures. Copies of the SOPs should be provided to the centre's inspector by 30 October 2015. The PR should review the findings of the audits for which there was no documentation of corrective actions. The centre's inspector should be	The missing SOPs are currently being written and will be forwarded. The audits will no documentation of corrective	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

SLC T 33 (b) Corrective actions resulting from audits are not always documented and in most cases there is no record of the implementation of these corrective actions. SLC T36. The centre has not established QIs for all activities. SLC T35.	provided with a summary report documenting any required corrective actions and the timescale for their implementation by 30 October 2015. The PR should ensure the establishment of QIs for all activities. Documentation demonstrating the establishment of the QIs should be provided to the centre's inspector by 30 October 2015.	actions are being reviewed. A summary report will be forwarded detailing any corrective actions that were necessary. The missing QIs are being incorporated into our quality system. Details with a timetable for implementation will be forwarded.	
4. Equipment and materials The following medical devices used by the centre are not CE marked: • tubes used for egg collection • tubes used for sperm preparation • serological pipettes. SLC T30.	The PR should ensure that CE marked medical devices are used where possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this it is expected that all medical devices should be CE marked by 30 January 2016.	We are researching and risk assessing the replacement of non CE marked medical devices.	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.
5. Witnessing The centre uses an electronic witnessing system and does not carry out additional manual	The PR should conduct a formal risk assessment before introducing or changing witnessing protocols, or	A risk assessment is to be carried out on this witnessing step. A report will be forwarded.	The Executive acknowledges the PR's responses and his commitment to fully implementing the

witnessing steps at insemination. SLC T71.	departing from HFEA guidance (Code of Practice 18.28). A copy of the risk assessment should be provided to the centre inspector by 30 October 2015.		recommendation. 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
6. Information Information for patients regarding donation of embryos for use in training does not include information that they can vary or withdraw consent until the embryos are used in training, and whether any information will be fed back to them. SLC T97c and d.	The PR should ensure that information provided to patients when considering whether to consent to the use of their embryos in training includes all the requirements of T97. The PR should provide this information to the centre's inspector by 30 October 2015.	The relevant information is under review and will be forwarded.	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.
7. Witnessing The placing of gametes and/or embryos into storage is witnessed but the time of this witness step is not recorded. SLC T71.	The PR should review the relevant procedures for the documentation of witnessing steps. A summary report of the review findings including corrective actions and copy/copies of any amended documentation should be forwarded to the centre's inspector by 30 October 2015.	A review of this process to be undertaken, and any corrective action implemented. A summary and any amended documentation will be forwarded.	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.
8. Record keeping and document control	The PR should review how staff complete prescription	The requested action will be done	The Executive acknowledges the PR's responses and his

The drug prescription chart was difficult to understand because in the box where a signature would indicate that a drug was administered; there was a 'tick'. Staff must make a clear, accurate and immediate record of all medicine administered, intentionally withheld or refused by the patient, ensuring the signature(s) is clear and legible; Nursing and Midwifery Council Standards for Medicines management (2010) Standard 8. SLC T2. Document control was omitted inn three SOPs reviewed. SLC T34.	charts, specifically documentation of the administration of drugs. A summary of the findings of the review and corrective actions and timescale for implementation should be provided to the centre's inspector by 30 October 2015. Within three months, the centre should carry out an audit of medicine management procedures to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the audit findings should be sent to the centre's inspector by 30 January 2016. The PR should ensure that their process for document control is adhered to, and the three SOPs noted are updated. Confirmation of this should be provided to the centre's inspector by 30 October 2015.		commitment to fully implementing the recommendation. Further action is required.
9. Confidentiality and privacy	The PR should ensure that all information is kept confidential	We will consult with our IT support to identify what	The Executive acknowledges the PR's responses and his

An external company provides the centre with ongoing IT support for their electronic medical records systems. However, the inspection team was not assured that the centre had reviewed or considered how they protect access to electronic patient records or mitigate the risks of inadvertent access to patient identifying information by this third party. SLC T43.	and only disclosed in circumstances permitted by law. The PR should review the centre's processes to protect access to electronic records and mitigate the risks of inadvertent access to patient identifying information. A summary of the findings of the review including any corrective actions and the timescales for implementation should be provided to the centre's inspector by 30 October 2015.	information they have access to. And what actions are required if necessary. A report will be submitted.	commitment to fully implementing the recommendation. Further action is required.
10. Safety and suitability of premises and facilities The centre has eight full gas cylinders stored in a room on the ground floor. When designing the cylinder store a risk assessment should be carried out to ensure that the chosen location meets regulatory requirements. BCGA guidance note 2 guidance for the storage of gas cylinders in the workplace revision 5: 2012. Health Technical	The PR should ensure safe storage of medical gases. The PR should complete a risk assessment for the suitability of the medical gas store. The completed risk assessment and findings, with a corrective action plan and implementation dates should be provided to the centre's inspector by 30 October 2015.	A risk assessment of the medical gas store is currently in progress. A report will be forwarded.	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

Memorandum.02-01: Medical gas pipeline systems Part B: Operational management SLC T17.			
11. Disclosure of information, held on the HFEA Register, for use in research Of 28 records reviewed during the inspection, there were two discrepancies between completed patient/partner consent to disclosure to researchers in the patient's records and that recorded on the HFEA register. General Direction 0007. Guidance Note 5: Consent to treatment, storage, donation and disclosure of information. Chair's Letter CH (10)05 and guidance supplementary to Chair's Letter CH (10)05.	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. The PR should confirm that the incorrect submissions identified have been corrected when responding to this report. The PR should review the centre's systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 30	The incorrect information will be corrected. The processes will be reviewed and a report submitted. A follow up audit within 6 months to be conducted and report forwarded.	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

	October. The PR should conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. A summary report of the findings of the audit should be provided to the centre's inspector by 30 January 2016.		

Reponses from the Person Responsible to this inspection report

We (GCRM-BELFAST) were happy with the feedback given at the conclusion of the inspection. We have worked very hard in our first 2 years to comply with the requirements of our various regulators. We appreciate there is some overlap in the roles of the various regulators but are disappointed that different conclusions are reached by different regulators even when looking at the same area of inspection.
We were also disappointed that there were 5 area of non compliance graded as major.
We will work with the HFEA and other regulators to achieve full compliance and provide our patients with the best possible service.